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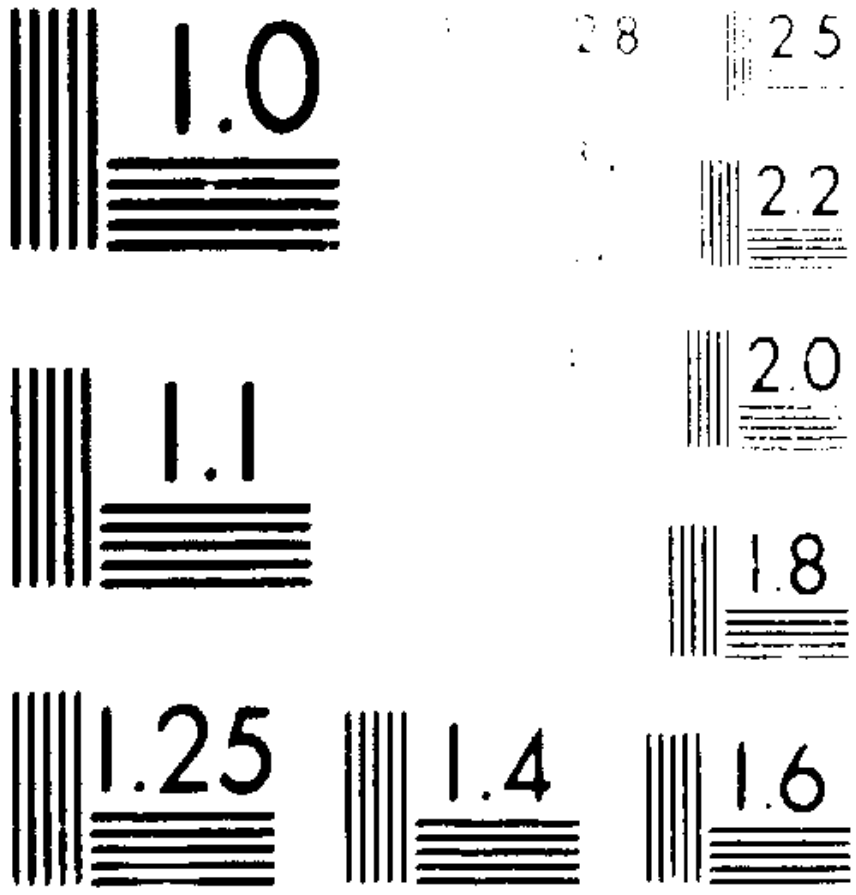
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U N I D O

Peru.

ASSISTANCE TO THE MINISTRY OF INDUSTRY, TOURISM AND INTEGRATION IN THE PHARMACEUTICAL SECTOR

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## *ACKNOWLEDGEMENTS*

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# A B S T R A C T

1. *The duties described in the terms of reference of the mission and the subsequent orientations outlined in the time of the briefing period at the headquarters have been fulfilled.*

2. *The mission was initiated with a general discussion of the project with the Vice-Minister of Industry, the Director General of Industry and the Director of Evaluation and Industrial Recording Office, the latter appointed national counterpart of the project.*

3. *Field visits to samples of pharmaceutical plants, national and foreign, drugs' quality control services, national association of pharmaceuticals manufacturers and Andean Group Countries Secretariat were undertaken under the orientation and guidance of the national counterpart.*

4. *Attendance to regular meetings and deliberations of the bisectorial advisory board on price regulation were accomplished. Periodic meetings and panel discussions with pharmaceutical manufacturers were attained.*

5. *A concise country profile unveils a low gross product per capita income and a minimum wage close to the level of starvation. High indexes of unemployment and subemployment contrast with a small percentage of families sharing almost a half of total remuneration income. This disparate distribution of wealth not only exhibits an unfavourable picture but upsets the consumption of medicaments by social strata. High rates of inflation and monetary devaluation indexes contribute to a steady decline in the purchasing power of the economically active segments of the population.*

6. *The pharmaceutical industry remains confined to formulation operations except for a dynamic national producer of essential antibiotics. Foreign pharmaceutical affiliates share a substantial segment of medicinals demand. The magnitude of the annual demand within the private sector in 1982 is expected to be about 10% lower in terms of units sold as compared to 1981.*

7. *An analysis on pharmaceuticals pricing to the consumer utilizing model-examples has been carried out. The preliminary outcome of this exercise disclosed that current price level of a number of essential drugs is equitable only to the upper strata of the middle class.*

8. *It is estimated that the national-owned segment of the pharmaceutical industry shares about 40% in number of units sold and 15% in terms of value whereas it owns 50% of the total investment.*

9. *A financial analysis of a group of pharmaceutical manufacturers representing about 40% of the annual demand was examined. The conclusions unfolded that the working capital of the industry is declining whereas its indebtness is augmentming. Meanwhile the increase in production cost mainly due to price increases in raw materials is not compensated by corresponding sales revenue.*

10. *Price indexes of pharmaceuticals for the period 1975-1980 were 100-542 whereas cost of living indexes were 100-892 and exchange rate indexes 100-761.*

11. *Historical data, past repercussions and present dilemma of price adjustments along with their social, political and economic reactions have been examined. Past pricing ordinance nevertheless unveiled an inconsistent strategy guided by arbitrary adjustments. The latter not only did not provide the industry with equitable elements for its continuity but furthermore raised unfavourable public commentaries.*

12. *A strategy to implement a congruent pricing system illustrated with corresponding methodologies has been developed withing the working group of the Pricing Office at the Ministry of Industry. Descriptive data exemplified with tables and charts have been included in the body of the report.*

13. *The suggested pricing strategy of current pharmaceuticals has been established by adopting the following criteria : establishment of a ceiling of 20% profit on investment; avoidance of price transfer on imported bulk drugs by stating a ratio between the cost of the active substance in monopreparation and total production cost by product. Furthermore the adoption of a novel concept of sales and cost breakdown by therapeutic classes allow an appraisal of concentrated and diversified risk of the manufacturers.*

14. *The establishment of a system of international price information of bulk drugs, their producers and suppliers under the Ministry of Industry will be deferred at this time. A multi-sectorial committee for price monitoring under the chairmanship of the Ministry of Health already exists. The framing of a liason between the latter and the Andean Group Countries price information system will avoid an unrequired duplication.*

*15. An existing official regulation recommending the launching of generics has been quoted in the body of this report. Otherwise it is thought at the Ministry of Industry that launching of generics is a privelege of the Ministry of Health. Therefore an enlargement of the programme of basic medicaments expanding its coverage to the private sector has been discussed in this paper as an option to the introduction of generics.*

## *CONCLUSIONS AND RECOMMENDATIONS*

1. *The uneven distribution of wealth as well as the declining purchasing power of vast segments of population contribute to provide a disadvantageous environment making it difficult to coexist the continuity and the growth of the pharmaceutical industry with the establishment of fair medicaments prices to the ultimate purchaser.*

2. *The pharmaceutical industry is burdened with a number of adverse circumstances such as reduction of working capital, increase rate of indebtness, raising of financial costs and exchange losses, increase in the cost of raw materials and reduction of sales revenue due to inadequate pricing. Meanwhile current prices of medicinals are only acceptable to the higher social strata. The data embodied in this report unveiled the dilemma of harmonizing the continuity of the manufacturers with the establishment of price levels compatible to the interest of the ultimate purchaser. It has been inferred nonetheless that the pharmaceutical industry needs periodic price adjustments as a prerequisite for survival within the framework of an inflationary economy . The consumer, particularly the middle class and other lower social strata deserve the utmost protection which it is very unlikely to be obtained at the present price level of commercial medicaments. It is therefore recommended that the existing national programme of basic medicaments (generics within the public sector to be named shortly essential me-*

*dicaments) be expanded to the private sector, an option to a swift introduction of generics aimed to provide low-priced essential medicines to the low purchasing power social strata.*

*It is recommended hence that a UNIDO mission assist the Ministry of Health to accomplish the implementation of this programme.*

3. *The enforcement of a system to regulate prices of pharma - ceuticals described in this report is strongly recommended. The basis of the suggested pricing method is to focus price increments to come out from the cost of imported bulk drugs, thus describing the main parameter of the proposed price strategy.*

4. *The recommended pricing system has its foundation in the enforcement of fair international prices of high quality bulk drugs regardless the import prices furnished by local manufacturers. The utilization of equitable import prices as yardstick for cost calculation and subsequent pricing to the consumer will represent a safeguard against overbilling and transfer prices, a matter at times verified in other areas of the developing world. Under this regime nevertheless the pricing office would accept at the beginning import prices of bulk drugs furnished by manufacturers but only until it start to receive international pricing inputs from the multi-*

*sectorial committee in charge of price monitoring.*

5. *A multi-sectorial pricing committee had been appointed . It is expected that it will provide the Ministry of Industry with regular up-to-date inputs on bulk drugs international pricing. If the output of said committee does not meet expectations shortly it is recommended that a price monitoring system in conjunction with the Andean Group Countries Price Information Systems be established.*

6. *As regards the forthcoming Programme of Essential Medicaments it is hereby recommended that when public tenders for the acquisition of medicinals are announced, pharmaceutical companies established in the country be exclusively permitted to participate.*

7. *National basic production of essential drugs must be encouraged. It is recommended that foreign companies established in formulation operations be given a reasonable period of time to engage in basic production activity. This strategy has been succesfully employed in other developing areas.*

8. *There is a sole manufacturer named SINQUISA engaged in basic production. This national producer manufactures semi-synthetic antibiotics from late intermediates being its production capacity above country requirements.*

*Although this national producer enjoys some sort of mechanism of protection it has been learned nevertheless that sporadic imports of ampicillin have been authorized in detriment of the national producer. It is recommended therefore that all imports of bulk drugs which are produced by SINQUISA be banned.*

9. *Pharmaceutical products imported in finished dosage form represent in terms of value about 10% of the annual demand. Their price control has remained under the Ministry of Health. With the aim of improving the homogenity of the new pricing system it is recommended that their regulation be transferred to the Ministry of Industry which is well equipped to implement a sound national pricing policy.*

## 1.0 INTRODUCTION AND BACKGROUND OF THE PROJECT.

The problematic of pricing of pharmaceuticals in Perú consistsof producing a scheme which simultaneously to safeguarding the interest of the ultimate purchaser allow the local pharmaceutical industry to expand and to develop so that its continuity be fully preserved.

