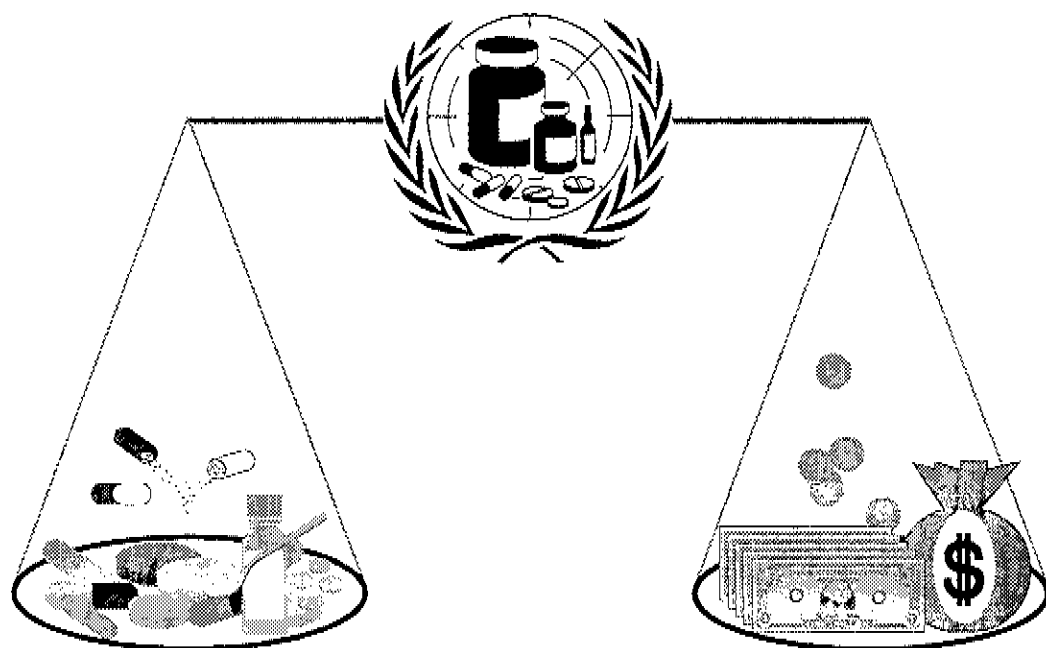
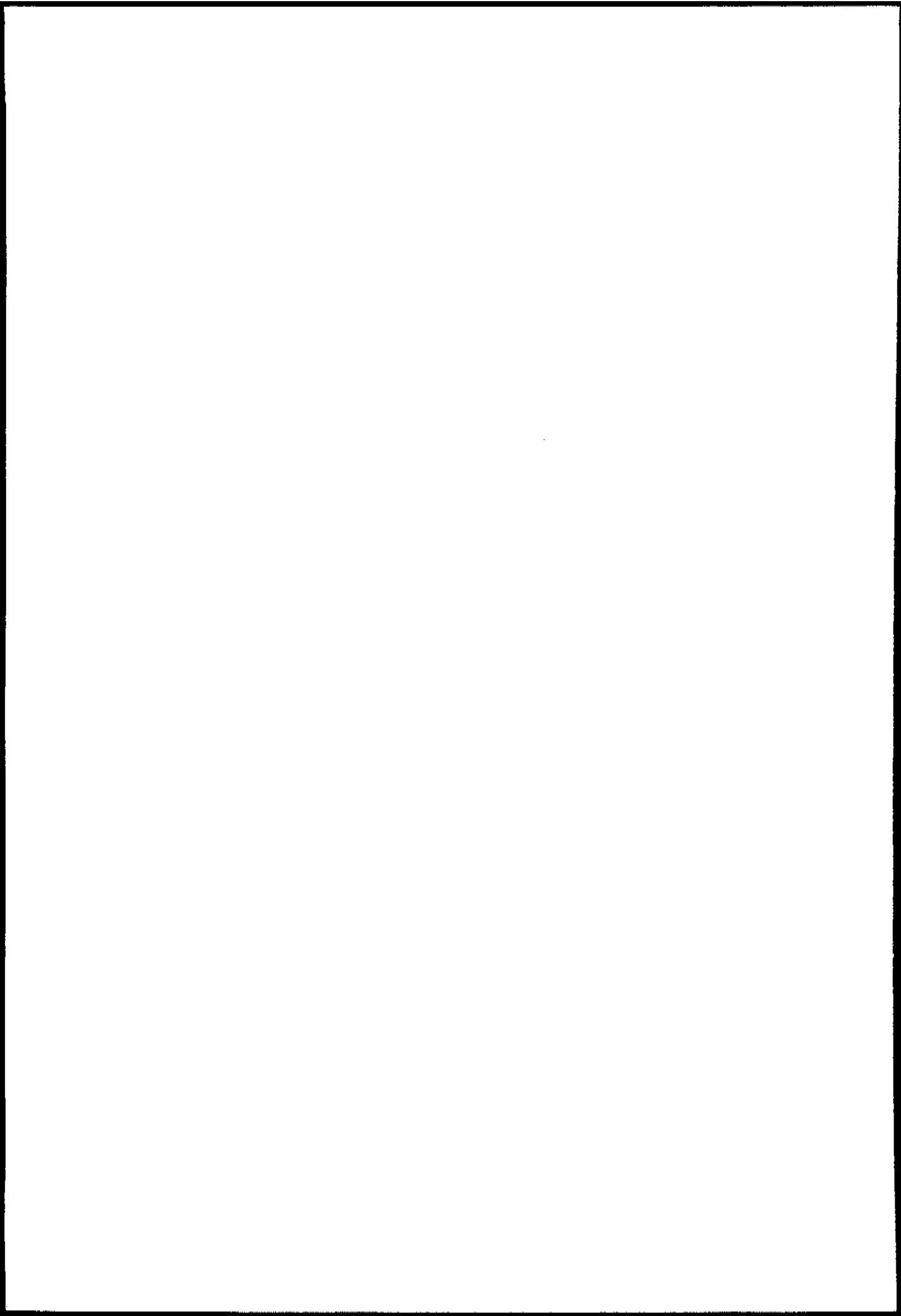


