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THE IMPACT OF LEGISLATION ON THE PHARMACEUTICAL INDUSTRY IN PAKISTAN: A STUDY OF THE DRUGS (GENERIC NAMES) ACT, 1972

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# THE IMPACT OF LEGISLATION ON THE PHARMACEUTICAL INDUSTRY IN PAKISTAN: A STUDY OF THE DRUGS (GENERIC NAMES) ACT, 1972

By

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ABSTRACT

THE IMPACT OF LEGISLATION ON THE PHARMACEUTICAL INDUSTRY IN PAKISTAN: A STUDY OF THE DRUGS (GENERIC NAMES) ACT, 1972

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During the last twenty years, the operations of the worldwide pharmaceutical industry have been subject to considerable scrutiny. Critics of the production and marketing structure of the pharmaceutical industry argue that patent privileges, cross-licensing agreements, and research which is directed at molecular manipulation to produce "me too" products, and the resultant monopolistic advantage through the use of brand names and trade mark protection, have served to "exploit" the customer through high prices and concomitant high profits. A significant issue that has been raised is whether drug products should be marketed by generic names rather than brand names to increase price competition among chemically equivalent drugs.

In 1972, the Pakistan government introduced the Drugs (Generic Names) Act, which prohibited prescribing, manufacturing, and marketing of drugs (with certain exceptions) by brand names. This legislation also adopted a National Formulary which allowed only a restricted list of drugs to be marketed in the country.

This study was designed to examine the effects of the legislation on sales concentration in the pharmaceutical market, its impact on drug prices in Pakistan, and its influence on the product and promotional strategies of pharmaceutical manufacturers in Pakistan.

In addition, the study attempts to document both the events leading to the introduction of legislation and the reactions of pharmaceutical manufacturers, importers, the trade, and the medical profession to the government's action. It is hoped that the Pakistani experience may serve as a guide to health policy makers in other developing countries contemplating similar actions and may assist them in formulating and implementing such a plan.

The information indicates that in 1975 multinational companies still dominated the Pakistani market, and the leading multinational manufacturers had increased their combined market share. Pakistani local manufacturers were unable to make any notable increases in their market shares.

The information also indicates that, contrary to government expectations, nominal retail prices of drugs in 1975 were not lower than nominal prices in 1971, at least for the sample of comparable products studied in this research. A notable factor, other than price, which accounted for competition between generic drugs was product quality.

A number of new entrants into pharmaceutical manufacturing did not have adequate manufacturing and quality control capabilities. Product changes which either were necessitated by the introduction of the National Formulary or were made by already established Pakistani

manufacturers who expanded their product offerings as they perceived an opportunity to compete with their generic drugs resulted in difficulties in maintaining product quality.

The poor quality products of lesser known Pakistani manufacturers not only helped to strengthen the market position of the leading multinationals but also contributed to a general mistrust of all Pakistani drug products, including those of reputable companies.

Multinational pharmaceutical manufacturers emphasized the "quality" of their products in their promotion. In addition, multinationals maintained their promotional emphasis on the doctor, and their detailmen persuaded doctors to include the manufacturer's name on their prescriptions for generic products.

The promotional efforts by local manufacturers directed at chemists through discount and bonus schemes were countered with similar schemes by leading multinational manufacturers. In addition, since doctors and customers had become increasingly conscious of drug quality, they were unwilling to accept products of many local manufacturers. One consequence was that, in general, chemists exercised "discrimination" and caution in the products they stocked and dispensed, refusing to stock products of many Pakistani manufacturers.

In conclusion, government objectives in introducing the Generic Names Act--to increase price competition between drug products and strengthen the market position of indigenous manufacturers to compete against multinational producers--were not achieved.

To Akila and Raschid Quraeshi

and Mrs. M. R. Khan

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# CHAPTER I

# INTRODUCTION TO THE STUDY

## The Study

The present study is an attempt to investigate the consequences of governmental legislation on the operations of the pharmaceutical industry in Pakistan. Specifically, the research investigates the effect on the pharmaceutical sector of the Generic Names Act of 1972, legislation which abolished the use of brand names for drugs and through the introduction of a National Formulary allowed only a restricted list of drugs to be marketed in Pakistan.[1] The effect of this legislation on sales concentration in the pharmaceutical market, its impact on prices of drugs in Pakistan, and its influence on product policies and promotional strategies are the major areas of investigation.

## Importance of the Study

Several governments in both the developed and developing countries have, in recent years, expressed considerable concern with the operations of the pharmaceutical industry, in particular with its pricing and marketing practices.[2] Many countries have contemplated taking legislative action similar to Pakistan's adoption of the Generic Names Act. For instance, in 1959, Sri Lanka's Health Ministry made it a rule that in government hospitals, prescribing

should be by generic names only.[3] The use of generic names of drugs was eventually introduced also in the private sector, with pharmaceutical suppliers required to have generic names in large type and the brand names only half the size of the generic names. The Sri Lankan government also introduced a restricted National Formulary of products allowed to be marketed in that country.[4]

In Afghanistan, a Generic Drugs Law passed in 1976 specified that from 1979 locally producing institutions could produce and distribute their products under generic names only, and only those products would be allowed which were included in the Afghan National Formulary.[5]

In India, a government investigative committee in 1975 recommended a gradual changeover to the use of generic names for drugs.[6]

A much publicized study done under the auspices of the United Nations suggests that developing countries should adopt policies which would lead to the replacement of brand names of drugs by generic names; it recommends that drug production and marketing should be restricted to only those included in a National Formulary which would be composed of a list of "essential" drugs.[7]

This research, hopefully, will assist policy makers, particularly in the developing countries, to realize some of the problems with the implementation of similar policies. This study of the Pakistani experience could aid policy makers in recognizing some unanticipated consequences of legislative action (such as Pakistan's Generic Names Act) and also help policy planners to realize that

objectives (such as reduction in sales concentration and reduction in prices) may not be achieved through legislation, particularly if the legislation is not carefully planned and executed.

## Study Format

The study is organized into nine chapters. The present chapter provides a background of the worldwide pharmaceutical industry and briefly describes the pharmaceutical industry in Pakistan.

Chapter II reviews major issues, underlying criticism, and defense of the practices of the pharmaceutical industry, and evaluates the relevance of these issues in the Pakistani context.

Chapter III describes the Pakistani government's introduction of the Generic Names Act and documents the consequent reactions of those affected by the legislation. The chapter attempts to re-create events which occurred after the introduction of the generic policy and can be particularly useful as a guide to policy makers, who should anticipate similar events and reactions in other developing countries if legislation is introduced in a corresponding manner.

Chapter IV describes the methodology employed in the investigation and introduces the hypotheses that were examined in the research.

Chapters V through VIII provide research findings regarding the changes in (a) market shares within the pharmaceutical industry in Pakistan (Chapter V), (b) drug prices (Chapter VI), (c) product policies of the industry (Chapter VII), and promotional strategies

adopted by the industry (Chapter VIII) after the Generic Names Act was introduced.

Chapter IX provides a summary of the research findings and forwards suggestions for the use of other developing countries contemplating similar "reforms" in their pharmaceutical sector.

## Historical Background

To provide a historical perspective of the modern pharmaceutical industry, the next section discusses the evolution of modern drug therapy. Another section describes the development of the modern pharmaceutical industry--a post-World War II phenomenon. The industry's methods of entry and involvement in overseas markets are examined. Next, a section discusses the establishment by pharmaceutical companies of manufacturing facilities in developing countries, a method of entry which is essentially the result of efforts of these countries to have their own pharmaceutical industry. Finally, the main features of the Pakistani pharmaceutical industry and trade are outlined.

### Drugs: The Pharmacological Revolution

Most modern drugs have recent origins. Only about 40 years ago there were no antibiotics, antidepressants, antihistamines, diuretics, and vaccines against polio, measles, or mumps. There were no oral contraceptives, no effective antidiabetics, no corticosteroids, and there were only a few sulfa drugs, a few vitamins, and a few tranquilizers.[8]

Certain substances with therapeutic capability, such as opium, quinine, and morphine, existed prior to 1900, but the major drugs in use at that time were limited to purgatives, emetics, and narcotics. Before the turn of the century there were only three synthetic drugs--aspirin, phenacetin, and barbitone--and the Germans were responsible for their development.[9]

In 1909, Paul Ehrlich discovered arsphenamine, a cure for syphilis. The discovery by the German Domagk, in 1935, of the first sulfonamide is credited "with setting in motion, the mass discoveries of the modern chemotherapeutic and antibiotic agents."[10] The first of the antibiotics, penicillin, was a chance discovery by an English bacteriologist, Alexander Fleming; he observed that bread mold spores, which accidentally had contaminated a staphylococcus culture, destroyed staph germs in the vicinity of the spores.[11] Florey and Chain, scientists at Oxford University, subsequently developed penicillin and it was produced on a small scale until 1944. World War II was the impetus for the combined efforts of the U.S. government and industry to solve technical problems in producing penicillin on a large scale. Fermentation technology was developed, and the mass production of penicillin began.[12]

The introduction of sulfa drugs and penicillin initiated "the great drug therapy era."[13] Within ten years after World War II, intensive research, both public and private, led to the development of other antibiotics. Among these were streptomycin (1943), chloramphenicol (1947), and the most important of the post-penicillin discoveries, the tetracyclines. The tetracyclines are broad-spectrum

antibiotics, active against a wider range of organisms than penicillin. The first of the tetracyclines was Lederle's chlortetracycline (Aureomycin), marketed in 1948, followed by a variant, oxytetracycline (Terramycin), marketed in 1950. These were closely followed by a number of others.[14]

The introduction of the first sulfa drugs also intensified companies' efforts to develop other drugs through modifying the molecular structures of the original. A number of companies in England, France, Germany, and the United States developed sulfanilamide derivatives through "molecular modification."[15] Some of the results have yielded superior products, such as the development of prednisone from cortisone. This process has also produced products which have been criticized as being of little clinical value as compared to the original.[16]

Along with product innovations, production techniques and quality control have improved dramatically since World War II.

Since the 1950s, vaccines for the control of polio, mumps, measles, and rubella have been discovered. Important to the control of mental illness was the discovery of chlorpromazine in 1954 (a result of molecular modification of the early histamines), the first effective major tranquilizer, followed by discoveries in the 1960s of chlordiazepoxide (Librium) and diazepam (Valium) by scientists of Hoffman La Roche.[17,18]

Hypertension heart diseases have been controlled by the discovery of hexamethonium, hydralazine, and the rauwolfia alkaloids. Oral antidiabetic tablets have replaced uncomfortable and inconvenient

daily injections of insulin for some diabetic patients.[19] Advances have been made in the treatment of epilepsy, parkinsonism, asthma, thyroid disease, and certain types of cancer. Research into steroid hormones has resulted in relief for arthritis and in development of oral contraceptives.[20] New drugs have been introduced to fight malaria and control infections such as cholera, bubonic plague, dysentery, typhoid, yellow fever, and a number of other parasitic infections.[21]

Figure 1-1 illustrates some major drug discoveries between 1875 and 1965.

## The Modern Pharmaceutical Industry

The post-World War II revolution in drugs gave birth to the modern pharmaceutical industry. The most prominent companies either began as apothecaries and then entered into limited manufacturing (Merck is an example), initiated operations with limited manufacturing (such as Upjohn and Lederle), initially manufactured dyes (as did Hoechst), or were manufacturers of fine chemicals (for example, Pfizer and Hoffman La Roche).[22]

The pre-World War II pharmacist compounded prescriptions in much the same way as the apothecaries of earlier times. The pharmacist started with bulk powders which he obtained from a drug "manufacturer," who in turn prepared active ingredients by purchasing basic chemicals from a "fine chemical" firm (such as Pfizer). To the bulk powder, the pharmacist added excipients and binders, made his own pills, filled capsules, and prepared liquid suspensions.

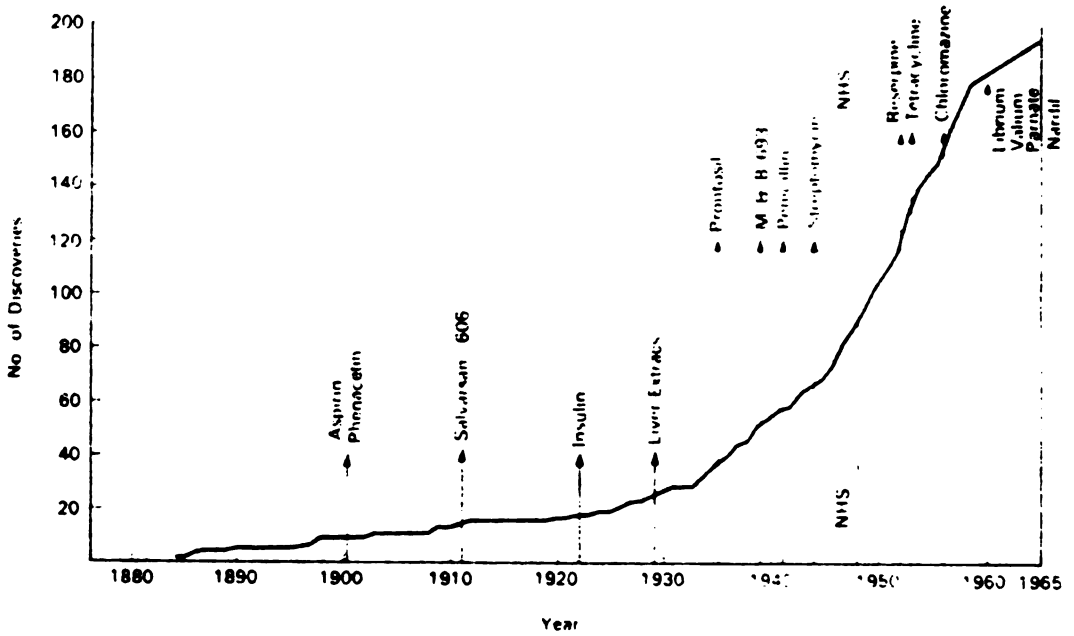


Figure 1-1.--Cumulative major drug discoveries (1875-1965).

Source: Michael H. Cooper, Prices and Profits in the Pharmaceutical Industry (New York: Pergamon Press, 1966), p. 7.

Brand names at this time played an insignificant part. The advent of World War II created an enormous demand, and many firms invested in mixing, tableting, and encapsulating equipment to provide finished products that could be readily administered.[23] Companies such as Pfizer that were suppliers of chemicals to drug manufacturers emerged after World War II as leading producers of drugs in finished form. The brand name now became a significant factor in the marketing of drugs.

## Multinational Operations

The expansion of the modern pharmaceutical industry overseas was a natural development. The limited domestic market for such Swiss producers as Ciba-Geigy, Hoffman La Roche, and Sandoz made it necessary for them to seek markets abroad. Even though the large domestic U.S. market meant less need to seek sales elsewhere, the potential of overseas markets has encouraged many U.S. companies to extend their operations into worldwide markets. Today, companies such as Pfizer and Richardson Merrill obtain more than 50 percent of their sales from overseas. As Table 1-1 indicates, a majority of leading pharmaceutical companies obtain a significant portion of their sales from markets abroad.

The production and marketing effort has been concentrated in the developed western nations. However, most leading pharmaceutical firms have varying degrees of involvement in the developing world. In addition to the export of finished drug products to wholly owned manufacturing subsidiaries outside the home country,

Table 1-1.--Overseas sales volume as a percentage of total sales volume of major multinational pharmaceutical companies (1973).

| Company | % | Company | % |
|---|---|---|---|
| Abbott | 35 | Merck & Co. | 45 |
| Astra | 51[a] | E. Merck | 42 |
| AKZO | 88 | 3M | 40 |
| American Home | 29 | Pfizer | 52 |
| Beecham | 58 | A. H. Robins | 28 |
| Banyu | N.A. | Rhône-Poulenc | 22 |
| Boehringer-Ingelheim | 62 | Roussell-Uclaf | 50 |
| Boehringer-Mannheim | N.A. | Richardson-Merrell | 56 |
| Bayer | 67 | Sterling Drug | 38 |
| Bristol-Myers | 24[d] | Sandoz-Wander | 97 |
| Clin-Midy | N.A. | Squibb | 33 |
| Ciba-Geigy | 98 | Schering-Plough | 41 |
| Cyanamid | 32 | Schering AG | 58 |
| Dow | 46 | Shionogi | N.A. |
| Eisai | N.A. | Smith, Kline | 31[a] |
| Fujisawa | 5 | G.D. Searle | 31 |
| Glaxo | 56 | Sankyo | N.A. |
| Hoffman La Roche | 90[c] | Syntex | 100[b] |
| Hoechst | 58 | Takeda | 5 |
| ICI | 84[a] | Tanabe | N.A. |
| ICN | 67[a] | Varta | 12 |
| Johnson and Johnson | 22 | Upjohn | 38 |
| Lilly | 33 | Wellcome | 90[a] |
| Morton-Norwich | 9 | Warner-Lambert | 42 |
| Montedison | N.A. | Yamanouchi | 1 |

Source: Barrie G. James, The Future of the Multinational Pharmaceutical Industry to 1990 (New York: Halsted Press, 1970), pp. 252-53.

N.A.--Not Available.

[a]Pharmaceuticals only.

[b]Panama based.

[c]Estimate

[d]International Pharmaceutical Marketing, Sogen-Swiss Corp. (N.Y. 1973).

a number of other types of arrangements for entering overseas markets exist. Among these are: (1) marketing agreements through which a multinational company manages the sales of imported finished products of another; (2) licencing agreements whereby a local firm, either multinational or indigenous, is responsible for dosage form fabrication from ingredients usually patented by the licensor; (3) contract manufacturing by which a company may use the under-utilized production facilities of others in a country while using either its own or others' sales/distribution networks; and (4) joint ventures, in which an involvement in local production may be seen either as competitively advantageous or as the only route that can be taken because of host country restrictions.[24]

The increasing demand for drugs in world markets has resulted in an expansion of the operations of multinational pharmaceutical manufacturers. World production of ethical drugs is estimated to have doubled between 1962 and 1970.[25] In 1971, pharmaceutical production (excluding the socialist countries of Eastern Europe and China) was estimated at about $21 billion.[26]

Of this total, the developed market economy countries account for approximately 85.7 percent, the developing countries for about 10 percent. (See Appendix, p. 298). However, the rates of growth in the developing nations have been at least as high as, and in many cases higher than, those in the developed countries, and an optimistic prediction is that the worldwide market for drugs will double every five years or so if the trend continues.[27] Although present per capita drug consumption in developing countries is low

(see Table 1-2) (in Pakistan, for example, it is about $1), the likelihood of better health care and population increases means that growth rates are expected to be high.[28]

Table 1-2.--Estimated per capita consumption of pharmaceuticals in selected countries--1967.

| Country | Per Capita Consumption (in U.S. Dollars) |
|---|---|
| United States | $20+ |
| Japan | 15 |
| Western Europe | 14 |
| Latin America | 4 |
| Asia & Black Africa | 1 |

Source: Lawrence H. Wortzel, Technology Transfer in the Pharmaceutical Industry, UNITAR Research Report No. 14 (New York: UNITAR, 1970), p. 41.

In his study of the future of the multinational pharmaceutical industry, James suggests that, for the larger firms, "the only new areas for substantial growth are the less developed markets of Asia, Africa and South America and the industrialized markets of Eastern Europe."[29]

## Multinational Pharmaceutical Companies in Developing Countries

Increasing interest in the markets of developing countries has led to the establishment of manufacturing facilities in those

nations by leading multinationals. The reason for establishing manufacturing facilities through joint ventures or as wholly owned subsidiaries has much to do with the policies of developing countries, which are making a determined effort to establish their own pharmaceutical industry.

The term "manufacturing" in the pharmaceutical sector has different connotations. Simply stated, it consists of two components: (1) raw materials or active ingredients manufacture, and (2) dosage form fabrication from raw materials.

Raw material or active ingredient production requires a variety of processes that range from chemical synthesis to fermentation. Technology can range from simple to complicated and sophisticated. In general, the more complex processes are likely to be capital intensive, which in turn suggests economies of scale in production.

The technology of fabrication of the dosage form is less sophisticated, requiring relatively simple equipment and easy-to-follow procedures. Tablets or capsules can be formulated, regardless of active ingredient, using essentially the same procedures.[30,31,32]

Multinational pharmaceutical companies would prefer to locate at central sources. Since the relatively capital-intensive aspect lies in the production of raw materials, company preference would be to manufacture the active ingredient so that economies of scale in production could be obtained, fabricate this into dosage

form at these locations, and export the finished product. As a pharmaceutical manager of CIBA has remarked: "We have chemical factories and finishing plants all over the world. It does not make sense. We could do it all in four locations."[33] Because pharmaceutical products can be transported at low cost, the desire of pharmaceutical firms to concentrate production at central locations seems natural.[34]

The geographical dispersion of pharmaceutical production is more a function of external barriers which limit exploitation of market potential than of cost advantages and resource availability. These barriers, such as import quotas and tariffs, imposed by a developing country to promote import substitution, vary according to the stage of evolution of the pharmaceutical industry in a developing country.

The stages of that evolution have been described as follows:[35]

Stage 1: Developing countries have no pharmaceutical product manufacturing, for example, Kuwait, Saudi Arabia, and Uganda.

Stage 2: Developing countries have a pharmaceutical industry in an early stage (engaged in packaging and dosage form fabrication), as in Bolivia, Ghana, Iraq, Thailand, and Zambia.

Stage 3: Developing countries have a well-established pharmaceutical sector aiming at a certain level of backward integration, at least for certain product lines (engaged in bulk drug manufacture). Taiwan, Korea, Pakistan, the Philippines, and Singapore are examples.

Stage 4: Developing countries have reached a high level of self-sufficiency, become oriented toward full integration, at least for the main sectors of the pharmaceutical industry (starting the development of medicinal clinical manufacture). Brazil, India, Mexico, and Spain are examples.

Stage 5: Countries have a well-established pharmaceutical industry, for example, the United States, United Kingdom, Switzerland, and Japan.

The policies of a developing country may differ as it attempts to move from one stage to another. For example, a country in Stage 1, which is largely reliant on imports of finished drug products, may impose restrictions on imports through quotas or tariffs and at the same time provide incentives such as tax benefits to foreign firms to begin manufacturing (dosage form fabrication) operations. Given favorable incentives, and if the market is of sufficient size and potential, the foreign pharmaceutical firm may establish low cost, standard, technologically simple packaging and finishing (tableting, encapsulating) facilities.

A developing country then may start imposing gradual restrictions on the import of raw materials from abroad (as in the case of India) to foster backward integration. Again depending upon the market potential (which may also include export potential from the country), some foreign firms may start "basic" manufacture of certain active ingredients (Stage 3).

As the extent of basic manufacture increases, the pharmaceutical industry moves into Stages 4 and 5.

## The Pharmaceutical Industry in Pakistan

The origins of the pharmaceutical industry in Pakistan can be traced to the colonial period. British manufacturers had trading agencies in India, which was a captive market for mainly British finished drug products.[36] After partition in 1947, although post-partition India had some leading multinational drug corporations with some dosage form fabrication facilities, Pakistan did not, relying primarily on imported drugs.

This situation prevailed until the 1960s, when the government made a deliberate attempt to foster pharmaceutical manufacturing in Pakistan. The liberal foreign investment atmosphere existing at the time was an incentive for American, British, German, and Swiss firms to establish facilities. This situation, together with tariff regulations which protected the industry, led to the establishment of a dosage fabrication pharmaceutical industry in Pakistan (Stage 2).[37]

Although the Pakistani industry developed fairly rapidly in terms of dosage fabrication, it was and still is heavily reliant on imported raw materials and active ingredients. Until the 1970s there were only a few drugs for which there was "basic" manufacture (active ingredients manufacture).[38] Pakistan lacks a necessary chemical base for the manufacture of active ingredients. Besides, it may also not be economically feasible to be involved in "basic" manufacture in markets of limited size. Even in countries such as India, with a population about 10 times that of Pakistan (600 million

Table 1-3.--Cost of imported versus locally manufactured drug ingredients in India.

| Chemical Ingredient | Cost of Imported Chemical Ingredient[a] (per kg) (in Indian Rupees) | Cost of Locally Manufactured Chemical (in Indian Rupees) | Ratio: Local Cost/ Imported Cost |
|---|---|---|---|
| Chloramphenicol | 112 | 400[c]<br>600[d] | 3.60<br>5.35 |
| Tetracycline HCℓ | 283 | 1000[b] | 3.53 |
| Vitamin B-12 | 45[e] | 88[c] | 1.95 |
| Vitamin C | 25.50 | 88.79[c] | 3.48 |
| Vitamin B-1 | 151 | 487[b] | 3.22 |
| Phenobarbitone | 48 | 150[b] | 3.12 |
| Diethylcarbamizine Citrate | 104 | 190[b] | 1.86 |
| Streptomycin | 227 | 350[b] | 1.54 |
| Folic Acid | 516 | 1200[b] | 2.32 |

Source: Ottuketkal, "Facts About Drug Prices," Economics and Political Weekly 21 (March 1970): 507-508.

[a]Landed cost inclusive of duty.

[b]Manufactured in the public sector.

[c]Manufactured in the private sector.

[d]Price charged by the State Trading Corporation of India for imported product.

[e]Price per gram.

versus about 60 million), efforts to foster backward integration have been successful but costly. Chemical ingredients produced locally in India have proved to be more expensive than imported ingredients. (See Table 1-3.)

Ten multinational companies engaged primarily in dosage form fabrication, importing active ingredients from abroad, from among a total of about 300 registered in Pakistan in 1971, accounted for about 54 percent of sales in that year.[39] Of these firms, six were subsidiaries of U.S. companies, three were subsidiaries of British companies, and one was a subsidiary of a German company.

The major therapeutic submarkets in Pakistan are antibiotics, vitamins, and cough and cold preparations. These submarkets accounted for approximately 45 percent of total sales of drugs and medicines in 1971.[40]

All the multinational pharmaceutical manufacturing companies are members of the Pakistan Pharmaceutical Manufacturers Association (PPMA). Most of the leading Pakistani manufacturers are also members. A press release by the PPMA in 1972 provided the collective information regarding association members, reported in Table 1-4 below.

To the extent that this information is accurate,[41] it provides some interesting insights. First, the data contradict the charge that multinational pharmaceutical firms understated their profits in Pakistan by using high transfer prices for imported material. The ratio of cost of imported materials to corporate net sales is

Table 1-4.--Income of the

Table 1-4.--Income of the pharmaceutical industry in Pakistan[a] (in millions of rupees).

| | | | |
|---|---|---|---|
| Sales at maximum retail price | | | Rs. 350.804 |
| Less: discount to chemists | | Rs. 52.846 | |
| Net sales at chemist level | | | 297.958 |
| Less: distribution expenses or distributor's commission | | 30.197 | |
| Corporate net sales | | | 267.761 (100.0%) |
| Cost of raw materials | | | 103.870 ( 38.8%) |
| Total cost of imported material | | 57.083 (21.3%) | |
| Cost of imported material | Rs. 49.028 | | |
| Customs duty | 6.213 | | |
| Landing and clearing charges | 1.842 | | |
| Total cost of local material | | 46.787 (17.4%) | |
| Manufacturing cost | | | 42.023 ( 15.7%) |
| Total manufacturing cost | | | 145.893 ( 54.5%) |
| Other expenses | | | 65.199 ( 24.3%) |
| Administration and financial expense | | 31.386 (11.7%) | |
| Sales promotion and advertising expense | | 33.813 (12.6%) | |
| Total costs | | | 211.092 ( 78.8%) |
| Corporate income | | | 56.669 ( 21.2%) |
| Less: royalty and technical fees | | 5.345 | 51.324 |
| Less: income taxes | | 35.187 | |
| Net income | | | 16.137 ( 6.0%) |

Source: Special release, Pakistan Pharmaceutical Manufacturers Association (Karachi, April 1972).

Note: Numbers in parentheses are computed as percentage of corporate net sales.

[a]Information based on data made available by 32 PPMA members.

about 1:5. This does not preclude the possibility that specific companies may be transferring raw materials to their subsidiaries at a high price.[42]

Sales promotion and advertising amounted to 12.6 percent of corporate net sales. Whether this is high or low is a matter of subjective judgment.[43]

The drug industry is an important component of the Pakistan economy. A substantial amount--approximately 62 percent of corporate income--is paid in taxes. The PPMA members employ about 10,000 workers. In addition they purchase materials locally from the glass, plastics, metal, paper and cardboard, and printing sectors, thus contributing to the development of those industries. For their continued existence in the business, a large number or retail channel members involved in the distribution of drugs are dependent on the development and growth of the pharmaceutical industry.[44]

## The Pharmaceutical Trade in Pakistan

In Pakistan, the term pharmaceutical trade refers to the activities of the middlemen in the channel of distribution of drugs. (See Figure 1-2.) A majority of drugs reach the consumer through the retailer (chemists and druggists). Sales to institutions are about 10-15 percent of total sales.[45]

Wholesalers, distributors, and stockists.--Wholesaling functions are performed by those who are classified as either wholesalers, distributors, or stockists.

Sour

Note

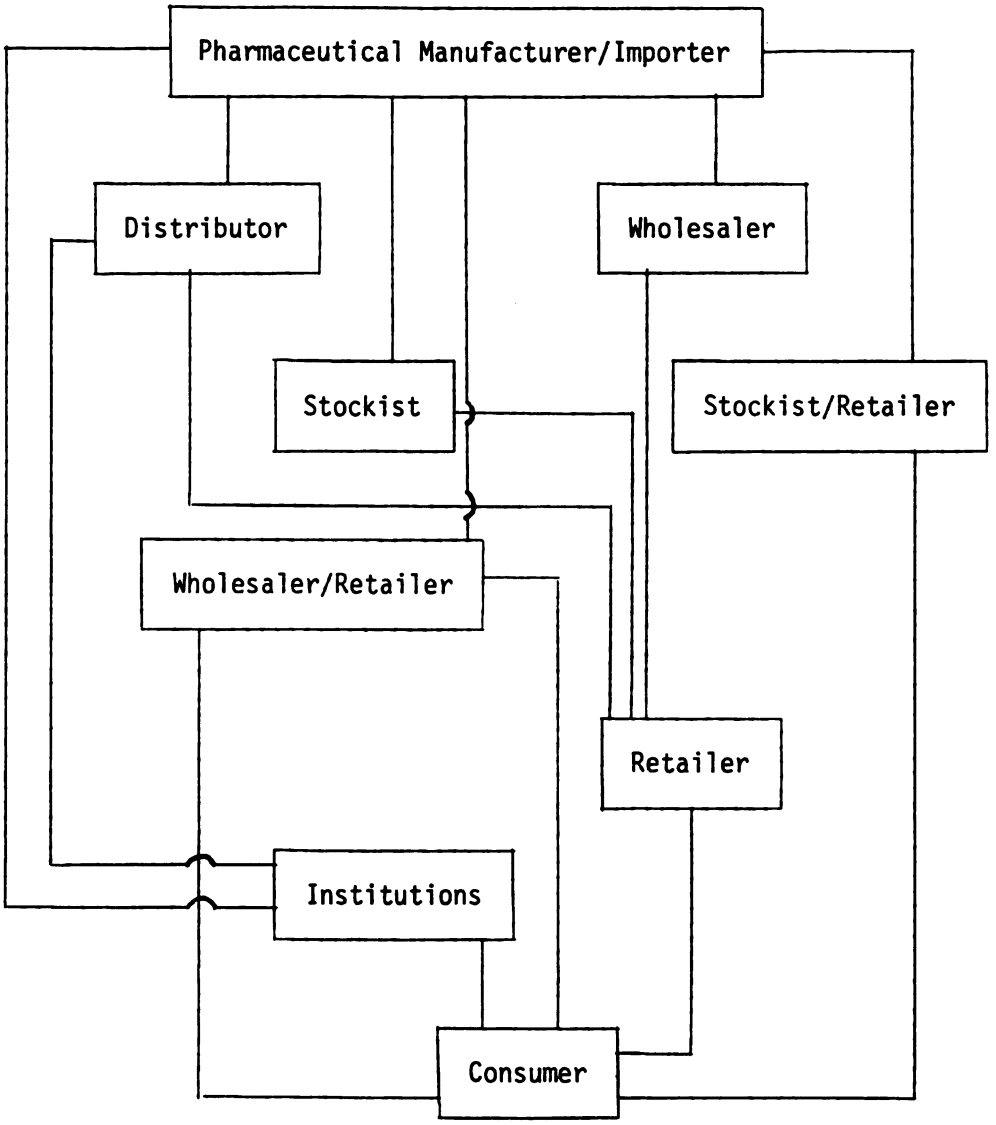


Figure 1-2.--Channel of distribution of drugs.

Source: Author.

Note: Pharmaceutical importer refers to an importer of drugs in finished form.

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The independent wholesaler caters to retail chemists and druggists, purchasing from any of the pharmaceutical manufacturers or importers in bulk quantity. These wholesalers are concentrated in specific areas of urban cities. In Karachi, for example, the wholesale market is in New Challi, and chemists and druggists come to this area to make their purchases. The independent wholesaler usually does not have sales representatives, maintains an established relationship with certain chemists and druggists, and conducts most of his contractual transactions over the telephone. In a number of cases, these wholesalers have the flexibility of giving larger discounts to their "established" clientele than do the pharmaceutical manufacturers.

The distributor represents a number of major companies and restricts his product mix to the offerings of only the client firms. Most local companies utilize the services of these distributors, who maintain a small sales staff which periodically visits retail chemists and druggists to obtain orders for the products of the manufacturers he represents.[46]

The stockist is appointed by manufacturers to keep a reasonable inventory of their products. He is usually a leading chemist and druggist (retailer), and he also provides feedback to the manufacturer about the sales trend in his particular market area.

One of the important functions of the wholesaler and, to a lesser degree, the distributor and stockist is to extend credit,

particularly to the small chemist and druggist. Many leading pharmaceutical manufacturers prefer not to deal with certain retailers, considering them credit risks, and the wholesaler absorbs this risk to cater to this group.

Chemists and druggists.--There are about 10,000 chemists and druggists in Pakistan.[47] Although their functions are similar to those of their Western counterparts, the pharmacists, there are some significant differences.

First, although a qualified pharmacist is required by law in druggist shops, there are very few actually working in these. One survey found that among 4,000 retail "pharmacy" stores, only 20 had qualified pharmacists.[48] Another report in the Medical Gazette asserted that 90 percent of chemists and druggists were not qualified to dispense drugs if the law was strictly applied. To obtain a license to sell drugs, a large number of chemists and druggists were paying "retainers" to qualified pharmacists to use their names on the application forms. Some qualified pharmacists' names appeared on a number of applications, even though they had no intention of participating in the operations of these retail outlets.[49]

Second, although by law a doctor's prescription is necessary to obtain certain medicines from the chemist, it is well known that most of these products can be easily obtained from a chemist's shop without a prescription. Self-medication is not uncommon. A friend may suggest to another than he has used a particular drug before for similar symptoms, and that it was very effective; the

friend then goes to his neighbourhood chemist, demands the drug by name, and purchases it. Or someone may describe his ailment to the chemist, who then suggests and dispenses a drug accordingly.

Particularly in rural areas, the chemist frequently prescribes and dispenses drugs without a doctor's advice or prescription. For some over-the-counter items this may not prove harmful, but sometimes advice is given for serious illnesses, and drugs such as antibiotics, antitubercular drugs, antispasmodics, and antidepressants are sold without consultation with a doctor.

Third, the chemist sometimes provides only a portion of the prescription if the patient is unable to pay for the full amount. The chemist may feel no obligation to inform the patient that the quantity sold may not be enough for his recovery. Chemists also have been known to provide refills of strong and potent drugs without authorization.

Fourth, generally, no prescription records are maintained after medicines have been sold, with the exception of a few drugs such as antibiotics. Some chemists have "arrangements" with doctors whereby they can purchase free samples from them at a prenegotiated discount. Another "arrangement" is with customers who work for companies that provide free medical care for their workers. The workers go to the company doctor, describe their symptoms, and the doctor prescribes certain medicines. The patient then visits a chemist authorized by the company and presents the prescription, is given a receipt for the medicines, but instead purchases consumer goods ranging from cereals to toiletries.

Fifth, storage facilities in chemists' shops usually are inadequate. Environmentally sensitive drugs are kept without regard to the specified conditions in which they are to be stored, and many preparations lose their potency on the chemists' shelves.[50]

Although some chemists, particularly in the urban sector, have acquired considerable expertise through years of experience, as one WHO consultant pointed out, the trade is in the hands of laymen.[51]

## Summary

The pharmacological revolution in drugs, particularly since World War II, has resulted in outstanding discoveries of new products which fight many dreaded diseases and illnesses. Concomitant with the "explosion" in drug therapy since 1945 has been the development into its present form of the modern pharmaceutical industry. The leading companies have extended their operations in markets in both the developed and the developing countries. Although the latter account for a minor share of the production and consumption of drugs today, burgeoning populations and increased emphasis on health care should lead to increasing demands for drug products. Developing countries, including Pakistan, have engaged in policies designed to establish an indigenous pharmaceutical manufacturing industry. For most developing countries, this has meant inducing leading multinational pharmaceutical companies, through incentives such as tax benefits and disincentives such as tariffs on finished products, to initiate operations. Manufacturing in most developing countries,

including Pakistan, is restricted primarily to dosage form fabrication, with the raw materials being imported from abroad.

The Pakistani pharmaceutical industry, as in most developing countries, is "dominated" by multinational pharmaceutical firms.[52] Finished drug products reach the consumer through chemists and druggists who are "laymen."[53]

The fact that the pharmaceutical industry in Pakistan, as in other developing countries, is characterized by a relatively small number of foreign firms with dominant market shares and a large number of local firms with a relatively minor share has led to charges of "excessive" market power through "restrictive" business practices. These latter include the "extensive use of patent and trademark rights . . . to eliminate competition,"[54] resulting in the inability of indigenous manufacturers to compete, while maintaining profits for the multinationals and prices of their products at "exorbitant" and "high" levels.

Criticism of the practices of the worldwide pharmaceutical industry strongly influenced the Pakistani Government to adopt the Generic Names Act. This criticism and the industry's defense of its practices are the subject of the next chapter.

See

## Footnotes--Chapter I

[1]The details of this legislation and the legal environment for the pharmaceutical industry prior to the introduction of the Generic Names Act are the subject of Chapter III.

[2]For a comprehensive discussion, see Sanjaya Lall, Major Issues in Transfer of Technology to Developing Countries: A Case Study of the Pharmaceutical Industry (Geneva: United Nations, 1975).

[3]Senaka Bibile, Case Studies in Transfer of Technology: Pharmaceutical Policies in Sri Lanka (Geneva: United Nations, 1977), p. 14.

[4]Ibid.

[5]Ibid.

[6]Lall, op. cit., p. 53.

[7]Ibid.

[8]Earle L. Arnow, Health in a Bottle: Searching for the Drugs That Help (Philadelphia: Lippincott Co., 1970), p. 236.

[9]Barrie G. James, The Future of the Multinational Pharmaceutical Industry to 1990 (New York: John Wiley and Sons, 1977), p. 1.

[10]Michael H. Cooper, Prices and Profits in the Pharmaceutical Industry (New York: Pergamon Press, 1966), p. 5.

[11]Walter S. Measday, "The Pharmaceutical Industry," in The Structure of American Industry, 4th ed., edited by Walter Adams (New York: The Macmillan Co., 1961), p. 158.

[12]Ibid., p. 158.

[13]Milton Silverman and Philip R. Lee, Pills, Profits, and Politics (Los Angeles: University of California Press, 1974), p. 4.

[14]Measday, op. cit., p. 158.

[15]Silverman and Lee, op. cit., pp. 4-5.

[16]For a criticism of the process of "molecular modification," see Chapter II, pp. 46-50.

[17]Cooper, op. cit., p. 6.

[18]Silverman and Lee, op. cit., p. 5.

[19]Measday, op. cit., p. 183.

[20]Silverman and Lee, op. cit., p. 10.

[21]Ibid., pp. 10-13.

[22]James, op. cit., p. 3. See also James, op. cit., p. 255, for the origins of major multinational pharmaceutical companies.

[23]Measday, op. cit., p. 159.

[24]For a discussion of these various methods of entry into overseas markets adopted by pharmaceutical companies, see Robert H. Jones, "The Modern Multinational Structure of the Pharmaceutical Industry," in The Pharmaceutical Industry and Society, ed. George Teeling-Smith (London: White Crescent Press, Ltd., 1972), pp. 1-18.

[25]James, op. cit., p. 17.

[26]Lall, op. cit., p. 4. Lall also gives figures from other sources, one of which estimates world pharmaceutical production to be about $17 billion and another about $20 billion. James estimates 1970 production to be about $19.5 billion. See James, op. cit., p. 17.

[27]Lall, op. cit., p. 5. In another, more conservative estimate, Barrie G. James, in The Future of the Multinational Pharmaceutical Industry to 1990, predicts that by 1990 the worldwide production of medicines will be about $100 billion.

[28]Lall, op. cit., p. 5.

[29]James, op. cit., p. 53.

[30]Lawrence H. Wortzel, Technology Transfer in the Pharmaceutical Industry (New York: United Nations, 1971), pp. 17-19.

[31]Jones, op. cit., p. 7.

[32]One critic of the pharmaceutical industry argues that "the simple technology of the preparation of most finished dosage forms, the low operating costs of these processes, and the modest capital requirement for such facilities, renders this stage of the industry ideally suited for workably competitive market performance. The processes involved for most dosage forms are technologically routine and elementary, tabletting and bottling being particularly trivial operations technically. (After all, every pharmacist is taught--and taught well--to do such compounding operations on his

own premises. It is both amusing and dismaying to observe industry attempts to convince the general public that there is some magic in the preparation of even the simplest dosage forms, which is by implication a secret known only to the major brand name firms.) . . . . There is no purely economic reason why numerous small firms could not contract out the manufacture of the active ingredient and then tablet and package the finished dosage forms on the basis of a quite moderate total investment." Henry B. Steele, statement before the U.S. Senate, in Competitive Problems in the Drug Industry, pt. 5 (Washington, D.C.: Government Printing Office, 1967), p. 17.

[33]Walter Guzzardi, Jr., "The Untranquilized Drug Makers," Fortune 68 (December 1963): 209.

[34]A similar argument is cited by Jones, who reports on a survey of the pharmaceutical industry, commissioned by the National Economic Development Office in the United Kingdom. See Jones, op. cit., p. 7.

[35]This division into developmental stages was suggested by the UNIDO expert working groups on the Establishment of Pharmaceutical Industries in Developing Countires; cited in Wortzel, op. cit., pp. 20-21.

[36]Case Studies in the Transfer of Technology: The Pharmaceutical Industry in India, a study prepared by the Jawaharial Nehru University and the Indian Council of Scientific and Industrial Research (New Delhi: United Nations, 1977), p. 1.

[37]This information was obtained through the author's conversations with representatives of the Pakistan Pharmaceutical Manufacturers Association.

[38]In general, these are Ephedrine and Santonin drug products.

[39]For details on market shares of foreign and Pakistani manufacturers in the drug industry in Pakistan, see Chapter V.

[40]Details on sales in these therapeutic submarkets are provided in Chapter V, pp. 146-154.

[41]This information was released immediately after the generic policy was proposed (April 1972). The data were provided by the PPMA to refute government charges of "excessive" profits and prices.

[42]See Chapter VI, pp. 165-171.

[43]Silverman, a critic of "heavy" promotional expenditures, estimates these expenditures (including detailmen's salaries), in the United States, to be 20 percent of corporate sales. In Pakistan,

since drug promotion is mainly directed at 8,500 practicing physicians, the promotional expenditure per physician is Rs. 3,798. Critics could decry that this expense is "excessive" in a country with a per capita income of Rs. 700 at that time. However, it should be recognized that the major--and in many cases the only--source of drug information for doctors in Pakistan is the detailman (see Chapter VIII), and if promotional expenditures, particularly on detailing efforts, are curtailed, there would be problems of making drug information available to doctors.

[44]Pakistan Pharmaceutical Manufacturers' Association, Fact Book, 2nd ed. (Karachi: 1970).

[45]Estimate provided by the Pakistan Pharmaceutical Manufacturers' Association (December 1976).

[46]Many of the large pharmaceutical companies, such as Pfizer, prefer to use their own distribution outlets in lieu of the wholesaler or distributor, particularly in urban areas such as Karachi, Lahore, Rawalpindi, and Hyderabad.

[47]Estimate provided by the Pakistan Chemists and Druggists Association, January 1978.

[48]Naseem Allahwala, "Pharmacy Services in Pakistan," Medical News Supplement, June 25, 1975, p. 16.

[49]"Precautions in Renewal of Drug Sales Licenses," Medical Gazette, October 1, 1975, p. 7.

[50]"Unsatisfactory Storage Facilities at the Chemist Shops," Medical News Supplement, June 25, 1975, p. 1.

[51]William Hewitt, "Pharmaceutical Quality Control, Pakistan" (Unpublished assignment report, World Health Organization, December 1976).

[52]The market shares of multinational pharmaceutical firms in the late 1960's in selected developing countries were: Brazil, 78 percent; Argentina, 65 percent; Peru, 95 percent; Venezuela, 90 percent; the Philippines and Central America, over 80 percent. See Sanjaya Lall, "The International Pharmaceutical Industry and Less-Developed Countries, With Special Reference to India," Oxford Bulletin of Economics and Statistics, August 1974, p. 158. In 1971, the combined market share of multinational pharmaceutical firms in Pakistan was over 75 percent. For data indicating the "overwhelmingly" dominant position of the multinational pharmaceutical firms in developing countries, see Lall, Major Issues in Transfer of Technology to Developing Countries, pp. 18-19.

[53]This is a particularly important point. When the government abolished brand names in 1972, the chemists and druggists who were not qualified pharmacists were unfamiliar with "generic names" and had tremendous difficulties in filling "generic" prescriptions.

[54]Restrictive Business Practices: Review of Major Developments in the Area of Restrictive Business Practices (New York: UNCTAD, April 1975), p. 17.

# CHAPTER II

# THE "GENERIC NAME" CONTROVERSY

## Introduction

During the last 20 years, a controversy has been raging within the field of medicine. The debate concerns doctors, pharmaceutical manufacturers and the pharmaceutical trade, consumers, politicians, and other officials throughout the world. The issue is whether the use of generic names for medicines, rather than brand names, would be an effective and efficient way of lowering prices to consumers.

A brief summary of the arguments at this point may prepare the reader for the review of the underlying issues which follows in the rest of this chapter.

The worldwide pharmaceutical industry, which has been under considerable attack for the causes of "high" profits as seen by critics, defends its profits, pointing to its high risks and considerable research investment. Critics are unwilling to accept the high-risk argument. Critics maintain that patents are formidable barriers to price competition and help promote restrictive business practices such as discriminatory pricing and cross-licensing agreements. The industry claims that patents lead to a search for improvements in the patented products by other manufacturers. But the search

or research direction of the industry also comes under fire. Critics argue that very little basic research is conducted; most efforts focus on molecular manipulation to produce "me-too" products. Yet another debate centers on whether molecular manipulation results in useful products.

Perhaps the most controversy surrounds the generic product-brand name issue. Critics argue that brand names are widely advertised, and promotional efforts frequently concentrate on disparaging generically equivalent but lower priced products as being of lower quality and that brand name strategy of the dominant manufacturers has resulted in an unnecessary multitude of names for products that have the same active ingredients.

According to critics, the interaction of patent privileges, cross-licensing agreements, molecular manipulation of products to produce differentiated products of questionable improvement, and the resultant effect of monopolistic advantage through the use of brand names and trademark protection have all served to "exploit" the customer through "high" prices and, consequently, "high" profits.

Defenders counter that brand names are an important source of manufacturer identification. For example, doctors can designate an appropriate and specific product for a given therapeutic need based on their experience with the product. Proponents of brand names maintain that all products are not like. A chemically equivalent product may not be clinically or biologically (that is, therapeutically) equivalent, a claim that also is disputed.

The viewpoint of the critics of the pharmaceutical industry in the United States had a dominant influence on the thinking of the health authorities of Pakistan, and in this chapter the discussion that follows examines in some detail the positions of these critics (and proponents) regarding risks, patents, research, brand versus generic names, and the equivalency issue. The issues are then reviewed in the Pakistani context.

## The Issues

### The Risk Factor

The pharmaceutical industry in the United States has a consistent record of higher profits compared to other manufacturing industries. (See Table 2-1.) Defenders contend that profits are commensurate with the high-risk, research orientation of the industry. Stetler states,

> The development and marketing of new drug products is an uncertain enterprise at best. The percentage of the sales dollar which the research-oriented drug companies spend to discover and develop new products is by far the highest of any American industry. Only one out of about 6,000 compounds tested by drug companies turns out to be a marketable product, and even then it can reach the market only after years of animal and clinical testing. In addition, a competitor's new or improved product for treatment of the same disease can appear at any moment to overshadow or make obsolete a profitable product perfected at great cost.[1]

Another remarks,

> In one recent year, it is estimated, the industry examined some 114,000 new compounds of which only about 1,900 were considered safe and active enough to test on human beings, only about 40 proved worthy of marketing, and possibly only 3 or 4 will eventually be judged real contributions to medicine.[2]

Table 2-1.--Comparative drug profits, 1960-1972, of U.S. pharmaceutical manufacturers.

| Year | Drug Manufacturers (in %) | All U.S. Manufacturers (in %) |
|---|---|---|
| 1960 | 17.0 | 9.3 |
| 1961 | 16.7 | 8.9 |
| 1962 | 16.7 | 9.9 |
| 1963 | 17.0 | 10.3 |
| 1964 | 18.4 | 11.7 |
| 1965 | 20.5 | 13.1 |
| 1966 | 20.8 | 13.6 |
| 1967 | 18.7 | 11.8 |
| 1968 | 18.4 | 12.2 |
| 1969 | 18.7 | 11.7 |
| 1970 | 18.2 | 9.4 |
| 1971 | 19.3 | 9.7 |
| 1972 | 18.3 | 10.6 |

Source: Milton Silverman and Philip R. Lee, Pills, Profits, and Politics (Los Angeles: University of California Press, 1974), p. 328.

Note: Calculated from information available in Quarterly Financial Report for Manufacturing Corporations, Federal Trade Commission, Securities and Exchange Commission.

Average net profits after taxes as a percentage of net stockholders' equity, U.S. drug manufacturers and all U.S. manufacturing corporations, 1960-72. Net stockholders' equity defined as average of beginning and end-of-year stockholders' equity.

Cooper comments that

> Europe's largest drug company, Roche, calculated that in 1962 they synthesized 2,500 new chemicals and had 2,480 failures. Twenty drugs reached the clinical testing stage, then yet again, faced a large fall out. Of those getting through, one is a commercial failure, and is in fact never likely to recoup its share of past research expenditure and yet it is a pharmacological success (Afronad). This is still in production because, on the infrequent occasions it is used, it minimizes blood losses during brain operations (and sometimes, liver operations), by lowering the blood pressure by means of a slow drip into a vein.[3]

Stetler of the Pharmaceutical Manufacturers Association (PMA) justifies high profits:

> In this high-risk industry, a high rate of profit is essential to attract the capital and other resources necessary to achieve further breakthroughs in medical progress. . . . We agree that the profitability of the drug industry is above average. We say this is not a unique phenomenon. It is one which characterizes rapidly growing industries generally where there is a high rate of product innovation.[4]

Markham has outlined five risk categories which a pharmaceutical firm faces: (a) development of a superior competitive product, (b) discovery of unanticipated side effects, (c) product abuse requiring withdrawal, (d) drug withdrawal, and (e) quality control problems.[5] Each of these is discussed below.

Superior competitive product.--A competitor may develop a drug superior to one of a company's major products and virtually replace it in a short time. For example, in 1956 Lederle held a leading position in the diuretic prescription market with Diamox, which accounted for 53 percent of all diuretic prescriptions. In 1957, Merck, Sharpe and Dohme introduced chlorothiazide under the brand name Diuril. By 1958, Diuril accounted for 72 percent of

diuretic prescriptions; Diamox had fallen to about 17 percent. By 1965, Diamox accounted for less than 4 percent of the diuretic market. In another instance, Merck's brand of cortisone, the original steroid, fell from 100 percent of all new steroid prescriptions written in 1950, to 3 percent in 1956, to less than 1 percent in 1958 after Schering introduced prednisone and others, such as Squibb, Upjohn, and Lederle, entered into the market with their cortisone-related products.

Unknown side effects.--Discovery of unanticipated side effects may lead to the immediate limiting of indications. Smith, Kline and French lost 80 percent in sales of Parnate, an antidepressant, when it was ordered removed from the market for a few months by the Federal Drug Administration (FDA). The product was reinstated because the benefits were deemed greater than the dangers if appropriate warnings were given by physicians and patients.

On another occasion, a small manufacturer, Lakeside, was requested by the FDA to show cause why Imferon (iron dextrin injection) should not be withdrawn, and in 1969 the company recalled the product. The reason was the possible risk of carcinogens, which eventually was demonstrated to be extremely small after the company conducted additional research. Lakeside was permitted to market the product 20 months later, but the firm suffered considerable losses.