The existing methodology of price ordinance in the pharmaceutical sector in Peru has not pursued a uniform pattern. A preliminary attempt to establish a price control strategy was enforced back to 1977. The Ministry of Industry, Tourism and Integration under whose jurisdiction the pricing of medicinals has been placed recently, submitted to UNIDO an official request of assistance endeavoring to establish a consistent pricing policy. Said policy should be framed by a number of constituents such as the transfer of UNIDO's experience in the pharmaceutical sector in other areas of the developing world being the latter one of its major inputs. The system to be adopted nevertheless should be homogeneous as well as flexible. Moreover it must take into account the perspective to which the Peruvian pharmaceutical sector has been exposed. Likewise the methodology to be utilized should measure a

*number of issues that have been identified such as as equitable protection to the national producers of essential drugs and the assurance of adequate prices of imported active substances. The latter would involve however, the establishment of an information centre of worldwide producers and suppliers of bulk drugs and intermediates.*

*Pricing of imported bulk drugs at international level, a crucial issue, maintains a close dependence on the efficiency of a quality control system at national level. It is obvious that a functional scheme of the latter will furnish a stable support to a sound pricing system. Furthermore it would provide a structure for the launching of a line of generics in the near future, an important component in the struggle to reduce to fair levels the prices of pharmaceuticals to the consumer.*

## 2.0 BRIEF COUNTRY PROFILE AND STATUS OF THE PHARMACEUTICAL INDUSTRY.

2.1 Peru is the third largest Southamerican country. It has an estimated population of 17.3 million inhabitants 30% of which are settled in rural areas. The rate of growth of the population has remained steady in the last three years at approximately 2.6 per cent per annum. The internal gross product per capita is US$ 688 for the year 1980 . The net minimum wage is S/. 45,000 equivalent to about US$ 62. It has been postulated nevertheless that in some rural areas of extreme poverty the minimum earnings of the population are considerably lower which in many instances equal zero.

The active labour force in 1980 wa illion . Out of this total 43% were subemployed whereas 16% were unemployed. In respect of monthly earnings by social strata the ranges of income were as follows· high middle class (3% of total) earns around S/. 500,000; low middle class (30% of total earns S/. 100,000 - 250,000 while 8% earn minimum wage (S/. 45,000 net/.

As regards income from remuneration, 10% of the families earn 43% of the income; 15% of the families

earn 25%; 25% of the families earn 21%, and 50% of the families only earn 11%. This statistical data reflects a disproportionate distribution of the earning by remuneration that is highly detrimental to the economy of the lowest social strata.

The unequal distribution of the wealth, the unacceptable low levels of income among vast segments of the population and the dramatic high indexes of subemployment and unemployment generate an impact of an incredible dimension whereas millions of inhabitants can not afford to acquire even the essential medicines distributed through the Government programme of basic medicaments regardless its cost to the consumer because their level of earnings is insignificant.

The country's main sources of income are constituted by agricultural and mining products, fisheries and petroleum the latter devoted mostly to domestic consumption. The inflation index which rated 44.7% in 1976 climbed to 60.8% by the end of 1980. National currency devaluation has been under constant deterioration. This decline has become more critical lately. By the end of 1980 the exchange rate was S/. 299 to the dollar. Meanwhile the rate by middle August 1982 dropped to S/. 725. It is estimated therefore that the devaluation index by

*the end of 1982 will reach a dimension above 75%.*

*This situation constitutes a heavy burden to the population because the quarterly adjustments on earnings granted to the employees, labor force and the like, do not meet the impact of the cost of living increase. Many transactions of the daily life such as a number of house rents and selling and acquisition of real estate are stipulated in hard currency at the rate of exchange of the day. It can be stated therefore that the daily life of the Peruvian family is plagued with a number of uncertainties.*

2.2 *The pharmaceutical industry has remained stagnant during the past five years. It has been stagnant, however in the sense that it is confined to local formulation activity except for a dynamic national producer of semi-synthetic antibiotics. Furthermore, a small number of medicinals are still imported in finished dosage form. Therefore, it is crucial that a mechanism to stimulate basic production of essential bulk drugs is studied.*

*Formulation of pharmaceuticals for human use is undertaken by some 70 national and foreign laboratories which produce their own lines of medicinals or handle third party manufacturing. Medicaments*

*from all industrialized countries are marketed in Peru under their own brand names. The last issue of the IMS records the names of 155 pharmaceutical companies.*

*Medicinal products reach the ultimate purchaser through several channels: 72.8% through retail outlets; 13.8% through government institutions other than basic medicaments; 11.0% through private outlets; 3.7% through the network of the basic medicaments programme and 2.2% through miscellaneous channels.*

*Although the scope of the mission is mainly circumscribed to the issue of pharmaceuticals' pricing a number of illustrative tables describing the dimension of the demand and its distribution by therapeutic categories have been appended to this chapter envisaging to provide a better understanding of the problematic of the pharmaceutical industry.*

*The total market of pharmaceuticals (ethical and O.T.C.) for the year 1981 through retail outlets (excluding basic medicaments) computed at pharmacy purchase price was the following: 140.2 million units valued US$ 173.9 million yielding an average price per unit of US$ 1.24 equivalent to Soles 605*

at the rate of exchange of 487.80. Total ethical market for the same period amounted to 120.6 million units valued US$ 160.3 million giving an average unit price of US$ 1.32 equivalent to Soles 643.89. Ethical market in 1980 amounted to 124.6 million units valued US$ 164.3 million. The growth of the demand both in units and in terms of value in hard currency for the period 1980-1981 did not hold on during the first semester of 1982. Economic recession and price increases have contributed to reduce the demand to lower levels.

Although all the components of the cost of pharmaceuticals will be analyzed elsewhere in this report it is opportune to remark that the distribution mark-up represents a burden to the ultimate purchaser: the wholesaler or distributor profit is about 19% while the retail outlet mark-up consists of 25%. Therefore the price to the public represents 25% above the factory price in as much as the distributor mark-up is charged to production cost by the local formulator.

A study of the financial achievements of the pharmaceutical industry prepared by a reliable consultants firm has been reviewed. Said study summarized a survey of thirteen companies representing about 40%

*of billings of the local pharmaceutical industry. The study which refers to the period 1975-1980, concludes that the working capital of the industry is declining while its indebtness is increasing. It ascertains that the basic problem of the profitability of the industry is mainly due to an increase in raw materials and concludes that said increase has not been compensated by corresponding sales revenue. While the average selling prices indexes of pharmaceuticals for the period 1975-1980 were 100-542 the cost of living indexes were 100-892 and the exchange rate indexes 100-761. To some extent this situation is aggravated because of the lacking of a consistent national pricing policy.*

*It is oportune to observe at this time that the national-owned segment of the industry is among the most penalized in the pricing issue. Although it shares 50% of the total investment it only shares 40-45% in number of units sold and 15% in terms of value.*

## T A B L E I

DIMENSION OF THE ANNUAL DEMAND IN THE PRIVATE SECTOR BY THERAPEUTIC CLASSES IN 1981 COMPUTED AT RETAILER PRICES

| | U.S.$ $10^6$ |
|---|---|
| Antibiotic | 42.57 |
| Anti-cough/common cold | 16.13 |
| Antihistamines | 10.54 |
| Vitamins | 10.72 |
| Corticosteroids | 10.33 |
| Antiinflammatories/Antirheumatics | 6.73 |
| Antirheumatics (nonsteroidal) | 6.50 |
| Psychotropics | 4.59 |
| Analgesics | 4.47 |
| Antiinfectives (gynecological) | 3.05 |
| Antidiarhoea | 2.98 |
| Vasodilators | 2.76 |
| Anthelmintics/Antiprotozoa | 2.10 |
| Contraceptives | 1.75 |
| Tuberculostatics | 1.48 |

Source: IMS

## T A B L E II

SIZE OF THE ANNUAL DEMAND OF ANTIMICROBIALS IN FINISHED DOSAGE FORMS IN THE PRIVATE SECTOR AT RETAILER PRICE - 1981

| | U.S.$ $10^6$ |
|---|---|
| Broad spectrum penicillins | 9.87 |
| Aminoglycosides * | 8.45 |
| Tetracyclines | 6.03 |
| Macrolides ** | 5.04 |
| Chloramphenicol | 4.23 |
| Trimethoprim/Sulfamethoxazol | 2.23 |
| Medium spectrum penicillin | 2.23 |
| Cephalosporins | 1.66 |
| Rifampicin/Rifamicin | 0.89 |
| Penicillin/Streptomycin | 0.84 |
| Other antibiotics | 0.54 |
| Streptomycin | 0.45 |
| Carbenicillin | 0.05 |

* Neomycin, kanamycin, gentamicin, amikacin, tobramycin, paromomycin

** Erythromycin, Oleandomycin, Troleandomycin

| | U.S. $ $10^6$ |
|---|---|
| Lincomycin | 1.67 |
| Gentamicin (one brand) | 1.50 |
| Erythromycin (two brands) | 1.79 |
| Ethambutol | 0.47 |
| Doxycycline (one brand) | 0.26 |

Source: IMS

## 3.0 PRICE CONTROL REGULATIONS HISTORICAL DATA AND CURRENT STATUS .

A regime of price control of medicaments was first put into effect as of 25 January 1977 through the Decree-Law N° 21782. Said decree placed its enforcement under the jurisdiction of the Ministry of Health. Price regulation of pharmaceuticals formulated locally nevertheless as well as bulk drugs produced within the country was transferred to the Ministry of Industry under the stipulation of Law N° 23407 of 28 May 1982. Price control of imported finished dosage forms, however, remained under the jurisdiction of the Ministry of Health.