ALTERNATIVE DRUG PRICING POLICIES IN THE AMERICAS

Health Economics and Drugs
DAP Series No. 1



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Health Economics and Drugs
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Introduction

In the context of protectionist development policies - both in industrialized and least developed countries - in the 1960s and 1970s action was taken to limit the market power of large companies (mainly international corporations) so as to avoid excesses on their part, guarantee supplies of inputs at low prices, preserve the purchasing power of the large low-income sectors of the population and promote the creation of local industries. For this purpose, price fixing mechanisms involving a varying degree of intervention on the part of governments were adopted.

One of the products most subject to control was drugs because they are an important component of expenditure on health schemes in several countries, and consequently of public spending, but are also an essential component of the family shopping basket and thus have an impact on the level of well-being, especially that of the lower-income sectors.

From the 1980s onwards, with the forceful return of free market ideologies, state intervention went out of favour and price control policies were gradually lifted, including mechanisms involving less direct control. This trend was reinforced in the early 1990s by the discussions promoted by developed countries in the General Agreement in Tariffs and Trade (GATT) Uruguay Round, which led to a commitment by the signatories to accept the generalized patenting of pharmaceutical products and processes.

The response by companies and by the market itself to the lifting of controls led to different types of reaction when establishing drug prices: in some countries, there was a relatively significant change, whereas in others the change was more gradual, with a varied impact on inflationary trends as well. In the 1990s, this situation meant that at the international level several different schemes for fixing drug prices coexisted, involving a greater or lesser degree of freedom, and the objective of this study is to assess their effects, advantages and disadvantages.

Identification of the impact on social actors becomes essential in order to orient definition of those elements of government policy which establish the bases for the existence of a healthy pharmaceutical industry, with opportunities for research and development of new constituents to ensure health in countries with different levels of development and different causes of morbidity and mortality, while at the same time making sure that this industry is maintained by the population without having any adverse effect on family budgets and standards of living.

This document reviews the alternatives that have given the best results in terms of ensuring the availability of drugs and the possibility of access to them by population groups with varying levels of income, therapeutic need and geographical location. Recent experience in a number of countries in the Americas is examined in connection with the different schemes adopted for the purpose of fixing drug prices, which vary from total freedom to the state's discretionary authority, in relation to their effects on availability and price trends so as to identify policy alternatives for fixing and controlling prices.

For this purpose, the first chapter contains a detailed review of the economic theory of managed prices applicable to the case of pharmaceutical products. The second chapter describes the various mechanisms for regulating prices which exist in countries on the American continent, identifying in each case their effects, advantages and disadvantages, according to the information collected through Panamerican Health Organization/World Health Organization (PAHO/WHO) delegations in the region. This is followed by a review of existing legislation on generic drugs, and the last chapter contains the main conclusions.

Chapter 1

Theoretical aspects of schemes for the fixing of drug prices

A scheme for fixing drug prices is a departure from what economics has considered to be the traditional mechanism of leaving the market free to follow supply and demand.

Firstly, the demand for drugs is indirect, that is to say the person buying a drug is not making a choice among the various options on the market on the basis of a comprehensive flow of information on their characteristics, quality, advantages and price. This task of "selection" is performed by the medical professional, who is not making a choice transparently either because his decision is influenced by the agents representing the producers (manufacturers) without taking into account the price information on the market. The consumers are therefore subject to their physician's decision and to their budgetary limitations when spending money to relieve their suffering and in some cases to save their lives.

From the supply point of view, the price does not correspond to the reference price indicated by market trends to the producers, which enables them to take decisions regarding the quantities to be produced taking into account the level of marginal costs, as conventional economic theory maintains. The price in fact corresponds to what has become an institutional phenomenon developed by large companies; namely, the companies - and not the market - "manage" the price of their products (Clifton, 1985). These managed prices fulfil two objectives: they are used to promote market stability and, as an integral part of the financial controls exercised by large corporations, they objectively relate price policies to investment policy in markets in which the corporations are involved, thus achieving the aim of controlling production throughout the broad spectrum of the corporation's activities.