Other instances of restrictions because of the fear of side effects are meclizine hydrochloride, an antinauseant, dimethylchlortetracycline, streptomycin, and dihydrostreptomycin.

Product abuse.--Abuse of a product may require its control or withdrawal. Examples of drugs that might be brought under the Drug Abuse Control Act are meprobromate, barbiturates, and amphetamines. When a product is shifted from a nonprescription to a prescription status, sales generally are lowered, and this is a risk with which the industry must contend.

Drug withdrawal.--Withdrawal or restriction of products pending additional evidence of safety and efficacy is another risk. MER 29 is an instance of a drug withdrawn because of unexpected side effects. The bioflavinoids are another category of products that have been affected in this way.

Quality problems.--Despite costly and extensive control procedures, an error may occur in drug manufacturing. The effects can be more devastating in pharmaceuticals than in other industries because of the nature of the products. A mistake in labelling could cause an expensive recall, as could changes in government standards or regulations. An error on the part of the government also can be very costly. A case in point is the FDA's recall of 27 million heart drug tablets. The recall proved erroneous when mistakes were discovered in the FDA inspectors' assaying techniques.

Gordon Conrad, a senior staff associate with Arthur D. Little, has commented on a survey conducted by his company under the sponsorship of the PMA:

> Analysis of the results of this survey indicates that a significant degree of interproduct competition (within specific therapeutic classifications of pharmaceuticals) has been in

> evidence during the past ten years. This competition, we believe, points to the nature of some of the uncertainties and risks that individual products face in attempting to serve the needs of the public and the medical profession.[6]

Conrad and Plotkin have developed a risk measure which in their opinion

> . . . appears to be a valid measure of uncertainty that corporate managements face in deciding on the rates of return their investments must achieve, i.e. the profitability levels necessary for the enterprise to survive and grow within the risk environment these managements perceive. . . . The pharmaceutical industry fits well within the overall pattern of risk/return relationship for American industry. While displaying a high level of profitability, the pharmaceutical industry also shows a high level of risk expectations over the period 1950-1965.[7]

Many others dispute the argument that drug manufacturing is an exceptionally risky undertaking.

Arguing against the Conrad-Plotkin measure of risk, Mueller, an economist with the Federal Trade Commission, has said:

> It would be inconsistent with risk theory if nearly all firms in an industry made very high profits and few or none ever suffered losses.
>
> The Conrad-Plotkin measure of risk misses this point. Risk is quantified by Conrad and Plotkin by measuring the variance of individual companies' rates of return about the industry average in a given year and computing a simple average of these values for the sixteen-year period 1950 to 1965. This measure assumes that the greater the variation in the profit rates of firms about the industry average, the riskier the industry. The chief conceptual shortcoming of this measure is that it does not necessarily tell us anything about the probability of incurring losses. In truth, using this measure an industry may be defined as risky even though all firms in it earn excessively high profits; on the other hand, this measure may define an industry as having very low risk even though all firms are making little or no profit.[8]

Using another definition of risk--the variance of the profit rates of companies over time and taking into account trends in profit

rates--Fisher and Hall concluded that risk accounts for a very small portion of pharmaceuticals' high profits. During the period 1959-1964, U.S. drug companies earned an average return of 18.32 percent. Fisher and Hall maintain that only 1.68 percent of returns are assigned to cover risk. They conclude that the "risk premiums" for drugs are "very low," and the explanation for high profits "must be sought in factors other than risk."[9]

A Department of Health, Education and Welfare (HEW) task force was "unable to find sufficient evidence to support the concept of the drug industry as a potentially risky enterprise."[10] Mueller found that

> the high profit experience of the drug industry is related only minimally to risk and uncertainty in a causal way. On the other hand the high profits of the drug industry are more closely associated with the high barriers to entry of new competition. In other words, in the classic tradition, the market power enjoyed by drug firms has been achieved primarily because the leading drug companies have been able to fence themselves off from effective competition, and in this sheltered position they have garnered extremely high profits.[11]

Mueller claims "the preponderance of economic evidence argues that the persistently high profits of the drug industry <u>are the result of the absence of effective price competition in the sale of many products</u>"[12] (emphasis added).

Patent privileges, for instance, are criticized as being protective devices shielding products from price competition.

## Patents

In the field of pharmaceuticals, there are basically two types of patents, namely, process patents and product patents. The

form of patent protection varies from country to country. For instance, the United States allows both types of patents; several countries, including Pakistan, allow only process patents; a few more, notably Italy, grant neither process nor product patents. The usual duration of a drug patent is 17 years, althouth it varies by country.[13]

Critics in industry consider the patent privilege a formidable barrier to entry for small firms. Here Steele makes an additional observation. He states that in certain cases,

> it is easy to 'patent around' existing chemical patents, and if such efforts result in devising improvements on products made or processes employed by original patent holders, the logical solution is cross-licensing. Cross-licensing negotiations, involving as they do the mutual compromise of patent monopoly positions, supply the motivation for a greater sense of community interest in price and production policies, and serve to further limit competition . . . facilitating a high degree of market control from the supply side.[14]

Critics cite many instances of patent abuses and cross-licensing "restrictive" agreements. Mintz has referred to the private settlement of the dispute over the antibiotic oxytetracycline produced by Pfizer in the 1950s.

> Squibb and Upjohn were licensed by Pfizer merely to sell, but not to manufacture, tetracycline. In addition to paying a lump sum for infringement, Bristol received a license from Pfizer for the manufacture and sale of tetracycline with the payment of royalties. In turn Pfizer was granted access to any Bristol patents in the field; if it exercised this option, Pfizer was obligated to pay royalties to Bristol.[15]

The corticosteroid hormone market is frequently mentioned as illustrative of patent privileges and cross-licensing arrangements leading to higher prices.[16] Cortisone was not eligible for patent

production, and the price fell 75 percent in three years because of intense price competition (from $20 per gram in 1951 to $5.48 per gram in 1954).[17]

In the case of prednisone, five firms filed applications, and an interference proceeding was declared by the patent office. While awaiting the decision, the firms made an arrangement among themselves, which gave "interim royalties to one of the firms and . . . all five started selling prednisone at the same price ($17.90 per 100 five-milligram tablets)."[18] Another firm, Syntex, was later included in the interference proceedings but not in the interfirm arrangement because of its proclivity for price competition. Syntex however, sold the drug in bulk form to small firms in the United States at low prices and these firms provided the finished product at about one-tenth the price the other firms were charging.[19]

Vaitsos illustrates market structures and controls through licensing arrangements and patent privileges.[20] Basing his descriptions on the Kefauver Hearings in the U.S. Senate, Vaitsos cites several examples of monopoly, duopoly, and oligopoly practices. Monopoly practices, according to Vaitsos, are evident in the case of chlortetracycline. For several years after 1948, American Cyanamid followed a policy of not granting licensing agreements to third parties in various countries for that product. For chloramphenicol (Parke-Davis) and oxytetracycline (Pfizer), no licensing was offered during the same period. Upjohn Company was the exclusive supplier of tolbutamide in the U.S. market for a number of years. Vaitsos

also cites duopoly practices. For several years two firms, the Carter Company and American Home Products, in the marketing of meprobromate kept prices for that product in the United States virtually the same. This duopoly structure was preserved in the international market for a considerable time. Various products derived from tetracycline provide an example of oligopoly practices. These products were initially fabricated and sold internationally by five companies. Competition was basically in the form of brand names.

Vaitsos observes that the effects of patents as market controls on prices are illustrated in the histories of four antibiotics. In 1944, technological advances in the production of penicillin by the U.S. Department of Agriculture laboratory in Peoria, Illinois, made commercial exploitation feasible. Patents were available to any producer without charge. As a result, strong competition led to continuous price decreases. Slightly different was the case of streptomycin, which was patented and licensed to many on a royalty payment basis. This led to higher gross margins than for penicillin, but competitive forces were still relatively strong. Finally, chloramphenicol and oxytetracycline were patented and initially not licensed to third parties. Gross margins for these drugs were among the highest in the pharmaceutical industry and considerably higher than average gross margins in other industries.

Critics recommend that patent privileges for drug products should be abolished or provisions should be made for compulsory licensing at reasonable royalty rates for drug patents.[21]

Others defend the patent privilege as a necessary stimulant of pharmaceutical research. Cooper argues that

> patents are, in reality, no longer the reward for innovation but rather the rewards for teaching the discovery to others, by making findings public and allowing one's competitors to use and build on this knowledge rather than duplicate effort.[22]

Cooper offers several examples. Prontosil was patented, and other firms soon found improvements rather than mere imitations, which resulted in the progress made in sulfa drugs; chlorothiazide was followed by six improved diuretics; cortisone was followed by products with reduced side effects and improved effectiveness. Concerning the arguments to abolish patents, Cooper says that

> the falseness about these arguments is the result of a refusal to depart from traditional price competition theory and to recognize the force of substitution as a form of competition in its own right.[23]

Comparing Italy, which grants no patents, to Japan, Cooper attributes the meteoric rise of Japanese pharmaceutical production to research efforts to improve processes even though the products are imitations of foreign ones. Japan's internal patents have also increased substantially. Italy, which Cooper attacks for "legalized theft of the world's stock of intangible research knowledge," has a very poor research record. Drug prices in Italy are relatively high compared to the United Kingdom. The Italian market is fragmented in the absence of patents, and each firm produces a limited high-cost output. In some cases there are 15 or 20 identical versions of the same chemical. The prestige of Italian pharmaceuticals also was lowered when it was revealed that some firms had bought

stolen antibiotic secrets. The firms sold these products at a low price, which was cited as an indication of price differentials between equivalent products. Cooper also denounces some Italian firms for producing substandard drugs. He points out that most imitating companies are not in full possession of the patent holder's or innovator's knowledge or experience. Tests conducted on products produced in these circumstances have revealed alarming health hazards.

Opinion in the Italian drug industry is divided on the issue, one group favoring patent production, the other opposed. According to Cooper, it was Lepetit, a firm in the pro-patent camp, that was responsible for the one (post-Kefauver era) major drug discovery, Rifocin (an antistaphylococci drug).[24]

Cooper argues that evidence presented during the Kefauver Hearings indicating that, since 1940, drugs discovered in nonpatenting countries outnumber those in patent-granting countries was misleading because process patents were ignored. In a reanalysis of the information, he points out that the same list would not show a single drug as having been discovered in a nation without some form of patent protection.[25]

Industry apprehension about entering countries with restraints on patent privileges is indicated by a comment from a Roche representative:

> We recently decided against investing in a country which, while giving interesting terms, was in the process of discussing a law designed to weaken patent protection for

> pharmaceuticals. I have no doubt that many other companies react in the same way whenever they have to consider investing in a country that does not assure them of protection for their inventions.[26]

Vaitsos, however, maintains there is no empirical verification for the claim that patent protection is a necessary requirement for foreign investment. He cites a U.S. study which concluded that, "although investors and their patent attorneys may wish for better patent protection if it can be had, the nature of protection is rarely a significant factor in the ultimate decision whether to invest."[27]

## Pharmaceutical Research

Closely related to the patent question is the matter of research. Pharmaceutical firms believe they are entitled to protection because of the research investments they make. They strongly support patent privileges, considering these incentives which ensure pharmaceutical progress. As patents provide a legal "monopoly," a barrier is erected against other firms, which cannot market the same product. However, the barrier is not absolute, for companies can "invent around" the product, or develop another product which might be able to obtain patent protection.

Comanor notes that

> the impact of the patent system, however, has not been to create tight monopoly positions, since patented products are often highly substitutable and compete with one another. But rather, it has been to foreclose, to a great extent, rivalry between identical chemical entities as standardized commodities about which price competition might develop.[28]

Arguments flow from each side on the merits of this activity. Some charge that firms bring out "me-too" products, playing the game

of molecular manipulation to market products which do not provide any "genuine" advantages over existing ones. Others contend that this rivalry yields better processes.

Critics argue that very little fundamental research is done by pharmaceutical companies. A HEW task force on prescription drugs concluded that

> since important new chemical entities represent only a fraction--perhaps 10 to 20 percent--of all new products introduced each year, and the remainder consists merely of minor modifications or combination products, then much of the industry's research and development activities would appear to provide only minor contributions to medical progress.[29]

Steele contends that research is biased toward patentable inventions and not toward those areas in which patents cannot be obtained. Thus, applied, not, basic, research is stimulated. This circumstance, in turn, engenders "concocting" new products rather than fully investigating the properties of known compounds. According to Steele, research is imitative and directed at finding a "patentable vehicle for a 'blitz' sales promotion campaign." Since there is a commercial advantage in duplicating successful new drugs, research often tends to be duplicative, which misallocates resources and diverts talent from basic to applied research.[30]

The "molecular manipulation" issue involves developing a pharmacologically identical molecule similar to that of a profitable rival but sufficiently distinct to permit a patent to be obtained. Critics claim the typical imitation is of "dubious superiority if not absolutely inferior" to the original. D. A. Console, a former

employee of Squibb, has said that "the majority of [drug research] is in that category . . . and many of these products . . . promise no utility; they promise sales."[31] Weinstein, formerly with a division of Pfizer, has commented that the talents of research personnel should not be expended on "patent-bypassing chemical manipulations, on ridiculous mixtures of drugs, or inconsequential additives to established drugs."[32]

Critics cite examples that they believe illustrate this point. Williams notes that when Schering's patent on Chlortrimetron, an antihistamine, ran out, and the price of generic chlortrimetron was very low, Schering eliminated the L-isomer, the inactive isomer, and retained the D-isomer, the active form. The dosage was reduced from four milligrams to two, and the product was promoted at a much higher price with the statement that "Schering eliminates the molecular dross." Roche, which sold a good sulfa drug, Gantrisin Sulfisoxazole, when faced with expiry of the patent protection and hence lower prices of the generic product, came out with a minor molecular modification. Called Gantanol, the drug is an agent which has the same spectrum as the parent compound. The modified form is slightly longer acting, but it does not have a unique qualitative action different from Gantrisin.[33]

Silverman suggests that major molecular modifications representing uncommon breakthroughs are rare and that most alterations are minor modifications of older products such as a sodium rather than a potassium salt of an allergy drug, or a butyl rather than a

propyl ester of a tranquilizer. These usually are priced higher or at the same level as the parent compound. These minor modifications do not provide significant clinical advantages. They may offer, for example, slightly more rapid absorption, which Silverman claims may be of more interest to statisticians than to clinicians.[34]

Whether a drug is a minor or major advance is highly debatable. Cooper, for example, cites Beecham's antibiotic Penbritin as a revolutionary breakthrough through the process of molecular manipulation. He also points out that important products such as Nardil (phenelzine), Niamid (nialamide), and Marplan (isocarboxazid) resulted from a small change in Marsilid (iproniazid). The addition of other agents, says Cooper, has remarkable effects; an instance is dicalcium phosphate, which reduces the action of tetracycline, whereas glucosamine enhances it. Side effects may be reduced: Several sulphonamides in combination tend to reduce renal toxicity, and spironalactone in Aldactone improves its performance. Chance discoveries can also result: Diamox was intended for use as a diuretic but is also used to treat glaucoma. Lederle found a compound with antiviral capability but later discovered it had anthelminthic properties, and the product proved useful against protozoal infections.[35]

Beckman has compiled "an impressive but not exhaustive" list of useful drugs that "would not exist today if someone had not tinkered with the molecular structure of another drug already in use, or sought by synthetic means to develop useful congeners of such a

drug."[36] Although Beckman does not claim that all variants are useful, he is opposed to governmental restrictions because this might impede and exclude development of possibly valuable drugs.

Brand Names and Generic Names

Of the five areas discussed here--risks, patents, research, brand versus generic names, and the equivalency issue--the last two topics perhaps generate the most controversy. Before beginning the discussion, the clarification of certain terms may be useful. The following definitions are provided by the Pharmaceutical Manufacturers Association.[37]

Chemical names are the terms by which the chemical structure of a drug is described.

Generic name, as applied to pharmaceuticals, refers to the common, established, or nonproprietary name by which a drug is known as an isolated substance, or as a drug product, irrespective of its manufacture. The common definition of generic, i.e. relating generally to members of a genus or class as "mammal" or "Homo sapiens," is not directly applicable here: In drugs, "generic" denotes one particular drug, though not any particular formulation of it as a drug product.

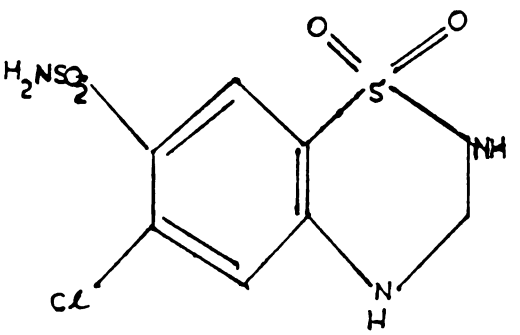
Tradenames are "individual names and surnames, firm names and trade names used by manufacturers, industrialists . . . the names or titles lawfully adopted and used by persons, firms, associations, corporations, companies, unions." Tradenames identify manufacturers, not necessarily products.

A trademark is "any word, name, symbol or device or any combination thereof adopted and used by a manufacturer or merchant to identify his goods and distinguish them from those manufactured or sold by others." It is the manufacturer's chosen name for his product.

Brand name, though a common term, has an imprecise legal standing: It is often used interchangeably with or in place of the term trademark.

The example shown in Figure 2-1 indicates the differences among these various terms.

Chemical Structure:




(a) Chemical name:

6-Chloro-3,4-dihydro-2H-1,2,4-benzothiadiazine-7-sulfonamide 1,1-Dioxide

(b) Generic name:

hydrochlorothiazide

(c) Tradenames of suppliers:

Abbott Laboratories
CIBA Pharmaceutical Company
Merck Sharp & Dohme

(d) Trademarks or brand names:

Oretic
Esidrix
HydroDiuril

Figure 2-1.--Drug nomenclature.

Source: Pharmaceutical Manufacturers Association, Brands, Generics, Prices and Quality (1971), p. 2.

Brand names have been called the "crux of the marketing system." Standard and Poors, for example, remark that

> once the trade-named product has won wide acceptance by physicians, it is difficult to supplant. Thus it may stubbornly hold its market share, despite subsequent development of more advanced competitive products or increased competition following expiration of the patent.[38]

From a marketing viewpoint, the successful brand name has a special significance. Obviously, through advertising and promoting brand names, manufacturers are attempting to induce brand loyalty among the prescribers and/or users of the product. When substitution is not allowed, this loyalty to brand name products is extremely important, since the pharmacist must fill the prescription with the particular product specified and no other.

Industry representatives defend the use of brand names on several grounds. (1) They argue that these help the physician identify reliable and high quality products upon which the manufacturer stakes his reputation. Thus the doctor can develop confidence in the quality of a certain product. (2) When a brand name is specified in a prescription, the physician has the assurance that it will be filled precisely as indicated. If a "generic" prescription is written, the particular product choice rests with the pharmacist. (3) Physicians find it easy and convenient to use brand names for specifying products. (4) The practice of using brand names is quite consistent with the practices of other firms in the economy, which direct attention to their product offerings.

Critics maintain that brand names create confusion for prescribers, making it difficult for them to recognize that two

products with different names may possess the same active ingredient. Meprobromate, a mild tranquilizer, is an example. It may be prescribed alone or in combination under any of the following trade names: Apascil, Atraxin, Biobamat, Calmiren, Cirpon, Cyrpon, Ecuanil, Harmonin, Mepantin, Mepavion, Meproleaf, Meprosin, Meprospan, Meprotabs, Miltown, Nervonus, Meuramate, Oasil, Pamaco, Panediol, Perequil, Perquietil, Petranquil, Placidon, Probamyl, Quanil, Quilate, Sedabamate, Sedasil, Urbil, and Viobamate.[39]

Modell observes that

> there is a real danger in confusion, when trade names are used because often these names of drugs are utterly without meaning. Many of the names are made up by Madison Avenue before the drugs are discovered. They have no connection with the meaning of the action or the chemical nature of the drug. Use of trade names is just support of a practice of ignorance and intellectual laziness.[40]

In a similar vein, Dr. Garb points out that the total number of different names for prescribed drugs is 7,000, and even this figure may be underestimated. He goes on to say that

> doctors cannot possibly keep up with the flood of private product names, and this situation leads to poor medical practice. It is not that the doctors are ignorant, it is not that the doctors don't want to know what is going on. The situation is simply that doctors are human beings, not computers and they have certain limitations, and they can't possibly learn this. Therefore they must compromise. They learn a few names and they work with those few. Unfortunately, the names that they learn and work with are not always necessarily the best ones for the particular patient that they are treating, and the doctor just has no way of encompassing the total amount of information needed in order to handle this.[41]

But it also can be argued that there are no restrictions against doctors prescribing by generic name if they want to. If proliferation of brand names causes "confusion," it should result

in an increase in generic prescriptions, particularly if the prescriber perceives the products to be of similar therapeutic quality.

During the Nelson Hearings and the Kefauver Hearings, data on drug prices indicated that brand name products, usually of larger firms, tended to be higher priced that generic name products of smaller firms.[42] For example, the Kefauver Hearings showed that the prices of brand name drugs generically known as reserpine and prednisone were 30 times more expensive than their generic equivalents. The Pharmaceutical Manufacturers Association argues that when large price differences exist between a brand name and a generic name drug, doctors have been known to prescribe generically. This was evident by the fact that prednisone and reserpine ranked sixth and ninth among the top generic prescriptions in the United States.[43]

Garb argues that

> the use of . . . private product names presents the operation of a free competitive market in drugs. Few if any physicians can keep up with all these names, let alone the prices of each product. Let us suppose that Equanil sold for 50 percent less than Miltown. A doctor accustomed to prescribing Miltown would be unlikely to change, if he did not know that Equanil was essentially the same thing, producing exactly the same result, but cheaper. I doubt if there are many physicians who know the composition of all the private product named drugs. In fact, I rather doubt if there are any physicians who know the composition of all those drugs.[44]

One also could argue that even if the same products were available by generic name only, doctors still might find it difficult to keep up with the various advantages of the different products.

Critics say that companies promote not only their brand-name products but also the practice of prescribing by brand names. More than 90 percent of prescriptions written in the United States refer to brand names, and the promotion of brand name prescribing thus precludes selecting drugs on the basis of price. Dr. Schifrin has observed that

> even for products sold by many firms, the popularization of the use of trade names in prescription writing has led to the dominance in those markets by a few major companies in that product line who can promote through massive advertising outlays the trade names of their specialties. . . . The competition among firms in the market is no longer one in which producers of comparable items seek customers through more attractive prices, but one in which a single seller often exists alone, or, if he shares the market with a few rivals, that rivalry is in advertising claims, and trade name repetition--certainly not in price. This is a large, costly and wasteful competition. It is excessive, confusing, and largely ignored, but it does serve its purpose. It popularizes particular trade names and strengthens the use of trade names in general, thereby rendering price competition ineffectual. Such advertising adds little if anything to drug therapy, yet is a large cost, easily shiftable to the consumer.[45]

Critics believe that the abolition of brand names would improve the drug selection effort and enhance the ability of physicians to compare costs, benefits, and uses of competing products. Intense product differentiation would be reduced, costs would be lower, and barriers to price competition would be weakened. To counter the influence of brand name promotion, "one route, in some sense an easier route, would be to provide information to the doctor which would reduce the impact of trade names and heavy advertising outlays."[46]

The most potent argument in favor of prescribing by brand names is that it allows the doctor to designate the particular product which he believes is the best therapeutic indication. The source identification provided by brand names is thus important, particularly because all products may not meet the same product quality or performance standards. Commenting on a statement that drug recalls were not limited to small "unknown" manufacturers, Stetler says that the fact that "mistakes are made by even the best manufacturers only proves the importance to physicians and patients of selecting the manufacturing source that has the best record of achieving quality, and the least likelihood of making future errors."[47]

He also believes that the most practical and reliable measure of consistent quality is manufacturer identification of drug products. Physicians and pharmacists cannot conduct their own tests and inspections. On the basis of a doctor's experience with a product for a particular patient, he can be reasonably certain that the same product from the same source will have a similar therapeutic performance.

Although government agencies have been established to monitor the quality of products, this is done by sampling and periodic inspection of manufacturing procedures. Stetler observes that

> there appears to be a rather common, mistaken belief that the federal drug laws somehow guarantee a uniform high level of quality in all drug products which reach and are dispensed from the shelves of a pharmacy. This is not so and as a practical matter, can never be so. Although Food and Drug Administration personnel do a conscientious job, it is impossible for them to inspect every manufacturer and distributor often enough to insure that every drug product meets even bare minimum quality standards. Maximum quality and reliability can only be built in by the manufacturer.[48]

The Equivalency Issue

Closely related to the brand versus generic name argument is the question of equivalency. The term "generic" equivalence has many interpretations and can be confusing. To clarify this, the HEW Task Force on prescription drugs used the terms "chemical equivalence," "biological equivalence," and "clinical equivalence," and defined these as follows:

> Chemical equivalents.--Those multiple-source drug products which contain essentially identical amounts of the identical active ingredients, in identical dosage forms, and which meet existing physicochemical standards in the official compendia.
> Biological equivalents.--Those chemical equivalents which, when administered in the same amounts, will provide essentially the same biological or physiological availability, as measured by blood levels, and so forth.
> Clinical equivalents.--Those chemical equivalents which, when administered in the same amounts, will provide essentially the same therapeutic effect as measured by the control of a symptom or a disease.[49]

Industry spokesmen argue that choosing a lower priced product is justified if the products are of the same quality and have therapeutic (clinical) equivalence, but this is usually not the case. The industry maintains that chemically equivalent drugs may not be either biologically or clinically equivalent. Lueck, a quality control director for Parke-Davis, has observed:

> It is important to note that the industry considers the USP, NF and FDA antibiotic regulations as essential and the tests and standards contained in them to be the strongest in the world. However, we must realize that these standards are not all-inclusive, and by no means should they be the sole basis for judging whether a product is suitable for use by a patient. Analysis of a product and adherence to the standards established by the official compendia does not mean that two products containing the same active ingredient will necessarily perform the same way in the body. Unfortunately,

> technology has not yet provided adequate laboratory tests to assure the physiological equivalence of drug products. Therefore, the gap must be filled with a complete program of strict adherence to the quality control concept.[50]

To support its contention on the clinical inequivalence of drugs, the PMA has elicited testimony from various professionals and has published the results of a number of studies that support this view.[51]

However, the evidence has been subjected to critical assessment and is not accepted by everyone. Dr. Lee, Assistant Director, Health and Scientific Affairs, HEW, commented:

> It is evident that the issue of chemical equivalency has been clouded by articles, publications, press statements, and promotional claims which seem designed to make the issue appear much larger. One example is a recent publication (by the PMA) entitled "Bibliography on Biopharmaceutics," which contains 501 documented references dealing with the influence of pharmaceutical formulation on the therapeutic activity of drugs. According to its publisher, this volume supposedly refutes what is termed the "myth of therapeutic equivalency." We have had this book reviewed by the professional staff of the task force, by the Food and Drug Administration, and by our consultant experts. They are in agreement on the following points. . . . It appears that there were only two or three [references] which demonstrated statistically significant lack of clinical equivalency, and in one case, the differences were described as being without any practical clinical importance.[52]

Dr. Lee also indicated that the HEW Task Force on Prescription Drugs concluded that,

> except in rare instances--drugs which are chemically equivalent, and which meet all official standards, can be expected to produce essentially the same biological or clinical effects. . . . The lack of clinical equivalency has been grossly exaggerated as a major hazard to the public health.[53]

Dr. James Goddard, a former commissioner of the Food and Drug Administration, has observed that he

> would challenge the claim that you always have to buy a brand-named product in order to be sure that a drug is good. Poor manufacture and control will produce a bad brand-named drug just as surely as it will produce a bad generic-named drug. Manufacturers of brand-named drugs have yet to show that their products are, in fact, produced in all cases to meet subtle refinements over and above basic standards of therapeutic excellence that in any significant way affects the health and well being of our people.[54]

Steele has stated that "the emphasis on the unique nature of each pill is reminiscent of the philosophical doctrine of nominalism which implies that no generalizations are possible since everything is in a unique category by itself."[55]

Questioning the therapeutic equivalence of chemically equivalent drugs, Dr. Alfred Gilman, Chairman, Drug Efficacy Study, National Academy of Sciences-National Research Council, wrote to Senator Gaylord Nelson in 1967 during the industry hearings. He said that he

> was appalled by many of those statements which imply that generic drugs, marketed cheaply by small drug companies are the equivalent of established trademarked preparations merely because chemical analysis indicates that the preparation actually contains the specified amount of the drug. . . . I am all in favor of open competition in the marketplace once the patent on a drug has expired . . . however it should be true competition and not legalized piracy . . . therefore . . . before the so-called "generic equivalent" can be marketed and can be described by the same package insert that applies to drug formulations that have been carefully studied, that laboratory and clinical data relating to absorption, side effects, duration of action, etc., should be required.[56]

In 1970, Schneller presented a status report on drug bio-availability and listed 40 drug substances

> which have been proved, or are definitely suspect, of intrinsic susceptibility to bio-availability problems. By this is meant that there is strong, if not conclusive, evidence (at

> least in the opinion of the authorities cited) that these drug substances are characterized by limited solubility in gastric or intestinal fluid and/or limited gastrointestinal absorbability, in consequence of which there exists a significant possibility of substantial differences in therapeutic effect occurring between dosage forms from different suppliers because of differences in the physical characteristics of the raw material, in the formula used, or in the processing.

In Schneller's opinion,

> despite all of the developments which have been discussed, it is clear to those most intimately involved that years of further intensive study of a large number of individual drug substances will be required before differences in bioavailability between different dosage forms of each drug will be thoroughly understood or the lack of such a difference thoroughly substantiated.[57]

Contrasting the earlier statements of FDA representatives, the PMA cites FDA Commissioner Edwards as stating that "it has become increasingly apparent that drug products which purport to be equivalent and which may satisfy chemical and other analytical tests of equivalence, may not be therapeutically equivalent." In 1970 Edwards indicated that "this has been demonstrated in the antibiotic area where batches which have been certified by the FDA after careful laboratory testing have been found to vary considerably in the blood levels they produce."[58]

In 1970, Secretary of HEW Robert Finch is reported to have written that

> we would be reluctant to impose constraints on prescribers until such time as the Department has acceptable answers to the question surrounding the equivalency of drug products. The problem is considerably more difficult than we had anticipated and will require substantial time and effort to resolve.[59]

## The Issues: Pakistani Perspective

This section summarizes the major arguments on the issues presented earlier in the chapter. Special reference is made to how the arguments may have been viewed by those who formulated Pakistani health policy.

### The Risk Factor

Undoubtedly, there is a high risk factor involved in the development and marketing of drugs. However, as discussed earlier, critics contend that the risk premium is not sufficient to justify the level of profits in the pharmaceutical sector. The Pakistani government obviously held this latter view. Although the pharmaceutical industry in Pakistan contended that profits were not high (about 6 percent of sales), the transfer prices used by some multinational firms for imported raw materials were much higher than the world market price for the same items (see Chapter VI, pp. 169-171), suggesting that profits may have been understated in certain cases.

Some argue that although there might be

> some justification in charging a premium for risk in areas for which new products were developed, this justification does not hold for the developing countries as the innovative efforts of the transnational companies are not geared to satisfying the markets of such countries. Developing countries should, therefore, not be required to pay for technology for which the marginal cost to the firms is nearly nil.[60]

Health policy makers in Pakistan responsible for implementing the Generic Names Act would concur with this view.

Patents

Although some argue that patents are a necessary stimulus for research and development efforts to provide better products, critics maintain that patents lead to restrictive business practices such as mutual cross-licensing and price fixing, resulting in higher prices and higher profits.

Vaitsos argues that patents have a predominantly negative effect on developing countries. They offer no significant benefits, and restrict technological advance because they impede imitation and adaptation. Vaitsos points out that most patents of industrial importance are owned by a few foreign countries, enabling them to achieve dominance and block competition. With reference to the pharmaceutical industry, Vaitsos says that "one rarely encounters other industries where such a large number of foreign firms operate in a developing country, with oligopoly or monopolistic positions in their particular product lines stemming basically from the effects of patents." Vaitsos cites several restrictive business practices that emanate from patent protection: price fixing, discriminatory rates through discriminatory royalties charged to different licensees, tie-in arrangements necessitating purchase of other products, territorial restrictions on domestic and export sales, and "grant-back" covenants concerning patented know-how. He suggests that international market control through patent cartels achieved by cross-licensing arrangements results in profit levels which would "otherwise be unattainable."[61] A U.N. study of

restrictive business practices in the pharmaceutical industry supports Vaitsos's view.[62]

In 1972, Pakistan already had stringent restrictions on patents (although some would argue that they were not strong enough). Pakistan did not belong to any international patent conventions and only maintained reciprocal arrangements with the United Kingdom and certain Commonwealth countries. Product patents were not allowed; only process patents were granted. The government had sanctions against nonworking patents, and a patent could be revoked if the demand for the patented article was "not being met adequately" or if "the establishment of new trade or industry is unfairly prejudiced by default of the patenter to manufacture." The government also reserved the right to revoke a patent "if it is found to be prejudicial to the public."[63] The government at the time of the introduction of the Generic Names Act had the power to correct specific "abuses" of patent privileges. For example, under existing regulations the authorities could allow cheaper imports from countries which do not recognize patents, such as Italy. The government probably felt that no significant gains could be made by abolishing process patents and so refrained from instituting any further restrictions.

## Pharmaceutical Research

Proponents argue that patents are necessary to stimulate research, and that investments in research have resulted in products with significant therapeutic differences. Critics maintain that

research by multinational pharmaceutical firms is primarily directed toward developing products which are minor molecular modifications of patented products, offering little clinical advantage over the original drug. The Pakistani government was inclined to accept the latter viewpoint. The introduction of the National Formulary under the Generic Names Act was basically a government effort to restrict the number of drugs and remove "nonessential" drugs from the market.

Critics also claim that much-needed research to combat diseases prevalent in the developing countries is lacking. "Foreign firms are not interested in research on drugs for tropical diseases as the global demand for such drugs, in their view, will not be sufficiently economic." In a different context, one source observes:

> In developing countries the scale of priorities for drugs is very different from that of most developed countries. Whereas developed countries are concerned with the treatment of diseases of the heart and the central nervous system and psychosomatic conditions, developing countries must give priority to treatment of parasitic and other communicable or infectious diseases.[64]

Critics imply that developing countries such as Pakistan should not be expected to contribute, through high prices, for research which is essentially directed toward development of drugs for the major markets of the Western world.

## Brand Names and Generic Names

Those who defend brand names maintain that these are justified because their use reflects doctors' confidence in a particular product made by a particular manufacturer. The doctor becomes aware of the therapeutic advantages of a brand name drug and has the

security of knowing that when he prescribes that drug, a patient is provided a medicine according to the doctor's evaluation of its clinical advantage.

Using generic names would shift the choice of drugs to the pharmacist, who would not be fully aware of the therapeutic requirements of a patient.

Critics claim that the use of brand names has led to a confusing array of drugs for chemically equivalent generic formulas. Brand loyalty induced by heavy promotional expenditures of dominant firms contributes toward sustaining prices of brand name drugs at higher levels than for generic name equivalent products.

In developing countries such as Pakistan, the use of brand names is usually the most strongly attacked aspect of pharmaceutical marketing practices. The leading brand name products of dominant multinational firms enjoy substantial market shares, even though "equivalent" products are available at cheaper prices.

In Pakistan, about 12,000 drugs were marketed in 1971.[65] The leading products were brand name drugs produced by well-known multinational pharmaceutical firms. Pakistani local manufacturers followed the lead of their foreign counterparts in developing their own brand name products. Instruction in the medical schools at the time, that is, prior to introduction of the Generic Names Act, did not commend the use of generic names, and most prescriptions specified brand name products. At times, doctors would switch from one brand name drug to another because of their impression that it was an

entirely different product, when in reality the drug was a chemically equivalent generic drug. Evidently, the government felt that it could reduce "product proliferation" by introducing a National Formulary and promote classical price competition by abolishing brand names.

The Equivalence Argument

Many believe that chemically equivalent drugs may not have the same therapeutic (clinical or biological) effect. Others have argued that the inequivalence argument is grossly exaggerated and that, except in rare cases, drugs which are chemically equivalent and meet official standards produce essentially the same biological or clinical effects.

The health authorities in Pakistan obviously were of the latter opinion; the government followed an unstated policy of assuming clinical equivalence among chemically equivalent drugs. Drugs were tested only to determine whether they met stated specifications of chemical composition.

With these arguments in mind, it is not surprising that when the government chose to adopt reforms, in addition to abolishing brand names, it selected to adopt a National Formulary composed of a limited number of drugs. This "reform" measure is the subject of the next chapter.

## Footnotes--Chapter II

[1]C. Joseph Stetler, statement before the U.S. Senate, Competitive Problems in the Drug Industry, pt. 4 (Washington, D.C.: Government Printing Office, 1967), p. 1420.

[2]Lawrence Lessing, "Laws Alone Can't Make Drugs Safe," Fortune 67 (March 1963): 143.

[3]Michael H. Cooper, Prices and Profits in the Pharmaceutical Industry (New York: Pergamon Press, 1966), p. 198.

[4]Stetler, op. cit., pp. 1420-21.

[5]Jesse W. Markham, statement before the U.S. Senate, Competitive Problems in the Drug Industry, pt. 5 (Washington, D.C.: Government Printing Office, 1968), pp. 2134-38. The examples of the five risk categories are those that the Pakistan Pharmaceutical Manufacturers' Association provided; see Markham, loc. cit.

[6]Gordon R. Conrad, Statement before the U.S. Senate, Competitive Problems in the Drug Industry, pt. 5 (Washington, D.C.: Government Printing Office, 1967), p. 1785.

[7]Gordon R. Conrad and Irving H. Plotkin, "Risk and Return in American Industry--An Econometric Analysis," in Competitive Problems in the Drug Industry, pt. 5 (Washington, D.C.: Government Printing Office, 1967), p. 1747.

[8]Willard F. Mueller, Statement before the U.S. Senate, Competitive Problems in the Drug Industry, pt. 5 (Washington, D.C.: Government Printing Office, 1967), p. 1831.

[9]I. N. Fisher and G. R. Hall, "Risk and Corporate Rates of Return," the RAND Corporation, Santa Monica, California, in Competitive Problems in the Drug Industry, pt. 5 (Washington, D.C.: Government Printing Office, 1967), pp. 2125-27.

[10]U.S. Department of Health, Education, and Welfare, Task Force on Prescription Drugs: Report and Recommendations (Washington, D.C.: Government Printing Office, 1968), p. 18.

[11]Mueller, op. cit., p. 1824.

[12]Ibid., p. 1827.

[13]For a survey of patent laws, see The Role of Patents in the Transfer of Technology to Developing Countries (New York: United Nations, 1964).

[14]Henry Steele, "Patent Restrictions and Price Competition in the Ethical Drugs Industry," The Journal of Industrial Economics 12 (July 1964); reprinted in Competitive Problems in the Drug Industry, pt. 5 (Washington, D.C.: Government Printing Office, 1967), p. 1975.

[15]Morton Mintz, By Prescription Only (Boston: Beacon Press, 1967), p. 356.

[16]Steele states that "very little quantitative data exist outside the material published in the Hearings [referring to the Kefauver investigation] which concerned themselves with four drug categories, antibiotics . . . , corticosteroid hormones . . . , tranquilizers . . . and oral antidiabetic drugs. . . . The corticosteroids market is easily the most representative of the four, since the pattern is not as clear in antibiotics nor as complete in tranquilizers or oral antidiabetics. Consequently, chief emphasis will be given to the corticosteroids market as a paradigm of the effect of patents and other drug marketing institutions on price competition." In Steele, loc. cit.

[17]Cited in Henry Steele, "Monopoly and Competition in the Ethical Drugs Market," Journal of Law and Economics, October 1962; reprinted in Competitive Problems in the Drug Industry, pt. 5 (Washington, D.C.: Government Printing Office, 1967), p. 1967.

[18]Ibid.

[19]Ibid.

[20]Constantine Vaitsos, "Patents Revisited: Their Function in Developing Countries," in Science, Technology and Development: The Political Economy of Technical Advance in Underdeveloped Countries, ed. Charles Cooper (London: Frank Cass, 1973), pp. 93-94.

[21]For the views of two major critics, see Steele, "Monopoly and Competition in the Ethical Drugs Market," pp. 1950-70, and Leonard G. Schifrin, "The Ethical Drug Industry: The Case for Compulsory Patent Licensing," Antitrust Bulletin, Fall 1967; reprinted in Competitive Problems in the Drug Industry, pt. 5 (Washington, D.C.: Government Printing Office, 1967), pp. 1890-1900.

[22]Cooper, op. cit., p. 154.

[23]Ibid., pp. 154-55.

[24]Ibid., pp. 160-65.

[25]Ibid., pp. 159-60.

[26]Ibid., p. 163.

[27]Vaitsos, op. cit., p. 77.

[28]William S. Comanor, "Research and Competitive Product Differentiation in the Pharmaceutical Industry in the United States," Economica, November 1964; reprinted in Competitive Problems in the Drug Industry, pt. 5 (Washington, D.C.: Government Printing Office, 1967), pp. 2074-75.

[29]U.S. Department of Health, Education, and Welfare, Task Force on Prescription Drugs, p. 12.

[30]Henry B. Steele, statement before the U.S. Senate, in Competitive Problems in the Drug Industry, pt. 5 (Washington, D.C.: Government Printing Office, 1967), pp. 1911-14.

[31]Dale Console, Statement before the U.S. Senate, Administered Prices in the Drug Industry, pt. 18 (Washington, D.C.: Government Printing Office, 1960), p. 10379.

[32]H. J. Weinstein, statement before the U.S. Senate, Administered Prices in the Drug Industry, pt. 18 (Washington, D.C.: Government Printing Office, 1960), p. 10254.

[33]H. L. Williams, Statement before the U.S. Senate, in Competitive Problems in the Drug Industry, pt. 2 (Washington, D.C.: Government Printing Office, 1967), pp. 472-73.

[34]Milton Silverman and Philip R. Lee, Pills, Profits, and Politics (Los Angeles: University of California Press, 1974), p. 39.

[35]Cooper, op. cit., pp. 89-92.

[36]Harry Beckman, "In Defense of Tinkers," The New England Journal of Medicine 267 (July 12, 1962): 72-77.

[37]Brands, Generics, Prices and Quality: The Prescribing Debate After a Decade (Washington, D.C.: Pharmaceutical Manufacturers' Association, 1971), pp. 2-3.

[38]Standard & Poor's Corporation, "Drugs, Medical Care, and Cosmetics, Basic Analysis," Trade and Securities, May 8, 1969, p. D-12.

[39]U.S. Senate, Competitive Problems in the Drug Industry, pt. 2, p. 529.

[40]Walter Modell, Statement before the U.S. Senate, in Competitive Problems in the Drug Industry, pt. 1 (Washington, D.C.: Government Printing Office, 1967), p. 290.

[41]Solomon Garb, statement before the U.S. Senate, in Competitive Problems in the Drug Industry, pt. 2 (Washington, D.C.: Government Printing Office, 1967), pp. 530-31.

[42]A number of examples of price variations were cited during the Senate Hearings. See, for example, Competitive Problems in the Drug Industry, pt. 3, 1967.

[43]Brands, Generics, Prices and Quality, pp. 14-15.

[44]Garb, op. cit., p. 526.

[45]Leonard Schifrin, statement before the U.S. Senate, in Competitive Problems in the Drug Industry, pt. 5 (Washington, D.C.: Government Printing Office, 1967), p. 1880.

[46]William S. Comanor, statement before the U.S. Senate, in Competitive Problems in the Drug Industry, pt. 5 (Washington, D.C.: Government Printing Office, 1967), pp. 2061-62.

[47]Stetler, op. cit., pp. 1417-18.

[48]Ibid., p. 1417.

[49]U.S. Department of Health, Education, and Welfare, Task Force on Prescription Drugs, p. 3.

[50]Leslie M. Lueck, statement before the U.S. Senate, in Competitive Problems in the Drug Industry, pt. 6 (Washington, D.C.: Government Printing Office, 1968), p. 2229.

[51]See, for instance, Brands, Generics, Prices, and Quality, chapter 3, pp. 31-42; Appendix, pp. 75-114.

[52]Philip R. Lee, statement before the U.S. Senate, in Competitive Problems in the Drug Industry, pt. 9 (Washington, D.C.: Government Printing Office, 1967), p. 3726.

[53]Ibid., p. 3718.

[54]James Goddard, statement before the U.S. Senate, in Competitive Problems in the Drug Industry, pt. 2 (Washington, D.C.: Government Printing Office, 1967), p. 797.

[55]Steele, Competitive Problems in the Drug Industry, pt. 5, p. 1920.

[56]Cited in Brands, Generics, Prices, and Quality, pp. 32-33.

[57]George H. Schneller, "Status Report on Bio-availability," American Journal of Hospital Pharmacy 27 (June 1970): 487.

[58]Cited in Brands, Generics, Prices, and Quality, pp. 39-40.

[59]Ibid.

[60]Sanjaya Lall, Major Issues in Transfer of Technology to Developing Countries: A Case Study of the Pharmaceutical Industry (Geneva: United Nations, 1975), p. 40.

[61]Vaitsos, op. cit., p. 87.

[62]United Nations Conference on Trade and Development, Restrictive Business Practices: Review of Major Developments in the Area of Restrictive Business Practices (New York: UNCTAD, April 1975), pp. 17-21.

[63]United Nations Department of Economic and Social Affairs, The Role of Patents in the Transfer of Technology to Developing Countries (New York: United Nations, 1964), pp. 78-79.

[64]United Nations Industrial Development Organization, Establishment of Pharmaceutical Industries in Developing Countries (New York: United Nations, 1970), p. 13.

[65]This figure was consistently cited by the Pakistani health authorities and trade sources. Other estimates vary from about 3,000 to 12,000. Quick Index of Medical Preparations (QIMP) listed approximately 3,000 drugs in 1972. A. H. Qureshi, Quick Index of Medical Preparations (QIMP), no. 1 (Karachi: n.p., 1972).

# CHAPTER III

## THE CHANGE IN THE LEGAL ENVIRONMENT FOR DRUGS: INTRODUCTION OF THE GENERIC NAMES ACT (1972)

### Introduction

In 1940, the first legislation regulating the pharmaceutical industry in British India was enacted. This Drugs Act was adopted by Pakistan after partition and served the regulatory purpose until 1972. In 1972, the government introduced a health policy which proposed, among other things, the abolition of brand names for drugs and the adoption of a National Formulary. These two aspects of the proposed health policy were made law first by a presidential ordinance and next by the passage of the Generic Names Act.

The proposed health policy and the new laws were marred by a series of problems. A report on the difficulties encountered in the process of introducing the "reforms" in Pakistan may be useful to policy makers, in other countries, contemplating similar reforms.

This chapter first examines the Drugs Act of 1940, which first regulated the pharmaceutical sector in Pakistan.

The next section discusses industry reaction to three aspects of the government's proposed health policy, namely, adoption of a National Formulary, compulsory use of generic names only, and the import of pharmaceutical raw materials through a central agency, the Trading Corporation of Pakistan.

The third section explores the reactions of leading doctors, pharmaceutical manufacturers, importers, and the trade to the Drugs (Generic Names) Ordinance, which was introduced by presidential fiat, and the government's counter-reactions.

There follows a discussion of the situation following the introduction of the Generic Names Act, which was basically the same as the Drugs Ordinance but was meant to replace presidential fiat with legislative action.

Finally, there is a commentary on the positions adopted by the government and the various affected groups in response to the proposed health policy, the Drug Ordinance, and the Generic Names Act.

## The Drugs Act of 1940

Until 1972, the major legislation controlling the production and marketing of pharmaceutical products in Pakistan was the Drugs Act (XXIII) of 1940, passed on 10 April of that year in British India (prior to partition) and adopted by the government of Pakistan. The Act was meant to regulate the import, export, manufacture, distribution, and sale of drugs. The salient features of the Drugs Act are described below.[1]

Perhaps the most significant aspect of the legislation was the measures designed to ensure that products were of standard quality (Section 18). Standard quality meant that the drug should conform to the specifications set by the government or by a designated list of international pharmocopoeiias.

The act also prohibited "misbranded" drugs. Under Section 9, a drug was misbranded

(a) if it is an imitation of, or substitute for, or resembles in a manner likely to deceive, another drug, or bears upon it or upon its label or container the name of another drug, unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other drug;[2] or
(b) if it purports to be the product of a place or country of which it is not truly a product; or
(c) if it is imported under a name which belongs to another drug; or
(d) if it is so colored, coated, powdered or polished that damage is concealed, or if it is made to appear of better or greater therapeutic value than it really is; or
(e) if it is not labelled in the prescribed manner; or
(f) if its label or container or anything accompanying the drug, bears any statement, design or device which makes any false claim for the drug or which is false or misleading in any particular; or
(g) if the label or container bears the name of an individual or company purporting to be the manufacturer or producer of the drug, which individual or company is fictitious or does not exist.

The Act stipulated that "the accepted scientific name of any drug should be displayed on the label or wrapper. . ." (Section 12).

Finally, a Central Drugs Laboratory was to be set up for the analysis and testing of drugs (Section 6).

Until 1972, the Drugs Act regulated the Pakistan pharmaceutical trade. Most products sold were by brand names. There were some products available by generic names; however, competition between "equivalent" products centered around firms, Pakistani and foreign, inducing doctors to specify their brand name drugs in prescriptions. (See Chapter VIII, pp. 246-248 .)

## The Proposed Policy

With the accession to power of Z. A. Bhutto in 1971, the Pakistani government embarked on a stated policy of controlling key industrial sectors. At the same time, the ruling People's Party assured foreign manufacturers that they would not be subject to nationalization or expropriation, despite the fact that many Pakistani firms in heavy industries (such as chemicals and petroleum) and in service industries (such as banking and insurance) had been taken over by the government.

Given the government's "socialist" leanings, the question was how it could control the operations of the "capitalistic" pharmaceutical multinationals with their "excessive" profits, develop the competitive position of local pharmaceutical manufacturers so that they could effectively compete against the foreign multinationals, and reduce the dominance in market share of the latter.

This hostility toward the large international firms was not peculiar to Pakistan. Multinational pharmaceutical firms throughout the world have come under fire in recent decades. The oligopolistic and monopolistic structure of the pharmaceutical industry has been criticized as leading to undesirable conduct and performance, specifically, high prices and excessive profits.

Negative comments about the "restrictive" business practices of pharmaceutical companies have been expressed by various commissions instituted to investigate the workings of the industry. Most notable among such proceedings have been the Kefauver and the Nelson

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Hearings in the United States, the Monopolies Commission and the Sainsbury Committee in the United Kingdom, and the Restrictive Trade Practices Commission in Canada.[3] These investigations, particularly the first, the Kefauver Hearings, triggered a chain reaction throughout the world as other countries instituted their own investigations (for example, Australia, Colombia, Argentina, Venezuela, Brazil, and India). Tomlinsen of Upjohn has commented that the Kefauver Hearings led to government investigation in 17 countries and left the U.S. pharmaceutical industry "under fire in 20 to 30 others."[4]

These investigations brought forward some very legitimate concerns regarding the market behavior of multinational pharmaceutical firms. They also prompted critics to suggest numerous reforms, among them those noted below.[5]

1. Abolish all patents on drugs.
2. Reduce drug patent protection from the present 17 years to 10, 5, or less, on the grounds that a drug company will normally recoup its investment in a new product in the first three years after it reaches the market.
3. Permit the manufacturer to have exclusive use of his brand name only until the expiration of his patent, at which time any qualified manufacturer may produce the drug and market it under its original, highly publicized name.
4. Abolish brand names on all drugs and allow them to be promoted only under their generic names.

5. Permit patents only on new drugs that offer clear-cut clinical or price advantages to the patient.
6. Require a manufacturer to license other companies to produce and distribute his patented products under an appropriate royalty agreement.

From among these alternatives, and others, the government of Pakistan chose the fourth one mentioned above to reduce the concentration of sales held by a few firms (all multinational) and to accelerate price competition in the pharmaceutical industry.

In March 1972, President Bhutto addressed the nation and proposed a health policy for Pakistan. One aspect of it would have a direct impact upon the pharmaceutical industry: A national formulary would be prepared, and only single-ingredient drugs and compounds on this list would be allowed in the Pakistani market. Another proposal was the replacement of brand name by generic name medicines. A third element of the policy was that the importation of raw materials for the manufacture of medicines would be under the aegis of the Trading Corporation of Pakistan, a government organization. Various references were made in the proposed policy to the economic aspect of the problem: "Cost of treatment is highly inflated due to higher prices of medicines," and "branded medicines are sold at enormous profits." The government proposed to take remedial measures.[6]

The proposed health policy generated considerable controversy among the various affected groups. The reaction was active

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hostility on the part of some, such as the Pakistan Pharmaceutical Manufacturers Association (PPMA), which manifested its opposition in the form of resolutions, news releases, publicity in major newspapers, and representation to the health authorities against the adoption of the proposals. Other responses were mixed. The Pakistan Chemists and Druggists Association (PCDA), importers who were members of the PCDA, and the Pakistan Medical Association (PMA) expressed reservations regarding the workability of the plan.