Existing price control mecanishms on pharmaceuticals, group all medicinal products under four categories as follows:

Basic Medicaments. This programme is now being recasted and it will be shortly designated Programme of Essential Medicaments. They comprise a selected group of pharmaceuticals approved by the Ministry of Health consisting of a list of 238 active substances. This group also includes modified milks and dietetic products, biologicals, immunizing agents, antidotes and radiologic contrast media. This category of medicinals was instituted by Supreme Decree N° 00167-71-SA of 16 September 1971. They are obtained through the Ministry of Health by public tender, labelled under generic names and dispensed through the

*health network in the public sector. This type of medicament reaches the ultimate purchaser at a lower cost as compared to the pharmaceuticals distributed through retail outlets in the private sector. At the dawn of the launching of this programme this type of medicament was also distributed by commercial pharmacies.*

*Commercial Products. This group is composed by all medicaments marketed throughout the country and it is subdivided into two categories very much alike:*

a. *Products placed under a rule of price control ("controlados") consisting of 52 generic substances (17 pharmacological categories) represented by 623 pharmaceutical forms. These are products containing one sole active substance and they share about 30 percent of the total pharmaceutical demand.*

b. *Products arrayed under a regime of price regulation ("regulados") consisting of some 4.000 pharmaceutical presentations.*

*Both categories, the "regulados" and the "controlados" are to a large extent under the same pattern of control being the slight difference that price adjustments of the "controlados" were authorized by individual products whereas price adjustments of the "regulados" were granted*

*altogether by computing a percentage applicable to the majority of products currently marketed. The nomenclature of "regulated" and "controlled" is misleading since both expressions are much alike. It is suggested therefore, that one of said vocables be deleted.*

*Programme of Essential Medicines. This category is composed by 31 products and 39 presentations which were selected through an agreement reached between the pharmaceutical industry and the Ministry of Health on January 1981. This programme was oriented toward the provision of essential medicaments to the public sector at low cost.*

*Generics. Although their launching was authorized by Decree N° 170-67 of 27 October 1967 and confirmed by the official communication N° 02-82-SA of 4 February 1982, the latter stating that generic product, either imported in finished dosage form or formulated by local laboratories were permitted, nevertheless they have not been introduced so far.*

3.1 *Mechanism of Existing Price Control. In an inflationary economy periodical price adjustments of most commodities including pharmaceuticals are accustomed. The strategy followed in Peru for price adjustments of medicinals, however had consisted of arbitrary flat adjustments. This had been the only option because a pricing policy had not been established so far.*

*Prior to the enforcement of the Law of Industries on early 1982 an attempt to establish a rational pricing system was undertaken by the Ministry of Health. Price adjustments were computed by using a trinomial formula. The latter was only in part utilized in the previous price adjustment. In fact said formula, nevertheless, was never rigorously adopted because when the different variables were substituted by numerical coefficients a distorsion of certain dimension was detected. If the formula had been applied altogether to compute the amount of the price adjustment said distortion would have led to undesirable price increases . Therefore, when these inconsistencies were verified the outcome was to enforce an arbitrary adjustment more favourable to the ultimate purchaser.*

*In order to explain why the trinomial formula is not suitable for continued use in the computation of prospective price adjustments a brief outline of its methodology is indicated. The trinomial formula considers three different components that must be weighed:*

a. *The first component consists of foreign currency to which it is attributed a value of 40% of the total cost.*
b. *The second component describes the cost of raw materials of national origin, services, utilities, etc. 42% of the cost is attributed to this component.*
c. *The third constituent consists of 18% and its is formed by personnel, salaries, social charges, etc.*

*With the elements described above the following formula was stated.*

$$P_t = P_o \left(0.40 \frac{M_t}{M_o} + 0.42 \frac{I_t}{I_o} + 0.18 \frac{MOD}{MOD_o}\right) \quad \text{where,}$$

$P_t$ = Price in time T

$T$ = Date of price adjustment request

$P_o$ = Former price

$M_t$ = Dollar rate at the date of the adjustment

$M_o$ = Dollar rate at a former price

$I_t$ = Soles exposed to domestic inflation

$I_o$ = Soles at the date of the former price

MOD (in Soles) = Direct labor at the date of the adjustment

$MOD_o$ = Direct labor at former date

In spite of some constructive angles that the methodology supporting the trinomial formula might imply the latter presents a number of uncertainties which ought to be examined. This method does not take into account the favorable effect of the production increments, a corollary of a sound sales revenue growth. This distorsion, however, could be overcome to a lesser extent by multiplying the three terms of the trinomial formula by a coeffccient $E_o$ which would describe a percentage of production increase.

Another vulnerable element in the trinomial formula refers to the term $\frac{M_t}{M_o}$ which describes the foreign currency component. This is likewise affected not only by the raw materials but also by the fluctuation in the obtention of foreign currency such as the acquisition of equipment, replacement parts and the like as well as the profit and royalties remittances, technical assistance commitments depreciation accruals, etc. Furthermore, the term $\frac{I_t}{I_o}$ could be also liable to produce similar distorsions as regards the national currency component. In fact, a rigorous application of the trinomial

*formula as a tool of a pricing policy could turn rather favorable to the industry to a large extent, and therefore detrimental to the consumer. Furthermore the trinomial formula is likewise constant in time and hence it could lead to a disproportionate growth thus originating a sequence of further distorsions.*

## 4.0 COST OF ESSENTIAL DRUGS TO THE CONSUMER

An illustrative example with a number of essential drugs was undertaken by selecting and grouping said products by therapeutic classes. These classes comprised a variety of products utilized in the treatment of an assortment of common pathologic conditions. Said products were chosen aiming to verify their cost to the ultimate purchaser. This shallow examination intended, therefore, to provide a broad orientation towards a better understanding of the problematic of pharmaceuticals' pricing.

This example comprised forty five drugs identifiedby their generic names and subsequently grouped by therapeutic classes. A number of tables and graphs appended at the end of this chapter consists of estimated lengths of theoretical treatments on which the average price calculation was based. Said therapies ranged 7-14 days for antimicrobials and for a potent diuretic named furosemide. A length of treatment of 15 days was estimated for genito-urinary antimicrobials whereas a span of 30 days was figured for a number of chronic conditions requiring either longer or sustained therapy. In respect of the illustration on tuberculostatics it is well known that a standard therapy would require 12-18 months.

The objective of the appended tables and charts is not only to picture the cost of a short term therapy to the ultimate purchaser but to measure the price effect in the context of a framework of price regulation. This exercise with random samples to exemplify representative medicinals would provide options to choose one drug within a known therapeutic range to the advantage of the consumer.

A quick review of antimicrobials prices in terms of local currency ranged S/. 2,426 - S/. 48,596. It has been observed, however, that as regards a majority of the surveyed example the cost of therapy fluctuated between S/. 2,426 and S/. 11,620. In respect of the antihypertensive drugs their cost ranges S/. 706 - S/. 4,360 per therapy - month except for certain type of diuretic. The lowest therapy cost, nonertheless, corresponded to the therapeutic class of contraceptive which ranges S/. 900 - S/. 1,015 per menstrual cycle. One of the appended tables records the effect of the cost of certain medicaments on the monthly earnings of various social strata. The most inexpensive medicaments however were chosen for this example. The percentage of therapy cost ranges of effect on monthly earnings are hereby described:

| % | % | % |
|---|---|---|
| HIGH MIDDLE CLASS | LOW MIDDLE CLASS | MINIMUM WAGE CLASS |
| 0.13 - 0.48 | 0.20 - 2.59 | 1.50 - 5.76 |

Expect for three drugs: gentamicin, rifampin and spirin price to the public of the surveyed group of 37 drugs fluctuated, in this preliminary search between S/. 929 and S/. 7,465 which appear within equitable ranges in respect of the consumer of the average higher income bracket. It must be observed, nevertheless that cost of therapy is not circumscribed to a sole medicinal. Physicians often prescribe nonetheless, an indiscriminate number of medicaments which leads to a large disbursement in pharmaceuticals. This practice hence is detrimental to the consumer.

The establishment of fair price levels of pharmaceuticals making them accesible to the segments of average income of the productive labor forces, without jeopardizing the continuity of the pharmaceutical

*industry, should be the kernel of an equitable pricing policy. As regards the lowest social strata with lesser purchasing power it is functioning the Programme of Basic Medicaments under the auspices of the Ministry of Health. In some instancesthey are dispensed at 50% cost of the commercial products. A chart annexed at the end of this chapter describes the price to the consumer of 20 essential drugs as compared to similar products in the private sector. Further to illustrating price discrepancies between commercial preparations and basic medicaments the above stated chart disclosed that the five most expensive drugs in the analyzed group consisted of antibiotics: gentamicin, refanpin, lincomycin, ampicillin and chloramphenicol whereas the five lowest priced drugs comprised tranquilizers, cardiovascular products and tuberculostatics: diazepam, isosorbide, propanolol, reserpine and isoniazid.*