In this context, the prices may be managed by companies in order to pursue their target of profitability, but also by governments in order to meet their policy objectives.

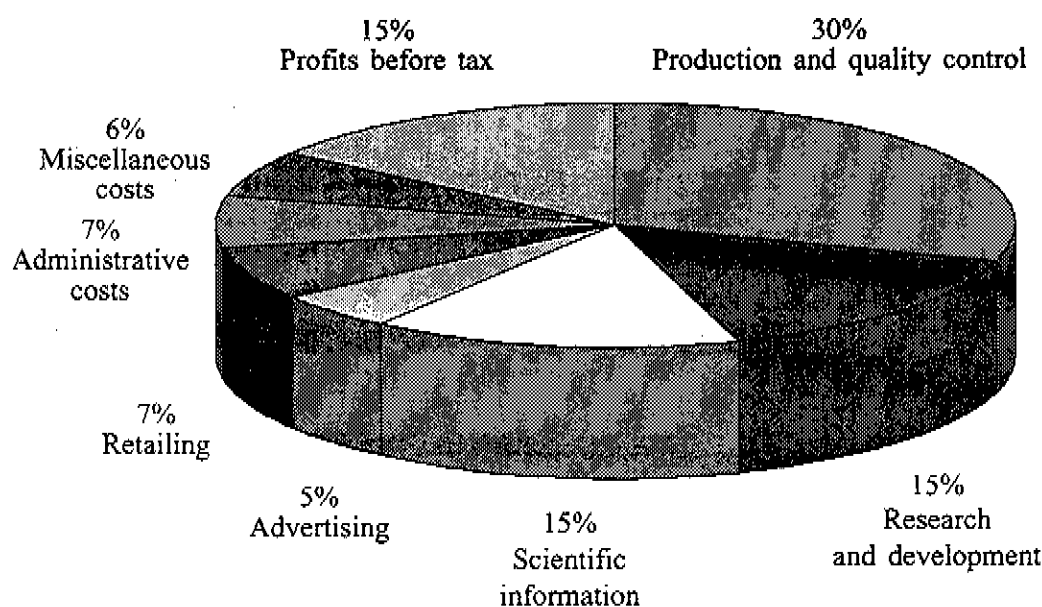
1. Prices managed by companies

Pharmaceutical companies use a combined scheme when calculating prices: for each drug, it is only possible to make an exact estimate of the manufacturing cost (real direct costs) and marketing cost; however, because it is impossible to calculate the overall cost of each product, the industry applies the principle of a contribution towards overall costs: the price of a drug includes contributions to research, administration, marketing, financing, as well as a "reasonable margin of profit". According to this combined scheme, producers of pharmaceutical products spread the overall costs over all the drugs (Blaser, 1980: 27).

The cost structure (in percentage of sales) in a pharmaceutical company carrying out basic research can be defined in the manner shown in Figure 1, although there are naturally differences among companies, according to the country concerned and the firm's size, regarding the way in which the amounts are shared out under the various headings (Ballance *et al*, 1992, chap. 5).

Figure 1

Cost structure in a pharmaceutical company studied
(in percentage of sales)



Source: Klaus von Grebmer. *Pharmaceutical prices: a continental view*, p. 8

This possible structure of average costs in the pharmaceutical industry gives rise to two very divergent opinions. Its critics point out that it usually involves expensive drugs with a trademark, which are sold at inflated prices far above the real production costs, which alone account for 20 to 30 per cent of the price fixed by a company carrying out research (Melrose, 1984: 494). These critics add that, because the period for writing off research costs never ends, these are in fact generating an "excess profit" without any limit in time, which allows higher profits. In response, producers argue that the research process now requires between eight to ten years of work and around US\$ 150 million for each new effective therapeutic drug developed; it is also alleged that the system for the calculation of prices by which overall costs are spread over all drugs allows drugs that are utilized far less to be sold at reasonable prices even though their research costs were not any lower (Afidro, 1985).

Nevertheless, the price of a drug (same dosage, same quantity) varies from one country to another and even within a country, sometimes costing two or three times as much (Table 1), which tends to show that the price of a drug has little to do with its actual manufacturing cost but with the extent of competition in the market (Challú, 1991: 94-109). Certain factors could explain these differences: living standards (income and wages), the amount of state intervention, the type of social security, exchange rate fluctuations and price levels. However, there are three other major reasons which affect decisions by innovating firms and by producers: the size of the market, whether or not there are patents protecting the drug, and the production of active constituents by companies which do not incur research and development costs.