Industry Reaction

The PPMA, whose requests for representation on the Health Committee considering the health policy had been rejected, sent a letter to the Central Minister of Health protesting that the proposed policy was "based on improper appreciation of facts and the measures suggested in the policy are contrary to national interests, inconsistent with the standard and system of ethical medical practice in the country."[7]

In an appeal to the President of Pakistan, the PPMA proposed that the following highly controversial issues required further discussion:

1. The implementation of a National Formulary;
2. A substitution of generic names for well-known and tried brand products;
3. A monolithic raw material procurement program.[8]

In a position paper addressed to the Central Health Minister, the PPMA disagreed with certain statements made in the policy draft.[9] To the statement by the health authorities that the "cost of treatment

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in Pakistan is inflated due largely to the high prices of medicines," the PPMA responded that it had provided an

> exhaustive study to the Health Ministry comparing the prices of medicines prevailing in Pakistan with . . . those prevailing elsewhere in the world, and it is unquestionably clear that the price of medicine in Pakistan is one of the lowest in the world considering the very low level of public spending on drugs and medicine.

The National Formulary: Industry comments.--Remarking on the suggested list of single-ingredient drugs for inclusion in the National Formulary, the PPMA contended that "this proposed list has been most arbitrarily prepared, in that it does not include quite a number of active ingredients which are widely used in the country." Commenting on the list of compounds and specifications to be prepared by the government, the PPMA remarked that the complexity of this measure had not been appreciated, since the development of a product

> does not end with the chemical compatibility of various ingredients. It includes complex phases of product development concerning pharmacology, toxicology, bio-chemical pharmacology, stability, etc. . . . [and] comprehensive clinical trials to confirm therapeutic efficacy and safety of a drug, [and] the existing government machinery is not equipped to undertake this task.

Generic names: Industry comments.--On the replacement of brand names with generic names, the PPMA termed this

> a definite bias in favor of the retail chemists . . . that the choice of selling the product of a particular manufacturer will be guided by the discount he [the chemist] gets . . . that the selection of a drug will have nothing to do with the quality of the product, but will be based on the discount . . . that members of the medical profession will have no say in the matter and . . . be at the mercy of the chemists.

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To generate support for brand name medicines among the public, the PPMA released various promotional pieces, among them one meant specifically for the layman. It raised several rhetorical questions.

1. Who will look after the patients' well being?

   After the doctor has diagnosed the ailment and prescribed a generic product, the selection out of several generic products supplied by different manufacturers will be left to the chemist, who is hardly qualified to make this important decision.

2. What about Home Remedies?

   Our people have been used to home remedy drugs for common ailments such as headache, sore throat, colds and fever. With the introduction of generics such household remedies as Eno, Burnol, Vicks, Aspro, Dettol will no longer be available.

3. Who will be responsible for misinterpretations?

   Brand names as compared to generic names are easier to remember. The use of complex generic names will create problems for both the Doctors and the Chemists. A small error may prove fatal.

4. Who will guarantee the Quality?

   Behind each name there is the support and guarantee of the Brand. The reputation and integrity of the manufacturer and the brand name are directly connected.

5. Who will guarantee the efficiency?

   Product differentiation through brand names is necessary because the therapeutic effects come from the total formulation and not simply from a product's active ingredients.

6. What about highly effective Drugs?

   The doctors in the country would be denied the use of highly effective drugs being introduced through the world because no import would be allowed of any drug under its brand name.

7. Will one generic product be sufficient to cure a particular disease for all patients?

   Research has proved that two identical drugs do not necessarily have identical effects. Different formulations of the same drug may differ in healing efficiency because of different rates of absorption. No two people react the same way to any given medicine.

8. Who will conduct Research?

   Brand names reflect in most instances, products of painstaking research and development by scientifically based companies whose forward thinking policies are directed towards better products for better health.

9. Can prices be reduced by the introduction of Generics?

   An international survey shows beyond doubt that prices of medicines in Pakistan are among the lowest in the world. There is no evidence that the introduction of generics will lower them further.

10. Are Generic Products sold in any other countries?

    No country other than Cuba has adopted an exclusive generic policy.[10]

At the same time, individual pharmaceutical manufacturers, mainly foreign, bought full-page advertisements in the medical and daily newspapers. Their content emphasized the differences in therapeutic capability of chemically equivalent drugs. This strong promotional effort by the PPMA was directed toward the public, the government, and to a certain degree the medical profession. An element of exaggerated distress and concern was evident in these promotional pieces,[11] but the PPMA did raise some important issues regarding the quality and "equivalence" of drugs and the question of the potential shift in responsibility of the patient's health away from the doctor.

Importation of raw materials by the TCP: Industry comments.--The Trading Corporation of Pakistan (TCP) was established in July 1967. Its primary function was to monitor and facilitate trade with the Eastern Bloc, particularly bilateral agreements and barter deals. The TCP had handled products such as rice, cotton textiles, jute, and leather goods being exported from Pakistan and

metals such as pig iron, steel billets, copper, lead, and zinc ingots imported from the socialist countries.

The industry questioned whether the TCP had the expertise to be the central raw materials purchaser for pharmaceuticals. The products with which the TCP had had experience were mainly undifferentiated staple commodities, whereas the importation of pharmaceutical raw materials would require a different kind of technical knowledge. Even if it was accepted that single ingredient pharmaceutical raw materials were also "undifferentiated" products, the industry argued that importation of environmentally sensitive fine chemical materials requires a closely coordinated schedule to ensure an acceptable, generally short, storage period between procurement and production. Quite correctly, the industry argued that the TCP did not possess the appropriate storage capability, and it would be some time before it could develop this. Pharmaceutical chemicals require care to prevent them from decomposing, losing potency, or changing their physical and chemical properties, and they have varying storage requirements. Lack of these facilities could result in a costly loss of imported materials. The TCP would be expected to procure all the active ingredients used in pharmaceutical manufacture while ensuring their quality, competitive prices, and consistent supply.

The TCP's experience was limited to handling a few products, not more than 10 items at a time.[12] Besides, specifications could vary by manufacturer. Also, manufacturing in different

dosage forms requires the same ingredient chemical to be of a different grade and specification, as in the case of injectable formulations versus other formulations of the same drug.

The industry also raised questions regarding "equivalence," indicating that product effectiveness varies according to the source of the raw material.[13]

The TCP's record was marred by its lack of coordination and bureaucratic tangles in handling imports, which could mean disruption of production schedules for manufacturers. The industry drew attention to this, indicating that if they were "deprived of control on supply of raw material," they would face "undesirable shortages and surpluses in the availability of raw materials," making it "impossible for the manufacturers to keep their production in line with the supply and demand trend in the market" and creating idle capacities which would "distort the cost structure."[14]

The government recognized some of these problems, and the proposal to import raw materials for medicines through the TCP was quietly dropped.[15] Some elements of the local press reported that the decision to abandon the TCP procurement scheme was a result of foreign pressure--American, German, and Swiss pharmaceutical interests.[16]

Following the announcement of its health policy, government restraints on the pharmaceutical industry were introduced in two phases. The first was initiated by a presidential ordinance issued in April 1972. The other began with passage of a bill by

tha National Assembly in September of that year, legislation which was known as the Drugs or Generic Names Act of 1972. Each of these will be discussed in turn.

## The Drugs Ordinance

Within a month after the health scheme was proposed, the national formulary and adoption of generic names for medicines were singled out for inclusion in a presidential ordinance. It was issued over the vehement protests of the most vocal affected group, the PPMA. Despite their opposition, on 20 April President Bhutto promulgated Ordinance No. XIV of 1972 "to provide for the National Formulary of Pakistan and to adopt generic names for drugs."[17]

Sections 4 through 6 of the Drugs (Generic Names) Ordinance required the establishment of a committee to propose a "national formulary."

Section 7 instituted the following prohibitions:

(1) No person shall import, manufacture, stock, distribute, sell or prescribe any drug under any brand, patent or proprietary names other than a drug under a generic name in accordance with the provisions of this Ordinance.
(2) No person shall import, manufacture, stock, distribute, sell or prescribe any drug not included in the National Formulary or which contains any material other than those expressly mentioned in the National Formulary as part of the formula for that drug.
(3) Notwithstanding anything contained in subsections (1) and (2), it shall be lawful for any person to stock, distribute, sell or prescribe any drugs having any patent or proprietary name and not included in the National Formulary up to the 20th day of October, 1972.

Sections 8 and 9 established an Appellate Board to review the decisions of the Formulary Committee.

Section 13 stated that "whoever contravenes the provisions of section 7 shall be liable to be punished with imprisonment of either description for a term which may extend to seven years, or with fine which may extend to one lakh rupees,[18] or both."

The ordinance also listed a schedule of single-ingredient drugs to be included in the national formulary.

On 28 April 1972 a PPMA press release said that "the industry has received with a sense of shock, the news that legally from today most of their manufactures must cease."

Shaikh Rashid, then Health Minister, a socialist and a member of the Pakistan Peoples' Party, was the driving force behind this ordinance. He was of the opinion that "prices were too high and profiteering was rampant," with foreign manufacturers exploiting Pakistani consumers. He was influenced by the much-publicized Kefauver and Nelson Hearings in the U.S. Senate.[19] According to observers, it is doubtful that he or his advisers ever carefully read or analyzed the testimony. It was the sensational headlines reported in the world press during that time that caught his attention.

The Nelson Hearings had brought out specific cases of overpricing in Pakistan (see Chapter VI, pp. 169-171). Rashid intended to halt this reprehensible behavior. Product "proliferation" would be reduced through the adoption of a formulary, and prices would be reduced as competition among generic name drugs increased. Shaikh Rashid had been a provincial political leader before his appointment

as Health Minister, a position for which he was ill-prepared; he had no experience or expertise in the health area. The proposals appealed to him because of their seeming simplicity, and he chose to push them "in the national interest."[20]

For the "peoples'" government whose (undeliverable) campaign pledge had been "Roti, Kapra and Makan" (Bread, Clothing and Housing), all this was another step in reducing the stranglehold of the capitalist-industrialists over the poor people of Pakistan who were forced to pay "exorbitant" prices for emergency goods. The policy was heralded accordingly by the government.

In certain instances, the PPMA projected a one-sided, biased position, and it should be recognized as such. The strong promotional effort to dispute the equivalence of generic drugs was heavily larded with quotes from foreign sources that subscribed to the PPMA's viewpoint. The PPMA adopted the high-risk, expensive research argument to support brand name "quality" products. "Who will conduct research?" was a rhetorical question asked in one of the promotional ads in the local press. Although the beneficial results of the risky research by the pharmaceutical industry world-wide are undoubtedly shared by the lesser developed countries, the industry's major research is conducted with an eye to the markets in developed countries. Very little research is being carried on in Pakistan by the industry.[21]

## Doctors' Reactions

The medical profession was clearly divided over the issue of brand versus generic names for drugs. Those who favored the proposal leaned heavily toward discussing the possible price reductions that might result from generic name use, criticizing the "unnecessary" promotional expenses to "maintain and further the sales of brand name products." They reprimanded the "vested interests" who were "trying to confuse the issue by talking of bio-availability, crystal structure, particle size of drugs, etc., just to save the myth of brand names."[22]

A past president of both the Pakistan Medical Association and the British Medical Association, and representative of the views of many others, expressed his reservations regarding the therapeutic equivalence of chemically equivalent drugs. He suggested that

> by restricting the availability of drugs and by insisting on the use of generic names a doctor will be deprived of the right to prescribe the drugs of his choice. . . . By the use of generic names the initiative will pass from the doctor and the patient to . . . the chemist.[23]

Many doctors showed reluctance in prescribing drugs under generic names, preferring to prescribe by brand names.[24]

## The Bribery Allegations

After promulgation of the ordinance, there were a series of allegations and counter-allegations between the PPMA and the health authorities. The Central Health Minister was quoted as

stating that "one of the medical firms approached him with an offer of Rs. 50 lakh to dissuade him from going ahead with the scheme of banning the brand names of medicines in the country."[25] The PPMA denied "trying to unethically influence the Minister" and asked that the minister should either make public the name of the individual or company that had made the offer or, "if the statement of the Minister had been incorrectly reported then a specific denial should be issued to the Press."[26] The Health Minister did neither.

In an address to a group of lawyers in Lahore, Shaikh Rashid said that "a lot of pressure, internal and external, was brought to bear on him before the decision to switch over from brand names to generic names was taken"; "the pressure is still continuing but he was determined not to yield." According to the Health Minister, the U.S. and West German ambassadors had asked him to withdraw the decision as the "business of medicines in their countries would be badly affected by this decision."[27] This was immediately refuted. The West German Ambassador denied meeting with the Health Minister or having pressured him.

> He has only written him a letter containing the suggestion to consult local representatives of the pharmaceutical industry of Pakistan which was largely built up with foreign investments before the final formulation of those parts of the national health scheme which deal with the pharmaceutical industry.[28]

## The Uncertain Manufacturers

The pharmaceutical manufacturers, because of what they felt was a lack of guidelines, were "neither going ahead with the

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production of brand drugs nor with production under generic names." They ominously predicted that "when existing stocks were depleted, replacement would not be available." The manufacturers also expressed concern about the disposal of raw materials and finished supplies at hand, which would be unusable under the new restrictions.[29]

The PPMA summed up these worries, complaining that "the limited list of allowable drugs issued at that time [which] might lead to a curtailment of output . . . the [possible] winding up of business allowed only a limited line of products," and about "the lack of guidelines even with the allowed list with respect to components, formulae and quality control procedures."[30]

The confusion worsened when the State Bank of Pakistan issued a circular that it was stopping the opening of Letters of Credit for the importation of pharmaceutical raw materials as of 21 April 1972. This embargo was eventually lifted the next month.[31]

All this uncertainty resulted in an initial curtailment of production. In the wake of the ordinance, many employees were sent "on leave for indefinite periods," and there were reports of layoffs. A survey by one local newspaper indicated that "60 to 80 percent of the staff--mostly skilled, unskilled staff and packing girls--have been sent on leave . . . while only managerial staff including executives have been retained." Pharmaceutical marketing representatives, unnerved by rumors that they "would no longer be needed," made representations to the government authorities to reappraise the scheme.[32]

The pharmaceutical and chemical workers federation, in the meantime, directed its ire against the manufacturers, indicating that workers in the industry were faced with "retrenchment, termination of services, and dismissal." They cited the examples of one local company which had terminated the services of 10 workers out of a total of 17 and another which "was following in the same pattern."[33] The federation accused industry of making the ordinance an excuse to victimize workers.

Pharmaceutical Importers' Problems

Pharmaceutical importers, after the promulgation of the ordinance, were concerned that although officials of the Health Ministry had "confirmed the necessity of importing several pharmaceuticals in finished form from abroad . . . [they] have not so far made any declaration about the preparations which will be allowed to be imported."[34] The importers also were worried about possible unemployment in the pharmaceutical import sector.

In September 1972 the importers were faced with another element of uncertainty when the government, without a gazette notification or an announcement, stopped issuing licenses. Although the office of the Chief Controller of Import and Export refused to give reasons for the change in policy, it was believed it was instituted to prevent importers from buying brand name products in large quantities and later pressuring the government either to extend the deadline for branded sales or to buy the excess stocks.[35]

The Pharmaceutical Trade's Reactions

The Pakistan Chemists and Druggists Association (PDCA) said that "the feasibility aspect of the ordinance was not seriously conceived to permit smooth implementation of the scheme" and "urged that enforcement of the ordinance may be held in abeyance till all aspects were considered and decided upon."[36] The pharmaceutical trade was completely at a loss as to how to cope with the situation. This led to many undesirable reactions. One immediate effect was that many life-saving drugs "disappeared," and many drugs registered illegal price increases.[37]

Druggists also objected to the 20 October deadline for exhausting their brand name stocks. In Lahore, hundreds of angry chemists and druggists kept their shops closed for 12 hours on Monday, 8 May 1972, to protest the government's deadline.[38]

Meanwhile, institutions complained that they had difficulty in obtaining life-saving drugs from the chemists. The Medical Superintendent of the Mayo Hospital in Lahore said that druggists had been refusing to sell certain medicines to the hospital but were selling the same medicines to patients at four to five times the fixed price.[39]

The PCDA later appealed to the President of Pakistan to "withdraw the Drugs (Generic Names) Ordinance, 1972 or to amend it to apply only to the Public Sector." The PCDA said that it "has been under pressure from its members, to place before you the catastrophic consequences of the enforcement of generic names in place of

Trade or Brand Names." The association said that "generic names" are not easily remembered, that there are possibilities of "accidental errant prescribing," that quality might suffer, that price reduction could be attained through fixing ceilings on prices, that the policy would ruin chemists who had stocks left over after the deadline, and that it would cause massive unemployment.[40]

At the same time, chemists cut back on their purchases because they feared that pharmaceutical manufacturers might refuse to take back unsold branded products after the 20 October deadline.[41]

The Government's Response

The central government, realizing the problems in implementing the ordinance, deliberated extending the 20 October 1972 deadline. On 29 May the government announced a six-month extension for the manufacture and import of brand name drugs. The period of sale, distribution, and prescription of brand name medicines was also extended to 31 March 1973. The Central Health Minister, Shaikh Rashid, emphatically stated that "the government will not retract from the revolutionary step regarding adoption of generic names of medicines in the interest of the people."[42]

In response to the rising criticism against what was commonly called the "generic policy," the Health Minister issued a statement[43] arguing that the concerns expressed by the pharmaceutical manufacturers were unfounded. The statement included a comparative price chart of eight products with price variations between the brand name product and the same products marketed under their generic

names.[44] The Minister defended the national formulary, indicating that 38 specialists had approved the list and that 16 members of the National Formulary Committee would be constantly reviewing it for amendments. Shaikh Rashid also expressed his opinion that "the notable difference with the introduction of generic names for drugs would be that multiple brands of one and the same drug be eliminated to the greater advantage of the medical profession and the patients."

There would be no problem of unemployment because "there will be no decrease in production. On the contrary, production would increase manifold as the prices of drugs under generic names will come for the first time within the easy reach of the common man." Furthermore, because of rural health expenditures under the People's Health Scheme, there would be "a tremendous increase in the consumption of drugs and medicines."

The Health Minister also stated that "the real need for the field staff will also continue to be there to project the name of the manufacturer."[45]

Addressing the problem of raw materials in stock, he stated that they "will be used for production of medicines under generic names, while the small surplus, if any, will be consumed for the manufacture of medicines under brand names meant for export purposes" which the government would allow.

The growing concern regarding the future quality of medicines under the generic policy prompted the Health Minister to establish a committee to "devise ways and means for effective quality

control of drugs at the Central and Provincial level." The committee was composed of government health department officials. Rashid, on a visit to the Drug Control and Research Division of the National Health Laboratories in Islamabad, indicated that he was "very much impressed by the adequacy of facilities which existed in terms of equipment and technical know-how in the laboratories for effective quality control."[46]

## The Drugs (Generic Names) Act

On 22 September 1972, the National Assembly of Pakistan passed the Drugs Generic Names Act. During the legislative debate, Rashid reiterated that the government had decided "to adopt the generic names" with the object of "bringing down the prices of drugs." He said that a list of 850 drugs had been completed by the National Formulary Committee and that all pharmaceutical companies would be allowed to manufacture all drugs in the formulary.[47] He continued to assert that arrangements had been made for effective quality control and that there would be no shortages.

On 25 September 1972, the Drugs (Generic Names) Act (XXIV of 1972) received the assent of the President. Since this legislation was intended to replace the earlier presidential ordinance, Section 16 of the act repealed the Drugs (Generic Names) Ordinance. The major purpose of the act was "to provide for the national formulary and to adopt generic names for drugs."[48]

Section 7 listed several prohibitions.

> 1. No person shall, --
> (a) after the 23rd day of December, 1972, import, or except for the purpose of export, manufacture, or
> (b) after the 31st day of March, 1973, prescribe, dispense, sell, distribute, or except for the purposes of export, stock
> any drug under any brand, patent or proprietary name or any drug not included in the National Formulary or any drug which contains any active material other than those expressly mentioned in the National Formulary as part of the formula of that drug; nor shall any person sell or stock or offer or expose for sale, any drugs unless the name of its manufacturer is printed in indelible ink on the label of both its container and the carton containing it.

Under the act, the federal government could grant exceptions.

Section 13 (i) stated:

> Notwithstanding anything contained in this Act, the Federal Government may, if it is of the opinion that the public interest so requires, at any time of its own motion or on a representation made to it, by notification in the official Gazette, exempt any drug or class of drugs bearing a brand or patent name, whether single-ingredient or formulations, from the operation of all or any of the provisions of this Act, subject to such conditions, if any, and for such period as may be specified in the notification.

Penalties for offenders were "imprisonment of either description for a term which may extend to seven years and shall also be liable to fine which may extend to one lakh rupees."

After the Generic Names Act was adopted, the Health Minister, in an address[49] to workers of the Pakistan People's Party, expressed the hope that the fall in prices of medicines which adoption of generic names was expected to create would range between 25 and 99 percent.

Rashid explained that any stock of medicines left over after the 31 March 1973 deadline could be exported, and the government

would make provisions for the manufacture of brand name medicines for export purposes. According to Shaikh Rashid, the Formulary Committee had prepared a list of about 1,000 medicines (from over 12,000 marketed previously).[50] Certain brand name drugs would be exempted from the provisions of the act "if it was in the public interest." Once again, the Minister alleged that "millions of dollars in foreign exchange had been earned by foreign firms through brand-name medicines using expensive promotion techniques." The changeover to the generic system in Pakistan was "a success of the present regime over the international imperialist movement."

The Exemptions

At this time the local press reported rumors that the government was considering granting permission to some foreign pharmaceutical firms to manufacture medicine under brand names. They had threatened to close down their operations otherwise, and at the time there was no alternative production arrangement.[51]

On 9 December 1972 the health authorities released a list of 200 medicines which were exempted from the operation of the Generic Names Act.[52]

Rashid said that the pharmaceutical industry was demanding that except for 250 drugs, the remaining 750 included in the formulary should be exempted. He added that "very essential" drugs had been exempted, including those not manufactured in Pakistan but imported in finished form, and patent drugs. The Ministry of Health also issued a directive to pharmaceutical importers and

manufacturers to furnish by 15 December 1972 the information required for the preparation of a list of drugs for exemption from the Generic Names Act.[53]

The Call for Extending Deadlines

The PCDA appealed for an extension of the 23 December 1972 Deadline for the manufacture and import of brand name medicines and asked for an indefinite extension of the 31 March 1973 deadline for sale of brand name medicines. The association stated that if unsold stocks were not taken back by the manufacturers or, in the case of imported finished drug products, by the exporters abroad, and if the government did not purchase the unsold stock after the deadline, chemists would have no alternative but to shut down their shops to avoid prosecution.[54]

Pharmaceutical manufacturers also protested the deadlines, estimating that they could lose approximately Rs. 120 million. Industry representatives said that "packaging material worth Rs. 8 million which included printed literature, direction slips, labels, bottle slips and bottle caps will go to waste"; "raw material worth Rs. 12 million not to be utilized in the production of drugs with brand names will remain unutilized." Finally, they "would not be able to dispose of finished stocks worth Rs. 100 million by March next, the last date for their sale in the open market."[55]

The Drug Shortages

On 15 December 1972, a medical newspaper, Medicoment, listed 121 medicines which were "either completely out of market or running in short supplies."[56]

In a press release dated 8 December 1972,[57] the PCDA said that drug shortages reported in the news were "not unexpected" because of a "complete sense of uncertainty in the industry, the import sector and the chemist trade in the absence of a National Formulary and list of exemptions under Clause 13 of the Drugs (Generic Names) Act, 1972 though the deadline for termination of import and manufacture of drugs except those in the National Formulary is December 23, 1972." The statement continued:

> The draft copy of the National Formulary . . . appears to be a collection of formulations with glaring omissions of the drugs which have been in use in this country for the last twenty-five years and with conspicuous addition of drugs which have never been imported in the country in the past and have only a selective use.

The PCDA called for immediate publication of the national formulary "whatever it is worth," along with a list of exemptions "without further delay to meet the growing crisis."

Production of generic drugs was slow. Manufacturers blamed the late publication of the national formulary (gazetted on 8 December 1972), just two weeks before the deadline. The formulary also contained technical mistakes, and production planning was delayed. Packaging material with generic nomenclature was also delayed, and there was a feeling that for the next two months,

February and March 1973, the supply of drugs to the market would be erratic.[58]

On 22 December 1972, the Director-General of Health, probably in response to the growing reports of drug shortages and black-marketeering, issued a directive that all chemists and druggists would have to exhibit immediately a complete list of drugs and medicines in stock and their prices.[59]

A Ministry of Health press release of 2 January 1973 said that the government "will take all possible steps to combat artificial shortage of drugs and medicines and profiteering." Offenses punishable under the law were: (1) failure to exhibit price lists of the commodities on his premises by importer, producer, and dealer; (2) destroying, defacing, or altering labels or marks on the bottle or carton of drug/medicine indicating the price marked by the importer/producer; (3) refusal to give the purchaser a cash memo containing particulars of sale; (4) refusal to sell to any person any drug and medicine available from the dealer without reasonable excuse; and (5) selling or reselling any drug or medicine at a price higher than the maximum price fixed by the Controller General.[60]

The chemists and druggists against whom this step was directed responded strongly through the PCDA.[61] "The Authorities have the impression that the trade had hoarded the stocks and that it was indulging in black-marketing," said the PCDA. "This charge . . . has no substance. The reason for shortage of branded products

is that the trade is making reduced purchases because it does not know if it can get rid of the existing stock of branded products by 31 March 1973," and "it cannot take further risk by adding more branded medicines to the existing stocks." The association stated that "the chemist trade has been left with no alternative but to suspend the purchase of branded products from 1st January, 1973 until such time as the government announces its decision about the disposal of branded products remaining unsold after 31 March, 1973."

The PCDA also said that there was "no justification for resorting to a legal instrument under the Defence of Pakistan Rules which was used mainly against persons indulging in anti-state activities." It then threatened that chemists and druggists would go on an indefinite strike as of 1 March 1973 unless an acceptable decision regarding unsold inventory was made by the government.[62]

This plan was attacked by the Pakistan Medical Association as an "irresponsible gesture . . . an anti-patient move rather than anti-government. The medical profession shall oppose any strike at this hour."[63]

Pharmaceutical manufacturers responded differently to the chemists and druggists' threat of not purchasing any more stock. A number of companies (among the reported ones, Smith, Kline and French, Lederle, and Pfizer) offered to take back all of their brand name products unsold by 31 March 1973. Other firms were offering discounts of 30 to 50 percent on bulk purchases to chemists as incentives to purchase branded products. Only about a dozen drugs had

entered the market under generic names, and at the same prices as before.[64]

Some Pakistani manufacturers were particularly hard hit. they not only were having trouble obtaining new orders, but also were facing difficulties in collecting payments owed them by chemists. Manufacturers' inventory mounted, and with their money tied up, and with limited financial resources to begin with, they were in a serious financial bind.

Other Government Orders and Amendments

Amidst all the confusion, the government warned pharmaceutical manufacturers that they were liable to be arrested under the Defence of Pakistan Rules if they did not start producing drugs and medicines under generic names.[65]

Manufacturers bitterly complained that they were confused because of the lack of guidelines regarding the government's policy on such things as chemical specifications for drugs, the use of "inactive material" in drugs, possible restrictions on drug package forms, etc. The government responded with a general notice prepared by the National Formulary Committee:

1. It is permissible to use any non-active material like excipients, fillers, binders, preservatives, flavours, colours, coating materials, emulsifying suspending and thickening agents, vehicles, diluents, solvents, waxes, additives, stabilisers, anti-oxidents and anti-foams.
2. The standards and specifications for the drugs included in this National Formulary shall be the same as prescribed under the Drugs Act, 1940 and the rules made thereunder or as may be notified by the National Formulary Committee from time to time.

3. Notwithstanding the form of presentation stated in the Formulary, it will be permissible for the manufacturers to inter-change capsules for tablets, syrup for suspension, vial for ampule, ointments for cream and vice versa.
4. Consistent with the formulation strength as laid down for each product in the Formulary it will be permissible to manufacture the product in multiple or divisible pack.
5. Where only base has been mentioned in the National Formulary, it is permissible to use any appropriate salt of the base containing equal quantity of the base.[66]

A warning also was issued by drug importers and manufacturers that "only those consignments of branded drugs and medicines, including pharmaceutical raw material, not included in the National Formulary imported under Letter of Credits opened before 24th December, 1972, shall be allowed to be cleared from the customs."[67]

An ordinance called the (generic names) Amendment Ordinance, 1973, was issued by the President on 16 February. This amendment allowed the government to give powers to officers of the central and provincial government "to direct pharmaceutical trade and industry to declare any stocks and to disclose purchases or sales of any such stocks within a specified period."[68]

The central government also ordered that

> all dealers of the essential commodities . . . generally known as chemists and druggists shall, subject to the provisions of any law as to shops and establishment of hours of works of workmen, keep their shops or business premises open every day for sale of commodities to consumers from 9 a.m. to 9 p.m. and during such longer hours as they may desire.[69]

Meanwhile, the chemists and druggists who had earlier threatened to shut down their shops as of 1 March 1973 rescinded their decision after a meeting with the Health Minister, who assured them of a satisfactory solution to their problems.[70] But the

hostility continued as chemists and druggists protested that they were being unduly harassed by allegations of overcharging. The ministry refuted the charge, saying that there were many instances of overcharging detected by the officials.

To mollify the pharmaceutical trade, the government issued the following notification through the Ministry of Health:

> In exercise of the powers conferred by sub-section (1) of the Section 13 of the Drugs Generic Names Act 1972, (Act 4 of 1972), the Federal Government being of the opinion that the public interest so requires, is pleased to exempt all such classes of drugs bearing a brand or patent name on the tablets, capsules, ampules, collapsible tubes, the literature, whether single ingredient or formulation, as are included in the National Formulary, subject to the conditions that a sticker bearing the appropriate generic name is pasted on the cartons, and bottles containing such drugs so as to cover completely the brand or patent name.
>
> The exemption hereby granted shall be available during the period ending on September 30, 1973.[71]

Government hospitals were given an exemption until 30 June 1973 allowing them to utilize branded drugs still in stock. "Any hospital or dispensary failing to utilize the leftover stock during this period of exemption will have to write it off."[72]

At the same time, the Health Ministry asked all drug dealers to submit their stock positions as of 1 April 1973.

Pharmaceutical manufacturers were asked to submit information on the stocks of raw materials which were unusable in the preparation of drugs in the national formulary and were told to submit information about locally manufactured drugs in the formulary. The required information included cost of raw materials (both local and imported content), cost of packing materials, direct labor,

factory overhead, sales promotion and advertising expenses, selling and distribution charges, and prices charged at the trade and retail levels.

Pharmaceutical importers were required to submit information on the C and F price in local and foreign currency for imported drugs.

Two weeks before the 31 March deadline, the date beyond which brand name medicines no longer could be legally marketed, less than 10 percent of the drugs listed in the national formulary were available under generic names.[73]

By 31 March 1973, the national formulary listed 1,285 medicines, of which 337 were exempt from the Generic Names Act. The 337 drugs included 130 patent medicines. The Health Minister said that the exemption was not permanent; for 201 items it would be removed on 30 June 1973, for 136, in December 1973.[74] Among those drugs with the June deadline, 104 were later granted exemption until 31 December 1973.[75]

Shaikh Rashid indicated that there would be a "further" fall in prices with "competition coming in full play from the next month as . . . every company is allowed to manufacture any drug mentioned in the national formulary subject to quality control." Interestingly, he went on to warn that if that did not happen, the government would fix prices.[76]

## The Situation after the 31 March 1973 Deadline

The first week in April 1973 was chaotic for the pharmaceutical trade.[77] Many chemist shops were closed, owners claiming they were "evaluating" their stocks of brand name medicines. Many preferred to keep their shops closed rather than run the risk of "seven years imprisonment or a fine of Rs. one lakh for violating the law" by making errors. Most chemists did not have a copy of the national formulary or a list of "exempted" medicines. Stickers bearing generic names which were to be provided by the manufacturers were in short supply, and some chemists resorted to erasing brand names and writing in generic names. They also did not have sufficient literature indicating the "equivalent" generic names of branded products. Some pharmaceutical firms distributed a list of medicines manufactured by them with the brand names and the corresponding generic names for these products. Drug inspectors tried to persuade chemists to keep their shops open, but many declined, and others turned back patients saying that they could not decipher the prescriptions.[78]

Some chemists were "seemingly unaware" of the law and went on selling drugs under brand names. Others sold brand name drugs clandestinely to their "favored" customers, sometimes charging 20 to 30 percent more than the previous price.

The rural chemists and druggists lagged farther behind in terms of understanding the "generic" policy. Because they were less

acquainted with the generic names of products, they found it even more difficult than their urban counterparts to cope with the situation.[79]

Reports of unavailability of drugs, higher prices, and black marketeering kept appearing in the press.[80] The Pakistan Medical Association disputed government contentions that prices had fallen and said that the plan was a failure because of the poor implementation of the scheme.

In a press statement, the President of the Pakistan Medical Association (Punjab) said that the

> sudden switch-over from brand names of drugs to generic names with few exceptions has brought in its wake a chaotic state of affairs which has affected the prescribing physicians, the chemists and the druggists, the dispensers and most important of all the people.
>
> It is obvious that in spite of the Health Ministry's predominant occupation with the issue of generic names for the last 15 months many lacunae were left resulting in the present unhappy development. Repeated additions/deletions in the formulary, granting of piecemeal exemptions to brand products, changing of labels of existing stocks of non-exempted brand products to generic nomenclature, giving genuine name labels to products whose formulae approximate to these prescribed in the formulary have made the confusion worse confounded.[81]

This official representing the Medical Association commented that

> any product included in the formulary can be manufactured by any pharmaceutical concern and as such the open competition so engendered will help in lowering the prices. But there is no emphasis on quality control of these productions which has got to be rigid and sustained. We cannot equate manufacture of drugs with manufacture of buttons or socks--and leave things as to prove their worth by cost versus quality. Here the risks involved are too heavy.

What is needed, he said, is a period of smooth transition during which the doctor should have the option to write either the brand or the generic name.

## Demands of the Pharmaceutical Importers

In June 1973, the pharmaceutical importers asked for an opportunity to discuss certain issues with the health authorities. Among these issues[82] was representation of the National Formulary Committee and the chance to explain the feasibility of including some products in the national formulary and exempting certain others from the generic name restrictions. Also, the sale of brand name products, they suggested, should be allowed "until the last bottle is consumed." Another issue was that the Health Ministry had made it compulsory to register "new and unintroduced products" with the health authorities and had asked for

> specimen samples, literature, therapeutic indication, statement comparing in quality, efficacy, safety with similar products already introduced in Pakistan. Certificate to the effect that the sale of the product in question is not prohibited in the country of origin etc. are all to be submitted.

The pharmaceutical importers argued that

> when products were imported under brand names and the manufacture was based on individual manufacturers' own research according to international standard and thus free to sell in their own country as well as in other countries of the world . . . the importers in Pakistan were within their right to demand samples for test and analysis and ask them other sureties as to the efficacy, safety and quality of the products claimed. When the products are manufactured according to the formula given by others, the foreign manufacturers cannot stand guarantee for anything except the percentage of ingredients as provided in the National Formulary.

In a letter[83] to the Assistant Drugs Controller, Karachi, the importers said that "generally manufacturers abroad are not prepared to change their products according to the National Formulary of Pakistan." In the case of products that they were prepared to manufacture, the requirements of the Health Ministry could not be complied with. For example, concerning the required list of therapeutic indication, the PPIA said that foreign manufacturers

> will not be able to supply literature on the therapeutic indication of any product because manufacture of the product will be according to the formula provided by the importers in Pakistan and it will not be their own product on which research has been done and clinical trials made by them. In fact those who prepared the National Formulary of Pakistan ought to know the therapeutic indication of the product made according to their own formula.

Also, foreign manufacturers could not meet the Health Ministry's requirement that they produce a certificate to the effect that manufacture, sale, and distribution of the product is not prohibited in the country of origin because "products to be manufactured according to the National Formulary of Pakistan would not have been introduced and consumed in their own country or any other country of the world except Pakistan."

The importers went on to suggest that, regarding product quality, health inspectors could follow their usual practice of taking samples from chemists and sending them to the government testing laboratories to check whether the ingredients were as specified in the formulary. According to the importers, "foreign manufacturers cannot stand guarantee for anything except the percentage of ingredients as provided in the National Formulary."

These demands were rejected as "unreasonable" by the government.

Enforcement of the Act

The health authorities started in 1973 to take action against those who contravened the Generic Names Act. Various firms were "raided" by government inspectors. A subsidiary of a multinational firm was cited for selling brand name drugs. "The case memo issued for this particular purchase had listed the sale with generic names but brand named products without using stickers were provided."[84] Chemists were warned and then arrested for selling brand name drugs.[85]

Amidst confusion, the Generic Names Act became a reality and slowly within the next two years, pharmaceutical manufacturers and the trade developed strategies to cope with the new legislative environment.

## Commentary

As the discussion in this chapter indicates, each of the groups embroiled in the pre- and post-legislation controversy was at some time guilty of exaggerating or overstating the implications of not subscribing to their particular viewpoint.

The government obviously undertook the generic policy without doing preliminary planning as to how it would cope with the problems it would face. The government did not foresee the overwhelming antagonism on the part of those affected by the policy, which

included the dominant industry members, importers, the trade, and the medical profession. Nor did the government foresee the production and marketing problems that industry and trade would have to face because of the suddenness of the government action. The result was piecemeal responses such as amendments to legislation, orders, warnings, and exceptions. Most of these problems could have been foreseen by the government if the scheme had been adequately planned and implementation appropriately scheduled.

The industry, dominated by the leading multinational manufacturers, initially promoted organized opposition to the scheme, propagating a highly pessimistic view of the consequences of the Generic Act. It created fears among both the medical profession and the public regarding product quality and drug shortages. However, the industry faced some difficult problems. The government's delays in publication of the national formulary and its unclear policies enhanced uncertainty and made it harder for the industry to make its production and marketing plans.

Confusion in the pharmaceutical trades was compounded by the uncertainty of supply of drugs by manufacturers. There was apprehension due to the chemists' general inexperience in dispensing generic drugs, and there was genuine concern about the fate of the unsold inventory of brand name drugs.

Pharmaceutical importers were primarily concerned with whether or not they would be able to develop the supply sources necessary to import products which would conform to the specifications in the national formulary.

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Doctors initially had mixed reactions to the generic policy. However, the problems that arose immediately after the introduction of the scheme, such as drug shortages and the publicized cases of incorrect dispensing of generic drugs, resulted in their growing opposition to the plan. The propaganda by local subsidiaries of foreign manufacturers raised fears of inequivalence of products and suggested that the health of patients would depend more on chemists' decisions than on doctors' expertise. This increased the medical profession's antagonism to the generic policy.

It was under these circumstances that the Generic Names Act came into effect.

The next chapter starts by outlining the methodology employed in this research and proceeds to introduce hypotheses designed to examine whether the government's objectives in introducing the Generic Names Act were realized. Other hypotheses regarding the possible consequences of the government's action are also proposed in the next chapter.

## Footnotes--Chapter III

[1]The Drugs Act (XXIII of 1940), reprinted in The Drugs Laws (Lahore: Mansoor, n.d.).

[2]A prominent legal advisor to major pharmaceutical companies informed this writer that this section of the Drugs Act did not provide the legal protection required to prevent the imitations (of products) that proliferated the market during the generic period (1972-1975).

[3]The Kefauver Hearings were conducted between 1959 and 1962. The Nelson Hearings began in 1967. For an account of these proceedings and others, see for instance U.S., Congress, Senate, Committee on the Judiciary, Subcommittee on Antitrust and Monopoly, Administered Prices in the Drug Industry. Kefauver Hearings (Washington, D.C.: Government Printing Office); U.S., Congress, Senate, Subcommittee on Monopoly, Present Status of Competition in the Pharmaceutical Industry. Nelson Hearings (Washington, D.C.: Government Printing Office); U.K., Sainsbury Committee, Report of the Committee of Enquiry Into the Relationship of the Pharmaceutical Industry With the National Health Service 1965-1967 (London: HMSO, 1967); U.K., Monopolies Commission, Report on Proposed Mergers Between Beecham Group Ltd., and Glaxo Group Ltd., and Between Boots Company Ltd., and Glaxo Group Ltd. (London: HMSO, 1972); Report on the Supply of Chlordiazepoxide and Diazepam (Librium and Valium) (London: HMSO, 1973); Canada, Royal Canadian Commission Report (Ottawa: Queen's Printer, 1964).

[4]Cited in Wyndham Davies, The Pharmaceutical Industry: A Personal Study (London: Pergamon Press, 1967), pp. 169-70.

[5]Milton Silverman and Philip R. Lee, Pills, Profits, and Politics (Los Angeles: University of California Press, 1974), p. 43.

[6]"PPMA's Protest Note to Health Minister," Medical News Supplement, April 20, 1972, p. 18.

[7]"PPMA Appeal," Medical News Supplement, April 20, 1972, p. 5.

[8]"Health Scheme: PPMA's Position Paper," The Sun, Supplement on National Health, April 22, 1972, p. 10.

[9]"Pharmaceutical Industry's Contribution to the Economic Development of Pakistan," Dawn, September 15, 1972.

[10]Ibid.

[11]For example, the PPMA suggested that home remedies (over-the-counter, nonprescription drugs) would no longer be available. In actuality, the government had not put any restrictions on the sale of over-the-counter drugs except that they should be marketed by generic names. The prediction that drug products from other parts of the world would not be available because they could not be imported under brand names was an exaggeration; the government had indicated it would grant exemptions for the import of certain brand name drugs, if it was "in the public interest."

[12]"TCP and Import of Chemicals," The Sun, Supplement, April 22, 1972.

[13]The TCP's monopoly of imports could obviously result in real quality problems for manufacturers as the TCP would probably attempt to generate economies through using central import sources and through competitive price bidding. These circumstances could also provide a manufacturer with a convenient scapegoat for any deficiencies in finished product standards.

[14]"TCP and Import of Chemicals," loc. cit.

[15]The government had directed the TCP to start making arrangements for the import of drugs, after which the TCP chief had informed the press that it would start imports from July 1972. However, the Commerce Ministry subsequently advised the TCP to "refrain from saying anything about the matter as the Ministry had not yet decided anything about it. . . ." "Decision Withheld Under Foreign Pressure," Daily News, April 24, 1972.

[16]"Decision Withheld Under Foreign Pressure," loc. cit.

[17]The Gazette of Pakistan, Extra (Islamabad: Government of Pakistan Printing Press), April 22, 1972.

[18]One lakh = 100,000. One lakh rupees is equal to approximately $10,000 (according to exchange rates after June 1972).

[19]See for instance "Generics Can Reduce Prices up to 90 p.c.," Morning News, September 29, 1972; and "State-Run Drug Stores: Counter to Profiteering Tendencies," Medical Gazette, February 1, 1973, p. 2.

[20]Legislation regarding generic names had earlier been considered by President Ayub Khan's government in 1965 but did not go beyond the planning stages. Shaikh Rashid asserted that it was foreign pressure (American) that prevented implementation. Whether it was "pressure" or lobbying for a certain viewpoint is arguable; however, the more plausible reason is that the government at that time foresaw what it perceived to be practical difficulties in the implementation of a "generic" policy.

[21]See Chapter II, p. 64.

[22]Muzhar-ul-Haque, "Generic Names vs. Brand Names," Medical News Supplement, April 20, 1972, p. 2.

[23]Hamid Ali Khan, "An Appraisal of the People's Health Scheme," Medical News Supplement, April 22, 1972, p. 16.

[24]"Prices of Several Drugs Increase," Dawn, May 25, 1972.

[25]"PPMA Denies Any Offer of Bribe to Minister," Dawn, April 27, 1972.

[26]Ibid.

[27]"Bribes and Pressures to Abandon Generic Names of Drugs," Dawn, June 6, 1972; also "Rashid Speaks of Foreign Pressure," Medical News, June 15, 1972, p. 4.

[28]"German Envoy Had 'Only Written a Letter' to Rashid," Dawn, June 8, 1972; also "Prefix in a 'Fix,'" Medical News, June 15, 1972, p. 8.

[29]PPMA spokesmen said that "raw material worth about Rs. 10 crore and finishing supplies valued at about Rs. 5 crore . . . will have to be dumped in the waste bin unless enough time were allowed to make use of these assets"; Pakistan Times, May 9, 1972. This was probably an exaggerated estimate to underline the seriousness of their situation; if not all, at least part of the material could have been used to manufacture generic name drugs.

[30]"New Ordinance May Cut Down Pharmacy Output," Dawn, April 29, 1972.

[31]"Ban on Import of Raw Materials for Medicines Lifted," Dawn, May 6, 1972.

[32]"Drug Ordinance Deadline May Be Extended," Dawn, May 12, 1972.

[33]"Workers Threaten to Take Over All Pharmaceutical Firms," Dawn, May 18, 1972.

[34]"Drug Importers Face Undue Hardships," Medical News, June 15, 1972, p. 9.

[35]"Government Stops Issuing Fresh Drug Import Licenses," Medical News, September 1, 1972, p. 1.

[36]Pakistan Chemists and Druggists Association, Special Release, May 1972.

[37]"Prices of Several Drugs Increase," Dawn, May 25, 1972. Regarding the disappearance of life-saving drugs, one report indicated that "the worst sufferers are patients of diabetes, asthma, tuberculosis, anaemia, leukaemia, and cardiovascular diseases . . . as most of their drugs have gone underground. . . ." "Drug Ordinance Deadline May Be Extended," Dawn, May 12, 1972.

[38]"Druggists Resent Government Directive," Pakistan Times, May 9, 1972.

[39]"Chemists Refuse to Supply Medicines to Mayo Hospital," Medical News, July 1, 1972.

[40]"Appeal to Mr. Zulfikar Ali Bhutto, President of Pakistan," Pakistan Times, August 9, 1972.

[41]"Prices of Several Drugs Increase," Dawn, May 25, 1972.

[42]"Six More Months Allowed for Drugs Under Brand Names," Dawn, May 30, 1972.

[43]"Health Minister's Statement: Text," Dawn, May 30, 1972.

[44]The PPMA rejected this comparison as "misleading," as "products in the comparison were therapeutically inequivalent"; special release, PPMA, June 1, 1972.

[45]Interestingly, during the generic period, many manufacturers attempted to persuade doctors to include the manufacturer's name on generic prescriptions. This strategy of emphasizing company "quality" and "reliability" was one which helped the multinationals retain their market shares. See Chapter VIII.

[46]"Committee for Effective Quality Control of Drugs," Dawn, July 21, 1972.

[47]"Banking, Generic Names Bills Passed," Sun, September 23, 1972.

[48]Gazette of Pakistan, Extra (Islamabad: Government of Pakistan Printing Press), September 25, 1972.

[49]"Generics Can Reduce Prices up to 90 p.c.," Morning News, September 29, 1972.

[50]Ibid.

[51]See "Government May Submit to Threat by Drug Companies," Daily News, October 11, 1972; and "PPMA Readies to Sabotage Generic Names," Leader, October 31, 1972.

[52]"200 Medicines to Be Exempted From Generic List: Rashid," Dawn, November 24, 1972.

[53]"Directive to Drug Makers," The Star, December 7, 1972.

[54]Pakistan Chemists and Druggists Association, press release, December 8, 1972.

[55]"Drug Manufacturers to Suffer Loss of Rs. 12 Crores," Dawn, December 20, 1972 (note: one crore = 10 million).

[56]"Shortage Crisis of Drugs and Medicines," Medicoment, December 15, 1972.

[57]"Resolution: Central Executive Committee PCDA," special release PCDA, December 8, 1972.

[58]See for instance: "Sh. Rashid, You Have Failed," Editorial, Daily News, December 18, 1972; "Drug Manufacturers to Suffer Loss of Rs. 12 Crores," Dawn, December 20, 1972; "Massive Speculative Trade in Drugs," Star, December 18, 1972.

[59]"Directive for Druggists," Morning News, December 30, 1972.

[60]"Steps to Avert Shortage of Medicines," Dawn, January 3, 1973.

[61]Pakistan Chemists and Druggists Association, press release, January 9, 1973.

[62]"Chemist Body's Plea," Dawn, February 11, 1973; also "Druggists Threaten Strike," Morning News, February 12, 1973.

[63]"Chemists and Druggists Strike Deplored," Medical Gazette, February 15, 1973, p. 10.

[64]"Drug Stores to Earn More on Brand Names," The Sun, February 9, 1973.

[65]"Drug, Medicine Makers Warned," Morning News, February 9, 1973.

[66]"Use of Non-Active Material for Drugs Permitted," The Medical Gazette, March 1, 1973, p. 1.

[67]"Drug Importers Warned," Morning News, February 12, 1972.

[68]"Generic Names: Amending Ordinance Issued," Morning News, February 17, 1973.

[69]"Chemists' Strike Banned," The Medical Gazette, March 1, 1973, p. 12.

[70]"Chemists and Druggists Not to Go on Strike," Pakistan Times, February 27, 1973.

[71]"Brand-Name Drugs Sale Allowed Till September, 1973," Dawn, March 11, 1973. The deadline for sale of brand name drugs with generic "stickers" was eventually extended to June 30, 1975.

[72]"Drugs: Exemption to Government Hospitals," Dawn, March 29, 1973.

[73]"Generic Drugs: Confusion, Shortage Add to People's Miseries," Daily News, March 16, 1973.

[74]"Stern Action for Sale of Illegal Drugs," Business Recorder, March 31, 1973.

[75]"104 Drugs Exempted for Another Six Months," Morning News, July 7, 1973.

[76]"Stern Action for Sale of Illegal Drugs," loc. cit.

[77]See "Most of Medicine Shops Closed While Patients Suffer," Dawn, April 3, 1973; and "Confusion Reigns as Generic Drugs Law Takes Effect," Morning News, April 3, 1973.

[78]The average doctor also had difficulties prescribing generic branded drugs with no guiding literature. Some doctors "resolved" this by prescribing by the brand name and directing the chemist to dispense the equivalent generic named drug.

[79]Habibur Rehman Khan, "Generics and After," The Medical Gazette, June 1, 1973, p. 5.

[80]"No Fall in Prices of Essential Drugs; Life Savers Difficult to Obtain," The Star, May 18, 1972; "Disappearance of Life-Saving Drugs Feared," Morning News, June 18, 1973.

[81]"Generic Scheme: Dr. Muzaffar Demands Transition Period," Medical Gazette, April 15, 1973, p. 12.

[82]Pakistan Pharmaceutical Importers Association, letter to the Drug Controller, Government of Pakistan (No. PPIA/72/73), June 30, 1973.

[83]Pakistan Pharmaceutical Importers Association, letter to the Assistant Drugs Controller, Karachi (No. PPIA/33/73), June 19, 1973.

[84]"Large Stocks of Branded Drugs Seized in City," Morning News, July 7, 1973.

[85]"Arrested for Selling Branded Drug and Charging Higher Price," Dawn, July 13, 1973.

# CHAPTER IV

# RESEARCH METHODOLOGY AND HYPOTHESES

## Introduction

The first portion of this chapter outlines the methodology used in the course of this study. The study was conducted in two phases. In the first phase, the objective was to develop an understanding of how and why the Generic Names Act was introduced, the difficulties and problems encountered in the introduction and subsequent implementation of the legislation, the reactions of those who were affected by the proposed reform, and the government's counter-reactions.

It was upon this research that Chapter III was based. It is hoped that that chapter will be of use to policy makers in other developing countries who may be contemplating similar reforms. In particular, as mentioned in that chapter, it may help them become aware of some of the practical problems and difficulties involved.

The second phase of the research covered the prime objective of the study, which was to determine, first, whether the government-desired goals in introducing the legislation were achieved, and, second, to examine certain other propositions regarding the consequences of the Generic Names Act.

The latter portion of the chapter states the hypotheses and related questions which were examined in phase two of the research.

## Methodology

The study, as already mentioned, was conducted in two phases. Each of these is explored in turn, and the major sources of information used during each phase are discussed.

### Phase 1

The first aspect of the research was to establish and document the sequence of events from the time the government proposed reform measures in March, 1972, to July, 1973, at which time the government began rigidly enforcing the Act.

This phase of the research was conducted in 1976 in Pakistan and involved recapitulating events occurring three to four years earlier. Since interviews with participants could only produce ambiguous recollections, it was decided to concentrate on assimilating information from published accounts of the events. Significant events identified from published accounts were also checked for their accuracy by verifying them with the representatives of industry, trade, with importers, government health officials, and the medical profession.

It should be noted that there are limited sources of published information available in Pakistan. There are no journals that would be pertinent to the information sought and newspapers and government documents are not indexed, thus aggravating the task.

Among the meager resources available, the more useful publications were the medical and public press, government documents, and industry and trade records and publications.