## TABLE III

### AVERAGE COST OF TREATMENT BY SELECTED THERAPEUTIC CLASSES

| Therapeutic class | Generic Name | Brand Name | Pharm Form | Mg. Potency | Dosage | No. of Days | Cost of Treatment S/ | Cost of Treatment U.S.$ |
|---|---|---|---|---|---|---|---|---|
| Corticosteroids | Dexamethasone | Decadron | Tablet | 0.5 | u.i.d. | 30 | 929 | 1.28 |
| | Prednisone | Meticorten | Tablet | 5 | u.i.d. | 30 | 2,029 | 2.80 |
| | Betamethasone | Betnelan | Tablet | 0.5 | u.i.d. | 30 | 3,287 | 4.53 |
| | Triamcinolone | Kenacort | Tablet | 4 | u.i.d. | 30 | 3,750 | 5.17 |
| Antimicrobials | Doxycycline | Vibramycin | Caps. | 100 | u.i.d. | 6 | 2,426 | 3.35 |
| | Oxytetracycline | Terramycin | Caps. | 250 | q.i.d. | 10 | 2,700 | 3.72 |
| | *Ampicillin* | *Binotal* | Caps. | 250 | q.i.d | 10 | 4,723 | 6.52 |
| | Trimethoprim/Sulfa. | Bactrim | Tablet | 80/400 | q.i.d. | 10 | 5,250 | 7.24 |
| | Erythromycin | Pantomycin | Caps. | 250 | q.i.d. | 10 | 6,220 | 8.58 |
| | Lincomycin | Lincocin | Caps. | 500 | t.i.d. | 10 | 9,045 | 12.48 |
| | Cholramphenicol | Chloromycetin | Caps. | 250 | t.i.d. | 14 | 11,620 | 16.03 |
| | Gentamycin | Gentalyn | Amp. | 80 | t.i.d. | 10 | 48,596 | 67.04 |
| Antihypertensives/ Diuretics | Ethacrynicacid | Edecain | Tablet | 50 | b.i.d. | 10 | 364 | 0.52 |
| | Reserpine | Serpasol | Tablet | 0.25 | b.i.d. | 30 | 706 | 0.97 |
| | Hydrchlorothiazide | Diclotride | Tablet | 50 | u.i.d. | 30 | 1,000 | 1.38 |
| | Furosemide | Lasix | Tablet | 40 | t.i.d. | 10 | 2,301 | 3.17 |
| | Clonidine | Catapresan | Tablet | 0.30 | u.i.d. | 30 | 2,740 | 3.78 |
| | Methyldopa | Aldomet | Tablet | 250 | b.i.d. | 30 | 4,360 | 6.02 |
| | Spirinolactone | Aldactone | Tablet | 100 | b.i.d. | 30 | 13,092 | 18.06 |
| Cardiovasculars | Propanolol | Inderal | Tablet | 10 | q.i.d. | 30 | 2,592 | 3.58 |
| | Isosorbide | Isorbide | Tablet | 10 | q.i.d. | 30 | 2,988 | 4.12 |
| | Pentaerithritol | Peritrate | Tablet | 80 | b.i.d. | 30 | 3,201 | 4.42 |

Rate of Exchange 7 Aug. 82 S/ 724.89.

## TABLE IV

## AVERAGE COST OF TRATMENT BY SELECTED THERAPEUTIC CLASSES

| Therapeutic Class | Generic Name | Brand Name | Pharm Form | Mg. Potency | Dosage | No. of Days | Cost of Treatment S/ | Cost of Treatment U.S. $ |
|---|---|---|---|---|---|---|---|---|
| Tuberculostatics | Isoniazid | Nydiazid | Tablet | 100 | t.i.d. | 30 | 679 | 0.94 |
| | Ethambutol | Myambutol | Tablet | 200 | q.i.d. | 30 | 3,128 | 4.32 |
| | Rifampin | Rimactan | Caps. | 300 | b.i.d. | 30 | 30,112 | 41.54 |
| Antiinflammatories (Nonsteroidal) | Indomethacin | Indocid | Caps. | 25 | t.i.d. | 7 | 816 | 1.13 |
| | Phenylbutazons | Tanderil | Dragee | 100 | q.i.d. | 7 | 1,577 | 2.18 |
| Genito Urinary Antiinfectives | Meth. Mandelate | Mandelamine | Dragee | 500 | q.i.d. | 15 | 2,032 | 2.80 |
| | Nalidixic Acid | Wintomylon | Tablet | 500 | q.i.d. | 15 | 7,465 | 10.30 |
| Antihistamines | Chlorpheniramine | Chlortrimetron | Tablet | 4 | b.i.d. | 30 | 747 | 1.03 |
| | Promethazine | Phenergan | Dragee | 25 | b.i.d. | 30 | 1,575 | 2.17 |
| | d--chlorpehniramine | Polaramine | Tablet | 2 | q.i.d. | 30 | 2,130 | 2.94 |
| Tranquilizers | Chlordiazepoxide | Librium | Dragee | 5 | b.i.d. | 30 | 1,418 | 1.96 |
| | Diazepam | Valium | Tablet | 5 | b.i.d. | 30 | 1,581 | 2.18 |
| | Flupehnazine | Anatensol | Tablet | 2 | b.i.d. | 30 | 2,098 | 2.89 |
| Contraceptives | Norethindrome/ Ethynylestradiol | Loestrin 1/20 | Tablet | 1 | 1 cycle | 28 | 800 | 1.10 |
| | Progestagens | Ovulen | Tablet | 1 | 1 cycle | 21 | 1,015 | 1.40 |
| | Linestrenol/ Mestranol | Lindiol-E | Tablet | 25 | 1 cycle | 22 | 1,106 | 1.53 |
| Vitamins | Vitamin C | Redoxon | Tablet | 500 | u.i.d. | 30 | 1,141 | 1.57 |
| | Vitamin - Min. | Teragran | Tablet | - | u.i.d. | 30 | 1,459 | 2.01 |
| | Vitamin - Iron | Hemagran | Tablet | - | u.i.d. | 30 | 2,409 | 3.32 |

Rate of exchange 7 Aug. 82 S/ 724.89.

# TABLE V

## EFFECT ON THE MONTHLY EARNINGS OF ONE TREATMENT-MONTH WITH SELECTED DRUGS

| | SOCIAL STRATA | | |
|---|---|---|---|
| | High Middle Class | Low Middle Class | Minimum Wage Cl |
| Lowest Priced Drug ** | Monthly Earnings % | Monthly Earnings % | Monthly Earnings % |
| Corticosteroid | 0.18 | 0.37 - 0.92 | 2.07 |
| Antimicrobial | 0.48 | 0.24 - 0.97 | 5.39 |
| Antihypertensive | 0.14 | 0.28 - 0.70 | 1.56 |
| Cardiovascular | 0.51 | 1.03 - 2.59 | 5.76 |
| Tuberculostatic | 0.13 | 0.27 - 0.67 | 1.50 |
| Anti-inflammatory (Nonsteroidal) | 0.16 | 0.32 - 0.81 | 1.81 |
| Genitourinary Anti-Infective | 0.40 | 0.20 - 0.81 | 4.51 |
| Antihistamine | 0.14 | 0.29 - 0.74 | 1.66 |
| Tranquilizer | 0.28 | 0.56 - 1.41 | 3.15 |
| Contraceptive | 0.16 | 0.32 - 0.80 | 1.77 |
| Vitamin | 0.22 | 0.45 - 1.14 | 2.53 |

* Average Monthly Income

High middle class S/. 500,000
Low middle class S/. 250,000 - 100,000
Minimum wage (net) S/. 45,000

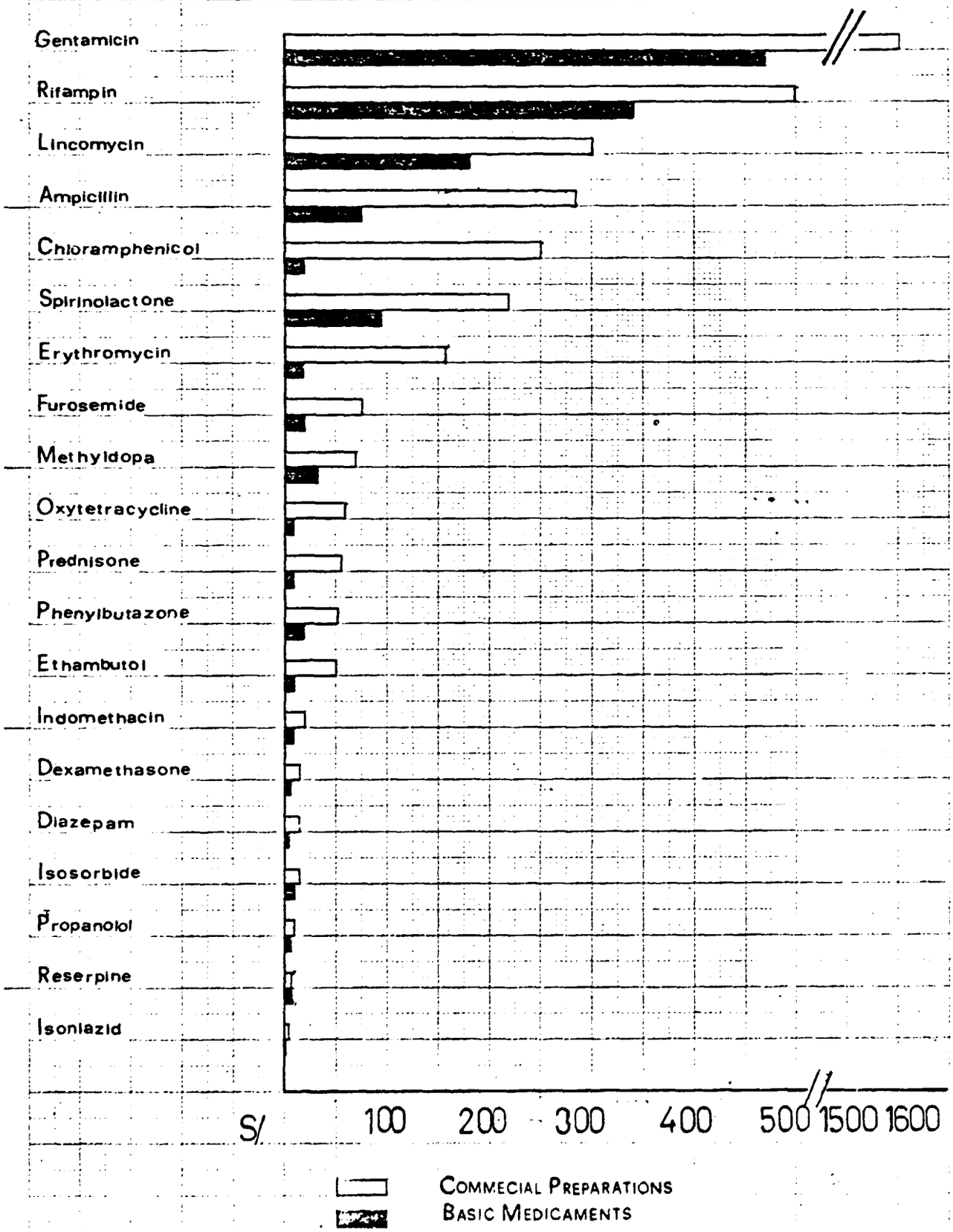
** From selected therapeutic classes.