Table 1

**Estimated trend in sales earnings in Argentina
as a result of the change from a competitive to a monopolistic market
(US\$ '000)**

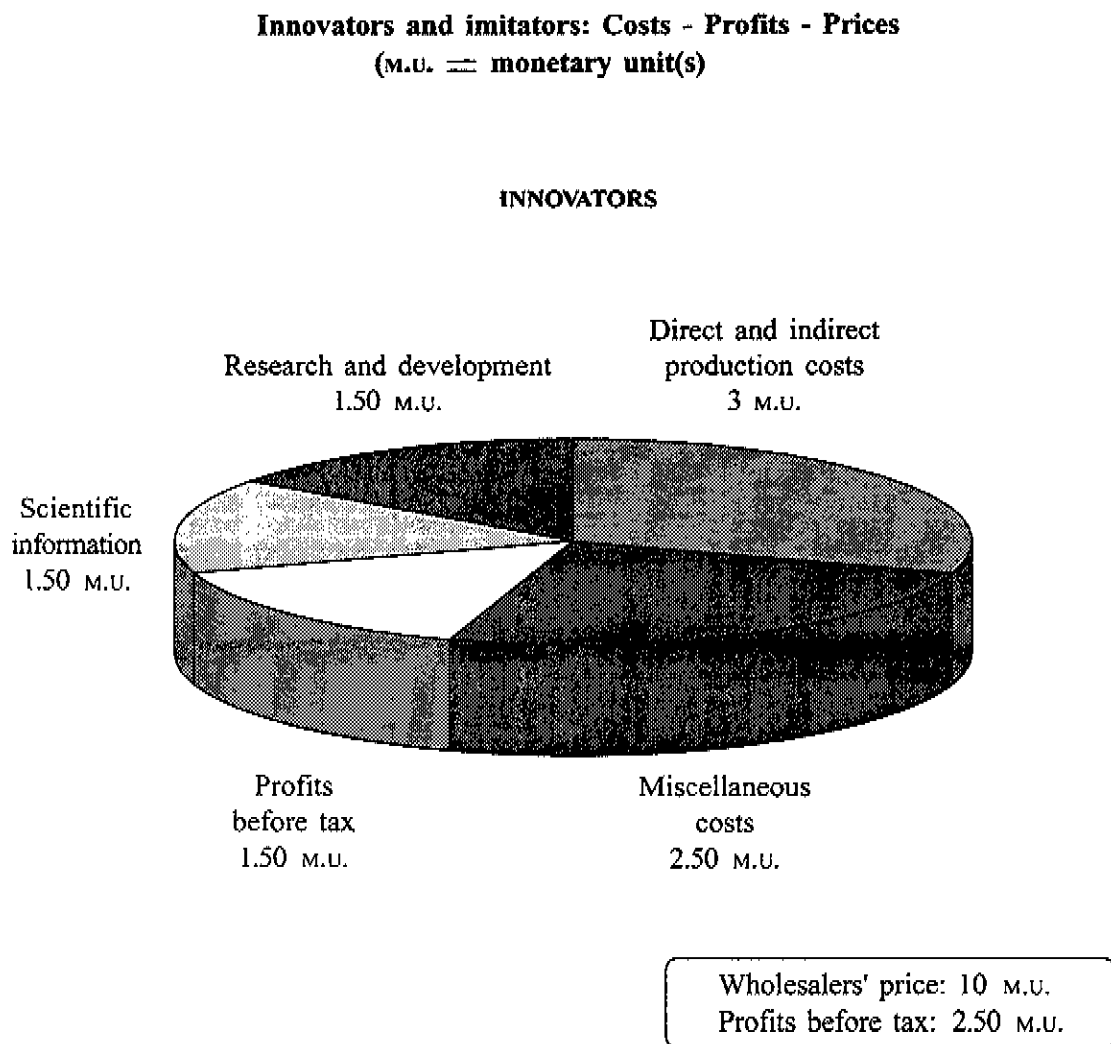
Drug	Earnings in a competitive market	Earnings in a monopolistic market	Percentage increase
Atenolol	4,553	10,489	130.1
Enalapril	18,309	27,238	48.8
Lorazepan	6,486	8,728	34.6
Piroxicam	16,171	37,289	130.6
Ranitidina	15,101	20,194	33.7