Major sources of information.--

The press: Of the three major medical newspapers in Pakistan, the Medical News, a private publication, and the Medical Gazette, published by the Pakistan Medical Association, appear regularly every fortnight. Issues for the period 1971 to 1976 were made available to this researcher by the editors of these newspapers and were examined for pertinent information. The other medical newspaper, Medicoment, also a private publication, appears irregularly. The editor supplied back issues which were, in his words, "relevant to the generic period."

The editors of the three newspapers also recapitulated, for the researcher, significant issues raised at the time of introduction of the legislation.

Within the popular press, there are two major newspapers, Dawn and Morning News. These were sources of supplemental information for this phase of the research. Unfortunately, these newspapers are not indexed, so that it was necessary to review each issue. These were reviewed for the period December, 1971, to August, 1976.

Government documents: Notifications in government publications such as the Gazette of Pakistan, pertinent to our topic, were examined for the period 1971 through 1976. In addition, certain internal circulars and memoranda of the health authorities were made available to the researcher by various groups, among them provincial health officials and the industry and trade associations.

Industry and trade sources: The Pakistan Pharmaceutical Manufacturers Association (PPMA) and the Pakistan Chemists and Druggists Association (PCDA) provided a variety of secondary data. The PCDA, in particular, allowed access to their records, for the period 1972 through 1975, which were useful, again, not only as a source of new information but also as a check for other information sources.

Representatives of the PPMA and PCDA also provided detailed accounts of industry and trade positions after the generic policy was introduced, and helped to confirm the reports in the medical press at that time.

The information from these various sources was cross-checked against each other, as indicated earlier, for certain significant accounts regarding the positions adopted by the industry, trade, and the medical profession. Representatives of these associations verified the reliability of the reports.

## Phase 2

In the second phase of the research, an attempt was made to obtain data, both qualitative and quantitative, to test the hypotheses (stated later in this chapter) and related questions.

When the research proposal was formulated, it was decided that the most relevant source of primary data would be industry members; thus, they were the chief focus of data collection during this phase of the research. To confirm and clarify the information obtained from representatives of pharmaceutical firms, the researcher

interviewed chemists and druggists, prominent members of the medical profession, and government representatives.

Major sources of information.--

Industry members: sample and data collection:

The sample. In-depth personal interviews were conducted with representatives of 26 pharmaceutical manufacturers. Of these, 14 were multinational companies with local manufacturing facilities (referred to as foreign local manufacturers) and 12 were indigenous Pakistani manufacturers (referred to as Pakistani local manufacturers).

Altogether, these 26 companies accounted for approximately 76 percent of rupee sales of drugs in the Pakistani market. The 14 foreign local manufacturers accounted for 69 percent, the Pakistani local manufacturers, 7 percent.

The individuals interviewed were senior executives, ranging from managing directors and general managers to marketing directors, marketing managers, and senior marketing executives.

Although the judgmental sample of companies was, in the opinion of this researcher, reasonably representative of the industry, there are certain limitations.

Most of the leading Pakistani local manufacturers contacted agreed to be interviewed, but some lesser known Pakistani manufacturers were not agreeable. Although they did not refuse to cooperate outright, they indicated that they were too "busy" at the time and could not suggest any time that would be convenient. Additional interviews with Pakistani manufacturers (particularly the lesser known

ones) would have enhanced understanding of the strategies adopted by this group as a response to the introduction of the legislation.

All the foreign local manufacturers contacted agreed to be interviewed except one. This person claimed to have "an extremely busy schedule" for the next couple of months.

In general, one representative per company was interviewed. In a few cases, that representative was joined by another during the interview.

Data collection. Initially, it was intended to use a combination of mail questionnaires and personal interviews to obtain the necessary information. However, when this data-collection procedure was discussed with some prominent industry representatives, they argued convincingly that industry members would be very sensitive about responding candidly to a mail questionnaire. This idea was discarded, and personal interviews, using an interview guide (see Appendix), were conducted by the researcher between November 1976 and February 1977.

The interviews, conducted in English, Urdu, or a mixture of both, depending upon interviewee preferences, generally lasted from two to three hours.

It was of crucial importance to obtain quantitative information on the pharmaceutical industry in the pregeneric and postgeneric periods. The interview guide initially included questions on such things as overall sales, sales by therapeutic class, product mix changes, number of people employed as medical representatives and

sales representatives, and so forth. In a pretest, industry representatives commented that individual companies would be wary of giving this quantitative information, and it was excluded from the questions. However, the quantitative data concerning market shares, prices, product offerings, and so forth were made available to this researcher by industry members who had access to compilations. These compilations are acknowledged by companies to be reliable. Their accuracy was also verified by comparing it with information provided by certain companies and with published information; in general, the data agreed. To maintain confidentiality, individual company names have not been used in this research.

The trade, doctors, government representatives: The purpose of meeting with chemists and druggists was to confirm some of the information obtained from manufacturers. A sample of 12 chemists and druggists in the Karachi area was chosen. Of these, seven were randomly selected, and five others were personally known to the researcher. The latter, particularly, responded very candidly to questions regarding their (and other chemists') practices. Because of time constraints, meetings with more chemists were not possible. However, the responses of the 12 were similar to one another, and in the judgment of this researcher, more interviews would not have yielded any significant additional information.

Informal discussions with five prominent members of the medical professions who were actively concerned about the legislation yielded some useful insights.

Two federal health officials in Karachi, two provincial health officials, and the Drug Prosecutor also provided information regarding specific aspects examined.

As mentioned earlier, during this phase of the research, information and data were collected concerning specific hypotheses and related questions about certain effects of the Generic Names Act on the pharmaceutical sector in Pakistan. These are presented next.

## Hypotheses

A series of hypotheses about the effects of the Generic Names Act on the industry were formulated. These were separated into four areas dealing with market shares, pricing, product issues, and promotional strategies in the pharmaceutical market in Pakistan after the introduction of the Generic Names Act.

The hypotheses developed in the areas of market shares and pricing do not require much explanation as they are stated to test whether the government's objectives in introducing legislation were achieved. Certain hypotheses in the area of product policies and promotional strategies are based on the comments of those who had reservations regarding the legislation, predicting some undesirable consequences. These hypotheses require more explanation.

### Market Shares

By introducing the Generic Names Act, the Pakistani government hoped to reduce the dominance of the leading multinational manufacturers. The reasoning was that by abolishing the use of brand

names for drugs, there would be increased competition among generic name products. The increased competition was expected to reduce the market shares held by the leading multinational pharmaceutical manufacturers. Furthermore, with Pakistani manufacturers no longer having to contend with the "monopolistic" barrier of brand names, they would be able to compete on "equal" terms against the leading multinational companies and increase their share of the market.[1]

To investigate whether market shares did indeed shift in the direction the government desired, the following hypotheses are forwarded:

$H_1$: The Generic Names Act would lead to a decrease in sales concentration.

$H_2$: The Generic Names Act would lead to an increase in market shares of Pakistani manufacturers.

Prices

Another intent of the legislation was to reduce the price of drugs to the customer. An official publication states the government's view:

> Any public health scheme which aims at providing medical facilities adequately to the common man is handicapped by the cost of drugs. Some of the drugs and medicines sold under the brand names were unduly costly. Large profiteering was rampant. It was necessary as a first step towards bringing medicines available within the reach of common man to rationalize their number and to scale down their prices to some reasonable and justifiable level. It was, therefore, decided to switch over, wherever possible, to the generic names of drugs which are scientific names known internationally.[2]

Increased price competition among generic name products was expected to follow after brand names were abolished, leading to lower prices. Thus, it was hypothesized that

$H_3$: The Generic Names Act would lead to a reduction in drug retail prices of drugs in Pakistan.

Another question meriting investigation was whether retail prices were "high" prior to the introduction of the Generic Names Act. This related issue would also be examined.

Product Issues

The government wanted to increase competition among manufacturers and had indicated that it would allow all manufacturers to produce any drug included in the National Formulary.[3] It could be expected that Pakistani entrepreneurs would avail themselves of this opportunity and that there would be a number of new entrants into pharmaceutical manufacturing (dosage form fabrication).

The government's view was not unusual. Others have held similar opinions. In a series of reforms he put forward in 1968, in testimony during the Nelson Hearings, Steele advocated

> elimination of unnecessary barriers to entry of new drug firms into the industry. If a drug has been cleared for marketing as the result of adequate data compiled by one applicant, the same drug should be approved for marketing by any firm capable of producing the identical drug. Unnecessarily burdensome requirements by way of conducting studies which merely duplicate existing studies should not be imposed.[4]

The Pakistani government obviously believed that by having a National Formulary with chemical specifications provided for each drug product and by encouraging all manufacturers to produce generic products, they would be removing all barriers to entry for manufacturers who could produce "identical drugs."

But, while Steele advocates allowing other manufacturers to market FDA-approved drugs, he emphasizes that these other manufacturers should be capable of doing so, stressing that "proper testing and evaluation of drugs is an important and time consuming task."

> . . . Before certain needed reforms were legislated in 1962, many firms yielded to the temptation to rush new drugs thru the development phase and on to the market as soon as possible, limiting experimental and clinical work to the minimum acceptable levels. . . , harassing FDA staff members into approving inadequate applications, and even skipping seemingly essential product development stages.[5]

During the Kefauver Hearings, Dr. Leake said: "There is no shortcut from chemical laboratory to clinic, except one that passes too close to the morgue."[6]

There is no evidence that the Pakistani government, while maintaining that all manufacturers would be given an opportunity to produce drugs from the National Formulary, gave the aspect of proper drug testing and evaluation enough consideration.[7] Thus, there was a possibility that new entrants might not have adequate manufacturing and quality control facilities. It was hypothesized that:

> $H_4$: The Generic Names Act would lead to an increase in the number of Pakistani local manufacturers, some of whom would have inadequate (marginal) manufacturing facilities.

With the introduction of the National Formulary, a number of companies would have to stop production of drugs not included in the National Formulary. To compensate for this, firms would begin manufacturing other products from the National Formulary. But since the government had indicated that it would be liberal in giving product

licenses to promote generic competition, manufacturers might be inclined to increase their product offerings.

Again, Pakistani manufacturers could be expected to enter into production of other drugs in the National Formulary. Thus, it was hypothesized that:

$H_5$: The Generic Names Act would lead to an increase in product offerings from the National Formulary by Pakistani local manufacturers.

A related question is: If there was an increase in product offerings by Pakistani manufacturers, were their products able to obtain significant shares of the product sales? This also was investigated.

Using the same arguments given earlier, there was a chance that increased product offerings could mean less emphasis on and a real possibility of a decline in product quality.

To counter such a decline and to monitor drug manufacture, there would have to be an adequate drug inspection system by the government.

While proposing abolition of brand names for drugs and "removal" of unnecessary barriers to entry of new drug firms into the industry, Steele again emphasizes that the FDA (in the United States) should be provided with

> sufficient authority, staff and funds to carry out a drug inspection program adequate not only to prevent the sale of substandard drugs but also the plausible insinuation of the possibility that substandard drugs might be on the market.[8]

It was questionable whether the government inspection system in Pakistan had the staff and facilities to effectively monitor new

entrants and an increased number of product offerings by various manufacturers.

Besides, inspection left to government agencies can also create difficulties. Writing of the situation in the Soviet Union, Bauer and Field comment that where pharmaceutical inspection was left to the government bureaucracy

1. Quality remained substandard.
2. Minimum standards also became maximum standards. Manufacturers had no economic incentives . . . to produce any quality beyond the minimum required by the established standards.
3. In addition to the fact that quality continued to be unsatisfactory, the system of inspection turned out to be cumbersome, expensive, and, to a large extent, ineffective.[9]

Since there was a possibility that substandard drugs would increase in the Pakistani market, it was hypothesized that:

$H_6$: An increase in product offerings and "marginal entrants" would increase the number of substandard drugs in the market.

Related to $H_6$ would be an investigation of the question posed earlier as to whether the government inspection system was qualified and equipped to cope with monitoring product quality.

Promotional Issues

With goverment-mandated compulsory use of generic names in prescriptions and the marketing of drugs by generic name only, the chemist could hypothetically provide any of the various chemically equivalent generic name drugs. If this happened, the chemist (who, it is claimed, does not have the expertise to make a proper choice of drugs[10]) could become the focus of the sales effort of the manufacturers.

To investigate this, the hypothesis is advanced that:

$H_7$: The Generic Names Act would lead to a decrease in promotional effort directed at doctors and an increase in promotional effort directed at chemists.

The four chapters which follow provide the research findings regarding the hypotheses and related questions in the areas of market shares, prices, product issues, and promotional strategies.

## Footnotes--Chapter IV

[1]See "Bribes and Pressures to Abandon Generic Names of Drugs," Dawn, June 6, 1972; "Generics Can Reduce Prices up to 90 p.c.," Morning News, September 29, 1972.

[2]Government of Pakistan, Finance Division, Pakistan Economic Survey, 1972-73 (Islamabad: Government of Pakistan, 1974), p. 20.

[3]"Banking, Generic Names Bills Passed," Sun, September 23, 1972.

[4]Henry B. Steele, statement before the U.S. Senate, in Competitive Problems in the Drug Industry, pt. 5 (Washington, D.C.: Government Printing Office, 1967), p. 1928.

[5]Ibid., p. 1915.

[6]Cited in Steele, Competitive Problems, pt. 5, p. 1915.

[7]One high-ranking official in the Ministry of Health commented during an interview, "The government was very eager to have as many manufacturers compete with generic name drugs. Product licenses were given liberally without asking the question 'Do you have the technical capability to manufacture these products?'"

[8]Steele, op. cit., p. 1928.

[9]R. A. Bauer and M. G. Field, "Ironic Contrast: U.S. and U.S.S.R. Drug Industries," Harvard Business Review, September-October 1962, p. 95.

[10]See Chapter I, pp. 23-25.

# CHAPTER V

# EFFECT OF THE GENERIC NAMES ACT ON MARKET SHARES

## Introduction

A series of related questions dealing with sales concentration in the pharmaceutical market in Pakistan are investigated in this chapter. Prior to the introduction of its "generic" policy, the government expressed concern about the high market shares held by foreign local (multinational) manufacturers, but it had no systematic information to support this contention. A logical first step would be to examine sales concentration (in 1971) prior to introduction of the generic policy in 1972. Doing so would reveal not only the market shares of multinationals, but also of Pakistani manufacturers.

The next step was to examine sales concentration after the Generic Names Act had been in effect for three years. Market shares were calculated for 1975. This year was selected because the 1972-1974 period was considered one of adjustment to the new situation,[1] and legislative amendments in 1976 changed the policy considerably, requiring that only single-ingredient drugs be marketed by generic name.[2]

Finally, it was necessary to determine whether there were any changes in market share in the major pharmaceutical therapeutic submarkets (systemic antibiotics, vitamins, cough and cold preparations) between 1971 and 1975.

As mentioned in Chapter IV, the government hoped to accomplish two objectives with respect to market shares: reduce the sales concentration of foreign manufacturers and increase the market share of Pakistani manufacturers. It was believed that the legislation would eliminate for the latter "the monopolistic barrier of brand names impeding them from effectively competing in the Pakistani pharmaceutical market." Consequently, two hypotheses were suggested.

$H_1$: The Generic Names Act would lead to a decrease in sales concentration.

$H_2$: The Generic Names Act would lead to an increase in market share of Pakistani manufacturers.

## Measures: Market Share

Brooke has written:

> Traditionally, economic concentration is measured in dollar sales. Within the pharmaceutical industry, concentration or market share can be measured by a number of other techniques. By the traditional method, one firm's sales could be stated as a percentage of total sales for a specified market. Another method would be to use prescriptions rather than sales. (Firm X has 50 percent of tetracycline prescriptions.) This method could be narrowed further if prescriptions for a particular dosage form are used rather than aggregating dosage forms. Yet another technique would be to measure concentration by number of days of patient therapy (number of prescriptions multiplied by days of therapy). This method would take into account the variation in size of prescriptions and in length of treatment. Finally, market concentration can be measured in unit terms--total number of pills (number of prescriptions multiplied by average prescription size).
>
> There are weaknesses and difficulties with each method. In market share defined by dollar volume, higher price alone clearly leads to higher dollar volume of sales and hence to a higher degree of concentration. The most expensive product will have a larger market share measured in sales rather than in units. However, the tendency of a firm to

> gain sales through the exercise of market power would not be fully apparent in unit measurement or in number of prescriptions measurement.
>
> To measure concentration in unit terms or prescription terms or days of patient therapy is to measure something other than economic concentration.[3]

The measure selected to examine economic concentration in this research, therefore, was sales volume (in rupees).

## Market Shares: Overall Market

Approximately 300 firms were competing in the Pakistani pharmaceutical market in 1971 and 1975. These included foreign firms with established manufacturing facilities in Pakistan (referred to in this research as foreign local manufacturers), Pakistani manufacturers (referred to in this research as Pakistani local manufacturers), and foreign firms exporting finished products to Pakistan (referred to in this research as importers).

The total sales of these 300 firms in Pakistan in 1971 was approximately 540 million rupees (approximately U.S. $54 million). The total in 1975 was about 635 million rupees (approximately U.S. $63 million). This represents an increase of 17.6 percent in 1975 over 1971 sales volume.

The next four sections discuss the changes in overall market share between 1971 and 1975 for all companies, for foreign local manufacturers, for Pakistani local manufacturers, and for importers.

Market Shares: All Companies

Of the approximately 300 firms competing in the Pakistani pharmaceutical market in 1971, 60 firms (20 percent of the total number) held approximately 95 percent of the market share in rupee sales in the years 1971 and 1975. Among these, 30 companies (10 percent of the total number) accounted for approximately 85 percent of the rupee sales of drugs and medicines in the same period. The remaining firms (90 percent of the total number) accounted for only 15 percent of the rupee sales in the pharmaceutical market.

The market shares of the 60 leading companies in 1971 and 1975 are provided in Table 5-1.

The cumulative market shares of the 60 sales leaders in 1971 and 1975 are illustrated in Figure 5-1. An examination of these figures indicates that between 1971 and 1975 there was an increase rather than a decrease in sales concentration. In 1971, 10 foreign local manufacturers accounted for about one-half the rupee sales in the pharmaceutical market. In 1975, half of the rupee sales in the market (50 percent) was held by only six foreign local manufacturers. The five sales leaders in 1971 held about 38 percent of the market share, while the five sales leaders in 1975 held about 46 percent of the market share.

A comparison of the 1971 and 1975 figures for combined market shares of groups of firms (see Table 5-1) indicates that the first 10 leaders in rupee sales experienced gains in their combined market shares in 1975. Nine companies in the top 10 in rupee sales

Table 5-1.--Market share of the leading 60 companies: 1971 and 1975.

| Companies | 1971 | | 1975 | | Increase/ Decrease in % of Market (1975-1971) |
|---|---|---|---|---|---|
| | Market Share (% of Total Rupee Sales) | Cumulative Market Share | Market Share (% of Total Rupee Sales) | Cumulative Market Share | |
| 1st five | 37.69 | | 46.00 | | + 8.31 |
| 2nd five | 15.60 | 53.29 | 16.63 | 62.63 | + 0.71 |
| 3rd five | 11.21 | 64.50 | 9.09 | 71.72 | - 2.12 |
| 4th five | 8.58 | 73.08 | 5.55 | 77.27 | - 3.03 |
| 5th five | 5.87 | 78.95 | 4.42 | 81.69 | - 1.45 |
| 6th five | 4.41 | 83.36 | 3.52 | 85.21 | - 0.89 |
| 7th five | 3.06 | 86.42 | 2.52 | 87.73 | - 0.54 |
| 8th five | 2.24 | 88.66 | 2.03 | 89.76 | - 0.21 |
| 9th five | 2.02 | 90.68 | 1.63 | 91.39 | - 0.39 |
| 10th five | 1.54 | 92.22 | 1.25 | 92.64 | - 0.29 |
| 11th five | 1.22 | 93.44 | 1.10 | 93.74 | - 0.12 |
| 12th five | 1.03 | 94.47 | 0.93 | 94.67 | - 0.10 |

Source: Companies data made available to researcher.

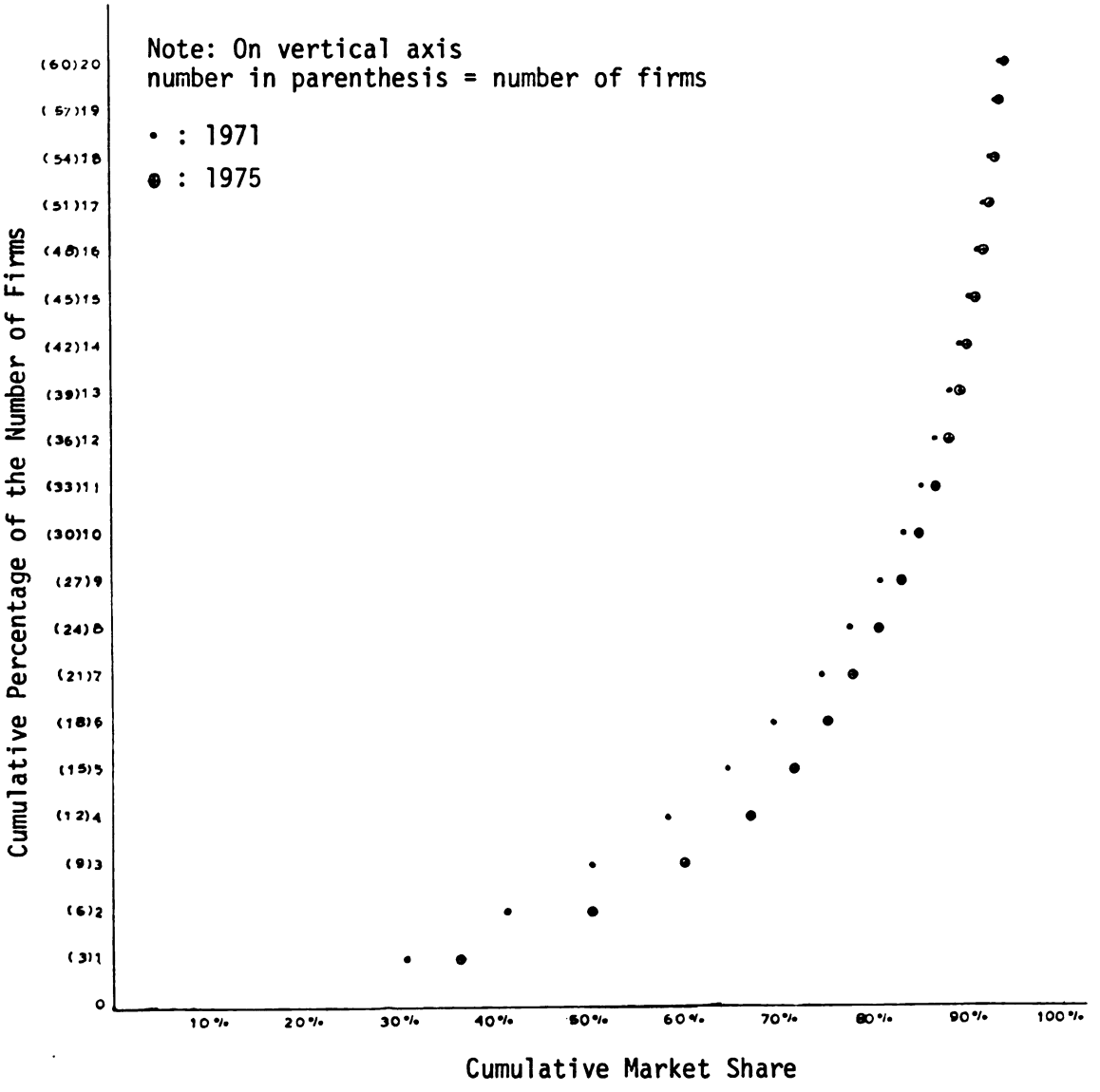



Figure 5.1.--Market share of sixty pharmaceutical companies (1971 and 1975).

Source: Companies information made available to researcher.

in 1975 were also among the 10 leading companies in 1971. One company fell from the top 10 in 1971 to twentieth position in 1975. This was due primarily to loss of the East Pakistan (now Bangladesh) market, where the company had concentrated its manufacturing and marketing operations. The company that replaced it in the ranks of the top 10 sales leaders jumped from twenty-second in 1971 to sixth position in 1975 with a very aggressive expansion of manufacturing and marketing effort.

### Market Shares: Foreign Local Manufacturers

In the top 60.--In 1975, 25 foreign local manufacturers among the leading 60 companies accounted for approximately 78 percent of rupee sales in the Pakistani market. This is in contrast to 1971, when 29 foreign local manufacturers held a combined market share of about 74 percent. These percentages are shown in Table 5-2. Of the four firms that did not rank among the top 60 in 1975, one discontinued its operations in Pakistan because it did not approve of the generic policy and was unwilling to function in the new legislative environment. Another closed down operations because of a parent company decision unrelated to the generic policy and joined the ranks of importers. One company, a division of another foreign local manufacturer, slipped from the ranks of the leading 60.

The 10 leading companies.--As noted earlier, 10 foreign local manufacturers shared half of overall sales in the Pakistani market in

Table 5-2.--Market share of foreign local manufacturers among the leading 60 companies: 1971 and 1975.

| Companies[a] | 1971 | | 1975 | | Increase/ Decrease in % of Market (1975-1971) |
|---|---|---|---|---|---|
| | Market Share (% of Total Rupee Sales) | Cumulative Market Share | Market Share (% of Total Rupee Sales) | Cumulative Market Share | |
| 1st five | 37.69 | | 46.00 | | + 8.31 |
| 2nd five | 15.60 | 53.29 | 16.63 | 62.63 | + 1.03 |
| 3rd five | 10.63 | 63.92 | 8.67 | 71.30 | - 1.96 |
| 4th five | 6.48 | 70.40 | 4.61 | 75.91 | - 1.87 |
| 5th five | 2.82 | 73.22 | 2.26 | 78.17 | - 0.56 |
| 6th five | 1.17[b] | 74.39 | | | |

Source: Companies data made available to researcher.

[a]In groups of five considering only the foreign local manufacturers in the leading 60 companies.

[b]Four companies.

1971. In 1975, only six foreign local manufacturers accounted for about 50 percent of sales.

The three leaders.--In 1971, three foreign local manufacturers, one American and two British, accounted for about 31 percent of the total rupee sales of drugs and medicines in the Pakistani market. These three led sales in 1975 with a combined market share of about 37 percent of total sales. This increased combined market share in 1975 was owing primarily to the increase in market share of the American firm. This firm in 1975 took over the leading position from 1971's leader, a British firm, experiencing an increase from about 13.5 percent of total sales in 1971 to almost 19 percent in 1975.

Market Shares: Pakistani Local Manufacturers

In the top 60.--In 1971, there were 13 Pakistani local manufacturers among the leading 60 firms; in 1975, there were 22. These 22 companies accounted for 9.58 percent of sales in 1975 compared to the 7 percent in 1971 held by 13 Pakistani locals. These figures are shown in Table 5-3.

Among Pakistani local manufacturers in 1971 was one company which had focused its sales effort on the East Pakistan market; after the secession of that province, it lost its position. Three other companies dropped out of the leading 60. The remaining 7 were joined by 15 other Pakistani locals in the leading 60.

Table 5-3.--Market share of Pakistani local manufacturers among the leading 60 companies: 1971 and 1975.

| Companies[a] | 1971 | | 1975 | | Increase/ Decrease in % of Market (1975-1971) |
|---|---|---|---|---|---|
| | Market Share (% of Total Rupee Sales) | Cumulative Market Share | Market Share (% of Total Rupee Sales) | Cumulative Market Share | |
| 1st five | 4.64 | | 4.63 | | - 0.01 |
| 2nd five | 1.69 | 6.33 | 2.09 | 6.72 | + 0.40 |
| 3rd five | 0.67[b] | 7.00 | 1.49 | 8.21 | - 0.82 |
| 4th five | | | 1.02 | 9.23 | |
| 5th five | | | 0.35[c] | 9.58 | |

Source: Companies data made available to researcher.

[a]In groups of five considering only the Pakistani local manufacturers in the leading 60 companies.

[b]Three companies.

[c]Two companies.

The 10 leading companies.--In 1971, the 10 leading Pakistani local manufacturers accounted for 6.33 percent of sales. The 10 leaders in 1975 had 6.72 percent of the total sales of drugs and medicines. The five leading Pakistani local manufacturers in 1975 included a new entrant,[4] with about 0.82 percent of total sales.

The three leaders.--In 1971, the three leading Pakistani local manufacturers had 3.02 percent of the market, or slightly less than one-third of the market share held by Pakistani locals among the leading 60 companies. The three leaders in 1975 had 3.38 percent of the market, or slightly more than one-fourth of the combined market share of the Pakistani companies in the leading 60 in that year.

Market Shares: Importers

In the top 60.--In 1975, there were 13 firms exporting pharmaceutical products to Pakistan who ranked among the leading 60 firms, contrasted to 18 firms that ranked among the leading 60 in 1971. In 1975, the combined market share of the 13 companies was 6.92 percent, compared to 13.08 percent for the 18 among the leading 60 in 1971. These figures are shown in Table 5-4.

The 10 leading companies.--In 1971, the 10 leading firms exporting products for sale in Pakistan had 10.8 percent of the market share, whereas the 10 leaders in 1975 had 6.22 percent of the total sales.

The three leaders.--In 1971, the three leaders accounted for 5.9 percent of total sales in the Pakistani market; the three leaders

Table 5-4.--Market share of importers among the leading 60 companies: 1971 and 1975.

| Companies[a] | 1971 | | 1975 | | Increase/ Decrease in % of Market (1975-1971) |
|---|---|---|---|---|---|
| | Market Share (% of Total Rupee Sales) | Cumulative Market Share | Market Share (% of Total Rupee Sales) | Cumulative Market Share | |
| 1st five | 8.14 | | 4.45 | | - 3.69 |
| 2nd five | 2.66 | 10.80 | 1.77 | 6.22 | - 0.89 |
| 3rd five | 1.67 | 12.47 | 0.70[b] | 6.92 | - 0.97 |
| 4th five | 0.61[b] | 13.08 | | | |

Source: Companies data made available to researcher.

[a]In groups of five considering only the importers in the leading 60 companies.

[b]Three companies.

in 1975 had about 3.36 percent of the market. A major reason for the decline was that one importer, with about 2 percent of the market share in 1971, curtailed exports to Pakistan after the generic policy was introduced. The specific reason was because its well-known tranquilizers were being imitated and sold there, and it had been severely criticized for its high prices.

The evidence indicates that the objective of the government to reduce sales concentration among the leading pharmaceutical manufacturers was not achieved. Instead, there was an increase in the combined market share held by the leaders. Specifically, among both foreign manufacturers and Pakistani local manufacturers, the three sales leaders in each of these groups experienced an increase in combined market share in 1975 as compared to 1971.

The data also do not indicate that Pakistani local manufacturers made any notable competitive inroads after the change in government policy.

## Market Shares: Therapeutic Submarkets

The discussion thus far has dealt with the positions of Pakistani locals and foreign manufacturers in the overall drug market. That market can be segmented into a number of separate and noncompeting therapeutic submarkets. For example, antibiotics cannot serve as substitutes for vitamins, nor vitamins for tranquilizers. What is the competitive position in the various submarkets? The problem is that comparative data are unavailable for specific therapeutic

classes. However, estimates can be made from the fragmentary information available for the major therapeutic classes.

Of 13 general groups into which pharmaceutical drugs can be classified, the three leading groups, alimentary tract and metabolism drugs, systemic anti-infectives, and respiratory system drugs, account for approximately 66 percent of rupee sales in the Pakistani market. As Table 5-5 indicates, the leading therapeutic submarkets which clearly dominate these general groups are vitamins, systemic antibiotics, and cough and cold preparations. Together, these therapeutic submarkets accounted for almost 50 percent of rupee sales in the Pakistani market in 1975.

Market Shares: Systemic Antibiotics

The sales of systemic antibiotics comprised about 20 percent of the total rupee sales of drugs in 1971 and about 25 percent of total rupee sales in 1975. Systemic antibiotic sales increased considerably during the period, rising from about 108 million rupees in 1971 to about 158 million rupees in 1975.

Seven foreign local manufacturers accounted for approximately 76.59 percent of systemic antibiotic sales in the Pakistani market in 1971. The figures are shown in Table 5-6. The same companies were the seven sales leaders in 1975 and accounted for 81.74 percent of the sales in the systemic antibiotics submarket in that year. This was an increase of 5.15 percent in their relative combined market share.

Table 5-5.--Market share of drug general groups and therapeutic classes in the Pakistani pharmaceutical market (1975).

| Rank | General Group<br>Therapeutic Class | Market Share of General Group (% of Total Rupee Sales) | Market Share of Therapeutic Class (% of Total Rupee Sales) |
|---|---|---|---|
| 1 | Alimentary Tract and Metabolism | 28.5% | |
| | 1.1 Vitamins | | 15.4% |
| | 1.2 Anti-diarrhoeals | | 2.6 |
| | 1.3 Anti-acids, anti-flatulants, anti-peptics | | 2.4 |
| | 1.4 Gastro-intestinal, anti-spasmodics, anti-choligomics | | 2.4 |
| | 1.5 Mineral supplements | | 1.5 |
| | 1.6 Laxatives | | 0.9 |
| | 1.7 Anti-diabetic therapy | | 0.8 |
| | 1.8 Digestives, including enzymes | | 0.7 |
| | 1.9 Anti-emitics, anti-nauseants | | 0.6 |
| | 1.10 Anabolics systemics | | 0.5 |
| | 1.11 Appetite stimulants | | 0.4 |
| | 1.12 Tonics | | 0.2 |
| | 1.13 Cholagogues and hepatic protectors | | 0.1 |
| 2 | Systemic Anti-infectives | 27.8 | |
| | 2.1 Anti-biotics systemics | | 24.8 |
| | 2.2 Tuberculostatics | | 2.3 |
| | 2.3 Systemic anti-bacterials | | 0.6 |
| 3 | Respiratory System | 9.8 | |
| | 3.1 Cough and cold preparations | | 7.5 |
| | 3.2 Antihistamines systemic | | 1.0 |
| | 3.3 Anti-asthmatics | | 0.9 |
| | 3.4 Pharyngeal preparation | | 0.2 |
| | 3.5 Nasal decongestants | | 0.1 |
| 4 | Central Nervous System | 6.7 | |
| | 4.1 Analgesics | | 4.1 |
| | 4.2 Psycholeptics | | 1.9 |
| | 4.3 Psychoanaleptics | | 0.4 |
| | 4.4 Anaesthetics | | 0.1 |
| | 4.5 Anti-epileptics | | 0.1 |
| | 4.6 Anti-Parkinson | | 0.1 |

Table 5-5.--Continued.

| Rank | General Group<br>Therapeutic Class | Market Share of General Group (% of Total Rupee Sales) | Market Share of Therapeutic Class (% of Total Rupee Sales) |
|---|---|---|---|
| 5 | Blood and Blood-Forming Organs | 4.9% | |
| | 5.1 Anti-anaemics | | 3.2% |
| | 5.2 Antihaemorrhagics | | 0.4 |
| | 5.3 Plasma substitutes | | 1.1 |
| | 5.4 Cholesterol reducers | | 0.1 |
| | 5.5 Anticoagulants | | 0.1 |
| 6 | Dermatologicals | 3.5 | |
| | 6.1 Topical antisteroids | | 1.7 |
| | 6.2 Antiseptics-disinfectants | | 0.9 |
| | 6.3 Topical antibiotics | | 0.6 |
| | 6.4 Antifungals | | 0.2 |
| | 6.5 Coal tar, sulphur, resorcin | | 0.1 |
| 7 | Genito-Urinary System and Sex Hormones | 3.4 | |
| | 7.1 Sex hormones | | 1.6 |
| | 7.2 Gynaecological anti-infectives | | 0.9 |
| | 7.3 Urologicals | | 0.7 |
| | 7.4 Other gynaecologicals | | 0.2 |
| 8 | Sensory Organs | 3.0 | |
| | 8.1 Ophthalmologicals | | 2.0 |
| | 8.2 Otologicals | | 0.5 |
| | 8.3 Eye-ear preparations | | 0.5 |
| 9 | Parasitology | 2.5 | |
| | 9.1 Antiparasitics | | 2.5 |
| 10 | Cardiovascular System | 2.2 | |
| | 10.1 Cardiac therapy | | 0.7 |
| | 10.2 Hypotensives | | 0.7 |
| | 10.3 Diuretics | | 0.6 |
| | 10.4 Vasoprotectives | | 0.2 |
| | 10.5 Peripheral vasodilatons | | 0.1 |

Table 5-5.--Continued.

| Rank | General Group<br>Therapeutic Class | Market Share of General Group (% of Total Rupee Sales) | Market Share of Therapeutic Class (% of Total Rupee Sales) |
|---|---|---|---|
| 11 | Musculo-Skeletal System | 2.1% | |
| | 11.1 Antirheumatics system | | 1.7% |
| | 11.2 Antirheumatics topical | | 0.2 |
| | 11.3 Muscle relaxants | | 0.1 |
| | 11.4 Antigout preparations | | 0.1 |
| 12 | Systemic Hormones | 1.7 | |
| | 12.1 Systemic corticosteroids | | 1.6 |
| 13 | Various | 4.0 | |

Source: Industry data made available to researcher.

Table 5-6.--Market share of leading companies in the antibiotics market (1971 and 1975).

| Ranking[a] | | Manufacturer | Percent Share of Rupee Sales | |
|---|---|---|---|---|
| 1975 | 1971 | | 1975 | 1971 |
| 1 | 1 | FLM | 34.07 | 33.81 |
| 2 | 5 | FLM | 15.17 | 5.75 |
| 3 | 4 | FLM | 10.76 | 7.45 |
| 4 | 6 | FLM | 6.55 | 4.08 |
| 5 | 2 | FLM | 6.31 | 14.13 |
| 6 | 3 | FLM | 4.48 | 7.63 |
| 7 | 7 | FLM | 4.40 | 3.74 |
| | | All others (combined) | 18.26 | 23.41 |

Source: Companies data made available to researcher.

Note: FLM: Foreign local manufacturer.

[a]By rupee sales in the antibiotics market.

A large number of companies (greater than 50)--Pakistan local, foreign local, and importers--accounted for the remaining sales in the systemic antibiotics market. The highest market share of a company other than the top seven was less than 2 percent of these sales.

The leader maintained a market share of about one-third of rupee sales during the period, although there was a slight increase from 1971 to 1975.

Two companies, both foreign local manufacturers, held a little less than one-half the market share in 1971. Two foreign local manufacturers also held one-half the market share in 1975. There is an indication of competitiveness in the systemic antibiotics market--the second leading company suffered a loss in market share between 1971 and 1975 while another rose from fifth position in 1971 to rank second in sales in 1975. It should be noted that these changes in competitive positions were between foreign local manufacturers.

Market Shares: Vitamins

Vitamin products comprised about 14 percent of total sales of drugs and medicines in Pakistan in 1971, approximately 16 percent in 1975. Sales of vitamins rose from about Rs. 75 million to about Rs. 98 million during the period.

As shown in Table 5-7, seven companies (four foreign local manufacturers, one importer, and two Pakistani local manufacturers) accounted for about 87 percent of vitamin sales in the Pakistani

market in 1975. The seven leaders in 1971, which also included four foreign local manufacturers, the same importer as in 1975, and two Pakistani locals, held about 75 percent of the vitamin market sales. This was an increase of about 12 percent in the relative market share of the leading seven companies in 1975 over 1971 levels.

Table 5-7.--Market share of leading companies in the vitamins market (1971 and 1975).

| Ranking[a] | | Manufacturer | Percent Share of Rupee Sales | |
|---|---|---|---|---|
| 1975 | 1971 | | 1975 | 1971 |
| 1 | 1 | FLM | 40.00 | 19.42 |
| 2 | 3 | FLM | 15.32 | 17.08 |
| 3 | 2 | FLM | 10.16 | 17.97 |
| 4 | 4 | I | 8.40 | 15.40 |
| 5 | 5 | FLM | 5.63 | 4.31 |
| 6 | (*) | PLM | 3.70 | (*) |
| 7 | (*) | PLM | 2.95 | (*) |
| | | All others (combined) | 13.84 | 24.82 |

Source: Companies data made available to researcher.

Note: FLM: Foreign local manufacturer; PLM: Pakistan local manufacturer; I: Importer; (*): Manufacturer whose individual market share in the vitamins market was less than one-half percent.

[a]By rupee sales in the vitamins market.

Again, a large number of Pakistani local and foreign manufacturers (greater than 50) accounted for the remaining sales of vitamins, none having more than 1 percent of the market share in vitamin sales.

It is noteworthy that the leader had about 40 percent of the vitamin market share in 1975, compared to 20 percent in 1971. Two Pakistani local manufacturers made relative gains in 1975 over 1971 levels, from a combined market share of less than 2 percent of vitamin sales in 1971 to about 6.65 percent in 1975. This suggests that these firms were able to make competitive inroads into the vitamin market during the generic period. However, it should be noted that the license of one of these manufacturers was eventually cancelled by the government for "inadequate quality control procedures and manufacture of substandard medicines."

Market Shares: Cough and Cold Preparations

Comparative information for the cough and cold preparation submarket was not available to this researcher for 1971. Sales of about Rs. 48 million of such preparations accounted for about 8 percent of total sales of medicines in 1975.

In 1975, nine companies, eight foreign local and one Pakistani local, held about 83 percent of the market share for this submarket. Figures are shown in Table 5-8.

Two leading companies, both foreign manufacturers, were responsible for about 58 percent of the sales in this submarket. The combined market share of the remaining seven sales leaders was less than the individual market share of the two leading firms. Limited information obtained from a company interview regarding the one Pakistani local manufacturer ranking fourth in sales in 1975

indicates that this firm had a higher market share in 1971 as compared to 1975. Therefore, the fact that this manufacturer was among the leading companies in 1975 is not indicative of competitive inroads by Pakistani manufacturers into this submarket, which was dominated by the two multinational firms.

Table 5-8.--Market share of leading companies in the cough and cold preparations market (1975).

| Rank[a] | Manufacturer | Percent Share of Rupee Sales |
|---|---|---|
| 1 | FLM | 29.56 |
| 2 | FLM | 28.77 |
| 3 | FLM | 4.48 |
| 4 | PLM | 4.36 |
| 5 | FLM | 4.27 |
| 6 | FLM | 3.57 |
| 7 | FLM | 3.27 |
| 8 | FLM | 2.63 |
| 9 | FLM | 2.25 |
| | All others (combined) | 16.84 |

Source: Companies data made available to researcher.

Note: FLM: Foreign local manufacturer; PLM: Pakistan local manufacturer.

[a]By rupee sales in the cough and cold preparations market.

## Conclusions

The data indicate that in the overall market for drugs there was an increase in market shares in 1975 held by the leading companies (foreign local manufacturers) compared to 1971. Three foreign local manufacturers together accounted for 37 percent of the rupee sales of

drugs in the Pakistani market compared to 31 percent in 1971. The evidence also indicates that there was no reduction in the market shares held by the leading companies in 1975 as compared to 1971 in the therapeutic submarkets. The data suggest that two leading firms (foreign local manufacturers) in each of these submarkets had 50 percent or more of the rupee sales in 1975, a higher market share than that held by the two leading firms in the same submarkets in 1971. There is evidence of a certain degree of competition within the systemic antibiotic market, and there was a shift in the vitamin submarket shares between 1971 and 1975. However, these shifts were primarily among the five leading foreign local manufacturers.

Recalling that two hypotheses were put forward earlier in this chapter:

$H_1$: The Generic Names Act would lead to a decrease in sales concentration.

$H_2$: The Generic Names Act would lead to an increase in market shares of Pakistani manufacturers.

The data indicate that the Generic Names Act did not lead to a decrease in sales concentration, nor did it lead to any notable increases in market shares of Pakistani local manufacturers, either in the overall drug market or in the major therapeutic submarkets. Thus, both these hypotheses cannot be accepted.

The reasons why sales concentration in the pharmaceutical market did not reduce and why leading foreign local manufacturers were able to strengthen their market position were due largely to the product policies and promotional strategies adopted by the foreign

local manufacturers as compared to the Pakistani local manufacturers. These strategies are the subject of discussion in Chapters VII and VIII. Briefly stated, a prime reason for the retention of market shares by foreign local manufacturers was that doctors and patients were unwilling to accept drugs produced by Pakistani local manufacturers as effective equivalents of the products of foreign local manufacturers.

The next chapter discusses another significant government objective in adopting the Generic Names Act--reducing retail prices of drugs.

## Footnotes--Chapter V

[1]The three years 1972, 1973, and 1974 were markedly chaotic for the pharmaceutical sector, as both industry and trade attempted to adapt to the new legislative environment. See Chapter III.

[2]The Drugs Act, 1976 (Act No. XXXI of 1976), Gazette of Pakistan Extra, May 18, 1976.

[3]Paul A. Brooke, Resistant Prices: A Study of Competitive Strains in the Antibiotic Markets (New York: Ballinger, 1975), p. 49.

[4]This manufacturer was closed down by the government health authorities in 1975 for inadequate quality control practices.

# CHAPTER VI

# PRICES

## Introduction

A primary objective of the Pakistani government in introducing the Generic Names Act of 1972 was to reduce prices to the consumer. The Minister of Health consistently emphasized this aspect, stating on one occasion that "the implementation of the law . . . would bring down the prevailing prices of medicines" (emphasis mine).[1] Government estimates of expected price reductions of medicines ranged as high as 70 percent of the prevailing price in 1971;[2] the most conservative estimate was 25 percent.[3] The drop in nominal prices was expected to result from increased price competition among generic drugs.[4] A secondary but not unimportant issue concerned the charges leveled against foreign manufacturers of maintaining excessively "high prices" for their established brand name products.[5]

This chapter discusses how prices are set at the customer, trade, and manufacturer/importer levels. It then examines the question of "high prices" of foreign local manufacturers' products in the Pakistani market and investigates the following central hypothesis:

$H_3$: The Generic Names Act would lead to a reduction in retail prices of drugs in Pakistan.

These matters are examined through a series of measures and relevant data. Certain limitations are also discussed in the various sections.

## Measures: Prices

Several steps were taken to determine whether prices were "high" in Pakistan prior to the introduction of the Generic Names Act. First, the retail prices of certain drugs and medicines in Pakistan were compared to retail prices of the same drugs in other countries. Second, active ingredient costs and their relation to finished product prices were examined.

To investigate whether, as hypothesized, prices decreased after the Generic Names Act was introduced, the following procedure was used. First, the trend over time in the wholesale price index for drugs and medicines in Pakistan was examined and compared to the wholesale price index for other commodities. Second, the retail prices of selected drugs in 1975 were compared with the retail prices of the same drugs in 1971.

It should be noted that measuring price levels of drugs is difficult, and attempts to make comparisons are vulnerable to criticism on several counts. The process is further complicated in an underdeveloped country such as Pakistan, where statistics for such items as the cost of raw materials and the history of prices are generally unavailable, particularly for a "sensitive" sector such as pharmaceuticals.[6]

Thus, each of the measures outlined earlier is susceptible to criticism regarding its validity. Some of the major data limitations are mentioned in the sections that discuss these measures in detail. Collectively, however, the measures support certain broad conclusions regarding the prices of drugs and medicines in Pakistan.

## Price Setting

The following three sections discuss how prices are set at the consumer, trade, and manufacturer levels.

### Consumer Prices

Retail prices of medicines in Pakistan, that is, prices charged to the customer, must be approved by the government for each pharmaceutical product. The approved price is the "maximum retail price" that the chemist or druggist can charge and is, in general, the usual selling price of a product.

### Trade Prices

The discount given to retailers (chemists or druggists) by manufacturers or importers is fixed at 15 percent of the "maximum retail price." The discount given to the wholesaler/stockist/distributor is fixed at 20 percent of the "maximum retail price." In certain cases there are deviations from the norm by manufacturers or importers (the "channel captain"), who at times use certain deals (bonus offers, quantity discounts, and so forth) to push the sale of particular products. These arrangements are not controlled or regulated by the government.[7]

Two different procedures are used to determine the "maximum retail price," one to establish the price for imported drugs (in finished form), the other to set the price for locally manufactured drugs. Each is discussed in the next two sections.

Importer Prices

Prior to and during the "generic" period (until May 1973), the technique for setting maximum retail prices for imported drugs was mandated by the government, which allowed a "25% margin on the 'landed cost' of the finished medicines."[8] In May 1973, after extensive lobbying and negotiations with the government by the importers, the formula for computing this price was altered to "50% of C and F price" (cost and freight price). The difference between the two methods is shown below in Table 6-1.

Table 6-1.--The difference between two methods of setting maximum retail prices for imported drugs.

| Before May 1973 | After May 1973 |
|---|---|
| C and F = Rs. 100 | C and F = Rs. 100 |
| Landing charges = Rs. 8 @ 8 percent of C & F[a] | |
| Total landed cost = Rs. 108 | |
| Mark up (25 percent of landed cost) = Rs. 27 | Mark up (50 percent of C & F) = Rs. 50 |
| Maximum retail price = Rs. 135 | Maximum retail price = Rs. 150 |

Source: Pakistan Chemists and Druggists Association.

[a]Fixed by the government.

Manufacturer Prices

The procedure for arriving at a maximum retail price for locally manufactured drugs involved negotiations between the

manufacturers and the health authorities. Manufacturers are required to supply information on the cost of raw materials (including excipients, binders, fillers, and so forth), packaging material, the ex-factory cost, and "all other charges" for each drug to the government. There was, and is, considerable ambiguity concerning the details required by the government, and requirements vary from one manufacturer to another.[9] As a result, the manufacturer typically initiates discussions with an inflated product price (based also on competitive conditions), which the governmental health authorities then reduce to what they consider an "appropriate" level.[10] Unfortunately, the government does not have any cogent cost-accounting procedures for establishing the accuracy of manufacturers' cost figures or for determining a "reasonable" profit margin.[11] Everything depends on how well the manufacturer presents his case for pricing a particular product and on the "inclination" of the governmental representative to accept the arguments put forward. A number of manufacturers (including most of the Pakistani local manufacturers interviewed) complain that the health authorities are relatively flexible in negotiating prices with certain manufacturers, but are more rigid in dealing with others.

## International Retail Prices

How did prices for pharmaceutical preparations in Pakistan compare with prices in other countries before the Generic Names Act was introduced? Tables 6-2 and 6-3 compare retail prices of medicines in Pakistan, India, Ceylon, Iran, and Turkey. These nations are

Table 6-2.--Comparison of retail prices in 1972 of selected pharmaceutical products in five countries (in dollars).

| Generic Name | Brand Name | Manufacturer | Strength; Package Size | Retail Prices | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | | Pakistan | India | Ceylon | Iran | Turkey |
| Oxytetracycline Capsules | Terramycin | Pfizer | 250 mg.; 100's | 7.09 | 8.65 | 17.45 | 15.60 | ... |
| Oxytetracycline Capsules | Clinmycin | Glaxo | 250 mg.; 100's | 5.00 | ... | ... | ... | ... |
| Oxytetracycline Pediatric Drops | Terramycin | Pfizer | 100cc | 0.50 | 0.45 | 0.93 | 0.78 | 0.54 |
| Oxytetracycline Syrup | Terramycin | Pfizer | 50cc | 0.74 | 0.87 | 1.60 | 1.17 | 0.64 |
| Oxytetracycline IM | Terramycin | Pfizer | 100 mg; 2cc | 0.22 | 0.14 | 0.38 | 0.34 | 0.20 |
| Oxytetracycline Topical Ointment | Terramycin | Pfizer | 5 gm. | 0.20 | 0.21 | 0.30 | 0.57 | 0.23 |
| Chloremphenicol Capsules | Chloromycetin | Parke-Davis | 250 mg.; 12's | 0.75 | 0.62 | ... | 1.70 | 0.75 |
| Penicillin G. Sodium | ... | Pfizer | 500,000 units | 0.05 | ... | 0.08 | ... | 0.12 |
| Penicillin G. Sodium | ... | Pfizer | 1,000,000 units | 0.08 | 0.16 | 0.10 | ... | 0.16 |
| Procaine Penicillin | Pronapen | Pfizer | 400,000 units | 0.05 | 0.08 | ... | ... | 0.13 |
| Procaine Penicillin | Pronapen | Pfizer | 2,000,000 units | 0.15 | 0.29 | ... | ... | ... |
| Streptomycin Sulphate | ... | Pfizer | 1 gm. | 0.06 | 0.10 | 0.12 | ... | 0.18 |
| Streptomycin Sulphate | ... | Glaxo | 1 gm. | 0.06 | ... | 0.11 | ... | ... |
| Penicillin/Streptomycin Combination | Combiotic | Pfizer | 1 gm. | 0.12 | 0.16 | ... | 0.27 | 0.22 |
| Penicillin/Streptomycin Combination | Combiotic | Pfizer | ½ gm. | 0.09 | 0.12 | ... | 0.20 | 0.17 |
| Prednisolone Tablets | Deltacortril | Pfizer | 5 mg. | 13.82 | 21.36 | 10.64 | ... | ... |
| Betamethasone Tablets | Betnalan | Glaxo | 0.5 mg.; 25's | 0.68 | ... | 1.84 | 2.40 | 1.20 |
| Betamethasone Tablets | Betnalan | Glaxo | 0.5 mg.; 500's | 13.64 | ... | 29.35 | ... | ... |
| Chlorpropamide Tablets | Diabinese | Pfizer | 250 mg.; 20's | 0.50 | 0.46 | 2.24 | 1.12 | 0.61 |
| Nitrofurantion Tablets | Furadantin | SKF | 50 mg.; 24's | 1.20 | 1.50 | ... | ... | ... |
| Nitrofurantion Tablets | Furadantin | SKF | 50 mg.; 100's | 4.54 | 6.27 | ... | ... | ... |
| Vitamin C Tablets | Calin | Glaxo | 100 mg.; 100's | 0.39 | 0.42 | 0.74 | 1.18 | ... |
| Vitamin $B_{12}$ Injections | Cytemen | Glaxo | 250 mg. | 0.41 | ... | ... | ... | ... |
| Iron Mineral Vitamin Syrup | Minadex | Glaxo | 6 oz. | 0.30 | 0.70 | 0.40 | 0.46 | 0.44 |
| Codein Cough Syrup | Corex | Pfizer | 4 oz. | 0.40 | 0.78 | 0.60 | 0.72 | 0.62 |
| Acetyl-Salicylic Acid Tablets | Aspro | Nicholas | 100's | 0.45 | 1.04 | ... | ... | ... |
| Chloroquine Diphosphate Tablets | Resochin | Bayer | 300's | 4.77 | 5.59 | ... | 4.74 | ... |
| Polyvinylpyrrolidone | Periston | Bayer | 500 ml | 2.59 | 2.51 | ... | ... | 2.57 |
| Salicylamide Phenacetin-Caffeine Tablets | Refagan | Bayer | n.i.; 200's | 2.96 | 4.15 | ... | 5.08 | 3.54 |
| Mebhydrolin Tablets | Incidal | Bayer | n.i.; 20's | 0.47 | 0.43 | ... | ... | 0.86 |
| Tetracycline Capsules | Achromycin | Cyanamid | 250 mg.; 100's | 5.90 | 8.00 | 10.00 | 14.54 | ... |
| Tetracycline Drops | Achromycin | Cyanamid | 10cc | 0.42 | 0.39 | 1.77 | 0.79 | ... |
| Demethylchlortetracycline Capsules | Ledermycin | Cyanamid | 150 mg.; 100's | 8.36 | 10.54 | 13.10 | 14.54 | ... |
| Demethylchlortetracycline Syrup | Ledermycin | Cyanamid | 2 oz. | 0.83 | 0.94 | 1.72 | 1.19 | ... |
| Acetazolamide Tablets | Diamox | Cyanamid | 250 mg.; 100's | 5.08 | 5.00 | 11.00 | 7.91 | ... |
| Trihexyphenidyl | Pacibane | Cyanamid | 2 mg.; 100's | 0.90 | 1.33 | 1.66 | 0.65 | ... |

Source: Pakistan Pharmaceutical Manufacturers Association, special release, 1972.