# CHART 1

## COST OF SELECTED MEDICAMENTS TO THE CONSUMER

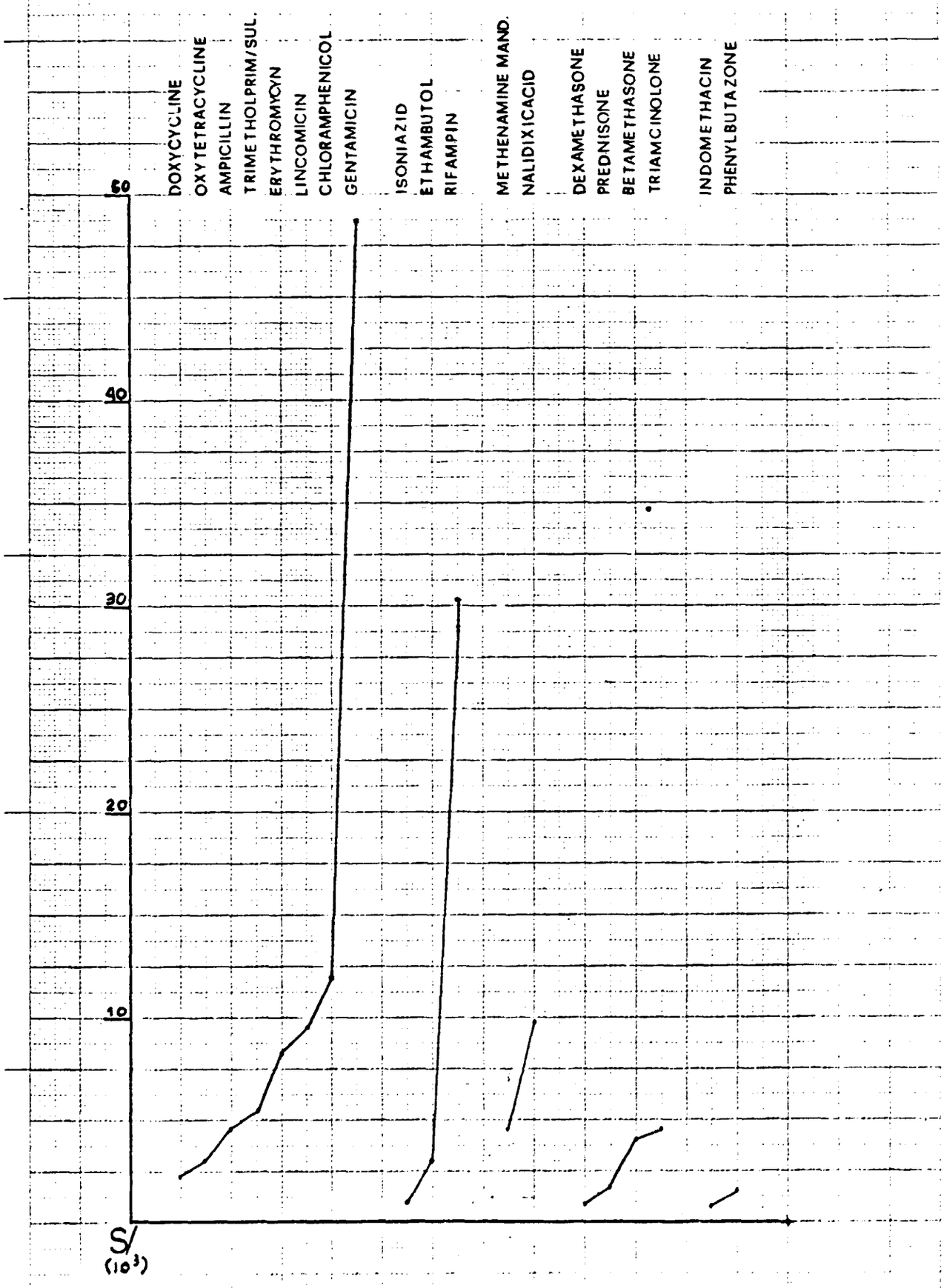
## COMMERCIAL PREPARATIONS VERSUS BASIC MEDICAMENTS

## (PER TABLET, CAPSULE OR AMPUL)



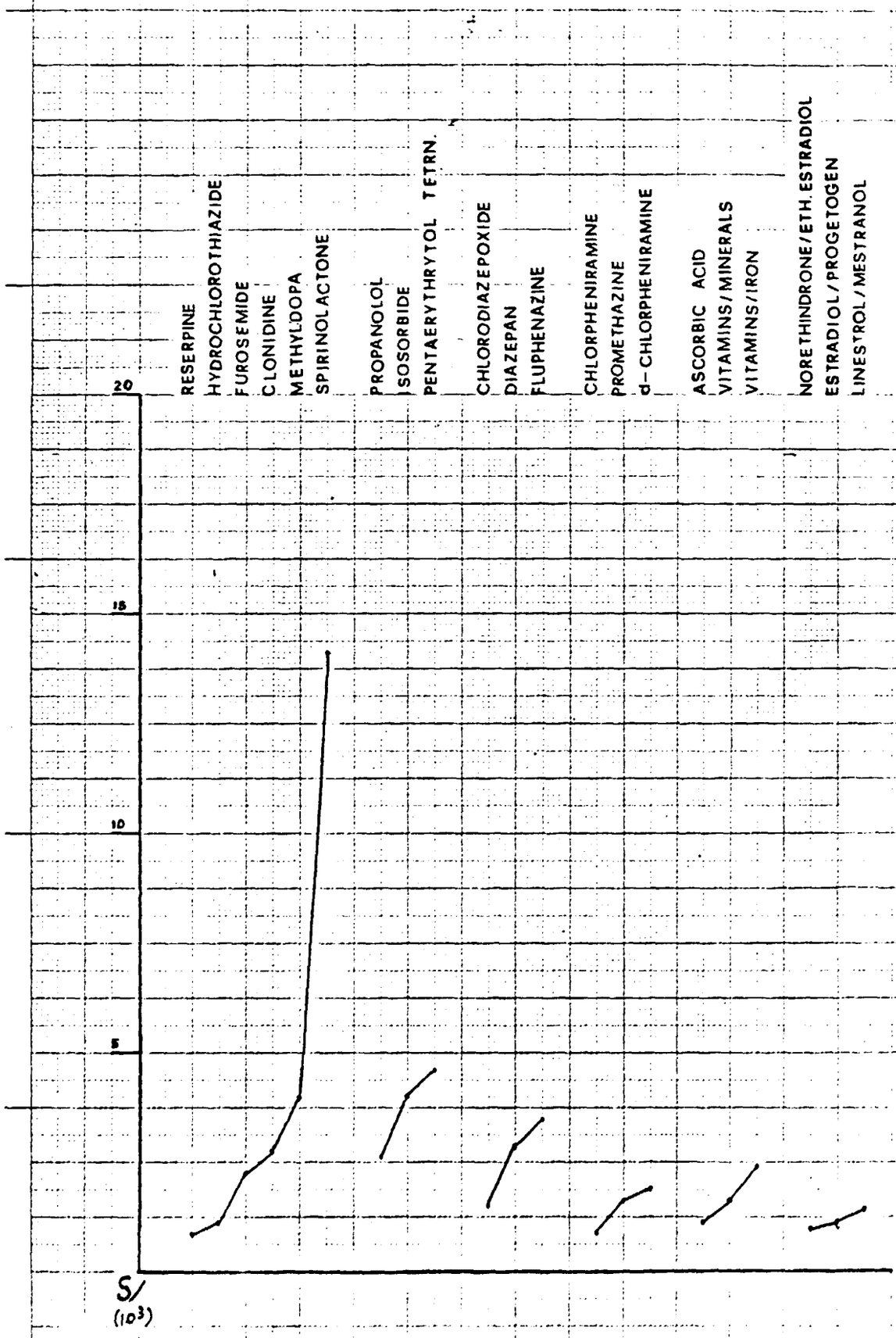
## CHART 2

## COST OF TREATMENT-MONTH WITH ESSENTIAL DRUGS (PART ONE)



# CHART 3

## COST OF TREATMENT-MONTH WITH ESSENTIAL DRUGS (PART TWO)



## 5.0 TOWARDS THE ESTABLISHMENT OF A CONSONANT PRICING POLICY.

### 5.1 General Background.

Within the framework of an inflationary economy it can not be expected stable pricing levels as regards a majority of commodities including those constituting the primary needs. Therefore, pharmaceuticals and foodstuffs as well must take in the impact of a changeable pricing situation. The perspective of the pricing issue, nevertheless, is aggravated when the inflation indexes become close or exceed 75-80% per annum as it occurs in Peru.

As it has been stated elsewhere in this paper pricing mechanisms of pharmaceuticals in addition to be flexible must be viewed by considering two essential parameters: the safe - guarding of the consumer and the assurance of continuity of the pharmaceutical industry. These two concepts at times divergent can be coupled within the scheme of a rational pricing system. It must be noted, however, that the medicaments' needs of the bottom social strata of the populace with insignificant or no income whatsoever should be an obligation of the state within the national health care scheme and , therefore, be supported by the health and welfare budgets.