Source: Taken from Pablo Challú (1991), p.106

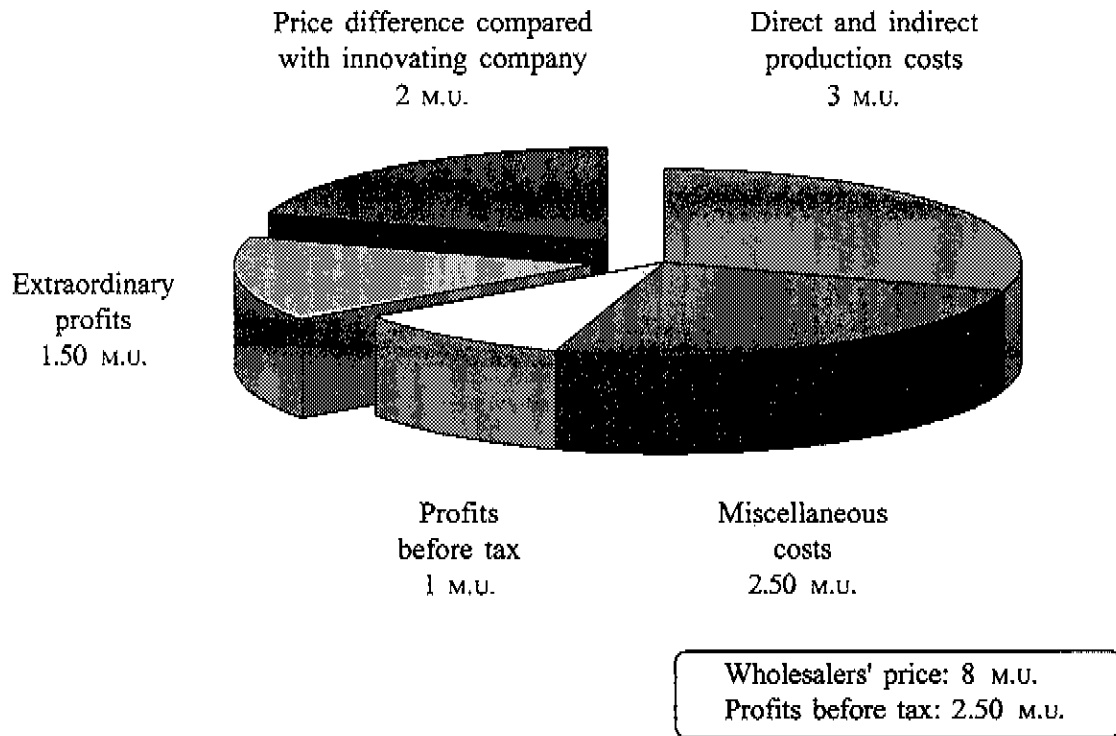
Despite the fact that multinational companies state that the price at which they sell drugs and/or active constituents is the same in all countries ("arm's length"), in practice they recognize that "pharmaceutical companies cannot quote real prices until they have quantified demand and defined for each country details such as the size of the packaging and their programmes for supplying the market" (Perete, 1984: 532).

Moreover, the simultaneous presence of manufacturers of the same active substance with different cost systems, due to the fact that some pharmaceutical companies carry out research to develop pharmacotherapeutic substances while others confine themselves to copying molecules already developed, has meant that prices for the supply of new active substances vary greatly among suppliers. On average, the difference in the distribution of profits and costs, as well as of prices for the same active substance, between companies which innovate and companies which imitate can be seen in the form shown in Figure 2.

Figure 2



IMITATORS



Source: Klaus von Grebmer. *Pharmaceutical prices: a continental view*, p. 12

The advantages of an imitating company over one that innovates in terms of cost are that the former does not incur research and development or scientific information costs. Its capital needs are less while its rate of return on investment may be one third lower compared with a company carrying out research. In other words, an imitator can easily offer a price that is lower by around 35 per cent (6.5 monetary units in the Figure) than the innovating company and yet still earn profits (Von Grebmer, 1978: 13). Using this argument, innovating companies have exerted pressure to ensure that the benefits derived from their research and development efforts should be protected by patents. However, other analysts consider that these protection instruments give companies the possibility of controlling the use of discoveries in order to impose higher prices and exercise a monopoly over the market. Pharmaceutical companies which carry out research have usually sought the most extensive and permanent protection possible through patents. "Without it ... there would be no incentive to innovate, particularly in view of the time and money required today to develop a new product and because of the enormous risks involved" (Organisation for Economic Cooperation and Development (OECD), 1984).

The opposite argument is equally true: the price of many active substances sold by pharmaceutical companies carrying out research corresponds to one hundred and up to one thousand times the cost of production and this price only tends to decrease with the passage of time. This is particularly the case when the system of allocating research investment is a fixed element spread over all the substances produced by the company irrespective of the time the drug was developed. "Patents grant privileges in countries where they are in force in such sensitive areas as health, in some cases they only serve to facilitate monopolies, speculation and high prices" (Alifar, 1987).

The "surcharge" which subsidiaries have to pay when importing pharmaceutical active substances is often defined as "over-invoicing of imports" as a result of the monopoly of the multinationals. Among the negative effects on the importing country are the following: "higher prices for raw materials, which is the case for multinationals (...), higher foreign currency expenditure with an adverse impact on reserves (...) in dollars, higher costs for finished products, less artificial profitability and less payment of taxes with manifest losses for national tax revenue. In practice, this means flight of foreign currency to the exterior and tax evasion in the interior" (Ibid).

In this way, the "transfer prices" are seen to be a strategy by the multinationals to optimize profits at the global level rather than the partial and individual result of transactions by their subsidiaries: "what is important to the transferor is the amount of the remuneration resulting from various combinations of inputs which together constitute the complex asset of branching out towards the exterior rather than the remuneration of each separate element (...). The profits earned by a subsidiary, which is the factor most usually evaluated, can be the least representative aspect of the actual profitability of the parent company" (Vaitsos, 1971: 53) as the company is in fact seeking results from its combined operations all over the world.

Despite the fact that transnational corporations attribute these price differences to the "unique characteristics of the pharmaceutical research industry", the costs of patenting are certainly high for developing countries. A study carried out on Colombia in 1990 estimated that the annual cost of adopting a patent system was US\$ 128 million (Zerda *et al*, 1990); for Argentina it was estimated to be US\$ 194 (Challú, 1991).