Note: n.i. = not indicated.

considered to have a relatively similar health environment, suggesting a similar importance in all five countries of the various products considered here.

The comparison indicates that retail prices in Pakistan in 1972 (at the time of the announcement of the new health policy) were generally lower than in India, Ceylon, Iran, and Turkey. The most relevant comparison, because of the close similarity in health conditions, is between India and Pakistan. For 25 products (83 percent) out of a total of 30, the retail price in Pakistan was lower than in India (see Table 6-3).

Table 6-3.--Comparison of retail prices of selected pharmaceutical products in Pakistan and four other countries.

| | Pakistan versus India | Pakistan versus Ceylon | Pakistan versus Iran | Pakistan versus Turkey |
|---|---|---|---|---|
| Products for which comparative price information was available | 30 | 22 | 21 | 18 |
| Products whose retail price in Pakistan was lower | 25 (83%) | 21 | 20 | 16[a] |

Source: Table 6-2.

[a]Excludes one product which was the same price.

This information should be accepted with caution for two reasons. First, although the data provide a price comparison among leading brands of commonly prescribed products, certain products

may be excluded that possibly were more expensive in Pakistan as compared to other countries. Second, the conversion to U.S. dollars may introduce distortions. For example, the devaluation of the Pakistani rupee in 1972 (from Rs. 4.76 to Rs. 11.00 for $1.00) "improved" the Pakistani prices in one stroke.[12]

## Active Ingredient Costs

Since pharmaceutical manufacturing in Pakistan consists primarily of "dosage form fabrication," that is, the active ingredients of a drug are imported and then formed into tablets, capsules, and so forth, the cost of the imported active ingredient is an important consideration. This is because if a company imports raw material at an inflated cost, it can not only effectively "transfer" profits abroad but it is also able to solicit the government to set a higher "maximum retail price" (based on the "high" cost of imported material).

The following three sections discuss three aspects of active ingredient costs: (1) the cost to affiliates of multinational firms in developing countries, including Pakistan; (2) this cost compared to the world market price; and (3) the price of the finished product compared to the active ingredient cost in Pakistan.

### Discriminatory Prices for Active Ingredients

During the investigative hearings conducted by Senator Nelson into the operations of the worldwide pharmaceutical industry, various discrepancies were found to exist in the price of raw materials charged to affiliates of pharmaceutical firms in different countries. For

example, the data in Table 6-4 suggest that in 1968-1969, multinational pharmaceutical firms transferred raw material for six medicines at higher prices to their Colombian affiliates as compared to their Pakistani affiliates, at lower prices for three drugs. Specifically, American Cyanamid charged its Pakistani subsidiary 1.62 times the price it charged its Colombian subsidiary for demethylchlortetracycline and 1.8 times the price for tetracycline hydrochloride. Pfizer priced raw materials for methacycline Hcl to its Pakistani subsidiary at 77 percent of the price it charged its Colombian affiliate, but it charged the latter 77 percent of what it charged its Pakistani affiliate for doxycycline.

The data in Table 6-4 also show that a Pakistani affiliate was paying more than five times what the Brazilian affiliate was paying for trihexyphendyl hydrochloride. Closer to home, triamcinolone was provided to the Indian affiliate of an international company for $7,960 per kilo, while the neighboring Pakistani affiliate was paying $13,930 per kilo. The Pakistani affiliate was purchasing triamcinolone acetate at 4.13 times the price the Indian affiliate was paying.

Thus, the information available on certain products tends to confirm at least the tendency of some multinational firms to charge differential prices to affiliates for the same active ingredients.

At the same time U.S. pharmaceutical firms were being questioned as to why prices of pharmaceutical products abroad were generally lower than in the United States,[13] the same firms were being attacked abroad for the "high" prices they were charging there.

Table 6-4.--Prices of raw material for selected pharmaceutical products charged by multinational firms to their affiliates in six countries (1968-1969) (in dollars per kilogram).

| | Brazil | Chile | Colombia | India | Pakistan | Turkey |
|---|---|---|---|---|---|---|
| Ampicillin Tryhydrate | | | 420.00 | | | |
| Benzathazine Penicillin | | 215.75 | 160.00 | | 44.10 | |
| Penicillin G | 294.50 | | | | | |
| Chlorocyclizine Hydrochloride | | | | | | 155.00 |
| Chlormethazone | 70.00 | | 70.00 | | | |
| Chlordiazepoxide Granulate | | | | | 245.00 | |
| Cyproheptadine Hydrochloride | | | 1,800.00 | 1,060.00 | 1,600.00 | |
| Dexamethasone Glucocortoid | | | 27.50 | | 27.50 | |
| Dexchlorpheniramine Maleate | | | 650.00 | | | |
| Diazepam Granulate | | | | | 99.20 | |
| Doxycycline | | | 2,250.00 | | 1,750.00 | |
| Ethoheptazine Citrate | | | 150.00 | | | |
| Methacycline Hydrochloride | | | 450.00 | | 350.00 | |
| Nalidixic Acid | 94.00 | | 94.00 | | | |
| Oxazepam | | 187.50 | 800.00 | | | |
| Chlortetracycline | | | 100.00 | | | |
| Demethyl Chlortetracycline | | | 250.00 | | 405.00 | |
| Oxytetracycline | | | 100.00 | | 100.00 | |
| Rolitetracycline | | | 550.00 | | | |
| Tetracycline Hydrochloride | | | 150.00 | | 270.00 | |
| Methyl Prednisolene | | | 5,100.00 | | | |
| Triamcinolone Glucocortoid | | | 12,000.00 | 7,960.00 | 13,930.00 | |
| Triamcinolone Acetate | | | 36,000.00 | 7,960.00 | 32,920.00 | |
| Trihexyphendyl Hydrochloride | 300.00 | | 1,800.00 | | 1,700.00 | |
| Dibenzocycloheptatrien Piperdine | | | | 1,060.00 | 1,060.00 | |

Source: U.S. Senate, Competitive Problems in the Drug Industry (Washington, D.C.: Government Printing Office, 1970), pt. 18, pp. 7330-31, 7400.

When asked by the Nelson subcommittee about the differences in prices between drugs in the United States and abroad, George Squibb,[14] former Vice-President of E. R. Squibb and Sons, responded:

> The justification for the lower price is that he [the pharmaceutical manufacturer] . . . could not sell the product at the price that he is selling it here . . . not . . . in adequate quantities . . . [and] could not make an entry in the market at this level. . . . The price that is established in any given country is the price that the market there will bear.

Senator Nelson asked the witness if there was "any question in your mind as to whether the firms make a profit in those foreign countries, where they charge one-third, one-fourth, one-fifth as much as they do in the market place [in the United States]?" Squibb replied, "No, because . . . the basic cost of the product is still low in comparison with the price. So, it gives you a wide range of opportunity" (emphasis added).

The operations, particularly financial, of international firms are usually closely integrated. Tax differentials between countries, restrictions on repatriation of profits, and the political visibility of "high" profits, particularly in a developing country, are powerful incentives for an international firm to "juggle" the transfer prices of pharmaceutical component materials and products. This is relatively easier in countries such as Pakistan, where prices of raw materials are not sufficiently monitored on a comparative basis with different sources and where raw materials may be considered suspect (not unreasonably) as to quality when the source prices are low (as, for example, are active ingredients

produced in Hong Kong and Italy).[15] The complexities of patent licensing relationships and the arguments forwarded by multinational companies of having certain established intracompany and intercompany affiliations provide a convenient cover for rationalizing transactions with a particular source, albeit an expensive one.

## Competitive Prices of Active Ingredients

How do the prices for active ingredients charged their affiliates by multinational firms to their Pakistani affiliates compare to world prices? Table 6-5 makes such a comparison. It indicates the European prices for certain active ingredients or for the pharmaceutical product which in the view of some medical authorities is just as effective from a therapeutic viewpoint. The data in Table 6-5 must be examined with certain caveats in mind. As noted in earlier discussions (see Chapter II, pp. 57-60), the equivalency issue is controversial. Also the allegation has been made that certain pharmaceutical raw material sources such as Hong Kong and the Eastern Bloc countries sometimes supply substandard materials and cannot be relied upon for a consistent supply. For this reason, the European price may be a more suitable base for comparison, even though prices in the world market may be less.

The competitive European price for raw materials for either a particular product or its therapeutic substitute was lower than the price charged by multinational pharmaceutical firms to their affiliates in Pakistan. A glaring example is that of tetracycline

Table 6-5.--Comparison of prices charged by multinational pharmaceutical firms to affiliates in Pakistan and European prices for active ingredients of pharmaceutical products (1968-1969).

| Active Ingredient | Recipient Affiliate | Price Charged to Pakistani Affiliate (in dollars per kilogram) | European Competitive Price (in dollars per kilogram) | Ratio of Affiliate Price to European Price |
|---|---|---|---|---|
| Tetracycline Hydrochloride | Cyanamid | 270 | 24-29 | 11.25 |
| Tetracycline Hydrochloride | Bristol | 190 | 24-29 | 7.92 |
| Doxycycline | Pfizer | 1,750 | n.a.; Tetracycline:[a] 24-29 | ... 60.34 |
| Demethylchlortetracycline | Cyanamid | 405 | --do-- | 13.96 |
| Methacycline | Pfizer | 350 | --do-- | 12.06 |
| Oxytetracycline Hcl | Pfizer | 100 | 30 | 3.33 |
| Benzathazine Penicillin | Wyeth | 44.10 | 31-32 | 1.41 |
| Chlordiazepoxide Granulate | Merck | 245 | 21.50-25 | 9.80 |
| Diazepam Granulate | Merck | 99.20 | 49 | 2.02 |
| Cyproheptadine Hydrochloride | Merck | 1,600 | n.a.; Chlopheniramine:[b] 20.50 | 78.05 |
| Dibenzocyclohepta Trienpiperadine | Merck | 1,060 | --do-- | 51.71 |
| Triamcinolone | Cyanamid | 13,930 | n.a.; Prednisone:[c] 550-580 | 24.01 |
| Dexamethasone | | 27,500 | 7,300; Prednisone:[c] 550-580 | 3.76 47.41 |
| Dexamethasone | Merck | 31,900 | 7,750; Prednisone:[c] 550-580 | 4.11 55.00 |
| Trihexyphendyl Hydrochloride | Cyanamid | 1,700 | n.a.; Brazil: 303[d] | 5.61 |

Source: U.S. Senate, Competitive Problems in the Drug Industry (Washington, D.C.: Government Printing Office, 1970), pt. 18, p. 7331.

Note: n.a. = not available.

[a]Substitute: Medical Letter, July 25, 1969.

[b]Substitute: Medical Letter, vol. 9, no. 7, p. 28.

[c]Substitute: Medical Letter, vol. 9, no. 11, pp. 42-43.

[d]Price to Brazilian affiliate.

hydrochloride, which was available in Europe for less than one-tenth of the price being charged to the Pakistani affiliate in 1969.

These data lend support to the argument that there is a tendency of some multinational firms to charge discriminatory prices for raw materials in different countries, and that raw materials were transferred to affiliated subsidiaries in Pakistan at prices substantially higher than the world market price by some multinational pharmaceutical companies.

Discrepancies such as these, which cannot be explained by differences in transportation costs (which are low),[16] also suggest that the Pakistani process of calculating the maximum retail price based on the manufacturer's stated cost of raw materials may not be an effective procedure for arriving at "reasonable" prices.

## Cost of Active Ingredient Versus Price of Finished Product

How does the price charged by multinational manufacturers for finished products compare with the cost of the active ingredients in these products? The spread provides an indication of what manufacturers are allocating as contributions to production cost (dosage form fabrication, cost of excipients, packaging, labelling and so forth), promotional costs and other "costs of doing business," and profits.

As shown in Table 6-6, prices of the finished product ranged from 2 to 4,000 times the cost of the active ingredient in the product.

Table 6-6.--Prices charged in Pakistan by manufacturers to pharmacists compared to the cost of active ingredients.

| Generic Name | Brand Name | Company | Dosage Form | Strength | Package to Pharmacist/ Consumer | Strength Equivalent Per Package | Price to Pharmacist[a] Per Package (in Dollars) | Cost of Active Ingredients[b] Per Kilogram (in Dollars) | Cost of Active Ingredients Per Unit Package (in Dollars) | Ratio of Price of Finished Product to Cost of Active Ingredients Per Unit Package |
|---|---|---|---|---|---|---|---|---|---|---|
| Chlorodiazepoxide Granulate | Librium | Merck | Tablet | 5 mg. | 30 per bottle | 150 mg. | 0.83 | 245 | .03675 | 22.58 |
| --do-- | --do-- | --do-- | --do-- | 10 mg. | 25 per bottle | 250 mg. | 1.08 | 245 | .061250 | 17.63 |
| Cyproheptadine Hcl | Periactin | --do-- | --do-- | 4 mg. | 20 per bottle | 80 mg. | 0.71 | 1,600 | .128 | 5.54 |
| --do-- | --do-- | --do-- | --do-- | 4 mg. | 100 per bottle | 400 mg. | 2.74 | 1,600 | .640 | 4.28 |
| Dexamethasone Glucorticoid | Decadron | --do-- | --do-- | 0.5 mg. | 10 per bottle | 5 mg. | 0.58 | 27.50 | .0001375 | 4218.18 |
| | | | | | 30 per bottle | 15 mg. | 1.59 | 27.50 | .0004125 | 3854.54 |
| | | | | | 100 per bottle | 50 mg. | 4.76 | 27.50 | .001375 | 3461.81 |
| Diazepam Granualte | Valium | --do-- | --do-- | 2 mg. | 30 per bottle | 60 mg. | 0.81 | 99.20 | .005952 | 136.08 |
| | | | | 5 mg. | 25 per bottle | 125 mg. | 1.23 | 99.20 | .012400 | 99.13 |
| Doxycycline | Vibramycin | Pfizer | Capsule | 100 mg. | 3 per bottle | 300 mg. | 2.07 | 1,750 | .525 | 3.94 |
| | | | | | 5 per bottle | 500 mg. | 3.15 | 1,750 | .875 | 3.60 |
| Methacycline Hcl | Rondomycin | Pfizer | Capsule | 150 mg. | 8 per bottle | 1200 mg. | 1.64 | 350 | .420 | 3.90 |
| | | | | --do-- | 16 per bottle | 2400 mg. | 3.01 | 350 | .840 | 3.58 |
| | | | | 300 mg. | 4 per bottle | 1200 mg. | 1.64 | 350 | .420 | 3.90 |
| | | | | --do-- | 8 per bottle | 2400 mg. | 3.01 | 350 | .840 | 3.58 |
| Demethylchlor-tetracycline | Ledermycin | Cyanamid | Capsule | 150 mg. | 8 per bottle | 1200 mg. | 1.67 | 405 | .486 | 3.43 |
| | | | | --do-- | 16 per bottle | 2400 mg. | 3.05 | 405 | .972 | 3.13 |
| | | | | 300 mg. | 8 per bottle | 2400 mg. | 3.05 | 405 | .972 | 3.13 |
| | Lederstatin | Cyanamid | Capsule | 150 mg. | 8 per bottle | 1200 mg. | 1.69 | 405 | .486 | 3.47 |
| Oxytetracycline | Terramycin | Pfizer | Capsule | 250 mg. | 8 per bottle | 2000 mg. | 1.49 | 100 | .200 | 7.45 |
| | | | --do-- | --do-- | 16 per bottle | 4000 mg. | 2.74 | 100 | .400 | 6.85 |
| | | | Tablet | 100 mg. | 10 per bottle | 1000 mg. | 1.71 | 100 | .100 | 17.10 |
| Tetracycline Hcl | Acromycin | Cyanamid | Capsule | 250 mg. | 8 per bottle | 2000 mg. | 1.35 | 270 | .540 | 2.50 |
| | | | | --do-- | 16 per bottle | 4000 mg. | 2.19 | 270 | 1.080 | 2.02 |
| Tetrachloride Hcl Phosphate Complex | Tetrex | Bristol | Capsule | 250 mg. | 8 per bottle | 2000 mg. | 1.62 | 190 | .380 | 4.26 |
| Triamcinolone Glucocortoid | Ledercort | Cyanamid | Tablet | 4 mg. | 10 per bottle | 40 mg. | 2.58 | 13,930 | .557 | 4.63 |
| | | | | | 30 per bottle | 120 mg. | 6.95 | 13,930 | 1.671 | 4.16 |

Source: U.S. Senate, Competitive Problems in the Drug Industry (Washington, D.C.: Government Printing Office, 1970), pt. 18, pp. 7401-7404.

Note: Prices converted from Pakistani rupees to U.S. dollars at the prevailing exchange rate in that period of time.

[a]The price charged to consumers by pharmacists/retailers can be calculated by dividing the pharmacist price by .85.

[b]Transfer prices charged by multinational firms to their affiliates in Pakistan.

The costs of active ingredients used in this table are the transfer prices charged to affiliates in Pakistan by multinational firms. As indicated in the preceding section, these transfer prices for active ingredients are higher than world market prices. Therefore, the actual spread between the finished product price and the active ingredient cost may be much more than the data indicate.

Since the process of fabrication is essentially the same for drug products of a particular dosage form (such as tablets or capsules),[17] it is difficult to explain the discrepancies in terms of variations of production costs. A defense can be made based on low volume of production in the Pakistani market. The explanation probably lies more, as Squibb indicated, in pricing products at "what the market will bear."

Considering the magnitude of the differences between the active ingredient costs and finished prices, it could be expected that if price competition between generic products had increased after the introduction of the Generic Names Act, the prices of products with a higher spread between active ingredient costs and finished product prices would fall. A comparison of 1971 and 1975 retail prices of the products for which the spread between the active ingredient costs and finished product prices was calculated indicates that prices did not change significantly in 1975 (see Table 6-7) even for those products with strikingly low raw material costs compared to finished product prices. For example, in the case of dexamethasone, the ratio of the price of the finished product to the

Table 6-7.--Comparison of prices to consumers of selected products[a] (1971 and 1975).

| Generic Name | Brand Name | Package to Consumer (Capsules or Tablets) | Strength | Price[c] 1971 (in Rupees) | Price[c] 1975 (in Rupees) | Percent Change |
|---|---|---|---|---|---|---|
| Chlorodiazepoxide | Librium | 30 per bottle | 5 mg. | 5.00 | n.a. | ... |
| | | 25 per bottle | 10 mg. | 6.50 | n.a. | ... |
| Cyproheptadine Hcl | Periactin | 20 per bottle | 4 mg. | 4.00 | 4.00 | 0 |
| | | 100 per bottle | 4 mg. | 15.50 | 16.15 | + 4.19 |
| Dexamethasone (Glucocorticoid) | Decadron | 10 per bottle | 0.5 mg. | 3.30 | 3.44 | + 4.24 |
| | | 30 per bottle | 0.5 mg. | 9.00 | 9.00 | 0 |
| | | 100 per bottle | 0.5 mg. | 27.00 | 22.94 | - 15.03 |
| Diazepam | Valium | 30 per bottle | 2 mg. | 4.90 | n.a. | ... |
| | | 25 per bottle | 5 mg. | 7.40 | n.a. | ... |
| Doxycycline | Vibramycin | 3 per bottle | 100 mg. | 11.75 | 10.19[b] | - 13.27 |
| | | 5 per bottle | 100 mg. | 17.85 | 16.97 | - 4.93 |
| Methacycline Hcl | Rondomycin | 8 per bottle | 150 mg. | 9.35 | 9.31 | - 0.40 |
| | | 16 per bottle | 150 mg. | 17.00 | 17.00 | 0 |
| | | 4 per bottle | 300 mg. | 9.35 | 9.31 | - 0.42 |
| | | 8 per bottle | 300 mg. | 17.00 | 17.00 | 0 |
| Demethylchlortetracycline | Ledermycin | 8 per bottle | 150 mg. | 9.45 | 7.56 | - 20.00 |
| | | 16 per bottle | 150 mg. | 17.21 | 13.76 | - 20.04 |
| | | 8 per bottle | 300 mg. | 17.21 | 13.76 | - 20.04 |
| Oxytetracycline | Terramycin | 8 per bottle | 250 mg. | 8.50 | 8.45 | - 0.58 |
| | | 16 per bottle | 250 mg. | 15.50 | 15.47 | - 0.20 |
| | | 10 per bottle | 100 mg. | 9.70 | 9.70 | 0 |
| Tetracycline Hcl | Acromycin | 8 per bottle | 250 mg. | 7.65 | n.a. | ... |
| | | 16 per bottle | 250 mg. | 12.41 | 7.50 | - 39.56 |
| Tetrachloride Hcl Phosphate Complex | Tetrex | 8 per bottle | 250 mg. | 9.20 | 8.00 | - 13.04 |
| Triamcinolone Glucocortoid | Ledercort | 10 per bottle | 4 mg. | 12.41 | 12.41 | 0 |
| | | 30 per bottle | 4 mg. | 33.41 | 33.41 | 0 |

Source: A. H. Qureshi, Quick Index of Medical Preparations (Karachi: n.p., 1971), and companies data made available to the researcher.

Note: n.a. = not available.

[a]The products are the same as those listed in Table 6-6.

[b]Calculated from the price for 24 tablets (Rs. 81.50).

[c]The same manufacturer's price in 1971 and 1975.

raw material cost was 4218 (for 0.5 mg. tablets, 10 per bottle) in 1971. By 1975, rather than a reduction, there had been an increase in nominal price for this package size. For the 0.5 mg. tablets, 30 per bottle, the 1971 ratio was 3854; in 1975, the price for the same size bottle had not changed; for the 0.5 mg. tablets, 100 per bottle, the 1971 ratio was 3461, and in 1975 the price had declined only 15 percent. The greatest declines in retail prices between 1971 and 1975 were on the magnitude of 20-39 percent for products offered by American Cyanamid. This firm was widely criticized for its high prices and undoubtedly felt pressured into making some concessions.

## Price Trends

The wholesale price index computed by the Statistical Division of the Ministry of Finance in Pakistan presents an interesting picture of the direction of prices for pharmaceutical products. To consider the wholesale price index in isolation may be misleading because of the problems of data collection and analysis faced by the Statistical Division.[18] A severe limitation in the interpretation of the data on the wholesale price index exists because the division does not explain the width and depth of commodity coverage and weighting procedures. On a comparative basis, it can be assumed that the statistics upon which price indices for other commodities are based have similar problems of interpretation, but because of the striking differences in price movements of drugs and medicines

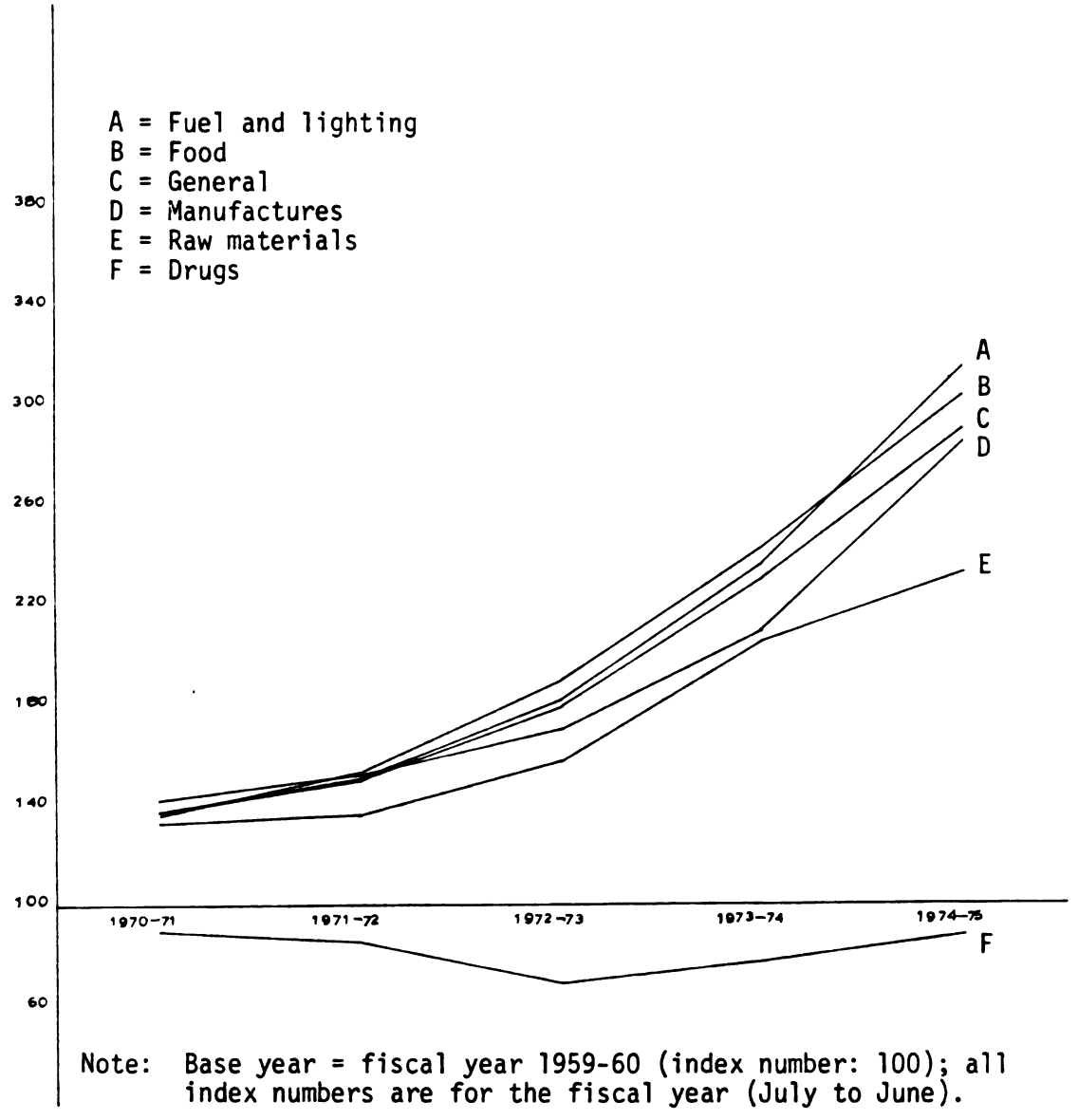
versus other commodities, broad conclusions may be drawn from the data.

## Wholesale Price Index for Drugs and Other Commodities

In marked contrast to other commodity groups, which showed an upward spiral in prices compared to the base index year (fiscal year 1959-1960), the wholesale price index for drugs and medicines has remained at a level below the initial base year price (see Figure 6-1). This is a reflection of the government's control on prices of drugs and medicines, illustrating the government's reluctance to renegotiate and allow increases in the ceiling price. The drop in prices in 1971-1972 and the more precipitous fall in 1972-1973 can be attributed to some extent to two major factors: price competition among generic drugs during this period and to "jawboning" by governmental authorities. A reason for the progressive increase in the wholesale price index after 1972-1973 onward was that postdevaluation price increases were allowed for certain drugs,[19] but, more important, there was a shift in emphasis by the leading manufacturers away from price competition and toward stressing customer and doctor awareness regarding product quality.

## The Wholesale Price Index for Drugs and Food

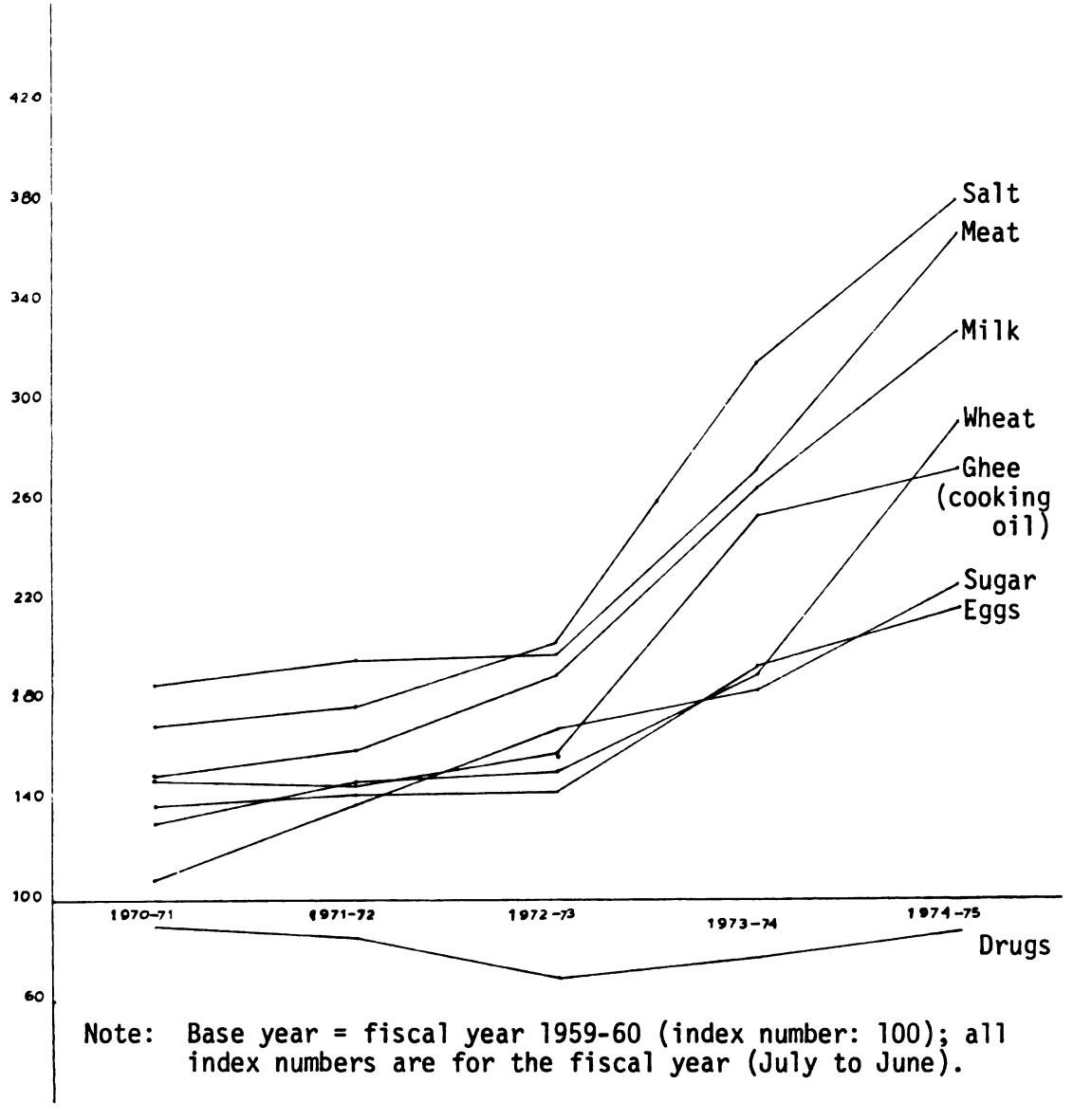
An appropriate comparison would be between the wholesale price index for drugs and medicines and other "necessary" commodities such as food items. As Figure 6-1 indicated, the 1974-1975




Note: Base year = fiscal year 1959-60 (index number: 100); all index numbers are for the fiscal year (July to June).

Figure 6-1.--Index numbers of wholesale prices of drugs and other commodity groups.

Source: Ministry of Finance, Planning and Economic Affairs, Statistical Division, Monthly Statistical Bulletin 24 (March-June 1976): 82.




Note: Base year = fiscal year 1959-60 (index number: 100); all index numbers are for the fiscal year (July to June).

Figure 6-2.--Index numbers of wholesale prices of drugs and food items.

Source: Ministry of Finance, Planning and Economic Affairs, Statistical Division, Monthly Statistical Bulletin 24 (March-June 1976): 83, 89.

wholesale price index for food was at a level three times that of the base year (F.Y. 1959-1960). As pointed out earlier, the wholesale price index for drugs and medicines in that year was lower than in the base year.

Since the broad category of foods encompasses a number of different commodities, another suitable comparison would be between the wholesale price indices for drugs and medicines and particular "essential" food items such as wheat, milk, ghee desi (cooking oil), eggs, meat, sugar, and salt. None of the commodities for which statistics are obtained by the government exhibit a wholesale price index trend even remotely similar to the index for drugs and medicines (see Figure 6-2).

Although the wholesale price comparisons indicate a marked contrast in price behavior of drugs and medicines versus other commodities, it should be noted that they do not and cannot provide any indication of how high the price of drugs and medicines was in the base year (F.Y. 1959-1960). It is possible, as is evident from earlier discussions, that price levels initially may have been negotiated at "high" levels for some products included in the wholesale price index.

## Drug Retail Prices, 1971 Versus 1975

According to the Ministry of Health, the intent of "generic" legislation was to lower the "high" retail prices of chemically equivalent drugs produced by different manufacturers.[20] Since the reference was to "nominal prices," a comparison was made of "nominal"

retail prices in 1971 and 1975. The year 1975 was chosen for comparison because it is argued that it was approximately two years before the chaotic situation created by introduction of the "generic" legislation stabilized. In the interim "adjustment" period, pharmaceutical companies scrambled to adjust marketing strategies to the new environment and develop, within the legal constraints of the legislation, product, pricing, and promotional initiatives to cope with the situation.

There are problems in making price comparisons between the two years. A primary obstacle is that, with the introduction of the National Formulary, certain products offered in 1971 had a different composition (formulation) and/or strength in 1975. Also, package sizes offered by some manufacturers in 1971 differed from those offered in 1975. For example, if a manufacturer sold a package of 1,000 tablets in 1975 as compared to one with 10 or 100 tablets in 1971, the price per tablet was touted as a price reduction, even though this could be a reflection of lower unit cost due to marketing in bulk quantities.

To overcome this problem, the approach here was first to compare prices of 24 products with equivalent formulations offered in the same package size in 1971 and 1975 and calculate an "average" change in price. Although the criteria of equivalent formulation and packaging undoubtedly limit the number of products for which price comparisons can be made,[21] the 24 products, for which such comparisons were made following these guidelines, are widely used

and are reasonably representative of different therapeutic classes. (See Appendix for a list of the 24 products and the therapeutic classes they represent.)

Second, because each product is sold in different package forms, it was considered appropriate to compare prices, in 1971 and 1975, of the most frequently sold package form of the 24 products. For instance, ampicillin is sold in various package forms (250 mg. capsules, 8 per bottle; 250 mg. capsules, 100 per bottle; syrup 60 ml.; vial 250 mg.; etc.) The most frequently sold package form is 250 mg. capsules, 8 per bottle, and the comparison would indicate whether prices in 1975 for this were different from 1971.

Third, another comparison was made of the prices charged in 1971 and 1975 by the leading manufacturer (in unit sales) for the most frequently sold package form of the 24 products. For example, Beecham was the leading manufacturer (in unit sales) of the most frequently sold package form of ampicillin (250 mg. capsules, 8 per bottle) in 1971 and 1975. The comparison would show whether Beecham's price for ampicillin sold in the 250 mg. capsules, 8 per bottle package, in 1975 differed from Beecham's price for the same in 1971.

The next three sections present the results of the three above-mentioned approaches.

## Changes in "Average" Price: All Package Forms

Between 1971 and 1975, there was an "average" price increase of 2.6 percent for the 24 products included in the comparison. This was computed as follows.

First, the average price of each package form in 1971 was calculated by taking the mean of the prices of the different manufacturers in 1971. This process was repeated for 1975 and the calculations are reported in Table 6-8. For example, the product multivitamin + minerals was sold generally in five forms. For form A of this product, there were three manufacturers in 1971. The average of the prices of these three manufacturers is reported as Rs. 8.72 in Table 6-8. Similarly, the average price in 1975 was Rs. 9.17.

Next, the percentage change in average price was calculated for each package form using 1971 as the base year, that is, percentage change in average price = $\left(\frac{\text{Average Price in 1975 - Average Price in 1971}}{\text{Average Price in 1971}}\right)$ x 100. Continuing with the previous example of package form A of multivitamin + minerals, the percentage change in average price = $\left(\frac{9.17 - 8.72}{8.72}\right)$ x 100 = 5.16 percent. These calculations are also reported in Table 6-8.

Next, the mean percentage change in average price for each product was calculated by summing the percentage change in average prices of the different package forms of that product, and dividing by the number of forms. For instance, the mean percentage change in average price for the five package forms of the product multivitamin + minerals is = $\left(\frac{-2.95 + 38.53 + 5.16 + .21 - 9.62}{5}\right)$ = 6.26 percent. These are reported in Table 6-9.

Next, an overall average of the mean percentage change was calculated by summing the mean percentage change in average price

Table 6-8.--Average price of different package forms of 24 drugs: 1971 and 1975.

| General Group / Therapeutic Class / Product / Package Form | | Number of Manufacturers 1975 | Number of Manufacturers 1971 | Average Price (in Rupees) 1975 | Average Price (in Rupees) 1971 | Ratio: Average Price (1975) / Average Price (1971) | Percentage Change in Average Price |
|---|---|---|---|---|---|---|---|
| 1. Alimentary Tract and Metabolism | | | | | | | |
| 1.1 Vitamins | | | | | | | |
| 1.1.1 Multivitamins + minerals | | | | | | | |
| | A* | 2 | 3 | 9.17 | 8.72 | 1.05 | + 5.16 |
| | B | 1 | 1 | 8.89 | 9.16 | 0.97 | - 2.95 |
| | C | 2 | 2 | 11.90 | 8.59 | 1.38 | + 38.53 |
| | D | 12 | 1 | 9.52 | 9.50 | 1.00 | + 0.21 |
| | E | 1 | 2 | 9.20 | 10.18 | 0.90 | - 9.62 |
| 1.1.2 Multivitamins | | | | | | | |
| | A* | 3 | 2 | 6.84 | 5.19 | 1.31 | + 31.79 |
| | B | 1 | 1 | 2.12 | 2.00 | 1.06 | + 6.00 |
| | C | 12 | 2 | 28.46 | 50.25 | 0.56 | - 43.36 |
| | D | 2 | 1 | 4.61 | 3.56 | 1.29 | + 29.49 |
| | E | 17 | 1 | 4.20 | 5.00 | 0.84 | - 16.00 |
| | F | 1 | 1 | 5.47 | 4.60 | 1.19 | + 18.91 |
| | G | 9 | 1 | 4.01 | 4.00 | 1.00 | + 0.25 |
| | H | 2 | 1 | 13.71 | 17.50 | 0.78 | - 21.66 |
| | I | 7 | 3 | 3.79 | 4.66 | 0.81 | - 18.67 |
| 1.1.3 Vitamin B. complex + C | | | | | | | |
| | A* | 4 | 2 | 9.14 | 7.00 | 1.30 | + 30.57 |
| | B | 6 | 1 | 9.37 | 8.90 | 1.05 | + 5.28 |
| | C | 1 | 2 | 12.00 | 8.07 | 1.49 | + 48.69 |
| | D | 1 | 1 | 9.90 | 7.00 | 1.41 | + 41.43 |
| 1.2 Antidiarrhoeals | | | | | | | |
| 1.2.1 Kaolin streptomycin compound | | | | | | | |
| | A* | 2 | 1 | 5.35 | 6.00 | 0.89 | - 10.83 |
| 1.3 Antacids, antiflatulants, antipeptics | | | | | | | |
| 1.3.1 Magnesium trisilicate compound | | | | | | | |
| | A* | 3 | 1 | 3.83 | 4.02 | 0.95 | - 4.73 |
| | B | 7 | 1 | 25.14 | 26.00 | 0.96 | - 3.31 |
| | C | 2 | 1 | 8.24 | 8.50 | 0.97 | - 3.06 |

Table 6-8.--Continued.

| General Group<br>Therapeutic Class<br>Product<br>Package Form | | Number of Manufacturers | | Average Price (in Rupees) | | Ratio: Average Price (1975) / Average Price (1971) | Percentage Change in Average Price |
|---|---|---|---|---|---|---|---|
| | | 1975 | 1971 | 1975 | 1971 | | |
| 1.4 Mineral supplements | | | | | | | |
| 1.4.1 Sodium acid citrate | | | | | | | |
| | A* | 2 | 1 | 2.96 | 3.10 | 0.95 | - 4.51 |
| | B | 7 | 5 | 3.28 | 2.65 | 1.24 | + 23.77 |
| | C | 1 | 3 | 8.35 | 8.92 | 0.93 | - 6.39 |
| | D | 4 | 1 | 10.29 | 6.00 | 1.715 | + 71.50 |
| 2. Systemic Anti-infectives | | | | | | | |
| 2.1 Antibiotics systemics | | | | | | | |
| 2.1.1 Ampicillin | | | | | | | |
| | A* | 5 | 2 | 10.45 | 11.92 | 0.87 | - 12.34 |
| | B* | 1 | 1 | 21.84 | 21.84 | 1.00 | 0 |
| | C | 6 | 1 | 112.06 | 134.40 | 0.83 | - 16.63 |
| | D | | 1 | 666.75 | 666.75 | 1.00 | 0 |
| | E | 9 | 1 | 12.65 | 14.28 | 0.88 | - 11.42 |
| | F | 3 | 1 | 6.99 | 8.05 | .86 | - 13.17 |
| | G | 1 | 1 | 12.70 | 12.70 | 1.00 | 0 |
| | H | 1 | 1 | 10.50 | 10.50 | 1.00 | 0 |
| 2.1.2 Oxytetracycline | | | | | | | |
| | A* | 3 | 2 | 5.45 | 6.55 | 0.83 | - 16.79 |
| | B* | 2 | 1 | 11.48 | 15.50 | 0.74 | - 25.93 |
| | C | 4 | 2 | 46.13 | 53.77 | 0.86 | - 14.20 |
| | D | 14 | 2 | 4.54 | 6.01 | 0.75 | - 24.46 |
| | E | 1 | 1 | 5.64 | 6.00 | 0.94 | - 6.00 |
| 2.1.3 Streptomycin | | | | | | | |
| | A* | 12 | 3 | .84 | .67 | 1.25 | + 25.00 |
| 2.1.4 Chloramphenicol | | | | | | | |
| | A* | 12 | 8 | 5.39 | 4.46 | 1.20 | + 20.85 |
| | B* | 34 | 8 | 4.05 | 4.04 | 1.00 | + 0.24 |
| | C | 3 | 5 | 40.86 | 20.01 | 2.04 | +104.19 |
| | D | 8 | 3 | 157.82 | 154.85 | 1.01 | + 1.91 |
| | E | 5 | 1 | 3.69 | 6.60 | 0.55 | - 44.09 |
| | F | 3 | 1 | 5.20 | 4.75 | 1.09 | + 9.47 |
| | G | 1 | 1 | 12.75 | 23.50 | 0.54 | - 45.74 |

Table 6-8.--Continued.

| General Group<br>Therapeutic Class<br>Product<br>Package Form | | Number of Manufacturers | | Average Price (in Rupees) | | Ratio: Average Price (1975) / Average Price (1971) | Percentage Change in Average Price |
|---|---|---|---|---|---|---|---|
| | | 1975 | 1971 | 1975 | 1971 | | |
| 3. Respiratory System | | | | | | | |
| 3.1 Cough and cold preparations | | | | | | | |
| 3.1.1 Codein cough syrup | | | | | | | |
| | A* | 23 | 1 | 4.36 | 3.50 | 1.24 | + 24.57 |
| | B* | 2 | 1 | 5.15 | 4.37 | 1.17 | + 17.84 |
| | C | 10 | 3 | 14.26 | 12.07 | 1.18 | + 18.14 |
| | D | 3 | 1 | 4.38 | 3.75 | 1.16 | + 16.80 |
| 3.1.2 Promethazine cough syrup | | | | | | | |
| | A* | 4 | 1 | 4.98 | 3.57 | 1.39 | + 39.49 |
| | B* | 1 | 1 | 7.27 | 4.25 | 1.71 | + 71.05 |
| 3.2 Antihistamines systems | | | | | | | |
| 3.2.1 Chlorophenaramine | | | | | | | |
| | A* | 2 | 3 | 1.33 | 1.43 | 0.93 | - 6.99 |
| | B | 16 | 3 | 15.76 | 27.64 | 0.57 | - 42.98 |
| | C | 1 | 1 | 7.05 | 16.45 | 0.42 | - 57.14 |
| | D | 4 | 1 | 39.10 | 40.00 | 0.97 | - 2.25 |
| | E | 1 | 1 | 3.00 | 4.37 | 0.68 | - 31.35 |
| 4. Central Nervous System | | | | | | | |
| 4.1 Analgesics | | | | | | | |
| 4.1.1 Dipyron | | | | | | | |
| | A** | 5 | 1 | 53.77 | 63.00 | 0.85 | - 14.65 |
| | B | 2 | 1 | 12.64 | 14.80 | 0.85 | - 14.59 |
| | C | 1 | 1 | 3.22 | 1.89 | 1.70 | + 70.37 |
| | D | 2 | 1 | 5.40 | 4.80 | 1.12 | + 12.50 |
| 4.1.2 Paracetamol | | | | | | | |
| | A** | 8 | 1 | 35.97 | 33.00 | 1.09 | + 9.00 |
| | B | 33 | 3 | 3.57 | 3.52 | 1.01 | + 1.42 |
| | C | 8 | 1 | 18.29 | 24.00 | 0.76 | - 23.79 |
| 4.2 Psycholeptics | | | | | | | |
| 4.2.1 Phenobarbitone | | | | | | | |
| | A* | 7 | 1 | 14.18 | 4.60 | 3.08 | +208.00 |

Table 6-8.--Continued.

| General Group<br>Therapeutic Class<br>Product<br>Package Form | | Number of Manufacturers | | Average Price (in Rupees) | | Ratio: Average Price (1975) / Average Price (1971) | Percentage Change in Average Price |
|---|---|---|---|---|---|---|---|
| | | 1975 | 1971 | 1975 | 1971 | | |
| 4.2.2 Diazepam | | | | | | | |
| | A* | 6 | 1 | 3.45 | 4.90 | 0.70 | - 29.59 |
| | B | 4 | 1 | 16.78 | 14.55 | 1.15 | + 15.32 |
| | C | 4 | 1 | 29.03 | 26.80 | 1.08 | + 8.32 |
| | D | 9 | 1 | 5.43 | 7.40 | 0.73 | - 26.62 |
| | E | 2 | 1 | 8.00 | 10.90 | 0.73 | - 26.60 |
| 5. Blood and Blood-Forming Organs | | | | | | | |
| 5.1 Antianaemics | | | | | | | |
| 5.1.1 Ferrous sulphate + folic acid | | | | | | | |
| | A* | 3 | 1 | 7.56 | 12.00 | 0.63 | - 37.00 |
| 6. Genito-Urinary System and Sex Hormones | | | | | | | |
| 6.1 Sex hormones | | | | | | | |
| 6.1.1 Methyltestosterone | | | | | | | |
| | A* | 5 | 1 | 9.35 | 8.41 | 1.11 | + 11.17 |
| 7. Sensory Organs | | | | | | | |
| 7.1 Ophthalmologicals | | | | | | | |
| 7.1.1 Sulphacetamide | | | | | | | |
| | A* | 15 | 4 | 2.24 | 2.37 | 0.94 | - 5.48 |
| | B | 7 | 2 | 1.98 | 2.17 | 0.91 | - 8.75 |
| | C | 10 | 4 | 2.60 | 2.77 | 0.93 | - 6.13 |
| | D | 1 | 1 | 3.73 | 3.90 | 0.95 | - 4.35 |
| | E | 4 | 3 | 4.10 | 3.39 | 1.20 | + 20.94 |
| | F | 1 | 1 | 4.72 | 4.20 | 1.12 | + 12.38 |
| 8. Parasitology | | | | | | | |
| 8.1 Antiparasitics | | | | | | | |
| 8.1.1 Piperazine | | | | | | | |
| | A* | 11 | 3 | 1.75 | 2.01 | 0.87 | - 13.00 |
| | B* | 3 | 1 | 2.11 | 2.35 | 0.89 | - 10.21 |
| | C | 1 | 1 | 4.47 | 4.50 | 0.99 | - 0.66 |
| | D | 3 | 1 | 12.56 | 13.50 | 0.93 | - 6.96 |
| | E | 1 | 1 | 19.76 | 21.00 | 0.94 | - 5.90 |

Table 6-8.--Continued.

| General Group<br>Therapeutic Class<br>Product<br>Package Form | | Number of Manufacturers | | Average Price (in Rupees) | | Ratio: Average Price (1975) / Average Price (1971) | Percentage Change in Average Price |
|---|---|---|---|---|---|---|---|
| | | 1975 | 1971 | 1975 | 1971 | | |
| 8.1.2 Chloroquine Phosphate | | | | | | | |
| | A* | 6 | 2 | 55.50 | 45.50 | 1.21 | + 21.97 |
| | B | 4 | 2 | 75.88 | 102.50 | 0.74 | - 25.97 |
| | C | 3 | 1 | 22.09 | 25.90 | 0.85 | - 14.71 |
| | D | 2 | 1 | 69.76 | 95.00 | 0.73 | - 26.56 |
| 9. Musculo-Skeletal System | | | | | | | |
| 9.1 Antirheumatics system | | | | | | | |
| 9.1.1 Phenylbutazone | | | | | | | |
| | A* | 4 | 1 | 8.39 | 5.62 | 1.49 | + 49.28 |
| | B | 6 | 1 | 66.95 | 127.00 | 0.52 | - 47.28 |
| 10. Systemic Hormones | | | | | | | |
| 10.1 Systemic corticosteroids | | | | | | | |
| 10.1.1 Prednisolone | | | | | | | |
| | A* | 6 | 5 | 6.80 | 5.93 | 1.14 | + 14.67 |
| | B | 1 | 2 | 22.94 | 20.53 | 1.11 | + 11.73 |
| | C | 12 | 4 | 90.50 | 120.78 | 0.74 | - 25.07 |
| | D | 3 | 2 | 48.68 | 50.20 | 0.96 | - 3.02 |

Source: Various sources including A. H. Qureshi, Quick Index of Medical Preparations (Karachi: n.p., 1971); company sources; Pakistan Chemists and Druggists Association.

*Most frequently sold package form to retail customers.

**Most frequently sold package form to pharmacists.

of each product and dividing by the total number of products, This was, as indicated earlier, computed to be an increase of 2.6 percent in 1975 over 1971 levels.[22]

There are some obvious problems with such a coarse measure because it does not provide for weighting of each product form according to its relative importance. For example, one particular package form may account for a high percentage of sales of a particular product, and the variation in price between 1971 and 1975 would obviously be of more importance in that case than in others.[23] Since unit sales of each package form were unavailable to this researcher, it was not possible to utilize a weighting procedure. In order to overcome the deficiencies in this measure, the most frequently sold package forms for each product were identified through industry and trade sources.