Sporadic albeit arbitrary price adjustments had been conceded to the pharmaceutical industry since 1978. Although said arrangements have assisted the latter to overcome in part the effect of the inflation and of the monetary devaluation

*on operating costs, they have produced, nevertheless a large number of price distorsions. Whereas prices of a number of medicaments were granted unrealistic adjustments, being said increments far below the national price and inflation indexes, prices of other products were left submerged for periods of time.*

*The above stated distorsions produced a reduction in sales revenue to the industry. Meanwhile all the components of the production cost continued to increase. Likewise the shortage of a steady cash flow led to increase the need of outside financial resources. The industry, therefore has been strongly hit by high interest rates on loans. It must be observed that prices of all other cost components in the formulation operations such as raw materials of national origin, packing materials, utilities and the like are not price controlled. Therefore, the establishment of an equilibrium which is fair to the industry ought to be unlikable to the consumer at least in its early stage of implementation. A long range pricing policy to be adopted should always be flexible and it must preserve the interests of the ultimate purchaser.*

*The dynamics of the establishment of a price control system must be oriented towards two categories of products: price regulation of new pharmaceuticals to be lauched in the market, and price adjustment of current medicaments. Different methodologies that will be applicable will go next.*

5.2 *Methodology to Determine Prices of New Products.*

*The general guidelines and the procedure to establish prices to the consumer of new medicaments and/or new presentations of products currently marketed designed within the work group were approved by consensus by the Ministries of Industry and of Health Joint Advisory Board on Price Regulations of pharmaceuticals. Said guidelines define the two groups named above and likewise describe the requirements and the components that must be analyzed to establish fair prices to the ultimate purchaser.*

*The office in charge of pricing of pharmaceuticals at the Ministry of Industry will undertake two types of analyses:*

*i. Examination of the cost structure by product, or*

*ii. Verification of a statistical cost analysis of similar products.*

*In respect to caption i) the manufacturer will be requested to submit annually all pertinent data that will allow the Pricing Office to establish factors linking the percentage ratio between the direct cost plus labor ("costo primo") and the aggregate of the following components: plant overhead, administrative overhead, manufacturing profit and retailer mark-up. Furthermore, the manufacturer will be requested to provide the following additional data:*

*1. Analysis of manufacturing expenses: historical and projected. Projected direct cost plus labor.*

2. *Analysis of administrative expenses and projection of administrative cost.*

3. *Exhaustive data on investment and profit from operation. The latter shall reflect a maximum 20% net profit on investment as per the closing of previous year financial statements.*

*Based on the memoranda provided by the manufacturers as explained above, the following formula has been developed by taking into account the manufacturer's component direct cost plus labor:*

$P = K_o \cdot CP$, *where*

*P = Price to the public to be enforced*

*CP = Direct cost plus labor by presentation*

$K_o$ *= Manufacturer's factor or coefficient ( Manufacturing expenses divided by direct cost plus labor).*

*Likewise the manufacturers will be requested to provide the Pricing Office with an analysis of the consumption of raw materials and miscellaneous materials plus direct labor, together with each new product price application request.*

*In respect to the methodology of the system of statistical analysis cost by equivalent similar products, the manufacturers will be requested to submit a listing of similar products currently marketed, provided that said similar products contain identical active substances. The statistical analysis of similar products will be carried out by a method which consists of the following:*

*a) A range of a number of prices in local currency taking into account the following components:*

i. Lowest price to retailers

ii. Average price of similar products

iii. Average cost per treatment

iv. Weighed average of cost of treatment of similar products.

v. Average of distribution of cost of treatment to 90% probability.

b) Class identification, symbolized (x); class weighed average symbolized ($\bar{x}$).

c) Frequency, symbolized (f) which could be defined as the limit of ranges of prices to the retailer of similar products within a known range.

d) Columns xf, $x-\bar{x}$, $(x-\bar{x})^2$, and $f(x-\bar{x})^2$ represent arithmetic operations of known quantities.

e) n = number of classes

f) s = varianza

g) t = probability

h) $L_s$ = upper limit

i) $L_i$ = lower limit

j) 0.90 = 90% probability (arbitrary)

k) 1.34 = arbitrary constant.

Probability multiplied by the deflection mean will provide the ranges of maximum and minimum selling prices to be established. TableVI in the following page summarizes an example of this methodology. The lowest price resulting from the analysis of both methods will be adopted to the product whose price approval

*has been requested. In the event that no similar products were in the market the method of analysis by cost structure would be employed.*

## TABLE VI

## EXAMPLE OF METHODOLOGY TO DETERMINE PRICES OF NEW PRODUCTS
## VERIFICATION OF STATISTICAL COST ANALYSIS OF SIMILAR PRODUCTS

| RANGE | CLASS $x$ | FREQUENCY $f$ | $xf$ | $(x-\bar{x})$ | $(x-\bar{x})^2$ | $f(x-\bar{x})^2$ |
|---|---|---|---|---|---|---|
| 0-1000 | 500 | 1 | 500 | - 2,062 | 4,251,844 | 4,251,844 |
| 1001-2000 | 1500 | 9 | 13,500 | - 1,062 | 1,127,844 | 10,150,596 |
| 2001-3000 | 2500 | 5 | 12,500 | -62 | 3,844 | 19,220 |
| 3001-4000 | 3500 | 0 | 0 | 938 | 879,844 | 0 |
| 4001-5000 | 4500 | 2 | 9,000 | 1,938 | 3,755,844 | 7,511,688 |
| 5001-6000 | 5500 | 1 | 5,500 | - 2,938 | 8,631,844 | 8,562,844 |
| | | 16 | 41,000 | | | 30,562,192 |

$$\bar{x} = \sum_{xf=1}^{xf=5}$$

$$\bar{x} = \frac{xf}{n} \qquad \bar{x} = \frac{41000}{16} = 2,562 \qquad S = \frac{\sqrt{f(x-\bar{x})^2}}{n} = \frac{\sqrt{30,562,192}}{16} = 1,382.14$$

$$90\%\ t = 0.90\ \frac{S}{\sqrt{n-1}} = \frac{1,382.14}{\sqrt{15}} = \frac{1,382.14}{3.8728} = 356.80 \qquad t\ 0.90 = 356.80 \quad 1.34 = \pm\ 478.22$$

DEFLECTION MEAN = $\pm$ 478, THEREFORE,

$L_s$ = 2,562 + 478 = 3,040

$L_I$ = 2,562 - 478 = 2,084

5.3 *Strategy to Adjust Prices of Current Pharmaceuticals.*

*The selection of the methodology to establish selling prices was based on the following criteria:*

*i. Establishment of a plateau of 20% profit on investment*

*ii. Development of a strategy to control transfer prices of imported active substances by figuring a ratio between the cost of the active substance in mono-preparations versus total production cost by product.*

*iii. Adoption of a novel concept of identification by therapeutic classes within three major groups to arrange manufacturers by concentrated or diversified risk.*

*Based on the above stated criteria the line of pharmaceutical products by manufacturer will be placed in three different groups: mono-preparations*, other ethicals and O.T.C. products. The mono-preparations group would be divided into five sub-classes: antibiotics, corticosteroids, antihistamines, psycholeptics and antihypertensives/diuretics.*

*The former three sub-classes were chosen considering their impact in the market demand and in the operations of the manufacturers whereas the latter three were selected because of their social impact. Summing up, the effect of the mono-preparations in the*

---

* *Mono-prepartions are described as products containing one sole active substance.*

*manufacturers' operations will assist their classification into companies with concentrated or diversified risk.*

*In order to utilize this methodology the manufacturer will be required to furnish the following data as regards each and all the classes and sub-classes described above:*

1. *Aggregate of units sold (current Jan.-Aug. + projected 4 months)*
2. *Unit price by presentation*
3. *Sales revenue by product*
4. *Sales revenue by class*
5. *Percentage contribution by class*
6. *Projection of manufacturer's production cost (breakdown)*
   a. *Raw material (active substance)*
   b. *Labor*
   c. *Plant overhead*
   d. *Administrative overhead*
   e. *Selling expenses*
   f. *Financial charges*

*In respect of the cost of imported active substances the Pricing Office will consider the lowest price recorded at the Board of Raw Materials (Comisión de Insumos) when data is received regardless the facts furnished by the manufacturer.*

*An illustration of a preliminary sketch of this methodology is*

described in Chart 4 whereas Chart 5 pictures in greater detail a further descriptive stage of the mechanisms of this pricing system.

As regards the lower shaded segment of column $I_A$ it describes projected cost minus the upper shaded segment which identifies the active substance. Its computation will allow the Pricing Office to measure the impact of the mono-preparations cost versus the manufacturers' projected revenue thus providing an indicator to come out to a price increment by therapeutic class.

The manufacturer's projected cost calculation being examined for a price adjustment will submit a cost breakdown of imported active substances and its ratio versus other cost components. Thus in the upper shaded segments $I'_{A...E}$ will be compared to $I_P$ (total manufactures revenue) therefore establishing an arithmetic connection between the cost effect of the active substance of each and every mono-preparation and manufacturer's total projected revenue. The value of the classes F and G (other ethicals and O.T.C.) will be computed by difference.

The following figures will assist a better understanding of the sketched pricing methodology. As regards the analysis at manufacturer's level, it has been stated that $I_o$ equals total revenue of manufactuerr which is equivalent to projected sales volume at current prices. Furthermore,
$I_o = I'_o + I''_o + I'''_o + ..... I^n_o$ where, $I'_o$, $I''_o$, $I'''_o$, $I^n_o$ illustrate revenue at current prices by therapeutic classes (mono-preparations, other ethicals and O.T.C.).