2. Prices managed by governments

Until the 1970s, the position adopted by governments in various countries regarding the phenomenon of transfer prices and the persistent high level of drug prices was to increase regulation and control measures over the trade practices of multinational companies. As awareness grew in these countries of the cost of drugs and its implications for tax revenue and international reserves, the price control mechanisms became stricter. Moreover, efforts were made to incite governments to encourage drug supply by promoting the use of generic products as a way of curbing expenditure or lowering pharmaceutical costs, thereby creating a mechanism which encouraged greater competition in markets.

The aforementioned factors, together with the fall in the rate of return on research funds, led to changes in the pharmaceutical industry and its new operational structure has been established at two levels: on the one hand, increased concentration, specialization and development of companies dedicated to the research and development of new drugs, and on the other extension and specialization in the production of generic drugs.

The first group includes a select number of European and North American companies which focus on research and continue to invest increasing amounts in the development of new drugs. The overall picture of activities in the 1980s seemed to show that the pharmaceutical industry was on the threshold of a new "golden era" of productivity in research (PAHO, 1984: 32-33). The facts have demonstrated the contrary: the number of active constituents introduced into the market fell sharply during the past decade (Ballance *et al*, 1992, chap.4). Furthermore, the results obtained up till now in biotechnological research have been even more disappointing and global sales of new molecular entities produced by advanced biotechnology have been poor (*Ibid*: 102-103), contrary to what had previously been predicted (Economic Commission for Latin America/United Nations Industrial Development Organization (ECLAC/UNIDO), 1984: 61).

The second category of producers, which mainly competes on the basis of prices in the generic drugs market with less need for investment in research and development (R&D), is divided into two sub-markets: firstly, the market in basic generic products, which allows the growth of medium-scale and small-scale industries in developing countries; and secondly the market in generic products with registered trademarks, in which the high cost of advertising and the multinationals involved in this sector play a decisive role. It should be noted that a trademark tends to be even more important than a patent for pharmaceutical companies.

In addition, the increasing globalization of markets and the characteristics of what has been called "new competition" have characterized unprecedented behaviour not just in pharmaceutical companies, but above all in these companies, and have resulted in the creation of so-called "strategic alliances" for cooperation in pre-competition stages of research into new products, new processes, sharing of markets, etc. The recent cases of some British and North American companies are indicative of such a trend with the pursuit of the increasingly important market in generic drugs and products that do not require a medical prescription before they can be sold.

State intervention in the market for pharmaceutical products has therefore been justified for reasons of efficiency and equity (Lobato *et al*, 1994). With regard to efficiency, attention has been drawn to the quasi-monopolies or oligopolies present in many sub-markets for specialized products, where there is also a considerable differentiation among products so that trademarks prevail over generic appellations, and important barriers to the entry of new products in the form of product patents, R. & D costs and mass promotion campaigns among the medical fraternity.

Concerning efficiency, it is considered that the price of a drug does not necessarily correspond to a situation of efficiency because it is not really relevant to demand and is not very flexible.

By intervening, the state seeks equity because drugs are a basic necessity and sick people are in a socially inferior position. Public spending on drugs pursues redistribution objectives which traditionally encompass three aspects:

1. To guarantee the safety, effectiveness and accessibility of drugs available on the market.
2. To promote the creation of a domestic pharmaceutical industry.
3. To control public spending on drugs.

3. Effects of the various forms of managed prices

Mechanisms for the fixing of managed prices have varying effects according to the agent applying them.

In a totally free scheme where prices are fixed by companies, which have leeway to pursue their objectives of profitability and utilize practices to differentiate products, the result is usually more expensive drugs due to the costs of presentation and promotion of trademarks, which are not always justified taking into account the nature of the product.

Producers can, however, include in the price their corresponding expenditure on R&D and investment programmes, which makes it possible to continue seeking drugs to attack the diseases afflicting mankind. Nevertheless, in practice the choice of methods and areas of research is also affected by the need for profitability as well as the morbidity and mortality factors among the population in the country where the pharmaceutical corporation has its headquarters with the result that diseases that are not considered priorities are left out; this is the case for tropical diseases even though they are priorities for developing countries.

On the other hand, in schemes where there is total control of price fixing by government authorities there are also a number of effects. Firstly, the price levels maintained are not very high, which can benefit a large number of consumers and contribute towards the well-being of the population. Secondly, the regulation of competition has facilitated the creation of domestic pharmaceutical industries thus helping to reduce the price of drugs.

Nevertheless, transnational companies producing drugs have sometimes reacted to controls by limiting supplies of certain key drugs to the local market, using the argument that the prices permitted or fixed by the government concerned do not allow the R&D costs of the products to be recovered and they cannot operate at a loss. Unfortunately, domestic companies have not sought to occupy the places left vacant by the transnationals and have even supported this position by raising prices to the levels fixed by the transnationals (Muñoz *et al*, 1988).

Many of these practices, together with the process of globalization of the economy and international integration at the level of blocs based on the principle of market liberalization, have incited States progressively to change their control practices or even abandon them completely. A review of these experiences on the American continent follows.