Changes in Price: Most Frequently Sold Package Forms

The percentage change in average price of the most frequently sold package forms was obtained from Table 6-8 and is noted in Table 6-9. This ranged from -29.59 percent for diazepam (a tranquilizer whose prices have been under attack in many other countries) to +208 percent for phenobarbitone (a barbiturate).

In only three cases was there at least a 25 percent decrease in average price of the most frequently sold package forms. These were diazepam, as mentioned earlier (-29.59 percent), ferrous sulphate + folic acid (-37 percent), and oxytetracycline (-25.93

Table 6-9.--Changes in average price of 24 drugs in 1975 from 1971 levels.

| General Group<br>Therapeutic Class<br>Product | Number of Package Forms | Range of Percentage Change in Average Price | Mean Percentage Change in Average Price (All Package Forms)[a] | Percentage Change in Average Price of Most Frequently Sold Package Forms |
|---|---|---|---|---|
| 1. Alimentary Tract and Metabolism | | | | |
| 1.1 Vitamins | | | | |
| 1.1.1 Multivitamins and minerals | 5 | - 2.95 to + 38.53 | + 6.26 | + 5.16 |
| 1.1.2 Multivitamins | 9 | - 43.36 to + 31.79 | - 1.47 | + 31.79 |
| 1.1.3 Vitamin B complex + C | 4 | + 5.28 to + 48.69 | + 31.49 | + 30.64 |
| 1.2 Antidiarrhoeals | | | | |
| 1.2.1 Kaolin streptomycin compound | 1 | - 10.83 | - 10.83 | - 10.83 |
| 1.3 Antacids, antiflatulants, antipeptics | | | | |
| 1.3.1 Magnesium trisilicate compound | 3 | - 4.72 to - 3.06 | - 3.70 | - 4.73 |
| 1.4 Mineral supplements | | | | |
| 1.4.1 Sodium acid citrate | 4 | - 4.51 to + 23.77 | + 21.09 | - 4.51 |
| 2. Systemic Anti-Infectives | | | | |
| 2.1 Antibiotics systemic | | | | |
| 2.1.1 Ampicillin | 8 | - 16.63 to 0 | - 6.69 | - 12.34; 0[b] |
| 2.1.2 Oxytetracycline | 5 | - 25.93 to - 6.00 | - 17.48 | - 16.79; - 25.93 |
| 2.1.3 Streptomycin | 1 | + 25.00 | + 25.00 | + 25.00 |
| 2.1.4 Chloramphenicol | 7 | - 45.74 to +104.19 | + 6.69 | + 20.85; 0.24[b] |
| 3. Respiratory System | | | | |
| 3.1 Cough and cold preparations | | | | |
| 3.1.1 Codein cough syrup | 4 | + 16.80 to + 24.57 | + 19.33 | + 24.57; + 17.84[b] |
| 3.1.2 Promethazine cough syrup | 2 | + 39.49 to + 71.05 | + 55.27 | + 39.49; + 71.05[b] |
| 3.2 Antihistamines systemic | | | | |
| 3.2.1 Chloropheniramine | 5 | - 2.25 to - 57.14 | - 28.14 | - 6.99 |
| 4. Central Nervous System | | | | |
| 4.1 Analgesics | | | | |
| 4.1.1 Dipyron | 4 | - 14.65 to + 70.37 | + 13.40 | - 14.65 |
| 4.1.2 Paracetamol | 3 | - 23.79 to + 9.00 | - 4.45 | + 9.00 |
| 4.2 Psycholeptics | | | | |
| 4.2.1 Phenobarbitone | 1 | +208.00 | +208.00 | +208.00 |
| 4.2.2 Diazepam | 5 | - 29.59 to + 15.32 | - 11.83 | - 29.59 |

Table 6-9.--Continued.

| General Group<br>Therapeutic Class<br>Product | Number of Package Forms | Range of Percentage Change in Average Price | Mean Percentage Change in Average Price (All Package Forms)[a] | Percentage Change in Average Price of Most Frequently Sold Package Forms |
|---|---|---|---|---|
| 5. Blood and Blood-Forming Organs | | | | |
| 5.1 Antianaemics | | | | |
| 5.1.1 Ferrous sulphate + folic acid | 1 | - 37.00 | - 37.00 | - 37.00 |
| 6. Genito-Urinary System and Sex Hormones | | | | |
| 6.1 Sex hormones | | | | |
| 6.1.1 Methyltestosterone | 1 | + 11.17 | + 11.17 | + 11.17 |
| 7. Sensory Organs | | | | |
| 7.1 Ophthalmologicals | | | | |
| 7.1.1 Sulphacetamide | 6 | - 4.35 to + 20.94 | + 1.44 | - 5.48 |
| 8. Parasitology | | | | |
| 8.1 Antiparasitics | | | | |
| 8.1.1 Piperazine | 5 | - 3.00 to - 0.66 | - 7.34 | - 13.00; - 10.21[b] |
| 8.1.2 Chloroquine phosphate | 4 | - 26.56 to + 21.97 | - 11.31 | + 21.97 |
| 9. Musculo-Skeletal System | | | | |
| 9.1 Antirheumatic system | | | | |
| 9.1.1 Phenylbutazone | 2 | - 47.28 to + 49.28 | + 1.00 | + 49.28 |
| 10. Systemic Hormones | | | | |
| 10.1 Systemic corticosteroids | | | | |
| 10.1.1 Prednisolone | 4 | - 25.07 to + 14.67 | + 0.42 | + 14.67 |

Source: Table 6-7.

[a]The overall average of the mean percentage change in average price for all package forms (excluding phenobarbitone) = 2.6 percent.

[b]Two package forms were identified as most frequently sold.

percent). Since systemic antibiotics account for about one-fourth of all sales of drugs and medicines, and since oxytetracycline is a frequently prescribed systemic antibiotic, the decrease in its average price is not insignificant.

Among other systemic antibiotics, a frequently sold package form of ampicillin registered a decline of 12.34 percent in average price from 1971 levels; however, the most frequently sold package forms of two other products in this therapeutic submarket, chloramphenicol and streptomycin, registered price increases.

In the other two leading therapeutic submarkets, vitamins and cough and cold preparations, the most frequently sold package forms registered increases in average price.

One indicator of the degree of price competition is the difference between the highest price and the lowest price of a product (see Table 6-10). Among the 24 products examined, there were 13 most frequently sold package forms with more than one manufacturer in 1971. All except one had a lower price spread in 1971 compared to 1975. (The price spread is calculated as the ratio of the highest price to the lowest price of a package form. The closer this ratio is to unity, the lower the price spread.) Furthermore, if one were to assume that price competition had increased by 1975, the picture should be considerably different. This is not the case. Among the 24 products studied, there were 28 most frequently sold package forms made by more than one manufacturer. (Six products had two forms that were identified as most frequently sold.) The ratio of

Table 6-10.--Price spreads of most frequently sold package forms of 24 products (1971 and 1975).

| General Group<br>Therapeutic Class<br>Product | Price of Most Frequently Sold Package Form (1971)(in Rupees) | | Price Spread Ratio: Highest Price / Lowest Price (1971) | Price of Most Frequently Sold Package Form (1975)(in Rupees) | | Price Spread Ratio: Highest Price / Lowest Price (1975) |
|---|---|---|---|---|---|---|
| | Lowest | Highest | | Lowest | Highest | |
| 1. Alimentary Tract and Metabolism | | | | | | |
| 1.1 Vitamins | | | | | | |
| 1.1.1 Multivitamins and minerals | 8.34 | 9.00 | 1.08 | 8.34 | 10.00 | 1.20 |
| 1.1.2 Multivitamins | 4.03 | 6.35 | 1.58 | 6.00 | 8.25 | 1.38 |
| 1.1.3 Vitamin B complex + C | 7.00 | 7.00 | 1.00 | 8.82 | 9.76 | 1.11 |
| 1.2 Antidiarrhoeals | | | | | | |
| 1.2.1 Kaolin streptomycin compound | 6.00 | * | * | 4.53 | 6.17 | 1.36 |
| 1.3 Antacids, antiflatulants, antipeptics | | | | | | |
| 1.3.1 Magnesium trisilicate compound | 4.02 | * | * | 3.75 | 4.00 | 1.07 |
| 1.4 Mineral supplements | | | | | | |
| 1.4.1 Sodium acid citrate | 3.10 | * | * | 2.40 | 3.53 | 1.47 |
| 2. Systemic Anti-Infectives | | | | | | |
| 2.1 Antibiotics systemic | | | | | | |
| 2.1.1 Ampicillin[a] | 21.84 | * | * | 21.84 | * | * |
| | 11.34 | 12.50 | 1.10 | 8.47 | 12.50 | 1.48 |
| 2.1.2 Oxytetracycline[a] | 4.60 | 8.50 | 1.85 | 3.94 | 8.47 | 2.15 |
| | 15.50 | * | * | 7.50 | 15.47 | 2.06 |
| 2.1.3 Streptomycin | 0.66 | 0.68 | 1.03 | 0.64 | 1.00 | 1.56 |
| 2.1.4 Chloramphenicol[a] | 3.00 | 7.10 | 2.37 | 3.10 | 8.01 | 2.58 |
| | 3.00 | 6.85 | 2.28 | 2.18 | 6.85 | 3.14 |
| 3. Respiratory System | | | | | | |
| 3.1 Cough and cold preparations | | | | | | |
| 3.1.1 Codeine cough syrup[a] | 3.50 | * | * | 3.35 | 6.23 | 1.86 |
| | 4.37 | * | * | 4.30 | 6.00 | 1.40 |
| 3.1.2 Promethazine cough syrup[a] | 3.57 | * | * | 4.23 | 6.74 | 1.59 |
| | 4.25 | * | * | 7.27 | * | * |
| 3.2 Antihistamines systemic | | | | | | |
| 3.2.1 Chloropheniramine | 1.40 | 1.50 | 1.07 | 1.31 | 1.35 | 1.03 |
| 4. 4. Central Nervous System | | | | | | |
| 4.1 Analgesics | | | | | | |
| 4.1.1 Dipyron | 63.00 | * | * | 41.17 | 63.52 | 1.54 |
| 4.1.2 Paracetamol | 33.00 | * | * | 18.82 | 64.78 | 3.44 |

Table 6-10.--Continued.

| General Group<br>Therapeutic Class<br>Product | Price of Most Frequently Sold Package Form (1971)(in Rupees) | | Price Spread Ratio: Highest Price / Lowest Price (1971) | Price of Most Frequently Sold Package Form (1975)(in Rupees) | | Price Spread Ratio: Highest Price / Lowest Price (1975) |
|---|---|---|---|---|---|---|
| | Lowest | Highest | | Lowest | Highest | |
| 4.2 Psycholeptics | | | | | | |
| 4.2.1 Phenobarbitone | 4.60 | * | * | 6.00 | 40.00 | 6.67 |
| 4.2.2 Diazepam | 4.90 | * | * | 2.50 | 4.90 | 1.96 |
| 5. Blood and Blood-Forming Organs | | | | | | |
| 5.1 Antianemics | | | | | | |
| 5.1.1 Ferrous sulphate and folic acid | 12.00 | * | * | 4.70 | 12.00 | 2.55 |
| 6. Genito-Urinary System and Sex Hormones | | | | | | |
| 6.1 Sex hormones | | | | | | |
| 6.1.1 Methyltestosterone | 8.41 | * | * | 6.75 | 10.00 | 1.48 |
| 7. Sensory Organs | | | | | | |
| 7.1 Ophthalmologicals | | | | | | |
| 7.1.1 Sulphacetamide | 2.25 | 2.50 | 1.11 | 1.88 | 2.75 | 1.46 |
| 8. Parasitology | | | | | | |
| 8.1 Antiparasitics | | | | | | |
| 8.1.1 Piperazine[a] | 1.75 | 2.55 | 1.45 | 1.41 | 2.55 | 1.81 |
| | 2.35 | * | * | 1.82 | 2.40 | 1.32 |
| 8.1.2 Chloroquine phosphate | 41.00 | 50.00 | 1.22 | 41.17 | 77.45 | 1.88 |
| 9. Musculo-Skeletal System | | | | | | |
| 9.1 Antirheumatic system | | | | | | |
| 9.1.1 Phenylbutazone | 5.62 | * | * | 4.49 | 10.58 | 2.36 |
| 10. Systemic Hormones | | | | | | |
| 10.1 Systemic corticosteroids | | | | | | |
| 10.1.1 Prednisolone | 4.20 | 8.15 | 1.94 | 4.20 | 8.40 | 2.00 |

Source: Various sources, including A. H. Qureshi, Quick Index of Medical Preparations (Karachi: n.p., 1971); and company sources.

*One manufacturer only.

[a]Two package forms of this product were identified as most frequently sold.

the highest price to the lowest price (price spread) for these package forms ranged from 1.03 (for chlorphenaramine) to 6.66 (for phenobarbitone). Excluding phenobarbitone, which may be a special case, the average price spread was 1.78.

The price spreads indicate that, even though the number of manufacturers offering "equivalent" generic products increased in 1975, competition was not along price lines, but depended more on other marketing mix variables.

### Changes in Price: Leading Manufacturers of Most Frequently Sold Package Forms

Since one manufacturer may have higher sales than another of the most frequently sold package form of a product, another appropriate comparison is to contrast the 1971 and 1975 prices of the leading manufacturers who led unit sales of the most frequently sold package form (see Table 6-11).

In all cases except two, foreign local manufacturers led in unit sales of the most frequently sold package form in 1971 and 1975, and, in general, the same foreign local manufacturer who led unit sales in 1971 was also the sales leader in 1975.

Except in seven cases, all other most frequently sold package forms of the leading manufacturers (in unit sales) were higher priced in 1975 compared to 1971. Of these seven, there were four package forms for which the leading manufacturer could not be identified. In order to make a conservative estimate, the lowest price in 1975 was used.

Table 6-11.--Retail prices of leading manufacturers (in unit sales) of the most frequently sold package form of 24 drugs (1971 and 1975).

| General Group<br>Therapeutic Class<br>Product | Price of Leading Manufacturer of "Most Frequently Sold" Package Form (in Rupees) | | Ratio: Price (1975) / Price (1971) | Percentage Change |
|---|---|---|---|---|
| | 1971 | 1975 | | |
| 1. Alimentary Tract and Metabolism | | | | |
| 1.1 Vitamins | | | | |
| 1.1.1 Multivitamins and minerals | 9.00 | 10.00 | 1.11 | + 11.00 |
| 1.1.2 Multivitamins | 6.35 | 8.25 | 1.39 | + 29.92 |
| 1.1.3 Vitamin B Complex + C | 7.00 | 9.76 | 1.39 | + 39.42 |
| 1.2 Antidiarrhoeals | | | | |
| 1.2.1 Kaolin streptomycin compound | 6.00 | 6.17 | 1.02 | + 2.83 |
| 1.3 Antacids, antiflatulants, antipeptics | | | | |
| 1.3.1 Magnesium trisilicate compound | 4.02 | 3.75[b] | 0.93 | - 6.71 |
| 1.4 Mineral supplements | | | | |
| 1.4.1 Sodium acid citrate | 2.70 | 3.53 | 1.30 | + 30.74 |
| 2. Systemic Anti-Infectives | | | | |
| 2.1 Antibiotic systemic | | | | |
| 2.1.1 Ampicillin[a] | 11.34 | 11.34 | 1.00 | 0.00 |
| | 21.84 | 21.84 | 1.00 | 0.00 |
| 2.1.2 Oxytetracycline[a] | 8.50 | 8.47 | 0.99 | - 0.36 |
| | 15.50 | 15.47 | 0.99 | - 0.19 |
| 2.1.3 Streptomycin | 0.68 | 0.68 | 1.00 | 0.00 |
| 2.1.4 Chloramphenicol[a] | 7.10 | 7.10 | 1.00 | 0.00 |
| | 6.85 | 6.85 | 1.00 | 0.00 |

Table 6-11.--Continued.

| General Group<br>Therapeutic Class<br>Product | Price of Leading Manufacturer of "Most Frequently Sold" Package Form (in Rupees) | | Ratio: Price (1975) / Price (1971) | Percentage Change |
|---|---|---|---|---|
| | 1971 | 1975 | | |
| 3. Respiratory System | | | | |
| 3.1 Cough and cold preparations | | | | |
| 3.1.1 Codeine cough syrup[a] | 4.37 | 6.00 | 1.37 | + 37.29 |
| | 3.50 | 3.35[b] | 0.95 | - 4.29 |
| 3.1.2 Promethazine cough syrup[a] | 3.57 | 4.50[c] | 1.26 | + 26.05 |
| | 4.25 | 7.27 | 1.71 | + 71.05 |
| 3.2 Antihistamines systemic | | | | |
| 3.2.1 Chloropheniramine | 1.40 | 1.35 | 0.96 | - 3.58 |
| 4. Central Nervous System | | | | |
| 4.1 Analgesics | | | | |
| 4.1.1 Dipyron | 63.00 | 63.52 | 1.00 | + 0.82 |
| 4.1.2 Parcetamol | 33.00 | 64.70 | 1.96 | + 96.06 |
| 4.2 Psycholeptics | | | | |
| 4.2.1 Phenobarbitone | 4.60 | 6.00 | 1.30 | + 30.43 |
| 4.2.2 Diazepam | 4.90 | 2.50[b] | 0.51 | - 48.98 |
| 5. Blood and Blood-Forming Organs | | | | |
| 5.1 Antianemics | | | | |
| 5.1.1 Ferrous sulphate and folic acid | 12.00 | 12.00 | 1.00 | 0.00 |
| 6. Genito-Urinary System and Sex Hormones | | | | |
| 6.1 Sex hormones | | | | |
| 6.1.1 Methyltestosterone | 8.41 | 10.00[d] | 1.19 | + 18.90 |
| 7. Sensory Organs | | | | |
| 7.1 Opthalmologicals | | | | |
| 7.1.1 Sulphacetamide | 2.50 | 2.50 | 1.00 | 0.00 |

Table 6-11.--Continued.

| General Group<br>Therapeutic Class<br>Product | Price of Leading Manufacturer of "Most Frequently Sold" Package Form (in Rupees) | | Ratio: Price (1975) / Price (1971) | Percentage Change |
|---|---|---|---|---|
| | 1971 | 1975 | | |
| 8. Parasitology | | | | |
| 8.1 Antiparasitics | | | | |
| 8.1.1 Piperazine[a] | 2.35 | 2.40 | 1.02 | + 2.12 |
| | 2.55 | 2.55 | 0.00 | 0.00 |
| 8.1.2 Chloroquine phosphate | 50.00 | 41.17[b] | 0.82 | - 17.66 |
| 9. Musculo-Skeletal System | | | | |
| 9.1 Antirheumatic system | | | | |
| 9.1.1 Phenylbutazone | 5.62 | 5.87 | 1.04 | + 4.44 |
| 10. Systemic Hormones | | | | |
| 10.1 Systemic corticosteroids | | | | |
| 10.1.1 Prednisolone | 7.64 | 8.15 | 1.06 | + 6.67 |

Source: Various sources, including A. H. Qureshi, Quick Index of Medical Preparations (Karachi: n.p., 1971); and company sources.

Note: Except where indicated, foreign local manufacturers led sales of the most frequently sold package form in 1971 and 1975.

[a]Two package forms of this product were identified as most frequently sold.

[b]The leading manufacturer in 1975 could not be identified. The price noted is the lowest price in 1975 for the package form.

[c]The same Pakistani local manufacturer led unit sales in 1971 and 1975.

[d]Foreign local manufacturer led unit sales in 1975 and an importer led unit sales in 1971.

Even more interesting is the situation in the major therapeutic submarkets--systemic antibiotics, vitamins, and cough and cold preparations. In systemic antibiotics the leading manufacturers (of the most frequently sold package forms) had little or no change in prices. In the vitamins and cough and cold preparation markets, the leading manufacturers (of the most frequently sold package forms) in general increased their prices. This indicates that "loyalty" to the products of these manufacturers did not decrease, but in fact rose. The reasons for this involve the product and promotion policies of the leading firms, the subject of later chapters.

## Conclusions

Several conclusions, subject to the reservations expressed earlier in this chapter, can be drawn from the preceding information.

First, at the time the generic policy was introduced, retail prices in Pakistan for widely used drugs were generally lower than in India, Ceylon, Iran, and Turkey.

Second, active ingredients were transferred to affiliates by certain multinational pharmaceuticals who have a high market share in Pakistan at transfer prices substantially higher than the world market price for these materials, and at prices that are substantially different from those charged affiliates in other countries.

Third, in certain cases there was a substantial difference between active ingredients cost and the finished product price, suggesting that prices could have been lowered under competitive

pressures. Apparently there was little pressure because prices in 1975 did not change significantly even where, in earlier years, there were striking discrepancies between active ingredient costs and finished product prices.

Fourth, wholesale price index numbers indicate that although prices of drugs have remained at a lower level than prices of other commodities and at a lower level than existed in the base year 1959-1960, they were higher in 1974-1975 compared to 1971-1972. It should be noted that the wholesale price index for 1972-1973 was at a lower level than 1971-1972, indicating that there may have been some pressure to reduce prices immediately after the act was introduced, but after some time had elapsed, prices rose again (probably because of the increasing emphasis on product quality).

Fifth, nominal prices in 1975 generally were not lower than nominal prices in 1971, at least for the sample of comparable products examined in this research. (1) The overall average increase in nominal price was 2.6 percent in 1975 over 1971 levels. (2) The average nominal price of the most frequently sold package forms of the products studied generally increased in 1975 from 1971 levels. (3) The nominal prices charged by leading manufacturers of the most frequently sold package forms were generally not lower in 1975 than the nominal prices charged for the comparable product in 1971. (4) The spread between the highest and lowest price of the most frequently sold package form was greater in 1975 as compared to 1971, indicating that competition in 1975 was based on factors other than price.

Thus, the hypothesis $H_3$: The Generic Names Act would lead to a reduction in drug retail prices in Pakistan cannot be accepted.

Why prices did not fall according to expectations has to do with the product policies and promotional strategies adopted by pharmaceutical manufacturers--the subject of the next two chapters.

## Footnotes--Chapter VI

[1]"Generics Will Bring Down Cost of Medicine, says Rashid," Medical News, September 1, 1972, p. 10.

[2]Ibid. See also "Six More Months Allowed for Drugs Under Brand Names," Dawn, May 30, 1972. In another press conference, the Health Minister stated that with the adoption of the Generic Names Act "prices will go down by at least 75 percent in the case of each drug"; see "Implementation Cue for Health Policy Loan," Dawn, July 23, 1972.

[3]"'Generics Can Reduce Prices Up to 90 p.c.': Rashid," Morning News, September 29, 1972.

[4]"No Shortage of Drugs Will Be Allowed Says Health Secretary," Morning News, April 9, 1973.

[5]"Health Minister's Statement: Text," Dawn, May 30, 1972.

[6]Pakistan is not unique in this respect. As Steele commented during the Nelson Hearings, "If the data were made available [an economist] could analyze cost price conditions within the individual drug firms, and the pattern of interfirm price and product competition and arrive at an informed judgment regarding the status of competition in the industry. But such data have not been made available, even to economists retained to defend the industry." Steele cites Dr. Markham's response to similar questions: "You are just not going to get those [cost] data and . . . I would be less than honest if I would say I would try to get them." See Steele, statement before the U.S. Senate, Competitive Problems in the Drug Industry, pt. 5 (Washington, D.C.: Government Printing Office, 1968), p. 1902.

[7]These deals increased considerably during the generic period, but they had little impact on retail (consumer) prices because they were intended as incentives to chemists (see Chapter VIII, pp. 264-269.

[8]Pakistan Chemists and Druggists Association, internal memorandum to the members of the PCDA, June 1973.

[9]Although manufacturers were required to provide these details on a schedule, it was usually at the discretion of the government representatives to accept or reject the information as being adequate or inadequate. Even in 1976, when the government issued a more rigid format for manufacturers to supply quarterly information of "the rate and cost of each component of the raw and packing material," the data were generally provided unsatisfactorily." Interview with Z. S. Saifi, member of the Drugs Registration Board, Pakistan,

February 1977. Hewitt also commented that, in general, application documents submitted by drug manufacturers in Pakistan were "not presented in a satisfactory manner." William Hewitt, Assignment Report: Pharmaceutical Quality Control (Pakistan: WHO, December 1976), p. 2.

[10]A number of Pakistani and foreign local manufacturers interviewed commented that the negotiation process almost "demanded" that they start negotiations at a higher price. In the words of one manufacturer whose opinion was echoed by others, "If we start off by requesting a reasonable maximum retail price level the government will reduce it because they are convinced that what we request initially is a 'padded' price."

[11]This is evident from the fact, as discussed later in the chapter, that the transfer prices of active ingredients for a number of drugs were higher than the world market price for the same ingredients. Since the cost of raw materials is a determining factor in fixing maximum retail prices, "raw material costs if declared at an 'inflated' level can lead to the maximum retail prices being set at higher levels and the profit margin to be considered as acceptable."

[12]Even though the countries for which the comparison has been made have relatively similar health environments (that is, disease patterns are relatively similar), any international price comparison should be interpreted with reservations.

The Sainsbury report in 1967 stated, in part, that "There are many reasons why international comparisons of prices are extremely difficult to make and even more difficult to interpret; the use of current rates of exchange as a means of putting prices expressed in different currencies on a comparable basis gives rise to many ambiguities. There are even greater difficulties if one adopts other bases for comparisons. The great differences in habits and in per capita incomes lead to differences in elasticities of demand, and the differences in the assortment of medicines consumed in different countries reduce the significance of comparisons." Report of the Committee of Enquiry Into the Relationship of the Pharmaceutical Industry With the National Health Service 1965-1967 (London: HMSO, 1967), p. 50.

[13]See, for instance, the statements of George S. Squibb before the U.S. Senate, during the Nelson Hearings, in Competitive Problems in the Drug Industry, pt. 5 (Washington, D.C.: Government Printing Office, 1967), pp. 1576-77.

[14]Ibid., p. 1577.

[15]Pakistani government officials interviewed, who are responsible for monitoring imports of drug products, consistently cited manufacturers from certain countries, including Italy and Hong Kong, for providing "low priced but substandard materials." See

also "Increase in Import of Sub-standard Drugs," Medical Gazette, January 15, 1975.

[16]Robert H. Jones, "The Modern Multinational Structure of the Pharmaceutical Industry," in The Pharmaceutical Industry and Society, ed. George Teeling-Smith (London: OHE, 1972), p. 7.

[17]Lawrence Wortzel, Technology Transfer in the Pharmaceutical Industry (New York: UNITAR, 1971), p. 18.

[18]According to the explanatory notes to the Statistical Bulletin, the Statistics Division "does not have its own 'field resources' for collection of wholesale prices and relies on voluntary cooperation of government departments and private agencies for the information . . . also . . . trade jounrals. . . . It is possible that some of the commodity indices may not fully reflect the changes in price level as presently, the commodity coverage is not sufficiently large." Monthly Statistical Bulletin, vol. 24, January 1976 (Karachi: Statistics Division, Government of Pakistan, 1976), p. xii.

[19]The fiscal year is July of one year through June of the next year. For instance, F.Y. 1971-1972 is the period July 1971 through June 1972. The rupee was devalued in May 1972 from an exchange rate of Rs. 4.76 = $1.00 to Rs. 11.00 = $1.00. The effect on the cost of raw materials imported was not substantial because at the previous lower rate, the importer of raw materials had to pay an additional amount, slightly less than the difference between the previous exchange rate and the new exchange rate under a scheme called "the bonus voucher" scheme. This scheme was scrapped after the devaluation. However, certain drugs were allowed increases in the maximum retail price in mid-1973 after the devaluation. If these drugs were included in the calculation of the wholesale price index, they would account for part of the increase after F.Y. 1972-1973 in the wholesale price index in F.Y. 1973-1974 and F.Y. 1974-1975.

One of the reasons for the fall in the wholesale price index in F.Y. 1972-1973 (July 1972-June 1973) from F.Y. 1971-1972 (July 1971-June 1972) levels was because manufacturers attempted to reduce their inventory of brand name drugs, before the December 1972 deadline of conversion to generic names, by reducing their prices to the pharmaceutical trade.

[20]"Banking, Generic Names Bills Passed," Sun, September 23, 1972.

[21]In this research a difference in (1) form (for example, capsules, tablets, syrups), (2) strength (for example, 500 mg, 250 mg), or (3) size of package (for example, 200, 500, 700, and so forth of capsules [or tablets]) is considered as a different package form.

[22]This corresponds to the change in the wholesale price index (+2.33 percent) between 1971 (86) and 1975 (88). Since the government reluctantly allows any upward price revision, the probability that prices would have been higher exists. However, the point is that the limited data indicate no decrease in nominal prices anywhere near the magnitude the health authorities predicted.

# CHAPTER VII

# PRODUCT ISSUES

## Introduction

By introducing the Generic Names Act, the government hoped not only to induce competition among generic drugs but also specifically to provide an opportunity for Pakistani local manufacturers to compete with their products against foreign local manufacturers. This chapter attempts to assess how well this plan fared. It opens with a brief description of Pakistani licensing procedures for drug manufacturing and then discusses new entrants into the industry. Next, the production alternatives of manufacturers after introduction of the National Formulary and the product strategies adopted by foreign local and Pakistani local manufacturers are presented. An examination is then made of government standards of product quality and the adequacy of government inspection in monitoring it after the Generic Names Act was passed. Finally, the question of whether product quality deteriorated after the act was introduced is discussed.

The chapter attempts to answer three specific and related questions. First, with the abolition of brand names and given the government's proclivity to be liberal in promoting the manufacture of generic drugs, were there new entrants? Were there increased product offerings from the National Formulary by Pakistani local

manufacturers? If so, did these products acquire a stronger market position? Second, was the government inspection system adequately qualified to monitor the products marketed to ensure that generic drugs being produced by different manufacturers were up to standard? Third, was there a decline in product quality with the abolition of brand names, as was inferred would be the case by those who opposed the generic policy?

The investigation was designed particularly to test the hypotheses developed in Chapter IV:

$H_4$: The Generic Names Act would lead to an increase in the number of Pakistani local manufacturers, some of whom would have inadequate (marginal) manufacturing facilities.

$H_5$: The Generic Names Act would lead to an increase in product offerings from the National Formulary by Pakistani local manufacturers.

$H_6$: An increase in product offerings and "marginal" entrants would increase the number of substandard drugs in the market.

## Measures

Various measures were used to obtain the information necessary to answer the questions posed above.

First, the number of new entrants was ascertained from the manufacturing licenses granted during the generic period.

Second, changes in product offerings were measured by the number of products offered prior to and after introduction of the Generic Names Act by Pakistani local manufacturers and by foreign local manufacturers.[1]

Third, to determine whether Pakistani local manufacturers enhanced their market positions, the share of product sales of these manufacturers was compared to the sales share of foreign local manufacturers in the major therapeutic submarkets--systemic antibiotics, vitamins, and cough and cold preparations.

Fourth, the adequacy of the drug control and inspection system was evaluated in terms of the quality, quantity, and application of the personnel and equipment available.

Finally, to investigate whether there was a decline in product quality after the legislation, various measures were used. Among these were (1) the percentage of samples declared substandard by the government control agencies; (2) the number of cancellations and/or suspensions of drug manufacturing licenses by the government; and (3) qualitative and quantitative information about substandard medicines in the market obtained from interviews with various participants in industry, trade, and government.

## Government Licensing: Drug Products

The government issued licenses to manufacture drugs to firms who could indicate "to the satisfaction of the authorities" that the applicant would have "satisfactory plant, equipment and personnel and follow 'good' quality control practices."[2] In addition to a manufacturing license, a pharmaceutical concern had to obtain licenses for every product that it produced.

As mentioned earlier, with the introduction of the Generic Names Act, two possibilities existed. New entrants into the sector

would increase as they perceived an opportunity to compete in the absence of brand names, and since the government had indicated that "all manufacturers would be encouraged to produce as many drugs as possible from the national formulary,"[3] established manufacturers would increase their product offerings, although these would be restricted to those permitted by the National Formulary.

## New Entrants

Interviews with health authorities indicate that although a "large" (unspecified) number of applications for manufacturing licenses were received between 1972 and 1975, and although the number of inquiries into the possibilities of obtaining licenses rose considerably after the Generic Names Act, most of these applications were rejected. The health authorities are on record as granting 13 manufacturing licenses between 1972 and 1974.[4] All were granted to Pakistani local manufacturers. This represents an increase of about 4 percent in the number of firms. The authorities termed this a "normal" increase, that is, it corresponded to the number of licenses granted in periods prior to the Generic Names Act. However, no records were provided to substantiate this.

Among the new entrants between 1972 and 1975, four were officially cited by the government for producing substandard drugs. By 1976, the licenses of 12 new entrants had been cancelled, and renewal of the other two was contingent on substantial changes in their manufacturing and quality control practices. It should be noted that a great many other Pakistani local manufacturers had their

licenses cancelled in 1976, when a growing uproar against "marginal" manufacturers resulted in strict government action.[5]

Another aspect which deserves mention, although measurement is impossible, was the emergence and growth of "underground" manufacturers. These operated without legitimate manufacturing licenses and specialized in forgeries and imitations of products, primarily those of foreign local manufacturers but also Pakistani locals.[6]

## The National Formulary: Production Alternatives

The National Formulary (NF) by the end of 1975 stipulated that production would be restricted to 1,200 specified drugs. This meant that all of a manufacturer's products might or might not be included in the NF. If all his products were included, he could continue to produce them; he also had the option of producing others from the NF. The more likely case would be that not all of a firm's products would be included in the NF. In this case, the manufacturer ceased to produce unlisted products and if he chose to do so, he began producing listed drugs.

Manufacturers could seek exemptions for their products. When the Generic Names Act was introduced, the NF listed 750 drugs, and about 200 were granted exemptions. As might be expected, all of these were made by foreign local manufacturers or were imported. Between 1972 and 1975, products were added to and deleted from the NF, until it included 1,200 drugs and exempted 300 by 1975.[7]

Most local manufacturers, both Pakistani and foreign, took the opportunity to market products included in the National Formulary

which they had not manufactured prior to the Generic Names Act. Most felt they could be competitive once brand names were abolished.

Table 7-1 presents the decisions made in this regard by 26 manufacturers interviewed for this research.

Foreign Local Manufacturers

The majority of foreign local manufacturers (12 of 14) ceased producing their unlisted, unexempted products and decided to produce others from the NF.

As Table 7-1 indicates, all the foreign local manufacturers interviewed sought exemptions for various products, and some were granted. The government, which initially indicated it would be very selective in giving exemptions, proved more liberal. This was due not only to the immediate opposition to the policy by foreign manufacturers, some of whom threatened to close operations, but also to the government's growing concern that there would be a scarcity of certain drugs and medicines.

At first, foreign local manufacturers viewed the new legislation as a threat to the established position of certain brand name products. It was not long, however, before they began to realize the possibilities of marketing generic products to compete with products of other foreign local manufacturers which had enjoyed a strong market position because of their brand names.[8] It is interesting that none of the foreign local manufacturers interviewed considered Pakistani local manufacturers to be even a minor threat to their competitive position. Most of the foreign locals named other foreign

Table 7-1.--Production alternatives adopted by selected manufacturers.

| Manufacturers | National Formulary Included All Products of The Manufacturer | National Formulary Did Not Include All Products of the Manufacturer | | Exemptions[d] |
|---|---|---|---|---|
| | Maintained[a] | Reduced[b] | Reduced + Other NF Products[c] | |
| Foreign Local Manufacturers | | | | |
| FLM-1 | | | X | Some |
| FLM-2 | | | X | " |
| FLM-3 | | | X | " |
| FLM-4 | | | X | " |
| FLM-5 | | | X | " |
| FLM-6 | (A) | | | All |
| FLM-7 | | | (B) | " |
| FLM-8 | | | X | Some |
| FLM-9 | | | X | " |
| FLM-10 | | | X | " |
| FLM-11 | | | X | " |
| FLM-12 | | | X | " |
| FLM-13 | | X | | " |
| FLM-14 | | | X | " |
| Pakistani Local Manufacturers | | | | |
| PLM-15 | | | X | None |
| PLM-16 | | | X | " |
| PLM-17 | | | X | " |
| PLM-18 | | | X | " |
| PLM-19 | | | X | " |
| PLM-20 | | | X | " |
| PLM-21 | | X | | " |
| PLM-22 | | | X | " |
| PLM-23 | | | X | " |
| PLM-24 | | | X | " |
| PLM-25 | | | X | " |
| PLM-26 | | | X | " |

Source: Company interviews.

Note: (A): Products of this manufacturer which were not included in the National Formulary were granted exemptions; (B): Products of this manufacturer which were not included in the National Formulary were granted exemptions. The manufacturer also produced other drugs listed in the National Formulary. To maintain confidentiality of the information provided to this researcher, the identification of manufacturers in this table and other tables that follow in this report does not necessarily refer to the same manufacturer. For instance, the manufacturer identified as PLM-15 in Table 7-1 is not the same as the manufacturer referred to as PLM-15 in Table 7-3.

[a]The manufacturer did not offer other products from the National Formulary.

[b]Ceased production of drugs not listed in the National Formulary (excluding exempted drugs).

[c]Ceased production of drugs not listed in the National Formulary (excluding exempted drugs) and produced other drugs listed.

[d]One or more exempted drug in 1975.

locals, particularly the leading five, as being present and potential threats to the competitiveness of their products.

Some of the opinions expressed by Pakistani executives employed by foreign local firms may be of interest.

"Pakistani manufacturers do not have the business acumen."

"They are out to make a fast buck and don't realize the long-run consequences."

"They don't have the resources or the capability."

One general manager of a foreign local manufacturer, who is well-regarded in the industry, commented:

> I've worked in a number of Pakistani manufacturer companies and in a number of foreign firms. The difference is that in a Pakistani company if the quality control department rejects a batch, the quality control manager is told by senior management "you are not being paid to reject, you are being paid to pass--let the government inspectors find out if they can." Of course, not all the Pakistani manufacturers think along these lines but too many of them do.

Another commented: "[Pakistani manufacturers] were scrambling to get into products in the NF without paying attention to whether they had the production or quality control skills." Similar opinions were expressed by other interviewees. Their comments were interspersed with such remarks as "mind you, we are nationalists too and we would like to see Pakistan manufacture develop," and "of course, there are some respectable Pakistani manufacturers too."

## Pakistani Local Manufacturers

All 12 Pakistani local manufacturers interviewed had to halt production of some products because they were excluded from the NF. Eleven of these decided to manufacture other products from the NF.

Pakistani local manufacturers, in general, did not seek exemptions for their products. A number of interviewees indicated that they felt there was little possibility of getting exemptions because "they were still considered as being fringe manufacturers by the government" and because, in most cases, they did not have any unique advantage with their own brand names.

Most Pakistani locals perceived the legislation as offering an opportunity to gain market position. Consequently, they proceeded to expand their product offerings, but they faced some problems.

One problem was that specific formulations adopted for the products in the NF were those for leading brand name products of foreign manufacturers. As one local manufacturer bitterly complained, reflecting the feelings of other Pakistani locals:

> Sheikh Rashid [The Health Minister] talked about the stranglehold of the internationals and how he believed that products of Pakistani local manufacturers were just as good; however, when it came to selection of formulations they [the government] went to the products of internationals. We had a well-accepted efficacious cough remedy, a histamol [expectorant] which in my opinion was better than the Pfizer product selected by the National Formulary Committee, and there was a good vitamin product for which they selected an Abbott product.

According to the Pakistani local manufacturers, they were placed at a relative disadvantage in organizing for production. "We had to reorient our production, whereas in general the sales leaders did not have to do this." The general manager of one of the oldest Pakistani local pharmaceutical companies commented that "we have very limited production resources and we have to work within this

constraint as opposed to international manufacturers." Another stated: "We started from a different base. International manufacturers have the technical resources and backing of their principals and we are a local company not being able to rely upon anyone but ourselves." Yet another commented: "The formulations of our well-established products were excluded from the national formulary. We had no help whatsoever from anyone in our production changeovers, and we had to cope with the situation entirely on our own."[11]

Foreign local manufacturers agreed that they were given considerable assistance by the parent company. One foreign local commented: "We had the support of the parent company staff to advise us, and where a product was new for us in the Pakistani market, we were assisted heavily by headquarters and other subsidiaries on production and quality control methods." This sentiment was echoed by most foreign local manufacturers.

## Pakistani and Foreign Local Manufacturers: Product Changes

Ideally, the degree and extent of product mix changes after the Generic Names Act should include determination of whether the changes were convergent with or divergent from production and marketing skills used in producing the product mix offered by the same firm prior to introduction of the Generic Names Act. Unfortunately, information of this type was not available to this researcher. However, data on the absolute number of products offered by companies was available for the two years 1971 and 1975.

There is a striking difference in the magnitude of changes between Pakistani local and foreign local manufacturers. This contrast serves as an indicator of the general approaches taken in product offerings under the Generic Names Act. (See Tables 7-2, 7-3, and 7-4.)

Faced with production restrictions imposed by the NF, Pakistani manufacturers, in general, increased the number of products offered. Data from Table 7-4 indicate that about 90 percent of Pakistani locals increased the number of products they offered in 1975 as compared to 1971. The comparable figure for foreign locals is 20 percent.

Among the five sales leaders among foreign local manufacturers (also the overall sales leaders in the total market), one increased the number of products offered and four decreased their offerings.

Of the five sales leaders among Pakistani local manufacturers, four increased the number of products marketed and one reduced the number.

Did these changes in product offerings and the increased competition generic drugs were supposed to induce enable Pakistani manufacturers to gain market share advantages for any specific products? The evidence indicates that they did not.

In 1971, 30 products accounted for one-fourth of the rupee sales in the Pakistani market. There were no products of Pakistani local manufacturers among these. In 1975, 15 products accounted

Table 7-2.--Number of products offered by foreign local manufacturers: 1971 and 1975.

| Company | Products Offered | | Increase/ Decrease | Percent Increase/ Decrease[a] |
|---|---|---|---|---|
| | 1971 | 1975 | | |
| FLM-1 | 60 | 66 | + 6 | + 10 |
| FLM-2 | 73 | 54 | - 19 | - 26 |
| FLM-3 | 54 | 47 | - 7 | - 12 |
| FLM-4 | 34 | 23 | - 11 | - 33 |
| FLM-5 | 30 | 19 | - 11 | - 37 |
| FLM-6 | 7 | 9 | + 2 | + 28 |
| FLM-7 | 16 | 17 | + 1 | + 6 |
| FLM-8 | 43 | 30 | - 13 | - 30 |
| FLM-9 | 28 | 21 | - 7 | - 25 |
| FLM-10 | 56 | 28 | - 28 | - 50 |
| FLM-11 | 22 | 12 | - 10 | - 45 |
| FLM-12 | 28 | 18 | - 10 | - 35 |
| FLM-13 | 52 | 38 | - 14 | - 27 |
| FLM-14 | 27 | 27 | 0 | 0 |
| FLM-15 | 17 | 22 | + 5 | + 29 |
| FLM-16 | 55 | 12 | - 43 | - 78 |
| FLM-17 | 18 | 14 | - 4 | - 22 |
| FLM-18 | 19 | 19 | 0 | 0 |
| FLM-19 | 20 | 32 | + 12 | + 60 |
| FLM-20 | 28 | 25 | - 3 | - 10 |
| FLM-21 | 38 | 15 | - 23 | - 60 |
| FLM-22 | 1 | 3 | + 2 | +200 |
| FLM-23 | 4 | 3 | - 1 | - 25 |
| FLM-24 | 20 | 4 | - 16 | - 80 |
| FLM-25 | 23 | 16 | - 7 | - 30 |

Source: Companies data made available to researcher.

[a] $\left(\frac{\text{Number of products in 1975 - Number of products in 1971}}{\text{Number of products in 1971}}\right) \times 100.$

Table 7-3.--Number of products offered by Pakistani local manufacturers: 1971 and 1975.

| Company | Products Offered | | Increase/ Decrease | Percent Increase/ Decrease[b] |
|---|---|---|---|---|
| | 1971 | 1975 | | |
| PLM-1 | 15 | 51 | + 36 | 240 |
| PLM-2 | 17 | 42 | + 25 | 147 |
| PLM-3 | n.a. | 36 | I[c] | > |
| PLM-4 | 29 | 58 | + 29 | 100 |
| PLM-5 | 16 | 10 | - 6 | - 37 |
| PLM-6 | 39 | 29 | - 10 | - 26 |
| PLM-7 | n.a. | 3 | D[c] | -- |
| PLM-8 | 30 | 44 | + 14 | 47 |
| PLM-9 | 10 | 20 | + 10 | 100 |
| PLM-10 | 13 | 62 | + 49 | 377 |
| PLM-11[a] | 0 | 18 | + 18 | > |
| PLM-12 | 1 | 33 | + 32 | 3200 |
| PLM-13 | 14 | 32 | + 18 | 128 |
| PLM-14[a] | n.a. | 29 | I[c] | > |
| PLM-15 | 1 | 11 | + 10 | 1000 |
| PLM-16[a] | 0 | 16 | + 16 | > |
| PLM-17 | 10 | 19 | + 9 | 90 |
| PLM-18[a] | 0 | 7 | + 9 | > |
| PLM-19 | 4 | 21 | + 17 | 425 |
| PLM-20 | 1 | 6 | + 5 | 500 |
| PLM-21[a] | 0 | 9 | + 9 | > |
| PLM-22 | 2 | 19 | + 17 | 850 |
| PLM-23 | 7 | 15 | + 8 | 114 |
| PLM-24[a] | 0 | 20 | + 20 | > |
| PLM-25 | n.a. | 19 | I[c] | > |
| PLM-26 | 3 | 8 | + 5 | 166 |
| PLM-27 | 4 | 8 | + 4 | 100 |
| PLM-28 | 1 | 9 | + 8 | 800 |
| PLM-29 | 1 | 5 | + 4 | 400 |
| PLM-30 | 16 | 25 | + 9 | 56 |
| PLM-31 | 1 | 15 | + 14 | 1400 |
| PLM-32 | 7 | 8 | + 1 | 14 |
| PLM-33[a] | 0 | 9 | + 9 | > |
| PLM-34[a] | 0 | 11 | + 11 | > |
| PLM-35 | 4 | 28 | + 24 | 600 |
| PLM-36 | 12 | 6 | + 6 | 50 |

Source: Companies data made available to researcher.

Note: n.a.: not available; >: greater than 100 percent; I: increase; D: decrease.

[a]New entrants.

[b]$\left(\frac{\text{Number of products in 1975 - Number of products in 1971}}{\text{Number of products in 1971}}\right) \times 100$.

[c]Determined by company information regarding product offerings.

Table 7-4.--Changes in number of products offered in 1975 as compared to 1971: Pakistani local manufacturers and foreign local manufacturers.

| | Pakistani Local Manufacturers | Foreign Local Manufacturers |
|---|---|---|
| Overall range of change | -10 to 49 | -43 to 6 |
| Number of manufacturers | 32[a] | 25 |
| Changes in absolute number of products | | |
| Average | 11 | - 8 |
| Median | 13 | - 7 |
| Most frequent range of change[d] | 5 to 9[b] | -10 to -14[c] |
| Manufacturers | | |
| who decreased no. of product offerings | 3 | 18 |
| who increased no. of product offerings | 29 | 5 |
| with same no. of product offerings | 0 | 2 |

Source: Tables 7-2 and 7-3.

[a]Excludes four Pakistani local manufacturers for whom 1971 data were unavailable.

[b]Ten manufacturers.

[c]Six manufacturers.

[d]Range of change characterized by the following intervals: lower than -14; -10 to -14; -5 to -9; 0 to -4; 1 to 4; 5 to 9; 10 to 14; 15 to 19; 20 to 24; 25 to 29; 30 to 35; 35 to 40; 40 and above.

for one-fourth of the rupee sales. Again, no Pakistani local manufacturer's product was included. In both years there was only one exempted product (marketed by brand name) among these leading products.[9]

The highest market share that a Pakistani local manufacturer's product (a vitamin) held was 0.44 percent, ranking forty-fourth in sales in 1975. The situation was not much different from 1971, when the highest market share held by a Pakistani local manufacturer's product (again, a vitamin) was 0.40 percent, or forty-fifth in rupee sales.[10]

Most Pakistani local manufacturers entered the generic market with products in three therapeutic categories: systemic antibiotics, vitamins, and cough and cold preparations.

Table 7-5 provides information regarding product groups within these three subcategories for 1975. In the systemic antibiotics market, for example, sales of tetracycline and combinations accounted for 31.9 percent of total systemic antibiotic sales. Foreign locals, with 16 products, obtained 92.4 percent of the sales of tetracyclines and combinations in 1975, whereas Pakistani locals, with 15 products, obtained only 6.7 percent of these sales.

For all product groups within the three therapeutic subcategories, the ratio of the market share of a particular product group to the number of products is much higher in the case of foreign locals as compared to Pakistani locals. It should be kept in mind that the data do not preclude the possibility of a few products of a

Table 7-5.--Market shares of products in the leading three therapeutic submarkets: foreign local manufacturers and Pakistani local manufacturers (1975).

| Therapeutic Submarket Product Class | Market Share of Product Class in Therapeutic Submarket Sales | Foreign Local Manufacturers | | | Pakistani Local Manufacturers | | |
|---|---|---|---|---|---|---|---|
| | | Number of Products (1) | Market Shares of Products in Product Class (2) | Ratio (2)/(1) | Number of Products (3) | Market Shares of Products in Product Class (4) | Ratio (4)/(3) |
| 1. Systemic Antibiotics | | | | | | | |
| 1.1 Tetracycline and combinations | 31.9 | 16 | 92.4 | 5.8 | 15 | 6.7 | 0.5 |
| 1.2 Ampicillins and combinations | 15.8 | 5 | 94.8 | 19.0 | 3 | 2.3 | 0.8 |
| 1.3 Chloramphenicol and combinations | 11.2 | 6 | 67.8 | 11.3 | 13 | 27.6 | 2.1 |
| 1.4 Trimethoprim and combinations | 11.1 | 1 | 97.4 | 97.4 | 1 | 2.6 | 2.6 |
| 1.5 Penicillin-streptomycin combinations | 9.0 | 4 | 100.0 | 25.0 | ... | ... | ... |
| 1.6 Other penicillins | 7.6 | 14 | 95.0 | 6.8 | 10 | 2.8 | 0.3 |
| 1.7 Streptomycin and combinations | 4.4 | 4 | 90.2 | 22.6 | 4 | 9.8 | 2.5 |
| 1.8 Macrolides and similar types | 6.2 | 1 | 71.7 | 71.7 | 2 | 4.9 | 2.5 |
| 2. Vitamins | | | | | | | |
| 2.1 Vitamin B complex | 38.5 | 20 | 81.4 | 4.1 | 52 | 17.9 | 0.3 |
| 2.2 Vitamins $B_1$ and combinations $B_1$,$B_6$,$B_{12}$ | 21.5 | 12 | 78.7 | 6.6 | 20 | 20.4 | 1.0 |
| 2.3 Multivitamins without minerals | 19.6 | 12 | 92.7 | 7.7 | 21 | 6.4 | 0.3 |
| 2.4 Vitamin C | 6.4 | 6 | 98.1 | 16.4 | 5 | 1.0 | 0.2 |
| 2.5 Vitamin $B_{12}$ plain | 5.7 | 6 | 84.0 | 14.0 | 17 | 13.4 | 0.8 |
| 2.6 Multivitamins and minerals | 4.5 | 2 | 67.7 | 33.9 | 25 | 32.3 | 1.3 |
| 2.7 Vitamin A and D | 3.1 | 4 | 87.8 | 22.0 | 9 | 12.0 | 1.3 |
| 2.8 Other plain vitamins | 0.8 | 3 | 29.5 | 9.8 | 10 | 32.1 | 3.2 |
| 3. Cough and Cold Preparations | | | | | | | |
| 3.1 Cough sedatives | 84.8 | 19 | 88.1 | 4.6 | 29 | 10.1 | 0.3 |
| 3.2 Expectorants | 9.9 | 6 | 76.0 | 12.7 | 39 | 22.7 | 0.6 |
| 3.3 Other cold and cough mixtures | 5.3 | 1 | 17.2 | 17.2 | 2 | 82.8 | 41.4 |

Source: Companies' data made available to researcher.

few foreign locals in a product group having substantial sales compared to other foreign locals' products. For example, it is possible and also likely that of the 16 systemic antibiotic products of foreign locals, two or three may have had a major sales share; the same could be the case for Pakistani local manufacturers' products.

In summary, the introduction of the NF resulted in changes in the product mix of both Pakistani and foreign local manufacturers, with the former, in general, substantially increasing the number of products offered. In the process, Pakistani locals fared less well than did foreign locals because they did not have adequate technical resources to adapt to the situation.