$I_p$ equals revenue comprising total projected cost plus profits applicable to a production volume identical to projected sales. Moreover, being

$I_p = I'_p + I''_p + I'''_p + \ldots I_p^n$ where, $I'_p$ , $I''_p$ , $I'''_p$ .... $I_p^n$ describe revenue by therapeutic class, i.e., mono-preparations, other ethicals and O.T.C. The latter are reckoned as follows:

$I'_p = K_o\, mp$,

$I''_p = K_o\, mp_{''}$

$I'''_p = K_o\, mp_{'''}$ where, $K_o = \frac{I_p}{m_p}$ being,

MP= Raw material at manufacturer level

mp= Raw material by mono-preparation

Revenue for other ethicals as already stated will be calculated by difference:

$I_p^n = I_p - (I'_p + I''_p + I'''_p + \ldots\ldots n)$ therefore the resulting increment would be:

By individual manufacturer, $I = \frac{I_p}{I_o}$

By therapeutic class,

$$i = \frac{I'_p}{I'_o}\ ,\quad i_{''} = \frac{I''_p}{I''_o}\ ,\quad i_{''} \frac{I'''_p}{I'''_o}\ ,\quad \ldots\ldots\ i_n = \frac{I_n}{I_o^n}$$

In the analysis of calculation of increments tables of prices' increments by manufacturer and by therapeutic classes will be arranged. By statistical analysis two components will be identified:

a. The degree in frequency of prices' increment

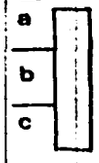
b. The concentration of increment's frequency.

If the frequencies are concentrated (sharp Gauss curve) the average of price frequency distribution will be verified and therefore the resulting increment will be applied to the whole pharmaceutical industry. On the contrary, if price frequencies are not concentrated (flat Gauss curve) increments will be granted by individual manufacturer. Numerical examples of this methodology have been described in Table VII and Table IX, placed at the end of this Chapter.

The above described strategy had foreseen to implement a coefficient system applicable to the whole universe of the Peruvian pharmaceutical formulators. However, when sample cases were tested it occurred that broad asymetries were disclosed. Said inconsistencies were due to two main components: first, the data furnished by a number of manufacturers was not only disperse but incomplete, and second, the uneven price adjustments in the past. Both elements will only be leveled off with time. In as much as the chosen methodology is consistent it will be enforced by individual manufacturer.

# CHART 4
## PRELIMINARY METHODOLOGY

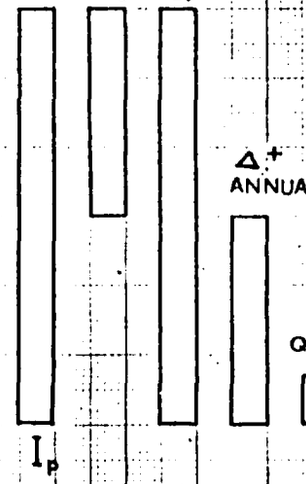
| THERAPEUTIC CLASS | UNITS SALES VOLUME | CURRENT UNIT PRICE | REVENUE* BY PRODUCT | REVENUE* BY CLASS |
|---|---|---|---|---|
| A | $Q_1$ | $P_1$ | $I_1$ | $I_A$ |
| B | $Q_2$ | $P_2$ | $I_2$ | |
| · | $Q_3$ | $P_3$ | $I_3$ | $I_B$ |
| · | · | · | · | |
| n | $Q_n$ | $P_n$ | $I_n$ | $I_N$ |
| | | | $I_o$ | |




AT MANUFACTURER LEVEL $I_o$ $I_p$

RAW MATERIALS
LABOR
PLANT OVERHEAD
ADMN. OVERHEAD
SELLING EXPENSES
FINANCIAL CHARGES

PROFIT ON INVESTMENT 20%




| MANUFACTURES (TOTAL) | |
|---|---|
| name | % Δ+ |
| X | M |
| Y | |
| Z | m % |

| MANUFACTURES WITH CONCENTRATED RISK | |
|---|---|
| name | % sales Δ |
| class A | M |
| class B | |
| class M | m % |

GENERAL INCREMENTS

MAXIMUM WEIGHED AVERAGE $\bar{X} + G$

– ANAVERAGE CURVE AND STANDARD DEFLECTION WITH MAXIMUM LIMITS WILL BE ESTABLISHED

CLASS "A"

| | | | | |
|---|---|---|---|---|
| $E_1$ | 0.80 | 8 % | 0.37 | 2.96 |
| $E_2$ | 0.75 | 7 % | 0.34 | 2.38 |
| $E_3$ | 0.60 | 6 % | 0.29 | 1.74 |
| | 2.15 | | 1.00 | 7.08 |

PRICE ADJUSTEMENTS TO MANUFACTURERS:
a. with diverified risk, Gauss curve
b. with concentrated risk, MAX 7.08 %

80 % OF PRODUCTS REQUIRE 8 % INCR.
75 % OF PRODUCTS REQUIRE 7 % INCR.
60 % OF PRODUCTS REQUIRE 6 % INCR.

* AT CURRENT PRICES

# CHART 5

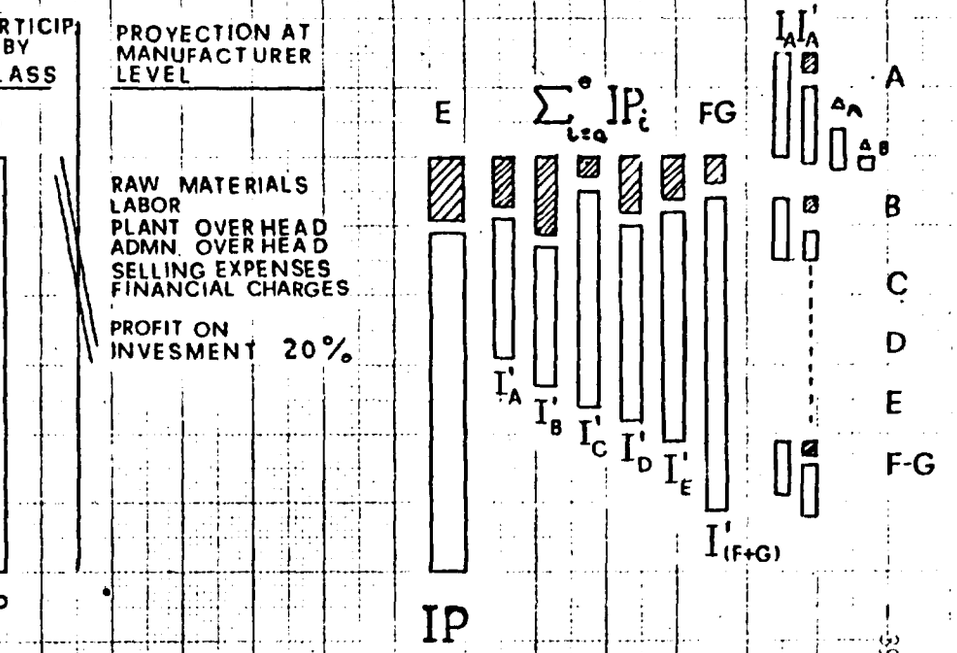
## METHODOLOGY TO CALCULATE PRICES' INCREMENTS

| THERAPEUTIC CLASS | * UNITS SALES VOLUME | CURRENT UNIT PRICE | REVENUE BY PRODUCT | REVENUE BY CLASS | PARTICIP. BY CLASS % |
|---|---|---|---|---|---|
| I. MONO-PREPARATIONS | | | | | |
| • ANTIBIOTICS | $Q_{1/n}$ | $P_{1/n}$ | $I_{1/n}$ | $\Sigma I_A$ | a |
| • ANTIHISTAMINES | $Q_{1/n}$ | $P_{1/n}$ | $I_{1/n}$ | $\Sigma I_B$ | b |
| • CORTICOSTEROIDS | $Q_{1/n}$ | $P_{1/n}$ | $I_{1/n}$ | $\Sigma I_C$ | c |
| • PSYCHOLEPTICS | $Q_{1/n}$ | $P_{1/n}$ | $I_{1/n}$ | $\Sigma I_D$ | d |
| • ANTIHYPERTENSIVES/DIURETICS | $Q_{1/n}$ | $P_{1/n}$ | $I_{1/n}$ | $\Sigma I_E$ | e |
| II. OTHER ETHICALS | $Q_{1/n}$ | $P_{1/n}$ | $I_{1/n}$ | $\Sigma I_F$ | f |
| III. O.T.C. | $Q_{1/n}$ | $P_{1/n}$ | $I_{1/n}$ | $\Sigma I_G$ | g |
| | | | | $I_O$ | 100 |

PROYECTION AT MANUFACTURER LEVEL

RAW MATERIALS
LABOR
PLANT OVERHEAD
ADMN. OVERHEAD
SELLING EXPENSES
FINANCIAL CHARGES

PROFIT ON INVESMENT 20%




see chart 6 for explanation of symbols

# CHART 6

## EXPLANATION OF SYMBOLS ON CHART No. 5

$\sum_{i=a}^{e}$ = AGGREGATE OF PROJECTIONS OF SALES REVENUE OF EACH OF THE MONO-PRERARATIONS

$\sum I_{A..6}$ = AGGREGATE OF VALUES BY CLASSES

$IP$ = PROJECTED REVENUE

$I$ = REVENUE

$I_o$ = REVENUE BY CLASS

$I'_A$ = PROJECTED REVENUE BY CLASS

$I_i$ = REVENUE BY MONO-PREPAPATIONS

$I_{(F+6)}$ = AGGREGATE PROJECTED REVENUE OF OTHER ETHICALS AND O.T.C.