Chapter 2

The experience of price fixing in the Americas

In countries on the American continent there is a wide range of schemes for the fixing of drug prices varying from total control by a government authority to absolute freedom for manufacturers to fix their prices, as can be seen in Table 2. This situation has been reached following a gradual move in recent years away from total control schemes to schemes with less state intervention. For example, Bolivia, Brazil, Chile, Colombia, Guatemala, Mexico and Peru have total state control schemes; the previous regime in Uruguay was mixed, and in the Dominican Republic there is freedom to fix prices with monitoring by the state. The different forms currently implemented by countries in the Americas, identifying their positive aspects and the problems, are described below.

Table 2

Price regimes in countries of the Americas, 1994

Total control		Mixed (Freedom and control)		Monitored freedom		Total freedom	
Country	Year	Country	Year	Country	Year	Country	Year
Ecuador	1985	Canada		Brazil	1992	Argentina	1989
Honduras		Colombia	1991	Costa Rica	1975	Bolivia	1985
Panama		Venezuela	1993	Mexico	1993	Chile	1980
Paraguay	1980			Uruguay	1991	Dominican Rep.	1985
						El Salvador	
						Guatemala	1993
						Peru	1990
						United States	

Source: Survey by PAHO/WHO representatives in countries of the Americas; Alifar, 1987.

1. Total control schemes

Four countries among those which replied to the request by PAHO/WHO Colombia¹ or for whom information came from other sources still have legislation under which prices are fixed by a government authority (Table 3).

The regulations in force usually predate 1985 and therefore maintain traditional patterns of control: manufacturers must submit to the competent body, which varies from the Ministry of Health to the Ministry of the Economy, documentation showing the costs incurred in producing the drugs. After reviewing this information, the authority approves a cost margin for the producer which ranges from 20 to 30 per cent, including operating and financial costs. On this basis, pharmacies add their margin, which fluctuates between 25 and 30 per cent, and the maximum retail sales price is then defined.

Table 3

Price fixing schemes with total state control in countries of the Americas, 1994

Country-control authority	Price to the pharmacy (producer's margin)	Price to the public (pharmacy's margin)
Ecuador (Ministry of Health)	<ul style="list-style-type: none"> — Domestically produced products: production costs plus 20% margin — Imported products: c.i.f. price + operating costs + 20% margin 	Pharmacy margin 25%
Honduras (Ministry of the Economy)	<ul style="list-style-type: none"> — Imported products: c.i.f. + operating costs + 4% financial costs 	Pharmacy margin 27%
Panama (Price Control Office)	<ul style="list-style-type: none"> — Costs according to documentation plus margin. Ethical products 30% Freely available products 25% 	Ethical margin 33% Freely available margin 30%
Paraguay	<ul style="list-style-type: none"> — Costs according to documentation (no information on margin) 	Updating: average variation exchange rate and inflation

Source: Survey by PAHO/WHO representatives in countries of the Americas; Alifar, 1987.

¹ The countries which replied to PAHO/WHO were Brazil, Chile, Colombia, Costa Rica, Dominican Republic, Ecuador, Guatemala, Mexico, Panama, Paraguay and Uruguay.

Three countries have evaluated these control policies positively and consider that controls have allowed uniform prices to be imposed thus preventing speculation and permitting normal supply of markets.

Honduras, however, considers that the control scheme has led to high prices because of the practice of over-invoicing by suppliers, which in turn has meant that the population has fewer possibilities of access to drugs whether through the public or private sectors. There is also a range of market prices due to the different origins of supply: domestic or Central American production (the most inexpensive), imported from Europe (the most expensive) and smuggled drugs. Nevertheless, according to the information provided, no strategy to control price rises has been implemented.

In Panama and Ecuador, the case is different and in the former high prices have been avoided by decreasing import tariffs from 22.5 to 5.0 per cent and freezing prices for one year. In Ecuador, there is specific domestic legislation on generic drugs, which are used to regulate the market; in addition, all the elements making up the production cost of drugs are controlled. Recently a Price Council has been set up in which three institutions participate: the Ministry of Health, the Ministry of Industry and the National Congress, and it is hoped that this will ensure improved monitoring of price trends.

2. Intermediate schemes

Seven countries apply price control schemes which combine control and freedom in the form of intermediate schemes whose general outlines are shown in Table 4. These countries have usually created their respective schemes recently, with the exception of Costa Rica, which has had its sporadic (and not very effective) scheme for the control of margins on imported products for the past twenty years.