Between 1972 and 1975, the leading Pakistani local manufacturers adjusted slowly, while other Pakistani locals lagged even farther behind in stabilizing production and quality. These production problems in the first two years after the introduction of the Generic Names Act led to publicity in both the popular and medical press regarding "deteriorating" product quality of medicines. This had an adverse impact on the reputation of Pakistani local manufacturers. There was a tendency to consider all products of Pakistani locals as suspect, which attitude could only benefit foreign local manufacturers, who in their initial campaigns against the legislation had threatened that product quality would diminish.

It became more difficult for even the established and reputable Pakistani local companies to overcome disadvantageous publicity regarding reduced product quality. The situation was

exacerbated by the drug inspection authorities, who concentrated their enforcement efforts on Pakistani local manufacturers and their products.[11]

## Product Quality: Government Standards

According to Section 16 of the Drugs Act of 1940, the term "standard quality" means "that the drug complies with the standard set out in the schedule."[12] Basically, the schedule's standards followed those of a "worldwide recognized Pharmacopaeia." The National Formulary introduced under the Generic Names Act specified strengths and formulations of both single ingredient and compound drugs for a restricted list of those that could be manufactured. The formulations were mainly those of leading brand name products which were manufactured prior to the Generic Names Act. The emphasis, then, was upon the chemical make-up of the drugs, and the quality of a product was related to how well it conformed to chemical specifications.

However, both chemical and biological aspects of a drug need to be considered in ensuring product quality. Beckett, summarizing from a WHO report, has indicated some aspects of drug production and control that may lead to a lack of product quality. These are indicated in Table 7-6.

The government's quality standard for generically equivalent drugs was in terms of their chemical rather than biological or clinical equivalence. Testing on samples was conducted for chemical equivalence to National Formulary specifications. Obviously, there

was the possibility that chemically equivalent drugs may not be therapeutically equivalent, but this aspect was largely ignored.[13]

Table 7-6.--Causes of lack of quality in drugs.

| |
|---|
| **Chemical aspects** |
| Unsuitable drug quality |
| Unsuitable drug physical form |
| Unsuitable quality of adjuvants |
| Interaction of drug with adjuvants |
| Manufacturing hazards |
| Partial decomposition during compounding |
| Inaccurate compounding |
| Incomplete mixing |
| Chemical cross contamination |
| Process errors |
| Microbial contamination |
| Packing errors |
| Impurities from containers |
| Uptake by containers |
| **Drug availability and biological aspects** |
| Unsuitable drug particle size |
| Unsuitable drug physical form |
| Unsuitable salt of drug |
| Unsuitable capsule contents for capsule form |
| Unsuitable adjuvants for drug in capsule or tablet |
| Unsuitable product coatings |
| Unsuitable enteric coating |
| Unsuitable base for drug in ointment or suppository |
| Powder compaction in capsules |
| Microbial contamination in non-sterile product |
| Non-sterility in sterile product |

Source: Arnold H. Beckett, "The Cost of Safety in Medicines," in George Teeling-Smith, The Pharmaceutical Industry and Society (London: Office of Health Economics, 1972), p. 23.

The government, in fact, had a dangerously liberal view about the use of any nonactive material such as excipients, fillers, and binders. An official notice stated:

1. It is permissible to use any non-active material like excipients, fillers, binders, preservatives, flavours, colours, coating materials, emulsifying suspending and thickening agents, vehicles, dilutants, solvents, waxes, additives, stabilisers, anti-oxidents, and anti-foams.
2. Where only base has been mentioned in the National Formulary, it is permissible to use any appropriate salt of the base containing equal quantity of the base.

Products which use excessive binding agents may fail to disintegrate. Antibiotics have been combined with presumably nonactive material which has reacted with the active agent and blocked its absorption. The use of some "inert materials" may alter the pharmacologic action of a drug.

However, as indicated earlier, the government did not express concern regarding the therapeutic equivalency of the generic drugs being manufactured locally. Thus, the term "substandard" as used in Pakistan refers to a drug which has one or more of the following characteristics: (1) an adulterated or contaminated drug or one that does not have the chemical composition specified in the National Formulary; (2) a "counterfeit," defined by the government as referring to drugs "whose label or outer packing is an imitation of . . . another manufacturer"; and (3) a "forgery" illegally manufactured and marketed as a product of another manufacturer.

## Product Quality: The Government Inspectors

Government inspection of drug quality covers five main fields of activity: pharmaceutical manufacture, distribution of medicines

by retail stores, import and wholesale dealings in medicines, distribution in the public sector, and dispensing of medicines by doctors.[14] Efforts of the quality control authorities generally have concentrated on the first two areas: investigation of pharmaceutical manufacturers, to eliminate substandard drugs at the source, and checking samples from retail outlets to trace the sources for substandard drugs.

The effectiveness of quality control depends on the adequacy of the personnel, the technical equipment available to them, and how the resources are utilized.

The Process

Under the Drugs Act of 1940, the provincial governments were responsible for checking the quality of drugs and their manufacture. Drug inspectors collected samples from manufacturers, retail outlets, or importers in the various provinces, and sent these to the provincial drug testing laboratories, where they were rejected if "substandard" or passed if of the specified standard. It should be noted that the aspect the inspection system concentrated on in judging a sample as "substandard" was whether the drug was contaminated, adulterated, or did not meet chemical specifications. If the sample was judged "substandard," the manufacturer or importer could agree either to recall the product or to destroy the consignment. If the manufacturer or importer disagreed with the judgment of the provincial testing laboratory, he could appeal to the Central Drugs Laboratory (CDL), which is under the Federal Health authorities. The CDL

then made the final judgment. Most manufacturers and importers appealed to the CDL if the provincial laboratories judged samples as substandard.

This inspection process remained the same after the Generic Names Act was introduced.

The Testing Facilities

As late as May 1975, two provinces, Baluchistan and N.W.F.P., did not have drug testing laboratories. Samples were sent to the provincial laboratories in Sind or the Punjab or, in most cases, to the Central Drugs Laboratory. With the extreme concern about "substandard" drugs in 1975, a spokesman for the Ministry of Health said in August of that year that

> to eliminate sale and circulation of substandard drugs in Baluchistan and N.W.F.P., a drug testing laboratory has been opened in Baluchistan . . . the N.W.F.P. government has made arrangements with the Pakistani Council of Scientific and Industrial Research and Khyber Medical College Laboratories for testing of drugs.[15]

Both the Sind and Punjab testing laboratories did not have adequate testing equipment. The Punjab laboratory had relatively better equipment but did not have the appropriate staff; the Sind government had neither the appropriate equipment nor the staff.[16]

The Central Drugs Laboratory, considered to be relatively better equipped than provincial laboratories, had problems keeping its equipment in working order. A report indicated that the CDL's two spectrophotometers, two fluorometers, and two calorimeters were constantly breaking down and needed replacement. The CDL also had

problems filling senior positions, and the laboratory was being operated by individuals with no specialized qualifications in pharmacology.[17] A medical news report on the CDL in 1974 said that

> for an institution charged with the task of quality control, it seems to be just an apology for a first rate laboratory . . . many precision instruments are reported to be either out of order or working partially. Sometimes, chemicals, reagents and solvents of high purity are not available, resulting in work being held up. Further facilities for performing pharmacologic tests are not available.[18]

It was the consensus of all those interviewed--industry, trade, and provincial inspection authorities--that the testing facilities were totally inadequate in 1971 and were not any better in 1975.

Drug Inspectors

In 1975, there were 24 drug inspectors for the four provinces in Pakistan. In Sind, the major manufacturing province in the country, there were six, three inspecting and drawing samples from retail outlets, and three whose job consisted primarily of visiting manufacturing units. According to the Drug Controller of Sind, six inspectors were not enough, especially with the changes in product mix occasioned by the abolition of brand names and introduction of the National Formulary.[19]

Inspectors should have a good general knowledge of all aspects of pharmaceutical manufacturing and have support personnel with specialized knowledge of subjects such as bacteriology, pharmaceutical analysis, and so forth. In Pakistan, inspectors are not

uncommonly recent graduates in pharmacy, lacking the experience and expertise to conduct proper inspections.[20]

Furthermore, Pakistani drug inspectors, including higher officials, are notoriously underpaid. The job itself has no particular career structure, and inspectors usually can be neither promoted nor demoted.[21] This situation also makes drug inspectors potential targets for corruption. A number of manufacturers and retailers freely admited to this researcher that they have resorted to bribes because "they would have to go through a long and complicated process to fight alleged malpractices on their part." Charges of corruption against the drug inspection personnel abound.[22]

A number of manufacturers cited instances of inspection staff corruption.[23] A general manager and a managing director of foreign local manufacturing concerns who were interviewed by this researcher had encountered inspectors who attempted to blackmail them "in order to extract bribes for not reporting alleged inadequate quality control procedures." Another senior-level government official in charge of drug inspections said that he had been transferred to his present position because his predecessor had been removed for corrupt practices.

Manufacturers also criticize the drug inspectors for "impatience and unwillingness to listen to the reasonable explanations given by factory management for procedures which do not conform exactly to the inspectors' preconceived ideas" and "a tendency to make a big issue of some transgression . . . of minor importance."[24]

Chemists and druggists interviewed voiced similar complaints about the drug inspection system, particularly the procedures during the "generic" period. At one time a delegation of the Pakistani Chemists and Druggists Association met with the Minister of Health to discuss a number of problems they were having. Among those discussed were (1) inspectors not providing test reports and protocol of tests which "deprived them [the chemists] of their right of defense"; (2) inspectors instigating prosecution even after the druggists produced warranties from the drug producer, "who should be the one prosecuted rather than the chemist";[25] (3) inspectors taking repeated samples without any compensation to the chemist (4) inadequacy of testing facilities resulting in different test results of the same drug batch; and (5) inordinate delay in getting test results, a sentiment also expressed by many manufacturers, who mentioned delays ranging from two months to a year.

In short, the drug inspection system during the generic period was not adequate. In the words of a critical report in the Medical Gazette:

> The provincial laboratories were ill-equipped. . . . Drug inspectors . . . who are supposed to keep a regular check are neither fully qualified for the job, nor have adequate facilities according to international standards. . . . Provincial Health departments in the four provinces have so far failed to regulate and maintain the standard of drugs.[26]

A WHO consultant assisting in a training scheme for Pakistani inspectors commented after the conclusion of the program: "Much more training will be needed to build up an inspectorate of the desired standards."[27]

## Product Quality: The Manufacturers

Government control and periodic inspection, even if properly done, cannot hope to eradicate the problem of substandard drugs in the market. Obviously, it is the manufacturer who either accepts the responsibility for good quality control procedures or shirks that responsibility. Unfortunately, evidence indicates that a number of manufacturers pursued the latter route during the generic period.

### Substandard Drugs

Recall that earlier it was pointed out that "substandard" refers to counterfeit drugs, forgeries, and drugs that are adulterated/contaminated or do not conform to chemical specifications. The incidence of each of these types of substandard drugs during the generic period is discussed below.

Counterfeit drugs.--There was a general increase in the number of counterfeit products in Pakistan during the generic period. (See Chapter VIII, pp. 273-276.) However, the government overlooked these transgressions of the Drugs Act of 1940, perhaps because of its desire to promote active generic competition.

It was not until the medical press and members of the medical profession protested against the increase in imitations and a number of these imitations were found not to be of the specified potency and/or adulterated that the government started to clamp down on counterfeits. Only in 1976 was new legislation introduced that

declared the government's intention of seriously prosecuting counterfeit (imitation) drug producers.[28]

Drug forgeries.--The extent of forgeries in the Pakistani market is not clearly established. Those interviewed indicated that forgeries existed prior to and after introduction of the Generic Names Act. Since these are mainly the products of "underground" manufacturers, not much is known about them. Opinions varied as to whether the number of illegitimate manufacturers had grown, with responses ranging from "substantial increases" to "about the same" and "decreases."

A number of manufacturers interviewed gave specific instances of forgeries. One manufacturer in the Punjab had obtained the strip packages of Parke-Davis's product, Ponstan, and had filled these strips with powdered ink. Labels for E. Merck products were discovered in the Punjab. Another manufacturer was busy producing a Wellcome product. Pfizer's oxytetracycline and a steroid preparation were forged. EPLA, a Pakistani local manufacturer, had its chloroquine phosphate tablets forged in 1973, when the real product was in short supply. Abbott's sulphadiazine was forged, and the forgery contained nothing but chalk. Glaxo's codopyrin was forged and contained only part of the ingredients. Beecham also discovered forgeries of its products.

A general manager of one international company described this incident:

> I was in the Punjab and I visited one of these hoax concerns. Of course, my identity was not known to them. During the conversation he mentioned that "we can give you a product of

> any manufacturer." I asked him what about [his company's] products. "Sure, I can give you syrups." What about capsules? "If you give me a large enough order!"

A Ministry of Health circular named three "fictitious manufacturing companies marketing drugs": Arsun Pharmaceuticals (Lahore), Richard Pharmaco Labs (Lahore), and Ambrosia Labs (Lahore).[29] Most illicit manufacturers are believed to conduct their operations in the Punjab.

Contaminated/adulterated drugs and drugs not having the specified composition.--The number of adulterated and/or contaminated drugs not of the designated potency increased considerably during the generic period according to all those interviewed in industry and trade. This opinion disagrees with official statistics published by the health department.

According to Deputy Director General of Health, F. R. Y. Fazli, "whereas the total number of drugs being tested has increased, the percentage of substandard drugs has decreased significantly." (See Figures 7-1 and 7-2.)

> It may be seen that in the Drugs Testing Laboratory, Lahore, the number of samples tested in 1971 was 139 out of which 32% of drugs were found to be substandard whereas in 1973 and 1974 (till June), the number of samples being tested increased to 1343 and 1139 respectively and the percentage of sub-standard drugs fell to 27 and in 1974 to 13. Somewhat similarly [sic] picture is seen in respect of testing conducted by the Sind Government and in the Central Drugs Laboratory, Karachi.

Most of those interviewed rejected these official statistics as incorrect, misleading, and propagandistic.

During interviews, the source of these substandard drugs was identified by foreign local manufacturers as Pakistani local

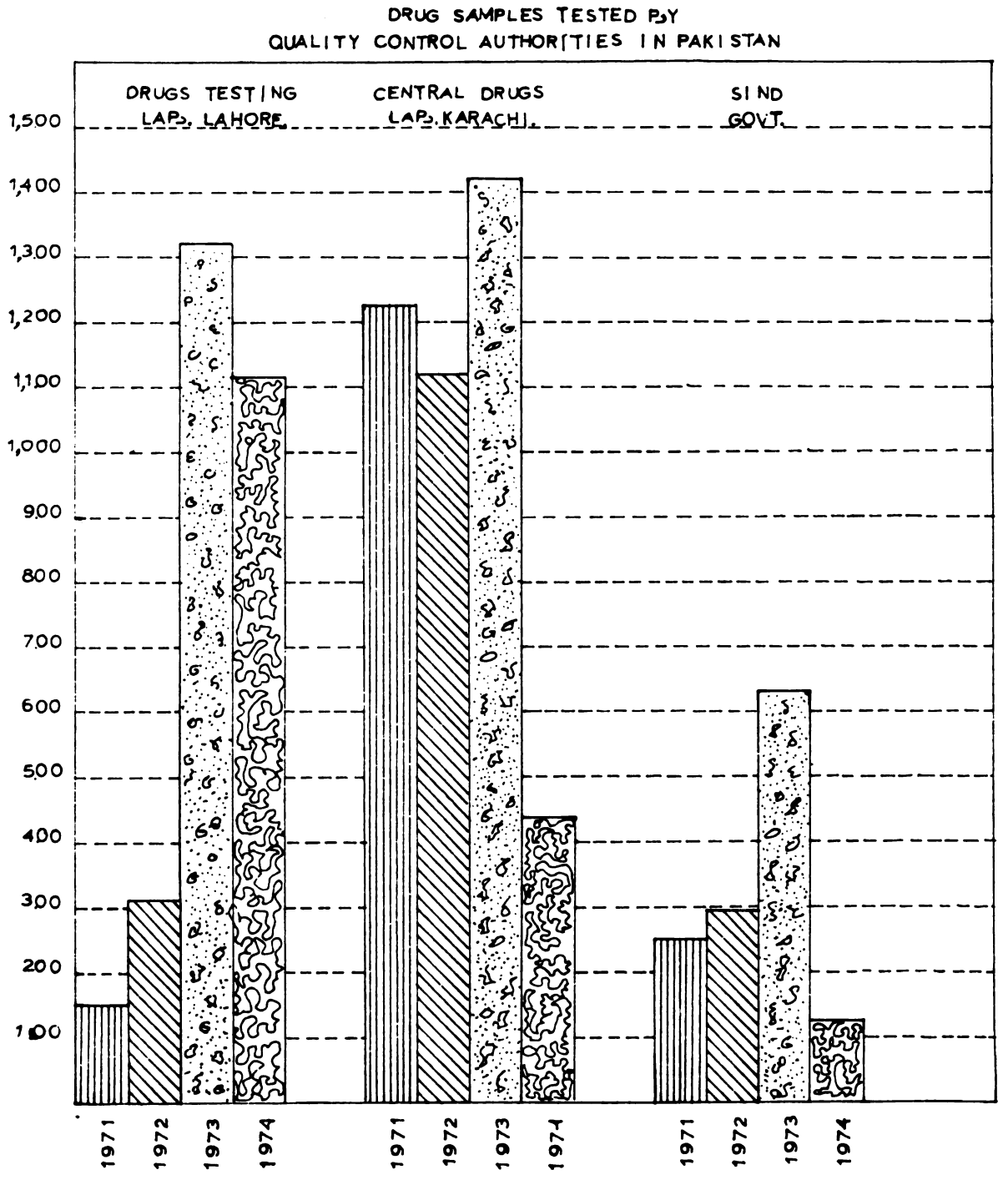



Figure 7-1

Source: F. R. Y. Fazil, "An Appraisal of Drugs: Generic Names Scheme," Medical News (Supplement), August 10, 1974, p. 4.

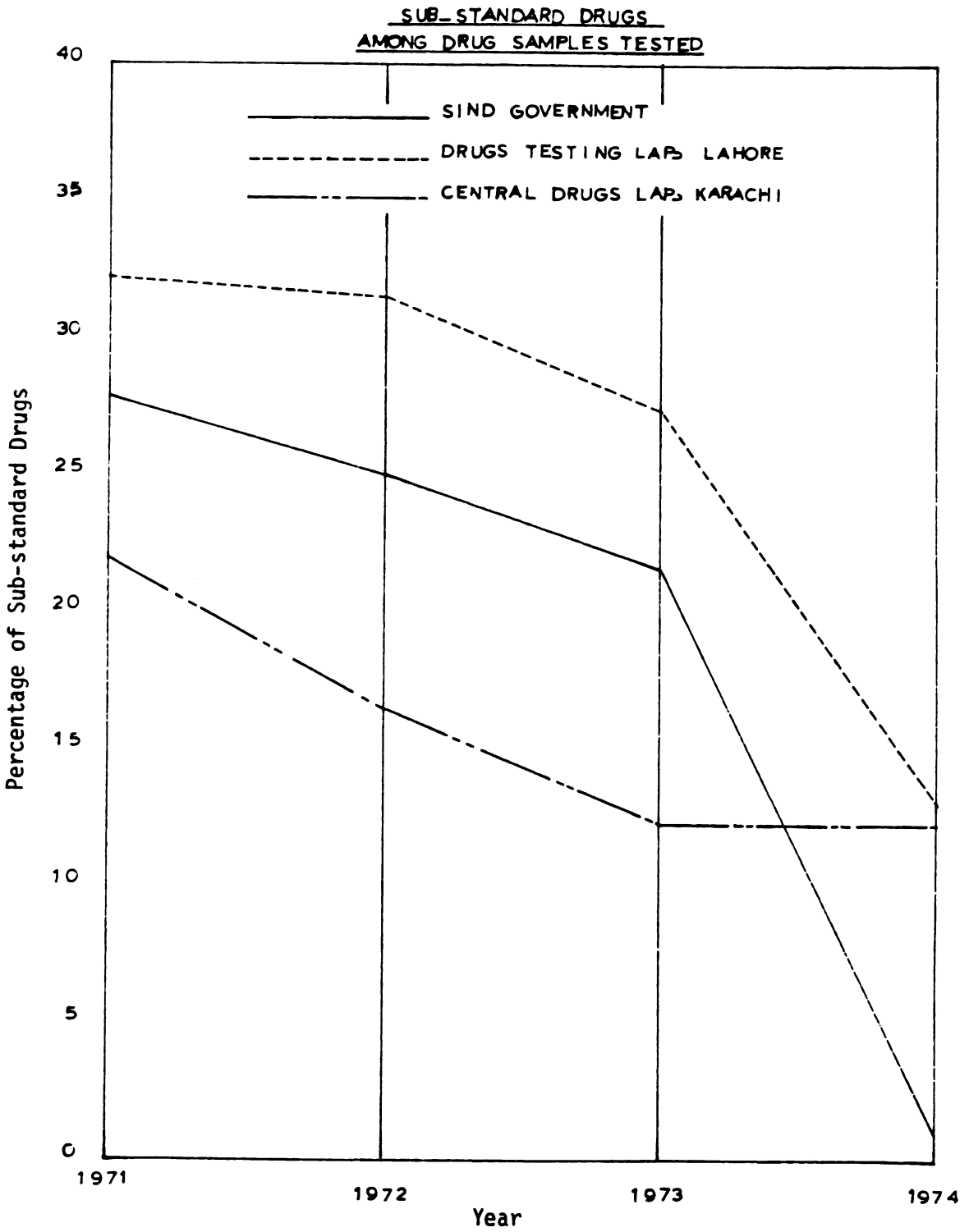



Figure 7-2

Source: F. R. Y. Fazli, "An Appraisal of Drugs: Generic Names Scheme," Medical News (Supplement), August 10, 1974, p. 4.

manufacturers and importers; by Pakistani local manufacturers as mainly "lesser-known" Pakistani manufacturers; by drug inspectors and the Chief Drug Prosecutors office as primarily lesser-known Pakistani manufacturers.

Unfortunately, the government did not publish comprehensive lists of drugs declared substandard during the generic period.[30] Those notices that were made available to this researcher[31] indicated the preponderance of both Pakistani local manufacturers' products and imported products adjudged as substandard by the quality control authorities. An unpublished list of imported substandard medicines indicated that, between 1974 and 1975, approximately 50 consignments of different imported finished products were declared substandard. The origin of these drugs was primarily Italy, Hong Kong, Japan, and West Germany. In one list of 18 products, 14 products of 9 Pakistani local manufacturers were declared substandard, and 4 imported products of 3 companies in Italy, West Germany, and Hungary were declared substandard. In another list, there were 5 products of unidentified foreign local manufacturers, 11 products of 8 Pakistani local manufacturers, and 9 imported products from Switzerland, West Germany, Italy, and Hong Kong. Most of these products were antibiotics, vitamins, or cough preparations. Another government circular cited 10 Pakistani local manufacturers for producing substandard drugs, primarily antibiotics and vitamin products.

All these above-mentioned products were judged substandard because they either did not conform to the chemical-equivalence standards of the National Formulary or were adulterated or contaminated.

There were also other lists of substandard drugs provided to this researcher which had a preponderance of products of lesser-known Pakistani manufacturers. These products, however, had not gone through the appellate process; that is, the Central Drugs Laboratory had not analyzed these samples.

At one time, the quality control authority issued a list of substandard drugs with the names of their manufacturers. The Pakistan Chemists and Druggists Association (PCDA) was asked to circulate the list among its members. There was an angry response from several manufacturers, who threatened legal action against the PCDA for damaging their reputation.[32] The manufacturers contended the list was based on a preliminary judgment, and "only such cases should be notified for circulation which have gone through the final test in the Central Drugs Laboratory, culminating in conviction of the accused party." They pointed out that "as the cases reported were based on the initial sampling at the chemist level," the manufacturers sometimes did not know about the case until their names appeared on the list. Accordingly,

> unless and until the first warrantor who is generally a manufacturer or importer is informed and given an opportunity of defense in support of quality, your circulars are apt to be questioned as unjustified since it is probable that some samples rejected by provincial chemical examiners are subsequently passed by the Central Drugs Laboratory.[33]

The medical profession, through the Pakistan Medical Association, expressed concern over some drug manufacturers who "were flooding the market with 'substandard' drugs," saying that

> some of the drugs are even prepared under unhygienic conditions and are devoid of the active ingredients mentioned on the label and sometimes even contain visible contaminants including dirt, insects and sediments. Even the injectable materials which are required to be in clear and stable solution are often observed to show a change of color and even precipitate.[34]

A resolution of the Medical Association in the Punjab called upon the government "to take immediate steps to stop the ever increasing incidence of sale and manufacture of substandard and spurious drugs which are posing a serious menace to the common man's health."[35]

The medical press also called attention to the incidence of substandard drugs.[36] One report deplored the substantial increase in manufacture, sale, and circulation of substandard drugs in recent months, alleging this was "in connivance with agencies entrusted with enforcing drug laws, checking quality control and testing drugs at provincial and federal levels."[37]

Given this growing concern, the government started to take action against marginal manufacturers.

## Cancellation/Suspension of Manufacturing Licenses

Even though the government had contested reports that there was an increase in "substandard" drugs marketed after the Generic Names Act was introduced, it obviously considered the problem serious enough to warrant severe action.

In 1973, three Pakistani firms had their manufacturing licenses cancelled.[38] By August 1974 there had been 4 suspensions of licenses (pending changes in manufacturing practices), 7 cancellations, and 29 citations, the latter requesting manufacturers to

"show cause" why their licenses should not be either suspended or cancelled.[39] By August 1975, manufacturing licenses of 38 pharmaceutical firms had been cancelled for producing substandard drugs.[40] This represented about 12 percent of all pharmaceutical manufacturing firms (from a total of 300) in Pakistan. All of these firms were "lesser known" Pakistani manufacturers.

Another indication of the growing problem of substandard drugs was the promulgation of an ordinance in February 1976, formalized later as the Drugs Act of 1976, which required revalidation of licenses of all pharmaceutical manufacturing firms.

As of September 1976, the government had revalidated 67 licenses. Nine Pakistani local manufacturers, who ranked among the leading 60 pharmaceutical companies in 1975, with a combined market share of about 3.5 percent, had not had their licenses revalidated. These manufacturers were asked to make substantial changes in their operations before a license would be issued.[41]

## Conclusions

Several general conclusions can be drawn from the information presented in this chapter.

First, there was an increase in the number of Pakistani local manufacturers after introduction of the Generic Names Act. However, it could not be ascertained whether this increase would have been of a similar magnitude without the legislation. The new entrants did not have adequate manufacturing and quality control capabilities.

Second, the introduction of the NF induced changes in products offered by all manufacturers. In addition, Pakistani local manufacturers perceived the abolition of brand names as an opportunity to increase sales through the manufacture of generic drugs. Consequently, they expanded their product offerings. However, Pakistani local manufacturers were unable to acquire a substantial market share with their products as compared to products of foreign local manufacturers.

Third, the product changes resulted in difficulties with manufacturing and quality control.

Fourth, product changes by manufacturers necessitated an adequate government inspection system to monitor whether these changes were being made and to maintain sound manufacturing and quality control practices. The government inspection mechanism was inadequate to the task.

Fifth, the inability of the government inspection system to monitor manufacturers' capabilities to produce drugs and the problems of Pakistani local manufacturers in particular led to an increase in substandard drugs.

Sixth, although government authorities contended that the incidence of substandard drugs did not increase, this was contradicted by the high number of government cancellations and suspensions of manufacturing licenses.

The evidence presented in this chapter supports the three hypotheses stated earlier.

$H_4$: The Generic Names Act would lead to an increase in the number of Pakistani manufacturers, some of whom would have inadequate (marginal) manufacturing facilities.

$H_5$: The Generic Names Act would lead to an increase in product offerings, from the National Formulary by Pakistani local manufacturers.

$H_6$: An increase in product offerings and "marginal" entrants would increase the number of substandard drugs in the market.

Well-publicized quality control problems and the incidence of substandard drugs were responsible for Pakistani local manufacturers not gaining increased market shares with their generic drugs. Promotional strategies adopted by foreign local manufacturers which centered around the theme of "quality" were also significantly responsible. These promotional strategies are the subject of the next chapter.

## Footnotes--Chapter VII

[1]There are obvious weaknesses in this measure because it cannot reflect the change in the width and depth of the product mix. An unsuccessful attempt was made to obtain this information. Interviews with representatives of manufacturers, trade, and government indicated that most of the change involved entries into antibiotics, vitamins, and cough and cold preparations.

[2]The criteria to be met in order to qualify for obtaining manufacturing licenses were made more explicit by the government under Schedule B of the Drugs Rules (1976).

[3]"Banking, Generic Names Bills Passed," Sun, September 23, 1972.

[4]Statement of F. R. Y. Fazli, Deputy Director-General, Drug Control, in an interview with Radio Pakistan, Rawalpindi, on August 28, 1974; cited in "Manufacture of Sub-standard Drugs Substantially Cut," Morning News, August 29, 1974.

[5]See pp. 237-238 of this chapter.

[6]See pp. 231-232 of this chapter.

[7]Interview with representatives of the Pakistan Pharmaceutical Manufacturers Association, January 1977.

[8]Among many others, Parke-Davis' Chloromycetin (chloramphenicol), Pfizer's Terramycin (oxytetracycline), and Lederle's Achromycin (tetracycline hydrochloride) are examples of brand name products which enjoyed high market shares.

[9]This is based on information provided to the researcher on a confidential basis.

[10]Ibid.

[11]A large number of individuals in pharmaceutical manufacturing and the trade (including representatives of multinational firms) made this observation. One government official, during an interview, denied that enforcement efforts concentrated on Pakistani local manufacturers. Another government official said, "Pakistani manufacturers have more problems controlling quality. Naturally more inspection activity is directed at their operations."

[12]"The Drugs Act (XXIII of 1940)," in The Drugs Laws (Lahore: Mansoor, n.d.), p. 13.

[13]This may have been a conscious decision on the part of the government in accepting the position of those who argue that lack of clinical equivalency among chemical equivalents is exaggerated.

[14]William Hewitt, Assignment Report: Pharmaceutical Quality Control (Pakistan: WHO, December 1976).

[15]"Substandard Drugs: Licenses of 38 Pharma-Firms Cancelled," The Medical Gazette, August 15, 1975, p. 1.

[16]"Quality of Quality Control?" Medical News, January 25, 1975, p. 1.

[17]"Health of the National Health Laboratories," Medical News, January 25, 1975, p. 18; "The CDL Spectrum," Medical News, February 15, 1975, p. 13; "Corruption Rampant in Drug Control Agencies," Medical Gazette, March 15, 1975, p. 1; "Quality Control of Drugs Sans Adequate Testing Facilities," Medical Gazette, May 1, 1975, p. 2; Shaukat Ali Jawaid, "Complete Overhauling of Drug Administration Imperative," Medical News, July 15, 1975, p. 1.

[18]"CDL Leaves Much to Be Desired," Medical News, August 10, 1974, p. 9.

[19]Interview with the Drug Controller of Sind in Karachi, February 1977.

[20]Interviews with representatives of the pharmaceutical industry and trade, December 1976-February 1977.

[21]Hewitt, op. cit., p. 9.

[22]See "Drug Inspector's Fee Rs. 10,000 Only," Medical News, June 10, 1975; and Malik Ali Sheikh, "The Honest Chemists and Poor Drug Inspectors," Medical News Supplement, June 25, 1975.

[23]This is not to imply that all drug inspectors are corrupt. There are many cases of those who have dutifully resisted huge bribes.

[24]Hewitt, op. cit., p. 9.

[25]This was a reflection of the government's belief that some chemists and druggists were in collusion with manufacturers of substandard drugs. At one time the vice-chairman of the Quality Control Authority in Islamabad warned the chemists and druggists that in case "a chemist is found dealing with any fictitious firm or with any substandard drug, he shall be liable for prosecution under Section 18 of the Drugs Act 1940. It will be no excuse that the chemist concerned did not know of the commital of such an offense." Vice-Chairman, Quality Control, letter to the PCDA (15-5/74-QC), January 21, 1974.

[26]M. A. Khan, "Quality Control and Drug Research," Medical News, January 25, 1975, p. 11.

[27]Hewitt, op. cit., p. 10.

[28]Drugs Ordinance, 1976 (IV of 1976).

[29]Vice-Chairman, Quality Control, Ministry of Health, letter to the PCDA [No. F-15-2/73-QC(G)], December 1, 1973.

[30]Attempts to obtain these from the provincial health authorities were unsuccessful. According to these representatives, even they were not notified at times of the appellate CDL's reports on substandard drugs.

[31]These were provided by the PCDA. See also "Government Officials Patronizing Fake Manufacturers," Medical News, January 1, 1975, p. 1; "Sale of Sub-standard Drugs," Medical Gazette, February 15, 1975, p. 4; "Import and Manufacture of Sub-standard Drugs Continue," Medical News, February 15, 1975, p. 1; "International Drug Houses Involved," Medical Gazette, February 15, 1975, p. 1; "Imitations of Standard Drugs Flood Market," Medical Gazette, April 1, 1975, p. 1; "Sub-standard Drugs," Medical News, April 15, 1975, p. 1; "Outbreak of Diarrhoea: Weevil Found in Farex," Medical Gazette, May 1, 1975, p. 16; "TCP Likely to Take Over Drug Import," Medical Gazette, May 15, 1975, p. 16.

[32]Pakistan Chemists and Druggists Association, letter to the Vice-Chairman, Quality Control, Ministry of Health (109/36-ADR/74), January 28, 1974.

[33]Ibid.

[34]"PMA Expresses Concern Over Sub-standard Drugs," Medical News, October 15, 1973, p. 11.

[35]"Sale of Sub-standard Drugs," Medical Gazette, February 15, 1975, p. 4.

[36]See, for instance, "Government Officials Patronizing Fake Manufacturers," Medical News, January 1, 1975, p. 1; "International Drug Houses Involved," Medical Gazette, February 15, 1975, p. 1; "Import and Manufacture of Sub-standard Drugs Continue," Medical News, February 15, 1975, p. 1; "Imitations of Standard Drugs Flood Market," Medical Gazette, April 1, 1975, p. 1; "Sub-standard Drugs," Medical News, April 15, 1975, p. 1.

[37]"Substandard Medicines: Corruption Rampant in Drug Control Agencies," Medical Gazette, March 15, 1975, p. 1.

[38]Vice-Chairman, Quality Control, Ministry of Health, letter to the PCDA (F5-1/73-QC), October 1, 1973.

[39]F. R. Y. Fazli, "An Appraisal of Drugs: Generic Names Scheme," Medical News Supplement, August 10, 1974, p. 4.

[40]"Licenses of 38 Pharma-Firms Cancelled," Medical Gazette, August 15, 1975, p. 1.

[41]Ministry of Health, Drug Information Service, September 1976, p. 7.

# CHAPTER VIII

# PROMOTIONAL STRATEGIES

## Introduction

In previous chapters, information has been provided which indicates that the Generic Names Act was not successful in either reducing sales concentration in the pharmaceutical drugs market or in introducing competition among generic drugs. The differential between the highest and lowest priced most frequently sold generic products indicates that doctors and eventual users perceived a difference among chemically equivalent generic drugs.

It is possible that the promotional strategies of the leading multinational pharmaceutical firms were singularly responsible for their retaining substantial market shares. In addition, some lesser known manufacturers, although inadequately prepared, had been permitted to manufacture certain drugs. The poor local products that resulted not only helped strengthen the market position of the leading multinationals, but also contributed to a general mistrust of all Pakistani drug products, including those of reputable companies.

This chapter begins with a description of the kinds of promotional activities undertaken by manufacturers in 1971 and focuses on the various promotional influences affecting doctors.

It then examines the promotional strategies adopted by foreign local and Pakistani local manufacturers during the 1972-1975 period.

When prescriptions are written by generic name only, the chemist assumes a significant role in the choice of drugs. He can fill the prescription with any of a number of "equivalent" generic products. Thus it was hypothesized that:

$H_7$: The Generic Names Act would lead to a decrease in promotional effort directed at doctors and an increase in promotional effort directed at chemists.

## Measures

Two measures were considered useful for gauging whether promotional emphasis had shifted from doctors to chemists during the generic period. First, the field staff--medical and sales representatives--are a very significant influence on "buyers." Therefore, changes in their responsibilities in terms of detailing chemists as opposed to doctors could be a useful barometer of promotional shifts. An increase or decrease in doctor/chemist calls and the frequency with which calls are made is another indicator of promotional emphasis. Second, other changes in promotional strategies, such as company literature and promotional deals, also provide indicators of the company's targets for promotional efforts.

## Promotion in the Pregeneric Period: 1971 and Earlier

Simply stated, the basic objectives of promotion are to inform, persuade, or remind customers about a company and its marketing mix. In the case of pharmaceutical products, the promotional

effort is designed to sustain, maintain, or induce brand loyalty to particular drug products.

The consumer of prescription drugs rarely determines the demand for or selects the drugs he purchases; he only pays for them. It is the doctor who makes the choice, depending upon his evaluation of the drug's risks and benefits for use in a particular case. The doctor is thus the decision maker in the sale of prescription pharmaceuticals. Among the channel members involved in the distribution of drugs, the pharmaceutical manufacturer is the one who decides on and implements the promotional effort, and the focus of this effort in the pregeneric period was the doctor. Promotion was geared to inducing the doctor to prescribe brand name products. Most of the drugs available were of this type (estimated to be about 12,000).[1]

Pakistani manufacturers took their cue from international companies and developed their own brand name products for a particular generic drug. For example, in the case of the antibiotic chloramphenicol (generic name), in addition to the widely used Parke-Davis brand name product, Chloromycetin, a host of Pakistani companies marketed the drug. Among others, chloramphenicol was sold under the brand name Amcomycetin, Atcomycetin, Atralphenicol, Biomycine, Cloramidina, Elcekor, Eplamycetin, Hymophenicol, Marcomycin, Nyscomycetin, Pharmaxin, Typhocetin, Sedomycin, and Schazomycetin.[2]

The doctor had to choose between these various brand name products, and a significant influence on his choice was the medical

representative of the pharmaceutical manufacturer. For this reason it is necessary to provide a brief description of doctors' prescribing practices and their sources of information, those who influenced prescribing patterns, and the nature of that influence.

## Doctors' Prescribing Practices[3]

Since most drugs were available by brand names, doctors generally prescribed brand name products. It would also not be an exaggeration to state that many doctors were unfamiliar with the generic names of those drugs. Doctors often would switch from a brand name product to another, believing it was a "different" product, that is, not chemically equivalent.

The doctor also was more inclined to prescribe the brand name products of foreign manufacturers and importers, believing the product would be of standard quality. An internationally known product used "all over the world" was a convincing argument, and these arguments were stressed by the medical representatives of foreign manufacturers who visited doctors.

Thus, the drug of choice for a given therapeutic indication in the case of most doctors was a foreign manufacturer's product, which meant a relatively higher priced one. At times, a doctor might prescribe lower priced products, but reluctantly, because he viewed these products as somehow not being of the quality of the higher priced foreign products.

Promotional Influences on Doctors

A Pakistani doctor's choice of brand name drugs could be influenced in several ways: personal conversations with other doctors regarding their experiences with certain drugs, articles in medical journals, direct mailings from manufacturers, and advertising in medical newspapers and in the Quick Index of Medical Preparations, commonly called QIMP. But it was the medical representative, because of his personal interaction with the doctor, who exerted the strongest influence.

The average Pakistani doctor has a very heavy daily case load. There are about 8,500 doctors in Pakistan, or about one doctor for every 7,000 people.[4] Doctors are more apt to set up practice in urban areas such as Karachi, Lahore, Rawalpindi, and Hyderabad. Even in these areas there is only about one doctor per 3,000 people.[5] Doctors thus have very little time for "keeping up in the field"[6] by reading articles in medical journals. Besides, "foreign journals are not easily available," and there are "no worthwhile Pakistani journals." The experiences of other doctors with certain drugs also influence their colleagues' prescribing practices, but this is not as significant a factor because of the "limited opportunities for interaction." The exception is the specialist who maintains professional relationships with others like himself and generally makes an attempt to read medical journals.

Because the medical newspapers are widely read and QIMP is extensively used by doctors, advertisements in these have an

indirect influence, but one that is difficult to measure. A discussion of these media follows.

The medical newspapers and QIMP.--The major Pakistani medical newspapers are the Medical Gazette, a publication of the Pakistan Medical Association (PMA), and two independent newspapers, Medicoment, published by an individual with interests in the trade, and Medical News.

All three newspapers regularly presented viewpoints in the "generic controversy."[7] The Gazette was naturally inclined to present the views of the PMA. However, since the medical profession itself was divided over the issue, both sides were represented in its articles. The other two newspapers are dominated by the editor's viewpoints. The News initially took an antigeneric stand, but the editor did include articles by both proponents and critics. As for Medicoment, unfortunately, very few past issues were available to this researcher. Those that were perused carried articles by the editor which were highly critical of the generic policy.

The editors of these newspapers deny any bias on their part, but there have been allegations that because their publications were so heavily dependent upon advertising revenues from leading manufacturers,[8] the articles they published reflected the antigeneric viewpoints of some of those manufacturers.[9] Advertising in these newspapers is dominated by foreign local manufacturers, particularly the top 10. A random sample of the medical newspapers indicated that 10 to 15 percent of the advertisements in 1971 were

placed by Pakistani local manufacturers, the rest by foreign manufacturers. Advertisements stressed the brand name of products rather than the company name.

Another advertising medium is the Quick Index of Medical Preparations (QIMP). There is no equivalent to the Physicians' Desk Reference (PDR)[10] in Pakistan. However, QIMP, a Pakistani publication, is widely used by doctors. It gives a listing of drugs with their chemical composition, retail price, and "normal dosage." For a publication that is used extensively, it has a significant deficiency. Although it provides some very general indications for use, it seldom mentions any contraindications or adverse reactions. The publisher states that contraindications are given "where notified" (emphasis mine). Because it is well known that QIMP is extensively used, it is indefensible for manufacturers not to provide this information.[11]

Unfortunately, in most drug advertisements in Pakistan, only the benefits of the product are stated, and in strong terms. The risks associated with its use are grossly understated.[12] At best, some leading manufacturers might add a short note to their advertisements to the effect that "full information is available upon request." Not many doctors write for "full information," relying more on the medical representative to provide some of these data.

The field staff.--As mentioned earlier, the medical representative is an important influence on the doctor's prescribing practices. Perhaps the most significant aspect of the Pakistani

medical representative is his role as a quasi-educator who informs the doctors about a drug's use. In addition, obviously, there is his role as persuader, convincing doctors to utilize the products of his company. This latter aspect has been strongly criticized not only in Pakistan but also in most other countries. There are allegations that the medical representative tends to emphasize a product's benefits and not give sufficient precautionary information regarding its use.[13] But even if a medical representative is conscientious, he does not have the time to give a thorough presentation. His average time with the doctor is about 10 minutes, during which period he must detail from 3 to 6 products. (See Figure 8-1 for the typical scheduled workload of a medical representative.) Even if the doctor has the time, the representative must make other calls. The net result is that the representative is anxious to communicate the favorable aspects of the drugs at the beginning of his presentation, and by the time he finishes there is little time left in which to describe contraindications, precautions, and undesirable side effects. He sometimes leaves company literature describing some of these aspects, but the doctor may or may not then read this material.

As with promotional activities in general, critics of pharmaceutical companies allege that it is not sufficient that the medical representative not tell an untruth; the <u>whole</u> truth must be told. Since the medical representative is the most significant contact between the company and the doctor, it is useful at this

| | |
|---|---|
| Working days: | 25 per month |
| Touring days: | 3 per month |
| Conference days (and days absent): | 2 per month |
| NET WORKING DAYS: | 20 per month |
| Doctors' calls: | 8 per day |
| Monthly coverage: | 160 calls |
| Doctors' detailing time: | 10-15 minutes |
| Clinic to clinic travel: | 10-15 minutes |
| Waiting time: | 10-15 minutes |
| TOTAL TIME PER CALL: | 35-45 minutes |
| WORKING TIME PER DAY: | 8 calls @ 45 minutes per call = 6 hours |

Figure 8-1.--Medical representatives: typical scheduled workload.

Source: Pharmaceutical industry sources.

point to discuss how the representatives of Pakistan local and foreign local manufacturers differ.

First, it should be noted that the medical representatives of foreign local manufacturers usually have easier access to doctors and have more supportive resources for their presentations. They are given detailed company literature on the products they sell and have the assistance of the company staff when responding to any questions a doctor may have which they are unable to answer to his satisfaction.

Better qualified and more articulate individuals are inclined to join the field force of a foreign local rather than a Pakistani local manufacturer. And most foreign locals hire the best students among pharmacy, science, and business administration graduates. That the more qualified should want to join a company such as Pfizer, Wyeth, Beecham, or Abbott is not surprising, considering the incentives offered. Among these is a compensation package which is 30 to 50 percent higher than leading Pakistani manufacturers provide. There is also the prestige associated with working for a prominent foreign firm. As mentioned above, representatives of the more prestigious firms have easier access to doctors, who are inclined to be more receptive to their presentations as compared to those of local manufacturers because of the "international stature of the foreign firms." In addition, foreign locals prepare their newly hired field staff through an intensive training program. Pakistani locals usually expect immediate

returns from their medical representatives, who are sent out with considerably less training. As a consequence of a combination of factors such as these, the medical representative of a Pakistani local manufacturer does not perceive his job as a career; rather, it is a stepping stone to employment by a foreign manufacturer. Indeed, the better performers among Pakistani representatives are hired away by the foreign locals. The result is that the products of foreign local manufacturers are promoted more "effectively" to doctors through the medical representatives.

Another important aspect of a medical representative's visit is the free samples of company products he provides to doctors. The representative is the more welcome, the more free samples he brings along. In fact, he is almost unwelcome if he does not supply these. Although both Pakistani local and foreign local manufacturers provide free samples, the more valued are those of foreign manufacturers. Some of these samples find their way, either through doctors' offices or medical representatives, into chemists' stores.

Medical representatives call primarily on doctors; another member of the field force, the sales representative, calls primarily on the trade, that is, the wholesaler/stockist/distributor or the chemist. These sales representatives act as order takers and monitor trade customer satisfaction.

In summary, promotion in the pregeneric period was primarily directed at doctors. The major influence on doctors, who prescribed generally by brand names, was the medical representative.

The medical representatives' efforts to induce doctors to prescribe the brand name products of their companies were supported by company advertisements in the medical newspapers.

## Promotion After the Generic Names Act: 1972 to 1975

After the introduction of the Generic Names Act, several significant promotional activities were undertaken by the pharmaceutical industry.

Recall that, prior to the abolition of brand name drugs, the promotional effort was directed primarily at doctors. The intent was to induce brand awareness and loyalty, and the prime influence on doctors' prescribing habits was the company medical representative. The replacement of brand by generic names meant that some basic changes had to be made in the promotional effort.

### Promotion: All Manufacturers

Promotional strategies adopted in the 1972-1975 period varied among manufacturers. In some cases, the prime focus of the promotional effort shifted from doctors to chemists. In other instances, there was a change in advertising, company literature, and direct mailings. Prior to 1972, these had emphasized the advantages of selecting brand name products; after 1972, these either merely substituted the generic name for the brand name wherever the latter was mentioned, or aggressively concentrated on "selling" the company name and its high standards of quality. Packaging gained new importance as a promotional tool. There were

packages with "visual" differentiation which carried pictures; packages (and capsules) that were close imitations in color, shape, and size of leading products; and packages which displayed the comapny name prominently on the label. Promotional "deals" such as "bonus" schemes, case-lot and "free-goods" offers, and other forms of discounting, including straight price discounts, became a competitive tool aimed at trade members.

Table 8-1 illustrates some of the significant changes during 1972 to 1975 in Pakistan of the promotional activities of 26 Pakistani and foreign local manufacturers.

Although it is difficult to generalize, since each firm adopted its own blend of promotion (and product) strategies to cope with the situation, there were some distinct differences between the approaches taken by the foreign local as compared to the Pakistani local manufacturers. These are discussed in some detail below.

Promotion: Foreign Local Manufacturers

With the abolition of brand names, foreign local manufacturers lost the advantage of unique identification of their product. As a substitute, they evolved a number of promotional strategies aimed at maintaining product identification. These primarily involved emphasizing the company name in promotional efforts, using "visual" differentiation for packages, and instructing the field staff to direct additional effort to the chemist, since he was

Table 8-1.--Promotional approaches of foreign local manufacturers and Pakistani local manufacturers during the generic period (1972-1975).

| Manufacturer | Detailing Emphasis on | | Number of Doctors Visited | Frequency of Visits to Doctors | Number of Chemists Visited | Frequency of Visits to Chemists | Promotional Emphasis on Company Name | Free Samples to Doctors | Promotional Deals to Chemists | Direct Mail to Doctors |
|---|---|---|---|---|---|---|---|---|---|---|
| | Doctors | Chemists | | | | | | | | |
| **Foreign Local Manufacturers** | | | | | | | | | | |
| FLM-1 | X[a] | | normal | normal | increased | increased | X | normal | increased | normal |
| FLM-2 | X[a] | | " | " | normal | " | X | " | normal | " |
| FLM-3 | X | | " | " | " | " | X | " | increased | " |
| FLM-4 | X[a] | | " | " | increased | " | X | " | " | " |
| FLM-5 | X[a] | | " | " | normal | " | X | " | " | " |
| FLM-6 | X[a] | | " | " | increased | " | X | " | " | " |
| FLM-7 | X | | " | " | normal | " | X | " | normal | " |
| FLM-8 | X[a] | | " | " | increased | " | X | " | increased | " |
| FLM-9 | X | | " | " | normal | " | X | " | " | " |
| FLM-10 | X[a] | | " | " | increased | " | X | " | " | " |
| FLM-11 | X | | " | " | normal | " | X | " | normal | " |
| FLM-12 | X | | " | " | normal | " | X | " | increased | " |
| FLM-13 | X[a] | | " | " | increased | " | X | " | " | " |
| FLM-14 | | X | reduced | reduced | " | " | X | " | " | decreased |
| **Pakistani Local Manufacturers** | | | | | | | | | | |
| PLM-1 | | X | normal | normal | increased | increased | X | reduced | increased | decreased |
| PLM-2 | | X | reduced | reduced | " | " | | " | " | " |
| PLM-3 | | X | " | " | " | " | X | " | " | " |
| PLM-4 | | X | " | " | " | " | | " | " | " |
| PLM-5 | | X | " | " | " | " | | " | " | " |
| PLM-6 | | X | " | " | normal | " | | " | " | " |
| PLM-7 | | X | " | " | increased | " | | " | " | " |
| PLM-8 | | X | " | " | " | " | | " | " | " |
| PLM-9 | | X | " | " | " | " | | " | " | " |
| PLM-10 | | X | " | " | " | " | | " | " | " |
| PLM-11 | | X | " | " | " | " | | " | " | " |
| PLM-12 | | X | " | " | " | " | | " | " | " |

Source: Company interviews.

[a]These companies, while maintaining primary detailing emphasis on doctors, increased the selling effort directed at chemists.

in a position to substitute generic products. These techniques are explained below.

Generic names and company names.--After 1972, most foreign local manufacturers began to emphasize the company's name rather than the brand name of products, which had been the focus previously. The theme was that the company name "meant" assured quality products for the patient, that the firm was a trusted and reliable manufacturer known internationally for its adherence to worldwide quality standards.

Hoechst, for example, stressed its "processing, technical knowhow," that it was a "technically well equipped research oriented company with high quality products." Pfizer stressed its "quality image and reputation." Lederle emphasized its "reputation for excellence." Abbott promoted the company name, suggesting that "our name stands for quality and reliability." Glaxo suggested that "they maintain quality . . . never any difference in quality." Beecham emphasized "prestige and quality." The promotional messages of other foreign local manufacturers were similar--the name of the company "meant" quality products.[14]

Obviously, the purpose was not only to maintain the doctor's confidence in their products but also to convince the doctor and eventual users that the products of multinational pharmaceutical manufacturers were reliable. In time, with the growing suspicion regarding product quality of Pakistani local manufacturers, this was an effective way to gain advantage over lesser known

Pakistani firms. Ultimately, most patient/customers were insisting on having the products of foreign manufacturers, which put pressure on the chemist to stock those products. This consequence was not the result of chance alone. A strong effort was made to cultivate the prescribing habits of physicians to the manufacturers' advantage.

Generic prescriptions.--The Generic Names Act prohibited doctors from prescribing medicines (except those exempted) by brand name.[15] This was a problem not only for chemists, who had difficulty becoming acquainted with the generic names, but also for many doctors, for they were used to prescribing by brand names.[16]

Most manufacturers circulated lists of their brand name medicines and the corresponding generic name to doctors and chemists. More important, they embarked on a campaign to induce doctors to write the manufacturer's name along with the generic name on the prescription. Since the law did not forbid this, a prescription for chloromycetin, for example, could be written as "chloramphenicol--Parke-Davis"; instead of terramycin, the prescription could read "Pfizer--tetracycline." A major task of the marketing representatives was to convince doctors to affix the company name to the generic name, effectively converting this to a "semi-brand" name.[17]

The medical profession, which had expressed concern about unqualified pharmacists making inappropriate generic substitutions, was responsive to this suggestion, for it meant retaining their decision-making authority regarding the choice of drugs. Companies made sure that doctors clearly understood this. Wyeth, for example,

sent out "Dear Doctor" letters to reassure them that "you are the most important" and emphasized Wyeth's "reputation in an international context," the doctor's "previous experience with [Wyeth's] products and the quality of these products."