$E$ = TOTAL MANUFACTURERS

$\Delta$ = INCREMENT

$1/m$ = 1.... m

* TWELVE MONTHS (8 ACTUAL PLUS 4 PROJECTED)

LENGTH AND WIDTH OF SHADED COLUMNS ARE ARBITRARY

# TABLE VII

## NUMERICAL EXAMPLE OF PRICING METHODOLOGY ( PART 1 )

### SALES VALUE AT CURRENT PRICES

| THERAPEUTIC CLASS | 1981 (S/.) TOTAL UNITS ($10^3$) | SALES REVENUE UNIT VALUE | SALES REVENUE TOTAL VALUE ($10^3$) | % | NAME | RAW MATERIAL (US$)[4] SUBSTANCE F.O.B. VALUE (per kg, lb, etc.) | SUBSTANCE VALUE [444] | TOTAL [44] |
|---|---|---|---|---|---|---|---|---|
| I. MONO-PREPARATIONS | | | | | | | | |
| 1. Antibiotics | | | | | | | | |
| A 250 | 29 | 2,524 | 73,196 | | a. | 5,500 | 1.841 | 53,380 |
| A 500 | 85.7 | 4,716 | 404,161 | | a. | 5,500 | 3.684 | 315,707 |
| Sub-Total A | | | 477,357 | 31.07 | | | | 369,087 |
| B 12,8 | 9.8 | 1,528 | 14,974 | | b. | 280 | 1,031 | 10,107 |
| B 50,8 | 27.9 | 5,849 | 163,187 | | b. | 280 | 4,294 | 119,816 |
| Sub-Total B | | | 178,161 | 11.60 | | | | 129,923 |
| 2. Antihistamines | --- | --- | --- | | | | | |
| 3. Corticosteroids | | | | | | | | |
| D | 44.2 | 974 | 43,051 | 2.81 | d. | 375 | 0.03 | 1.340 |
| 4. Psycholeptics | --- | --- | --- | | | | | |
| 5. Antihipertensives/ Diuretics | --- | --- | --- | | | | | |
| II OTHER ETHICALS | | | | | | | | |
| G | 103 | 1,065 | 109,695 | | | | | |
| Z 250 8,8 | 9.9 | 3,259 | 32,26 | | | | | |
| Z 500 8,8 | 23.4 | 6,235 | 145,86 | | | | | |
| Sub-Total | | | 287,81 | 18.74 | | | | |
| III O.T.C. | | | 549,774 | 35.78 | | | | |
| TOTAL | | | 1,536,201 | 100.0 | | | | |

[4] US$ utilized in raw materials in mono-preparations

[44] Total units multiplied by substance in sales package

[444] Value of the amount of substance per sales package

# TABLE VIII

## NUMERICAL EXAMPLE OF PRICING METHODOLOGY ( PART 2 )

## STRUCTURE OF SELLING PRICE TO RETAILERS

| | MANUFACTURER | | INDUSTRIAL ACTIVITY | | | MARKETING ACTIVITY |
|---|---|---|---|---|---|---|
| | 1981 ($10^3$) | PROJECTED ($10^3$) | HUMAN PHARMACEUTICALS ($10^3$) | OTHERS ($10^3$) | SERVICES ($10^3$) | |
| 1. RAW MATERIALS | 1,975 | 3,230 | 1,205 | 1,936 | 89 | |
| 2. LABOR | 190 | 278 | 123 | 141 | 14 | |
| 3. PLANT OVERHEAD | 222 | 347 | 173 | 162 | 12 | |
| PRODUCTION COST | 2,388 | 3,855 | 1,501 | 2,239 | 115 | |
| (INVENTORY ADJUSTMENT) | ( 416) | ( 672) | ( 270) | ( 402) | - | |
| INDUSTRIAL COST OF SALES | 1,972 | 3,183 | 1,231 | 1,837 | 115 | |
| COMMERCIAL COST OF SALES | 108 | 175 | - | - | - | 175 |
| TOTAL COST OF SALES | 2,080 | 3,358 | 1,231 | 1,837 | 115 | 175 |
| 4. SELLING EXPENSES | 285 | 478 | 175 | 261 | 17 | 25 |
| 5. ADMINISTRATIVE EXPENSES | 152 | 234 | 86 | 128 | 8 | 12 |
| 6. FINANCIAL CHARGES | 37 | 35 | 13 | 19 | 1 | 2 |
| PHYSICIANS' SAMPLES | 75 | 121 | 121 | - | - | - |
| TOTAL COST | 2,629 | 4,226 | 1,626 | 2,245 | 141 | 214 |
| PROFIT | | 72 | 28 | 38 | 2 | 4 |
| SALES VALUE EX-FACTORY | | 4,154 | 1,654 | | | |
| DISTRIBUTOR MARK-UP | | | 292 | | | |
| SALES VALUE TO RETAILER | | | 1,946 | | | |

* CP = PRODUCTION COST
MP = RAW MATERIALS
VVF = SALES VALUE TO RETAILERS
CV = TOTAL COST OF SALES

* $K_1$ = CP/MP = 1.2456
$K_2$ = VVF/CV = 1.5808
$K_3$ = $K_1 \times K_2$ = 1.9690

$$K_1 = \frac{\text{PRODUCTION COST}}{\text{RAW MATERIALS}}$$

$$K_2 = \frac{\text{SALES VALUE TO RETAILER}}{\text{TOTAL COST OF SALES}}$$

1.9690 = MANUFACTURER COEFFICIENT

1.25 = ADDED VALUE

# TABLE IX

## NUMERICAL EXAMPLE OF PRICING METHODOLOGY ( PART 3 )

## COMPUTATION OF PRICE INCREMENTS

| THERAPEUTIC CLASS | CURRENT SALES VALUE ( $10^3$ ) | PROJECTED SALES VALUE ( $10^3$ ) | REQUIRED PRICE** INCREMENT % | COMPUTATION * (yields projected sales value) |
|---|---|---|---|---|
| I. MONO-PREPARATIONS | | | | |
| 1. ANTIBIOTICS | | | | |
| A 250, 500 | 477,357 | 747,626 | 56.61 | $ 369,087 x 823 x 1.25 x 1.9690 |
| B 12's, 50's | 178,161 | 263,173 | 47.71 | $ 129,923 x 823 x 1.25 x 1.9690 |
| 2. ANTIHISTAMINES | --- | --- | -- | |
| 3. CORTICOSTEROIDS | | | | |
| D | 43,051 | 5,429 | 0.0 | $ 1,340x823x1.25 x 1.9690 |
| 4. PSYCHOLEPTICS | --- | --- | -- | |
| 5. ANTIHYPERTENSIVES/ DIURETICS | --- | --- | -- | |
| II. OTHER ETHICALS | 287,858 | 319,522 | 11.00 | |
| III. O.T.C. | 549,774 | 610,249 | 11.00 | |

* US$ rate of exchange = 823

1.9690 = manufacturer coefficient

25% = aggregated value in warehouse

** Required price increment = $\frac{\text{projected sales value}}{\text{current sales value}}$

(Computation* yields projected sales value)

## 6.0 INTRODUCTION OF GENERICS IN THE PRIVATE SECTOR

In order to take into consideration the launching of generics a visit to the Centre for the Quality Control of Bulk Drugs was undertaken . The Centre which operates under the supervision of the Ministry of Health has been appraised. It consists of a unit engaged in the analysis of bulk drugs and finished dosage forms, a prerequisite for the issuance of certificates of health registration. Said analyses are undertaken once and no further random samplingfor testing is accomplished among inventories of marketable products on the shelves of the retail outlets.

Training of the technical staff of the centre and a number of equipment was provided through an agreement with the Government of Germany. The centre consists of three areas of activity: a department of chemistry working at full capacity; a department of microbiology that is starting to operate, and a department of pharmacology which will not be operative until 1983 when the equipment on order is expected to arrive. Working at capacity the institute is equipped to carry out some 250-300 test per month comprising bulk drugs, cosmetics and galenic preparations. It has been learned nevertheless that a major portion of the tests consists of cosmetic preparations. If the introduction of generics in the private sector is endeavored the capacity of the centre to uphold this programme must be examined.

The launching of generics in industrialized countries has represented a substantial saving to the consumer. There are no reasons why this

*strategy should not be duplicated in developing countries.*

*The tables and charts attached to this paper explain that current price level of pharmaceuticals in Peru is equitable in respect of the highest bracket of the social strata. It is unquestionable that the intrcäuction of a line of generics would be advantageous to the economy of the low remunerated social classes.*

*A Peruvian version of generics named Basic Medicaments has beer functioning in the public sector for about ten years. It would not be advisable to suggest at this time the launching of a parallel line of generics when the general concept now exists at public health and welfare level. Since a broad assortment of essential drugs are at present dispensed by the former at about 50% average the price of commercial medicaments it is fair to assume that the experience gained by the programme of basic medicaments could be transferrred to the private sector in the sense that the latter medicaments could be also obtained through the national network of retail outlets. This preliminary stage should be succeeded by an orientation campaign to familiarize the consumer of the positive price advantages of generic products.*

## 7.0 THE ESTABLISHMENT OF A SYSTEM OF INFORMATION OF INTERNATIONAL PRICES OF BULK DRUGS.

The ideal location of a price information system should be as an auxiliary office to the Price Control Bureau now functioning at the Ministry of Industry. It is obvious that the latter is the core of the price control system and as such it should receive, as a major input all current data on the fluctuating market of international prices of active substances. It accurs, nevervetheless that it already exists in Peru a committee of active substances ("Comisión de Insumos") that was established by Supreme Resolution N° 00080-81-SA-DA of 11 March 1981. This resolution constituted a Multisectorial Committee of the System of Information on Prices of Raw Materials for the Pharmaceutical Industry. Said committee is formed by representatives of the Ministries of Health, Finance, Industry and Foreign Affairs and of the Medical and Pharmaceutical Associations being its executing office the Direction of Pharmacy of the Ministry of Health. The main information channels of this Committee are the commercial bureaus of the Peruvian consular network throughout the world.

The Andean Group whose seat is in Lima is likewise organizing a system of information of prices of bulk drugs for the countries of the Andean Region. In as much as there are two parallel committees in this area working towards the same objective it is not advisable at this time to give thought to set up an analogous price information office. It is suggested therefore, that a liason official between the two existing price monitoring systems be appointed.