It is difficult to determine how many prescriptions specified a company name since records of prescriptions are not maintained by chemists. Individual estimates, by companies interviewed, vary; the lowest figure cited was 50 percent, the highest, 80 percent. A survey conducted by a leading manufacturer indicated that about 60 percent of prescriptions included a specific company name. Even if a prescription included a manufacturer's name, the chemist still could substitute the product with that of another firm.

To prevent this possibility, a number of foreign local manufacturers devised a monitoring technique. They requested doctors to ask their patients to come back with the product and have it checked at the doctor's office, and firm representatives visited chemists and advised them of the need to fill prescriptions with the indicated manufacturer's product. As noted earlier, the "importance" of chemists was enhanced because of the possibility of substitution. As one representative of a leading pharmaceutical company stated, "chemists assumed an important role because of the possibility of substitution so that there was an increase in terms of coverage/contacts with chemists by our field staff."

The field staff.--Prior to the Generic Names Act, most foreign local manufacturers concentrated on building and maintaining

a field staff composed primarily of medical representatives; the relatively smaller staff of sales representatives acted primarily as order takers.[18]

After introduction of the Generic Names Act, most foreign locals made changes in their field staff. Among a number of possible alterations in structure and responsibilities, three in particular were used: (1) adding sales representatives, (2) adding medical representatives and assigning them functions of the sales representatives, and (3) assigning medical representatives to call on chemists also. Of the 14 local manufacturers interviewed, 5 adopted the first method, 5 the second, and 4 the third.

Whatever the method chosen, all the foreign locals interviewed said that the number of chemists visited by the field staff was not reduced, and in some cases increased. The frequency of visits increased, although the duration of visit was shorter. This was because companies felt that it was necessary to have more frequent contacts to keep the chemist "satisfied."

At the same time, all but one manufacturer indicated that the regularity of contacts with doctors was maintained. The one exception was a firm which shifted its sales effort focus from doctors to chemists.

In general, foreign local manufacturers during the generic period did not decrease the number of free samples that they provided to doctors.

Packaging: the promotional aspects.--In consonance with other promotional strategies aimed at retaining product loyalty, a number of foreign local manufacturers adopted "visual" differentiation in their packaging to distinguish their products from other generic products. These changes were of three basic types: (1) making the company name more prominent on the package, (2) emphasizing through the use of colors or bold print certain parts of the generic name, and (3) using symbols or other graphic illustrations to differentiate their product from other generic equivalents.

Hoechst shifted the company name to just below the generic name on its labels. Abbott made "the Abbott name more prominent and used 'more prominent colors' to differentiate products." Nicholas changed the name of its subsidiary in Pakistan to Aspro-Nicholas so as not to lose the strongly entrenched brand name for its aspirin tablets. The generic name of one of Beecham's high sellers, ENO's fruit salt, was "compound effervescent powder." Beecham used the name of the original manufacturer, J. C. Eno, at the bottom of the label, enlarged the size of the name ENO, and printed it in a bold, red color. Wyeth attempted to retain product identification for one of its brand name products, Streptomagma (generic name Kaolin streptomycin compound) by highlighting "streptomycin compound" on the label. For the brand name Entox, Wyeth, just below the generic name, clioquinol compound, printed "green diarrhoeal acting compound" to provide "a certain specification for the customer."

Pfizer used caricatures to "visually differentiate the product where substitution was likely" (for example, vitamin products). According to a Lederle representative, "it became necessary to have other identification processes to maintain customer loyalty." For this reason, Lederle also introduced illustrations on packages: a picture of a honeycomb on its vitamin B compound syrup, the picture of a coughing rooster on its promethazine cough syrup, and a picture of a boy and girl with a giraffe on their vitamin B complex syrup. Lederle also changed the color of the cap to an eye-catching gold. According to Lederle, "these changes helped us because the doctor could tell the patient to make sure he got the medicine bottle with the golden cap or that [the patient] should insist on getting the product with the picture of a rooster on it." The technique was particularly useful because many of the patients could not read English.

Promotional deals.--Although promotional deals such as bulk discounts, bonus deals, and free goods offers existed prior to 1972, their number increased substantially during the generic period (see Table 8-2). They were intended as incentives for the chemist.

One incentive, providing credit to chemists, existed in limited form prior to 1972. Between 1972 and 1975, a number of leading foreign locals, particularly those who had substantial market shares in antibiotics, vitamins, and cough and cold preparations, had liberal credit schemes that gave chemists between 60 and 180 days to pay for the products without interest. According to a representative

Table 8-2.--Some promotional "deals" offered between 1973 and 1975 by foreign and Pakistani local manufacturers.

| Manufacturers | Therapeutic Class of Product | Quantity Needed to Be Purchased for "Deals" (in Units) | Deal |
|---|---|---|---|
| Foreign Local Manufacturers | | | |
| FLM-1 | Vasoprotectives | 24 | 1 free |
| | Antiseptics | 144 | 18 free |
| | Vitamins | 100 | 10 free |
| | | 12 | 1 free |
| FLM-2 | Antianemics | 12 | 2% extra discount |
| | | 144 | 5% extra discount |
| FLM-3 | Antacids | 12 | 1 free |
| | | 144 | 14 free |
| | | 600 | 65 free |
| FLM-4 | Topical Corticosteroids | 72 | 7 free |
| | | 144 | 17 free |
| FLM-5 | Ophthalmologicals | 72 | 7 free |
| | | 144 | 17 free |
| | Eye-Ear Preparations | 170 | 25 free |
| | | 340 | 60 free |
| | Otologicals | 70 | 10 free |
| | | 140 | 23 free |
| | Topical Antibiotics | 150 | 25 free |
| | | 325 | 60 free |
| FLM-6 | Antidiarrhoeals | 12 | 1 free |
| | | 72 | 9 free |

Table 8-2.--Continued.

| Manufacturers | Therapeutic Class of Product | Quantity Needed to Be Purchased for "Deals" (in Units) | Deal |
|---|---|---|---|
| FLM-7 | Vitamins | 10 | 2 free |
| | | 50 | 12 free |
| | | 100 | 20 free |
| | | 500 | 120 free |
| FLM-8 | Urologicals | 12 | 1 free |
| | | 36 | 4 free |
| | | 72 | 9 free |
| FLM-9 | Topical Corticosteroids | 24 | 2 free |
| | | 144 | 18 free |
| | Antiseptic-Disinfectants | 12 | 1 free |
| | | 144 | 18 free |
| FLM-10 | Various Therapeutic Classes (different products) | Value of Purchase: | |
| | | Rs. 1,000- 6,000 | 3% extra discount |
| | | Rs. 6,000-12,000 | 4% extra discount |
| | | Rs. 12,000-25,000 | 5% extra discount |
| | | Rs. 25,000+ | special rates |
| FLM-11 | Systemic Antibiotics | 45 | 5 free |
| FLM-12 | Systemic Antibiotics | 12 | 1 free |
| | | 144 | 18 free |
| | | 288 | 42 free |
| | | 576 | 96 free |
| | Vitamins | 12 | 1 free |
| | | 72 | 9 free |
| | | 576 | 96 free |

Table 8-2.--Continued.

| Manufacturers | Therapeutic Class of Product | Quantity Needed to Be Purchased for "Deals" (in Units) | Deal |
|---|---|---|---|
| FLM-13 | Vitamins | 12 | 1 free |
| | | 100 | 10 free |
| FLM-14 | Systemic Antibiotics | 10 | 1 free |
| | | 100 | 12 free |
| | | 500 | 75 free |
| FLM-15 | Systemic Antibiotics | 12 | 1 free |
| | | 144 | 16 free |
| | | 10 | 2 free |
| FLM-16 | Topical Antibiotics | 12 | 1 free |
| | | 144 | 18 free |
| | | 576 | 96 free |
| | | 1,152 | 200 free |
| Pakistani Local Manufacturers | | | |
| PLM-1 | Systemic Antibacterials | 100 | 10 free |
| | Systemic Antibiotics | 12 | 1 free |
| | | 100 | 10 free |
| | | 1,000 | 150 free |
| | | 10 | 1 free |
| PLM-2 | Vitamins (different products) | | 10% extra discount |
| PLM-3 | Various Therapeutic Classes (different products) | | 11% extra discount |

Table 8-2.--Continued.

| Manufacturers | Therapeutic Class of Product | Quantity Needed to Be Purchased for "Deals" (in Units) | Deal |
|---|---|---|---|
| PLM-4 | Systemic Antibiotics | 100<br>500 | 13 free<br>75 free |
| PLM-5 | Cough and Cold | 10 | 1 free |
| PLM-6 | Vitamins | | 10% extra discount |
| PLM-7 | Topical Antibiotics | | 10% extra discount |
| PLM-8 | Systemic Antibiotics | 12<br>72 | 1 free<br>7 free |

Source: Companies data; Pakistan Chemists and Druggists Association and interviews with chemists.

of a leading foreign local manufacturer, "We wanted the chemist to stock our product and block his money. . . . We pampered the chemists." Another prominent manufacturer stated that "we wanted to fill the chemists' shops with our products so we gave liberal credit terms."

In a promotional mailing to chemists, one leading foreign local stated that the product was "a fast selling product. . . . This means a rapid turnover of your [the chemist's] investment resulting in multiple profits" and that "medical representatives would be detailing this product all over Pakistan with heavy sampling." Other manufacturers stressed "the opportunities to earn extra profits, "quick turnover," "golden opportunities," the "opportunity of earning huge profits," and so forth.

The strategy of promotional deals and liberal credit terms was fed by the growing insistence of customers for products of foreign manufacturers. According to a leading foreign local, "the chemist slowly realized the 'deals' being offered by Pakistani local manufacturers were not worthwhile, because even with wider profit margins, the products of these manufacturers were slow movers and in essence became 'dead' stock."

Advertisement in the medical newspapers.--The first advertising strategy relevant to our discussion was adopted by many foreign locals immediately after the announcement of the government's intention to abolish brand names in 1972. Advertisers such as Pfizer and Wyeth bought full-page advertisements in the medical

newspapers to present their opposition to the generic policy.[19] Their advertisements stressed, for example, the aspect of therapeutic inequivalence of generic drugs and the heavy research expenditures incurred by the multinationals "to serve humanity" which were "behind" each brand name drug. After the Generic Names Act was introduced, most leading manufacturers affixed the company name to the generic name in their advertising. Thus, advertisements for Erythrocin (a brand name) would read erythromycin-Abbott; for Terramycin, the advertisement would recommend prescribing oxytetracycline-Pfizer; for Penbritin, the advertisement would suggest the use of ampicillin-Beecham, and so forth.

Another popular strategy in the early period of the Generic Names Act was to print the brand name of the product, cross it out, and give the generic name and the manufacturer's name next to it.

According to the editors of the medical newspapers, there was no decrease in advertising by the leading foreign local manufacturers during the generic period.

## Promotion: Pakistani Local Manufacturers

Pakistani local manufacturers initially believed the compulsory use of generic names would give them an opportunity to make substantial inroads into the market shares of the foreign local manufacturers. As was discussed in Chapter V, this did not occur. While foreign locals were utilizing coping strategies, most Pakistani locals made relatively few changes in their promotional activities.

A major difference between foreign local and Pakistani local manufacturers was that the field staff of the former maintained its contacts with the medical profession, whereas that of the latter concentrated primarily on the chemists.

Generic names and company names.--Most Pakistani manufacturers thought the Generic Names Act would lead to classical price competition among generic name products. Their promotional literature in the early period (after 1972) reflected this; the only change that most leading Pakistani manufacturers made in their promotional literature was to replace the brand name with the generic name. Except for the leading Pakistani locals, the others did not feel that they had any particular advantage in promoting the company name. Compared to foreign locals, even the leading Pakistani locals, such as EPLA, Schazoo, PVP, and Hakimsons, had not been able to build a significant company reputation. However, they attempted to cultivate an image of being quality oriented.[20]

Generic prescriptions.--Most Pakistani local manufacturers were of the opinion that the chemist would assume added importance under the new dispensation, and they could thus increase sales by influencing the chemist to fill prescriptions with their products. At the same time that foreign locals were urging doctors to specify their company's name on prescriptions and attempting to persuade the chemist to fill prescriptions accordingly, Pakistani locals were trying to persuade the chemist to substitute these with their generic products.

When the issue of product quality became prominent, the effect on Pakistani locals was significant. The leading Pakistani locals took the cue of the foreign locals, stating that they, too, adhered to rigid quality control standards. The leading Pakistani manufacturers also attempted to persuade doctors to write their company name on the prescription. This strategy proved fruitless, as doctors were becoming increasingly wary of prescribing any Pakistani products. Their failure with the doctors prompted the Pakistani manufacturers to strengthen their sales efforts with chemists.

The field staff.--In their sales promotion efforts directed at chemists, Pakistani local manufacturers generally adopted two changes in the structure and/or responsibilities of the field staff: (1) reassigning medical representatives to concentrate on chemists, and (2) adding sales representatives to call on chemists. Of the 12 Pakistani local manufacturers interviewed, 10 adopted the first method. In two cases, the manufacturers decided to terminate their medical representatives and use only sales representatives. Those who shifted the prime responsibility of their medical representatives from doctors to chemists felt that this was the most appropriate strategy because they did not have the resources of foreign manufacturers to hire additional field representatives.

The reasoning of the Pakistani locals is exemplified by the statement of one leading Pakistani manufacturer: "[After the Generic Names Act] effectively the medical detailman's function was

finished," and "we moved our medical representatives to visit chemists." Another leading Pakistani local stated that "we maintained contacts with the medical profession but in a reduced manner. . . . Our sales team was disbanded, and the medical representatives took over their function." Yet another stated that "contacts with chemists became important, and most of our medical representatives were converted to sales representatives."

Consonant with this strategy of reduced emphasis on the doctor, the number of free samples provided to doctors was also reduced by most Pakistani local manufacturers.

Packaging: promotional aspects.--The most established Pakistani local manufacturers made few changes in the outward appearance of the package (other than the required change of replacing the brand name with the generic name). Some, such as EPLA, who perceived a slight advantage in doing so, made the company name prominent on the package.

More interesting was the approach taken by a number of lesser known Pakistani manufacturers. Because many Pakistanis are unable to read English, the manufacturers began imitating the package designs of the leading products of foreign manufacturers.[21]

Parke-Davis's chloramphenicol was a widely imitated product. An example was that of chloramphenicol palmitate suspension. A package with exactly the same color scheme, size, and outward appearance as the Parke-Davis product was made by Pioneer Laboratories, a lesser known Pakistani manufacturer. A Parke-Davis

representative interviewed for this research cited two other lesser known manufacturers who made products which imitated the firm's packages. A Merck, Sharpe and Dohme spokesman noted that an imitation of methyldope (brand name Aldomet) capsules was produced; they were identical in color and shape, the only difference being that instead of M.S.D. engraved on the capsule, the letters M.S.P. were used. Chemists were known to have mixed M.S.P. with M.S.D. capsules and sell them to the unsuspecting customer.

Hoechst's packaging was imitated by lesser known Pakistani manufacturers, and these imitations were passed off by chemists as a Hoechst product. One lesser known Pakistani manufacturer had a package identical to Hoechst's, with an insignia that was similar except that it used Dosaco (the name of the Pakistani firm) instead of Hoechst. Package imitations of dipyron and paracetamol coupound, both high-selling Hoechst products, were produced by Pakistani local manufacturers.

The color scheme, package, and logo for Pfizer's cough syrups, vitamins, and antibiotics were imitated.

American Cyanamid's Lederle division had many of its products imitated. Even as Lederle was attempting "visually" to differentiate its products with pictures and so forth, one lesser known Pakistani manufacturer adopted a similar carton and caricature. Instead of the Lederle mark, the name Federle was used in a deliberate attempt to deceive consumers into believing it was a Lederle product. Wellcome had problems similar to Lederle's.

A large number of Abbott's product cartons were imitated by lesser known Pakistani manufacturers. Among these was erythromycin. I.M.P. laboratories and Standard Chemical Works, both lesser known Pakistani local manufacturers, were producing cough syrup in a package with exactly the same color scheme (red with yellow print) as Abbott's. Another Pakistani local manufacturer marketed chloramphenicol with the same color scheme on the carton as Abbott used on its erythromycin, an obvious attempt to confuse people into believing it was an Abbott product.

Glaxo had a number of its products' package designs imitated. One, an analgesic, codopyrin, was produced by 18 different manufacturers with varying degrees of outward similarity to the Glaxo product.

Beecham's ampicillin, a high-selling product, was imitated both in package design and the appearance of the capsules.

Roche's tranquilizers, Valium and Librium, had imitations bearing logos of a striking resemblance to the Roche product.

In fact, all but two foreign local manufacturers interviewed mentioned that a number of their products had been imitated in packaging design. The two exceptions were Wyeth and SKF. The leading products of these firms are specialty products requiring relatively complex manufacturing skills.

Imitation packages proliferated during the generic period because the government, in its ardor to promote competition among generic products, ignored such transgressions of the Drugs Act of

1940. Public notices and warnings were circulated by some leading foreign local manufacturers without significant impact. One manufacturer summarized the viewpoint of most foreign locals: "In the opinion of our legal advisor, it would not be easy to get the courts to accept these practices as deceptions, because of the present government policy."

It was much later, in 1976, after it was found that a number of these lesser known manufacturers had inadequate facilities and were producing substandard drugs, that the government took formal action to stop imitations through the Drugs Act of 1976, which prohibited imitation packaging.

Promotional deals.--Pakistani local manufacturers also offered a number of trade incentives, such as bonus offers, case-lot discounts, and free goods offers, to push the sales of their products.

The lesser known Pakistani locals, particularly those who produced imitation packages of leading products, offered high discounts (up to 50 percent) on the maximum retail price. Some chemists accepted these deals, and very often, especially in rural areas, passed off the imitation product as being that of the manufacturer whose packaging was being imitated.

Some customers brought in the carton of the foreign manufacturer's product, but the chemist could easily refill the prescription with an imitation without the customer realizing the difference. As mentioned earlier, in selling tablets and capsules, chemists would often mix imitations with the original product.

Aside from the danger of being sold a substandard product, the customer did not gain any price advantage with these products. The maximum retail price (the usual selling price) of these imitations was kept the same as that of the imitated product, and the gains would be realized by the chemist.

Slowly, with the growing publicity regarding substandard drugs in the popular press, both doctors and customers became wary of imitations and insisted that prescriptions be filled with the products of foreign manufacturers.

Advertising in the medical newspapers.--To counteract doctors' growing association of Pakistani manufacturers with "less than quality drugs," leading Pakistani locals such as EPLA, Schazoo, and PVP began to emphasize in their advertisements that they maintained good quality control. Some of these advertisements included comments by "authorities," such as WHO representatives, who "commended" them for their manufacturing facilities.

In general, the Pakistani locals who advertised prior to the Generic Names Act continued to advertise in the medical newspapers during the generic period; with a very few exceptions, these were the leading companies among Pakistani manufacturers. The Pakistani/foreign local advertising ratios remained the same as in the pregeneric period, that is, 1:9.

## Conclusions

The hypothesis is only partially supported that the Generic Names Act would lead to a decrease in promotional effort

directed at doctors and an increase in that effort directed at chemists.

Foreign local manufacturers, in general, maintained their promotional emphasis on the doctor and influenced his prescribing practices by advising him to include the manufacturer's name in the generic description. The doctor was inclined to do this to prevent the decision on the choice of drugs from slipping into the hands of the chemists. Foreign local manufacturers also increased their promotional effort directed at chemists, using discounting schemes and increasing field staff contacts with chemists.

Pakistani local manufacturers, in general, decreased their promotional emphasis on the doctor, redirecting the efforts of their field staff toward an increased emphasis on the chemist. They, too, used discounting schemes to induce the chemist to purchase their products.

The strategy of Pakistani locals to persuade the chemist to stock their products by giving him discounts eventually proved ineffective. This was because leading foreign local manufacturers were able to impress upon doctors and eventual users that their products were of better quality. Because of this, and due to wide-spread publicity about some substandard "imitation" products, both doctors and users insisted upon products of foreign manufacturers. As a result, the chemist became more and more reluctant to stock the generic drugs of Pakistani local manufacturers.

## Footnotes--Chapter VIII

[1]This figure was cited by the Pakistan health authorities. Other estimates vary from about 3,000 to 12,000. Quick Index of Medical Preparations (QIMP) listed approximately 3,000 drugs in 1972. A. H. Qureshi, Quick Index of Medical Preparations (QIMP), no. 1 (Karachi: n.p., 1972).

[2]Qureshi, op. cit., vol. 3, 1971, pp. 64-66.

[3]The information on doctors' prescribing practices was obtained from interviews with five leading doctors in Karachi. Representatives of the PCDA and the PPMA agreed with the observations made by these professionals.

[4]"National Health Scheme," Sun, April 22, 1972.

[5]The World Health Organization considers an "acceptable" ratio to be one doctor per 1,000. "National Health Scheme," Sun, April 22, 1972.

[6]The quoted comments are extracted from conversations with a judgmental sample of five eminent doctors. No surveys, in the knowledge of this writer, have been conducted in Pakistan, as to the importance to the doctor of various sources of drug information.

Surveys conducted in the United States generally agree with the observation that the detailman is a prime source of information regarding products. See Theodore Caplow, "Market Attitudes: A Research Report From the Medical Field," Harvard Business Review 30 (November-December 1952): 105-12; Ben Gaffin and Associates, Attitudes of U.S. Physicians Toward the American Pharmaceutical Industry (Chicago, Illinois: 1959); Robert Ferber and Hugh G. Wales, The Effectiveness of Pharmaceutical Promotion (Urbana, Illinois: Bureau of Economic and Business Research, University of Illinois, 1958); Raymond A. Bauer and Lawrence H. Wortzel, "Doctor's Choice: The Physician and His Sources of Information About Drugs," Journal of Marketing Research 3 (February 1966): 40-47.

[7]Articles in the medical press are particularly influential because the popular press uses them as sources for their reporting or does follow-up stories on items reported in the medical press.

[8]The Medical Gazette, during fiscal year 1974, earned advertising revenues of Rs. 494,206. Income from subscriptions was Rs. 153. Its total income for the year was Rs. 115,693. "Balance Sheet," Medical Gazette, April 15, 1975, p. 6.

[9]This kind of criticism is not unique to Pakistan. Silverman points out that during the Kefauver Hearings one interesting disclosure was that, "in 1944 . . . the highly esteemed editor of the Journal of the American Medical Association had come out strongly in favor of generic prescribing, condemning the absurd practice of prescribing them when less expensive generic equivalents were available. Fifteen years later he came out against generic prescribing, but then he was no longer editor of the JAMA; he had become President of the Pharmaceutical Manufacturers' Association. . . ." Milton Silverman and Philip R. Lee, Pills, Profits, and Politics (Los Angeles: University of California Press, 1974), p. 144.

[10]The Physician's Desk Reference is a compilation of products offered by major companies. It is widely used in the United States, and the advertising material is essentially what the FDA has approved according to full-disclosure requirements. The advertising revenues enable the PDR to be distributed free to almost all U.S. physicians.

[11]QIMP ceased publication in 1973 after the Generic Names Act was introduced. However, in April 1973, the editor of QIMP published a supplement, "What to Prescribe Now," which listed former brand names of drugs and their "equivalent" generic names. This supplement was in great demand by doctors, who used it along with previous issues of QIMP, for prescribing purposes.

[12]For example, Entox (brand name) was listed in QIMP (1972) as a drug for "commonly occurring diarrhoeas." This drug contains dihydrostreptomycin, a potent antibiotic which can lead to irreversible diminished hearing. Besides, dihydrostreptomycin and iodohydroxyquinoline as a fixed combination compound (Entox) is considered hazardous and would not be approved for sale in the United States.

Another example is that of chloramphenicols; no warnings were given regarding its use, although the use of the drug could result in serious, even fatal, blood dyscriasis.

In fact, a review of advertisements in the medical newspapers and QIMP did not reveal a single instance of any drug product for which minimally adequate warnings regarding its use were provided.

[13]See, for instance, the chapter of Drug Promotion in Silverman, op. cit., pp. 48-80.

[14]The quoted comments were made by company representatives interviewed, regarding their promotional emphasis during the generic period. This was apparent from the advertisements during the generic period. For instance, E. Merck's advertisements stressed that "the

company behind a generic product matters when QUALITY is the first and last consideration."

Wyeth, in its advertisements, asserted "Behind every Wyeth prescription . . . over a century of reliability" and most multinational companies emphasized similar themes in their advertisements.

[15]Section 7, Drugs (Generic Names) Act (XXIV of 1972) prohibited prescribing of brand name drugs after March 31, 1973.

[16]Compared to Pakistani local manufacturers, foreign local manufacturers were quicker in providing to doctors and chemists the lists of their former brand name products with the "equivalent" generic name. Interview with PCDA representatives, February 1977.

[17]With growing concern regarding product quality, the Health Ministry also provided support for this strategy by suggesting that those doctors who were concerned could make sure that their patient received the product of the doctor's choice by specifying the manufacturer's name with the generic name. Interview with Assistant Drugs Controller, Government of Pakistan, Karachi, February 1977.

[18]Although commonly called medical representatives and sales representatives, the names of the field staff sometimes differed by company. For example, Pfizer called these employees professional sales representatives. They were divided into two teams: (1) the promotional team, essentially the same as medical representatives, as we have defined them; and (2) the marketing team, the same as sales representatives, as defined here.

[19]See, for instance, Medical News, April 20, 1972.

[20]For instance, EPLA advertised with the headline "Service to Humanity Among Quality Drugs"; Pakistan Pharmaceutical Products (PPP) emphasized in its advertisements that "our labs are meticulous about quality control."

Some lesser known Pakistani local manufacturers also followed this lead. For instance, Zafa Pharmaceutical advertised the company as "Zafa: A New Name in Quality Pharmaceuticals." Efroze had only two words in its advertisements--"Creating Confidence."

[21]These imitations were not limited to Pakistani manufacturers. A number of imported products from Italy and Poland appeared, which bore an uncanny resemblance to the products of foreign local manufacturers. For example, Beecham's ampicillin had a host of Italian imitations.

# CHAPTER IX

# SUMMARY AND RECOMMENDATIONS

## Introduction

This chapter first summarizes the findings of this research. It then outlines the major issues illustrated by the Pakistani experience, emphasizing aspects that other developing countries contemplating similar legislation may wish to consider.

## The Major Research Hypotheses

The following is a summary of the research regarding major hypotheses about market shares, pricing, product issues, and promotional policies after introduction of the Generic Names Act in Pakistan.

### Market Shares

Two major hypotheses were advanced concerning market shares.

$H_1$: The Generic Names Act would lead to a decrease in sales concentration.

$H_2$: The Generic Names Act would lead to an increase in market shares of Pakistani manufacturers.

On the basis of the information available, both hypotheses were rejected. The Generic Names Act did not lead to a decrease in sales concentration, and it did not lead to any significant increase

in market shares of Pakistani manufacturers in either the overall market or in the major therapeutic submarkets.

Pricing

The major hypothesis concerning pricing was:

$H_3$: The Generic Names Act would lead to a reduction in retail prices of drugs in Pakistan.

The data available indicate that this hypothesis cannot be accepted.

Product Issues

Three major hypotheses were put forward concerning product issues.

$H_4$: The Generic Names Act would lead to an increase in the number of Pakistani local manufacturers, some of whom would have inadequate (marginal) manufacturing facilities.

$H_5$: The Generic Names Act would lead to an increase in product offerings from the National Formulary by Pakistani local manufacturers.

$H_6$: An increase in product offerings and "marginal entrants" would increase the number of substandard drugs in the market.

The first hypothesis was not rejected, although it is indeterminate whether this increase in Pakistani local manufacturers would have occurred without the legislation.

The second hypothesis also was not rejected.

The third hypothesis was partially supported. Although government statistics indicate a decline in substandard products, these were contradicted by the number of suspensions and cancellations of licenses owing to the manufacture of substandard products. The third

hypothesis also is supported by comments from participants interviewed, with few exceptions, in government, industry and trade, and the medical profession.

### Promotional Policies

The major hypothesis forwarded concerning promotional policies was:

$H_7$: The Generic Names Act would lead to a decrease in promotional effort directed at doctors and an increase in promotional effort directed at chemists.

The hypothesis is only partially supported. Although efforts varied from one manufacturer to another, as a group, foreign local manufacturers did not decrease their efforts directed at doctors. However, the leading foreign local manufacturers increased their promotional effort directed at chemists. It was among Pakistani local manufacturers that there was the shift in emphasis as hypothesized.

## Major Issues: A Discussion

### The Introduction of Legislation

In discussing the Generic Names Act, a major consideration is the way in which the government introduced it. A primary reason for its failure to achieve the stated objectives was the uncoordinated way in which it was formulated and implemented.

The suddenness of government action, through presidential fiat (the Drug Ordinance of 1972), immediately after the health policy was proposed, took most of those affected by surprise. A more appropriate procedure would have been to hold hearings and invite industry, trade,

and medical representatives to express their viewpoints and positions.[1] Some of the problems and consequences of the legislation would have been made explicit, and consideration could have been given to certain modifications. The policy first could have been introduced in the public sector, that is, in the form of a restricted formulary of drugs to be prescribed and purchased by institutions such as government hospitals. The experiences gained could have slowly prepared industry and others for increased acceptance.

But let us assume the government was determined to introduce the legislation over any opposition. There should have been a schedule for slowly phasing in the replacement of brand names by generic names. For example, the major therapeutic submarkets are antibiotics, vitamins, and cough and cold preparations. Initiating the use of generic names for products in these submarkets might have contributed to acceptance of the policy. It also would have made both foreign and Pakistani manufacturers aware of the need to plan for an eventual full-scale adoption of generic names. As it was, neither the medical profession nor the trade was familiar with generic prescribing and dispensing.

Because of the introduction of an incomplete National Formulary, changes, modifications, additions, and deletions had to be made. The eleventh-hour appearance of the final list (only two weeks before the deadline for the change over) caused severe uncertainty among industry and trade members. Another result was the uncoordinated response by government to specific problems, such as permitting

"any excipient, binders, etc. to be used," allowing brand name drugs to be sold with generic name stickers or labels, and allowing various exceptions. Any developing country considering a National Formulary which would allow manufacturers to produce only from this list should give careful thought to its preparation and enlist the assistance of individuals with considerable expertise.

Nor should manufacture of products from a National Formulary be granted indiscriminately. Careful examination of the adequacy of both foreign and local manufacturers' facilities and of their quality control capability should be conducted before they are allowed to engage in production.

The opposition of "dominant" manufacturers to "reforms" should be expected. How to cope with strong antagonism is a more difficult issue. One way to reduce it is to plan the reform carefully, as indicated earlier, and introduce it in phases.

Reducing the "dominance" of foreign local manufacturers was a major objective of the Pakistani policy makers, and this issue is considered next.

Market Dominance

As the experience of Pakistan indicates, legislation did not reduce the "domination" of multinational pharmaceutical firms. As discussed in Chapter V, there was increased sales concentration, not only in the pharmaceutical market as a whole, but also in the major therapeutic submarkets. The sale of antibiotics, vitamins,

and cough and cold preparations continued to be the province of the foreign local manufacturers.

Legislation should not be expected to reduce this "domination." The sources, the causes, of such "domination" are more important and should be recognized. These involve the ability of foreign local manufacturers to "cope" and to "adapt" effectively to "reforms," as well as the inability of indigenous manufacturers in countries such as Pakistan to "adapt" effectively. Whereas the latter's inability is easily attributed by some to the "predatory" practices of the multinationals, the problem concerns much more than that. For example, the enthusiastic rush by Pakistani local manufacturers to produce products from the National Formulary without proper preparation led to the manufacture, by some, of substandard products. This consequence can be attributed to the "predatory practices" of foreign local manufacturers only through a considerable stretch of the imagination.

In fact, the "domination" may not necessarily be bad, as long as indigenous local manufacturers do not implement reliable manufacturing and quality control practices. It is unfortunate that the poor quality control procedures of a number of Pakistani local manufacturers undermined the confidence of doctors and consumers in the products of <u>all</u> Pakistani manufacturers. Among these were some with rigid and responsible manufacturing practices, and these were unable to make competitive inroads into market shares once public confidence was lost.

Under this situation, the leading foreign local manufacturers felt very little competitive pressure to reduce prices of their generic products.

Prices

It is not clear that prices were "high" in Pakistan at the time the generic policy was introduced. Indeed, compared to prices in other countries with health conditions similar to Pakistan's, there are some indications that the prices of leading manufacturers such as Pfizer and Glaxo were generally lower. Since the majority of products in Pakistan were sold by brand name prior to the legislation, there is no basis for comparing the price of brand name with generic products. However, it is the case that, prior to and after the legislation was enacted, several of the brand name products of foreign local manufacturers which led sales of the most frequently sold product forms were available under other brand names (under generic names after 1972) from Pakistani local manufacturers at lower prices.

Some of the transfer pricing practices of foreign firms in Pakistan and in other developing countries are questionable. Many foreign companies can "command" retail prices because of confidence in their products; a reform such as the Generic Names Act is not sufficient to control these practices. One proposed solution is that a central state organization should be responsible for the importation of active ingredients of drugs. However, this course has inherent drawbacks: maintaining supply to coincide with the requirements of various manufacturers, the range of storage facilities required for

sensitive drugs, and the lack of expertise among employees. What can be done is to monitor world market prices of raw materials and critically evaluate arguments of therapeutic or quality differences if they are forwarded as a rationale for high prices of the active ingredients.

The Pakistani experience also indicates that the government's method of abolishing brand names for drugs is an unsuccessful strategy to reduce prices. There is another way. Since retail drug prices in Pakistan must be cleared by the authorities, it can require firms to lower prices, particularly when it has proof that transfer prices of raw materials are relatively high.

Product Issues

One of the most frequently criticized aspects of pharmaceutical marketing in developing countries is the "unnecessary proliferation" of brand name products at high price levels. However, merely abolishing brand names and introducing restricted lists such as a National Formulary cannot reduce "product proliferation" or "bring down" prices. The Pakistani experience illustrates that such reforms can also lead to a "proliferation" of generic products unless other controls to prevent this are instituted. To lower prices by inducing "generic" competition, the government liberally allowed the manufacture of generic drugs from the National Formulary. This did not result in generic price competition, as hoped for, because many inadequately prepared firms were permitted to manufacture products. The subsequent marketing of some substandard drugs strengthened product

quality as a decisive element in the choice of drugs by doctors and patients.

Developing countries would do well to understand that without an effective government quality control authority to monitor and check the sale of substandard products, doctors and patients will be wary of generic products, and competition among firms will center more around quality than price competition.

Developing countries without strong government quality control inspection authorities also would be well advised to apply strong and rigid criteria before allowing firms to manufacture drugs.

But even high quality standards may not be enough: The promotion of a company as well as what it markets is an important requisite for product acceptance.

## Promotional Issues

There were some interesting consequences of Pakistan's generic policy in the promotional area. First, the strategy adopted by the leading foreign local manufacturers to maintain their promotional emphasis on the doctor was successful under the circumstances. The doctor proved amenable to firms' efforts to persuade him to include the manufacturer's name on the prescription, not only because he wanted to be certain his patient got a "quality" product, but also because it meant retaining his decision-making power.

Second, the concomitant strategy by leading foreign manufacturers of increasing promotional effort directed at chemists

successfully countered the promotional advances of Pakistani local manufacturers directed at this group.

Third, promotional efforts by leading foreign local manufacturers not only maintained customer confidence in their products but also "educated" the customer to question the reliability of drugs produced by all manufacturers, in general, and by Pakistani local manufacturers, in particular. Very few customers accepted the products of "marginal" manufacturers, and a consequence was that chemists were more "discriminatory" in the products they stocked.

Fourth, another lesson that emerged from the Pakistani experience was that even if the government mandates reforms, such as abolishing brand names, a replacement system can evolve. Both producers and consumers are likely to resort to other identification methods. In Pakistan, this was accomplished by dominant industry members inducing doctors to include the manufacturer's name on generic prescriptions; in the case of consumers, this substitution was manifested in their insistence on products identified as being manufactured by foreign firms.

## Suggestions for Developing Countries

### Pricing

To maintain prices at certain levels or to reduce them, price controls can be the most direct way of ensuring "acceptable" levels. Monitoring of the transfer prices of active ingredients is a must in order to ensure that the advantage of "tie-in" clauses requiring

affiliates to import raw materials from the parent company (or designated sources) are not being abused.

Product "Proliferation"

Concern about product "proliferation" often is expressed both in the developing and developed areas. There is a fundamental question involved here: Does the restriction of choice among drug products serve the public purpose? There is no easy answer. For the patient who does not respond to certain drug therapies, the unavailability of alternatives becomes an immediate, critical, and personal problem. On the other hand, the availability of numerous products which have "few differences" in therapeutic capacity yet high "price" differences can lead to charges that they result in "irrational prescribing," with prescriptions being written for these without regard to price considerations. If policy makers are of the latter view, then they have essentially two alternatives. The first, as mentioned earlier, is to prepare a list of products (a National Formulary), carefully planned before introduction. The second alternative, and in the opinion of this researcher the better one to adopt, is to make more effective use of the product registration procedures existing in many developing countries. Drugs should be screened on the basis of whether they offer significant price and therapeutic advantages over existing products before they are allowed to be manufactured.

FDA and WHO evaluations in addition to consultation with local pharmacological and medical experts are possible sources of information on the registration of products.

Not only product licenses but also manufacturing licenses should be awarded after a critical evaluation. It would probably be in the interest of the developing country to allow a few but well-prepared local firms to enter pharmaceutical manufacturing.

Brand Names

Abolishing brand names may not (as the Pakistani experience indicates) promote competition among "equivalent" products. If such a situation is desired, it should be sought selectively for a few products at first, such as leading drugs in the major therapeutic submarkets. Such a policy to promote competition also can be implemented initially in institutions, such as government hospitals, before being tried in the private sector. It would also be inadvisable to restrict doctors from designating their preferred manufacturer's name on the generic prescription; the decision to provide generic substitutes would then fall into the unqualified hands of the chemist, who, in most developing countries, is unfamiliar with generic names.

Promotion

Various proposals have been offered to reduce the promotional expenditures of multinational pharmaceutical firms. Among these are taxes on marketing expenses and limitations on the proportion of turnover devoted to advertising and free samples.[2] Such curtailments can only be useful if alternative sources of drug information are available, and if these alternatives are utilized by doctors. There is a strong possibility that the curtailment of promotional

expenditures, particularly on detailmen, may result in doctors' being uninformed about new products as well as current data regarding old products. Whether or not promotional expenditures are curtailed, some equivalent of the Physicians Desk Reference should be made available to all doctors.

One aspect of promotion which not only is vital but also has not been given enough emphasis in this research has to do with promotional messages through both the detailman and drug advertisements. In their drive for a competitive advantage, all manufacturers, whether foreign or local, neglect to provide information on side effects, contraindications, and precautions regarding drug usage. In the opinion of this researcher, this is an area which is in serious need of reform. Pakistan is not unique in this respect. Many other developing countries have the same problem.[3] Companies do not provide some necessary information because it is not required by law that they do so. A simple procedure to adopt would be to use the FDA-approved advertising and labelling requirements where possible for any drug products sold.

As mentioned earlier, the availability of a reference source book which includes precautions and warnings would be a useful first step in this direction.

## Epilogue

In January 1976 another drug regulating act was passed. Its passage was a de facto recognition of the deficiencies of the Generic Names Act.[4] The new law changed the mandatory requirement to

manufacture and market drugs by generic name. Only single-ingredient drugs were required to be marketed in this way. But the new legislation went a step further in making explicit the manufacturing and quality control requirements for firms involved in drug manufacture before licenses would be granted.[5] All drug manufacturers were to be scrutinized. In the first seven months after the new legislation, only 67 firms among all manufacturing units had been granted permission to continue operations.[6]

In addition, the new National Formulary became a list of registered products allowed for manufacture. A firm, if it wanted to produce a certain drug, would have to obtain approval from a registration panel appointed by the government. If approval for the product was granted, it was added to the list. Although initial applications under the 1976 act for product registration were for drugs that had been allowed under the previous National Formulary (or had been exempted), product registrations were not restricted to items listed in the previous National Formulary.

The consequences of this reform constitute a suitable area for future research.

## Footnotes--Chapter IX

[1]When this writer said as much to the Health Minister of Sind, he responded, "As you know we faced violent opposition from the dominant industry members after the policy was introduced. I don't believe that asking them to discuss it would have developed a better policy. They would have worked harder to subvert the plan." Conversation with A. W. Katpar, February 1976.

[2]Sanjaya Lall, Major Issues in Transfer of Technology to Developing Countries: A Case Study of the Pharmaceutical Industry (Geneva: United Nations, 1975), p. 53.

[3]See Competitive Problems in the Drug Industry, pt. 32 (Washington, D.C.: Government Printing Office, 1976), for the testimony of some experts regarding pharmaceutical company practices in promoting prescription drugs sold in Latin America. See also Milton Silverman, The Drugging of the Americas (Los Angeles: University of California Press, 1976).

[4]The Director-General, Health, wrote in September 1976 that "the experience over the last four years . . . necessitated complete reappraisal . . . and the Drugs (Generic Names) Act, 1972 . . . required modification to improve the situation. . . ." Ministry of Health, Drug Information Service, September 1976, p. 1.

[5]Schedules A and B of the Drugs Act, 1976, give detailed requirements of equipment, factory premises and quality control, necessary for obtaining a drug manufacturing license.

[6]Ministry of Health, Government of Pakistan, Drug Information Service, September 1976, p. 7.

# APPENDIX

Table A1.--Production of pharmaceuticals in selected countries.[a]

| | Production 1971 $ Million | Average Annual Growth Rate | |
|---|---|---|---|
| | | Percent | Period |
| A. Developed market-economy countries: Total[b] | 17,883 | | |
| Australia | 202[e] | 5.5 | 1963-70 |
| Austria | 69 | 12.3 | 1960-71 |
| Belgium | 205 | 15.8 | 1962-71 |
| Canada | 505 | 15.5 | 1963-71 |
| Denmark | 87 | 9.5 | 1960-71 |
| Finland | 40 | 10.0 | 1960-71 |
| France | 1,472 | 9.2 | 1961-71 |
| Germany, Fed. Rep. | 1,932 | 13.7 | 1960-71 |
| Ireland | 10[f] | | |
| Italy | 1,323 | 12.6 | 1960-71 |
| Japan | 2,914 | 19.0 | 1960-69 |
| Netherlands | 297 | 13.2 | 1960-71 |
| Norway | 13[e] | 9.0 | 1960-70 |
| Sweden | 107[e] | 11.5 | 1960-69 |
| Switzerland | 508 | | |
| United Kingdom | 799 | 6.5 | 1960-68 |
| United States | 7,400 | 7.3 | 1960-71 |
| B. Southern European countries: Total[b] | 899 | | |
| Greece | 53[e] | | |
| Portugal | 52 | 15.3 | 1969-71 |

Table A1.--Continued.

| | Production 1971 $ Million | Average Annual Growth Rate | |
|---|---|---|---|
| | | Percent | Period |
| Spain | 680 | 19.2 | 1967-69 |
| Turkey | 114[d] | 12.7 | 1968-70 |
| C. Developing countries and territories: Total[b] | | | |
| Argentina | 86[a] | 17.7 | 1963-70 |
| Bangladesh | 10[e] | | |
| Brazil | 471[e] | | |
| Colombia | 111[f] | | |
| Egypt | 95 | 24.4 | 1960-71 |
| India | 472[c] | 14.9 | 1947-73 |
| Indonesia | 9[e] | | |
| Iran | 37[d] | 27.8 | 1962-72 |
| Israel | 30 | 19.0 | 1963-71 |
| Korea, Rep. of | 104 | 35.5 | 1968-71 |
| Mexico | 215[d] | 14.0 | 1963-72 |
| Morocco | 14[f] | | |
| Pakistan | 63[e] | | |
| Peru | 38[h] | 14.2 | 1960-67 |
| Philippines | 40[h] | 7.6 | 1960-67 |
| Thailand | 23[f] | | |
| Tunisia | 17 | | |

Table A1.--Continued.

| | Production 1971 $ Million | Average Annual Growth Rate | |
|---|---|---|---|
| | | Percent | Period |
| Venezuela | 65 | 21.7 | 1960-67 |
| Yugoslavia | 187[d] | 11.5 | 1960-71 |
| D. Socialist countries of eastern Europe | | | |
| Czechoslovakia | 2,273[e] | 12.7 | 1968-70 |
| Hungary | 6,852 | 13.1 | 1960-71 |
| Poland | 12,504[e] | 16.4 | 1960-70 |
| Romania | 1,444[g] | 13.1 | 1966-68 |

Source: Sanjaya Lall, Major Issues in Transfer of Technology to Developing Countries: A Case Study of the Pharmaceutical Industry (Geneva: United Nations, 1975), Statistical Annex, pp. 1-3.

[a]Includes both basic and finished pharmaceutical products.

[b]The total refers to the sum of production data for the countries listed in the table under the major grouping. Note that the reference year is not identical for all countries.

[c]1973. [d]1972. [e]1970. [f]1969. [g]1968. [h]1967.

Table A2.--Products represented in retail price comparisons.

| General Group<br>Therapeutic Class | % of Total Rupee Sales (1975) | Rank of Therapeutic Class (in Rupee Sales) Within General Group | Product(s) Selected for Retail Price Comparison |
|---|---|---|---|
| 1. Alimentary Tract and Metabolism | 28.5 | | |
| 1.1 Vitamins | 15.4 | 1 | Multivitamins + minerals multivitamins; vitamin B complex + C |
| 1.2 Antidiarrhoeals | 2.6 | 2 | Kaolin-streptomycin compound |
| 1.3 Antiacids, antiflatulants, antipeptics | 2.4 | 3 | Magnesium trisilicate compound |
| 1.4 Mineral supplements | 1.5 | 5 | Sodium acid citrate |
| 2. Systemic Anti-infectives | 27.8 | | |
| 2.1 Antibiotics systemics | 24.8 | 1 | Ampicillin, oxytetra-cycline, streptomycin, chloramphenicol |
| 3. Respiratory System | 9.8 | | |
| 3.1 Cough and cold preparations | 7.5 | 1 | Codein cough syrup, promethazine cough syrup |
| 3.2 Antihistamines systemics | 1.0 | 2 | Chlorophenaramine |
| 4. Central Nervous System | 6.7 | | |
| 4.1 Analgesics | 4.1 | 1 | Dipyron, paracetamol |
| 4.2 Psycholeptics | 1.9 | 2 | Phenobarbitone, diazepam |

Table A2.--Continued.

| General Group<br>Therapeutic Class | % of Total Rupee Sales (1975) | Rank of Therapeutic Class (in Rupee Sales) Within General Group | Product(s) Selected for Retail Price Comparison |
|---|---|---|---|
| 5. Blood and Blood-Forming Organs | 4.5 | | |
| 5.1 Antianaemics | 3.2 | 1 | Ferrous sulphate + folic acid |
| 6. Genito-Urinary System & Sex Hormones | 3.4 | | |
| 6.1 Sex hormones | 1.6 | 1 | Methyltestosterone |
| 7. Sensory Organs | 3.0 | | |
| 7.1 Ophthalmologicals | 2.0 | 1 | Sulphacetamide |
| 8. Parasitology | 2.5 | | |
| 8.1 Antiparasitics | 2.5 | 1 | Piperazine; chloroquine phosphate |
| 9. Musculo-Skeletal System | 2.1 | | |
| 9.1 Antirheumatics system | 1.7 | 1 | Phenylbutazone |
| 10. Systemic Hormones | 1.7 | | |
| 10.1 Systemic corticosteroids | 1.6 | 1 | Prednisolone |

Source: Industry data made available to researcher.

Note: Two general groups are not represented in the product sample for retail price comparisons. These are Cardiovascular System (2.2% of total sales) and Dermatologicals (3.5%). Price data were not available for the therapeutic classes in these two groups.

# INTERVIEW GUIDE

The objective of the research is to determine the effects and/or consequences of the generic policy on the operations of the industry.[1] For this reason it is necessary to compare specific aspects of your company operations which existed both prior to and after the introduction of the Drugs (Generic Names) Act in 1972.

## PRODUCT ISSUES

### National Formulary

1.(a) After the National Formulary was introduced, a number of production alternatives (explain) were open to you.[2] What production alternatives did your company employ in the period 1973 to 1975 as a consequence of the adoption of a National Formulary?

(b) Did your company have any difficulties in adopting the production alternatives they chose (production, quality control, and so forth)? Please explain.

2. Did you seek exemptions under Section 13 for any of your products between 1972 and 1975 (after the introduction of the Generic Names Act)?

3. Are there any comments you would like to make regarding the adoption of the National Formulary?

Product Quality: Government Inspection

4. How would you rate the performance of the government inspection system prior to the legislation?[3]

   (a) The inspection process adequate/inadequate

   (b) The testing facilities adequate/inadequate

   (c) The drug inspectors adequate/inadequate

   Explain why. (Please cite company experiences.)

5. How would you rate the performance of the government inspection system in the post-legislation period (1973-1975)?

   (a) The inspection process adequate/inadequate

   (b) The testing facilities adequate/inadequate

   (c) The drug inspectors adequate/inadequate

   Explain why. (Please cite company experiences.)

6. How would you rate the performance of the government inspection system in the period 1972-1975 as compared to the period 1969-1972: more efficient/about the same/less efficient? Please explain.

7. Would you like to make any additional comments on the government inspection system?

Product Quality: The Manufacturers

8.(a) Were any of your products "counterfeited" between 1973 and 1975?[4]

   (b) Were any of your products "counterfeited" between 1969 and 1972? If "yes," could you please give specific examples?

9.(a) Would you say that the quantity of products counterfeited increased, decreased, or remained about the same in your company?

(b) Would you say that the quantity of products counterfeited increased, decreased, or remained about the same in other companies?

10. Would you say that the number of "forgeries" of products in the Pakistani market increased, decreased, or remained about the same in the postlegislation period (1973 to 1975) as compared to the prelegislation period (1969-1971)?[4]

11. In your judgment, did the occurrence of substandard drugs between 1973 and 1975, as compared to the period 1969-1971, increase, decrease, or remain about the same?

12. Would you like to make any additional comments regarding product quality during the period 1973 to 1975? The period prior to 1972?

PROMOTIONAL ISSUES

13. Between 1973 and 1975 were there any significant changes in the structure of your company's field staff (medical representatives, sales representatives, or their equivalent)? Please explain what these changes were. Were these in any way related to the Generic Names Act? Please explain.

14. Were there any changes in the responsibilities of the field staff (calling on doctors versus calling on chemists)?

(a) Number of doctors visited — increased/decreased/about the same

(b) Frequency of visits (to doctors) — increased/decreased/about the same

(c) Number of chemists visited — increased/decreased/about the same

(d) Frequency of visits (to chemists) — increased/decreased/about the same

(e) Any other changes? Please explain.

15.(a) In general, would you say that your company's primary detailing emphasis was directed at doctors or chemists

--during the period 1973-1975?

--prior to this period?

(b) What were the reasons for maintaining or changing your primary detailing emphases?

16.(a) What kinds of "incentives" (bonus schemes, discount schemes, and so forth) did you provide to chemists and druggists

--during the period 1973-1975?

--prior to this period?

(b) In comparing the postlegislation period (1973-1975) to the pre-legislation period (1969-1971), would you say that these "incentives" increased, decreased, or remained about the same?

17. What changes in your advertisements in the media (for example, medical newspapers) did you make specifically because of the Generic Names Act (for example, replacement of brand names by generic names, and so forth)?

18. What changes in your promotional material, other than advertisements, did you make specifically because of the Generic Names Act?

19. What changes did you make in package appearance (other than package size) specifically because of the Generic Names Act?

20. Would you say that the number of free samples to doctors increased, decreased, or remained about the same in the period 1973-1975?

21. Did direct promotional material to doctors increase, decrease, or remain about the same in the period 1973-1975?

22. In addition to what we have discussed, please give your general comments on the effects of the Generic Names Act.
    --Did it affect your company operations (in other areas)? How?
    --Did it affect industry operations? How?
    --Any other comments?

NOTES

1. This guide was used in conducting interviews with representatives of pharmaceutical firms. The information obtained was supplemented and cross-validated by primary and secondary information obtained through other sources, including government representatives, chemists, druggists, and the medical profession.

2. The alternatives were explained to the interviewee if necessary. For a discussion of the production alternatives, see p. 200.

3. Three elements of the government inspection system--the inspection process, testing facilities, and drug inspectors--were asked to be evaluated by respondents. These are explained in Chapter VII, pp. 224-229.

4. Counterfeit drugs as defined by the government refer to drugs "whose label or outer packing is an imitation of . . . another manufacturer." Forgeries refer to drugs illegally manufactured and marketed as a product of another manufacturer.

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