Table 4

Intermediate schemes for price fixing in countries of the Americas, 1994

Country competent authority	Price to the pharmacy (producer's margin)	Price to the public (pharmacy margin)
Brazil	Maximum 10.5% retailers' discount.	Pharmacy margin not controlled
Canada	Provincial Governments influence the final price according to a formula comprising a limited number of drugs. System of refund for the public sector. Control over patented drugs. Annual adjustments according to CPI average over the previous 3 years.	Not controlled
Colombia (Ministry of Economic Development)	Total freedom for 80% of products. 20% (family shopping basket), monitored freedom according to cost trends.	25% pharmacy discount
Costa Rica (Ministry of the Economy)	Sporadic control of margins. Importer: c.i.f. + 30% For essential drugs 25%	30% pharmacy margin and 25% for essential drugs
Mexico	Manufacturers apply a self-regulating formula. Indicators updating prices are fixed by the Government.	
Uruguay	Manufacturers fix selling prices to the public according to costs, margin and competitive prices. The Government monitors the increases applied for.	Pharmacy margin: n.a.
Venezuela	40.5 % retailers' discount. The state monitors active constituents. The remainder are subject to agreement. Basic basket is controlled.	37% pharmacy discount

Source: Survey by PAHO representatives in the Americas; Alifar; P. Lobato, *op.cit.*

Reasons for changing the scheme

The reason why the scheme was changed, at least in the cases of Colombia and Mexico, was the significant differences in prices for the same product due to the cost justifications submitted by manufacturers. In Colombia, the discretionary manipulation of periodic price adjustments by the Ministry of

Health introduced a political element and sometimes led to conflicts between the producers and the authorities, with an increase in the number of products registered far beyond the number of those actually marketed, artificial scarcity of certain key drugs (insulin, and oncological and coronary drugs, for example), resulting in genuine emergencies in the country's health system.

Another additional effect of schemes with no control is in some cases the tardy introduction of new therapeutic drugs and the total disappearance from the market of certain products.

Characteristics of current schemes

The schemes in effect in countries with intermediate schemes correspond to two major types of control practice: firstly, a practice that can be termed "mixed" in which the state controls the fixing of prices for a range of products (usually essential drugs) according to a procedure similar to that described for total control, while the price of other products remains free. In the other intermediate scheme, the producers fix the price and the state monitors it with the result that there can be price increases that are not fully justified.

Two price control schemes have characteristics that are interesting to examine in greater details: these concern Canada and Colombia.

The case of Canada

Since 1974, Canada has had a programme to assist out-patients receiving social welfare, who receive drugs through pharmacies. The latter are refunded the cost of the products listed on a drugs benefits form which gives the minimum price of all interchangeable products. In 1986, the regulations were changed to introduce the best available price (BAP), which is the lowest price calculated per gramme, millilitre, pill, etc. at which the refund is made.

The BAP for the most popular products is virtually controlled through inspection by the Ministry of Health and when it is noted that wholesalers and pharmacies are applying lower prices, the BAP is reduced to that level. Since 1988, the Consumer Price Index (CPI) has been utilized to determine whether a price increase is excessive or not even though there is no specific regulation regarding this. If there is an application for high prices that are not justified, the Ministry of Health excludes these products from the list.

In addition, since 1987 Canada has controlled the ex-factory price of patented drugs through an official agency set up for this purpose.

The case of Colombia

In Colombia, total control started to be implemented in 1968 and since then this practice has gone through a number of phases and forms until it recently became a scheme that combines freedom for a wide range of products with control over a limited number. Since 1992, essential drugs with less than five suppliers and so-called "critical drugs" have been subject to a monitored regime of freedom under which the producers or importers can change the maximum selling price to the public but must inform the Ministry of Development in advance of the new price. The Ministry can require the manufacturers to transmit the cost surveys in support of the price increase or impose the price level it deems appropriate.

In 1993, the Ministry returned to a method of price fixing that consists of multiplying by a factor of 3.4 the production costs of drugs subject to the system of monitored freedom which the Ministry considers require the submission of cost surveys. This factor takes into account overall costs and the manufacturer's profits, as well as the retailer's margin.

Results of the intermediate schemes

The intermediate price control schemes generally receive a favourable assessment from the countries which apply them because they not only help to stabilize markets and permit plentiful supplies of brand-name drugs but also simplify procedures vis-à-vis the competent authorities and lead to keener competition among companies (Mexico).

Nevertheless, in certain cases such as that of Uruguay it is considered that the new scheme (monitored freedom) has led to an increase in prices over and above the increase that would have occurred with the previous (mixed) scheme; there are even price differences for the same product according to whether it is manufactured locally or by a multinational company. As a way of avoiding steep price increases people are turning to generic drugs whose rhythm of price adjustment does not exceed the increases in the CPI.

In Costa Rica, the price control scheme has been in force for twenty years and its functioning has serious problems due to the difficulties which the authorities face in carrying out the required controls and monitoring of the retailer's and pharmacist's profit margins.

The change of regime in Colombia which began in 1988 led to an increase in drug prices, justified by the manufacturers because it was alleged that the former total control by the Ministry of Health had meant that the updating of drug prices had fallen behind.

In Canada, the new legislation increased the powers of the Patented Drugs Price Review Board to order decreases in prices or refunds of excess earnings received whenever over-charging is detected. New elements of price control have thus been added and they made it possible to economize resources and maintain the annual average increase in the price of patented drugs below the consumer price index between 1987 and 1992. Certain studies have shown, however, that the introductory price of new products has been higher than the average international price.

Moreover, the formula of interchangeable products lessened the impact of generalized prescription and showed an increase of 90.2 per cent between 1979 and 1988, whereas that of non-interchangeable products increased by 354.4 per cent. The introduction of the BAP brought costs per formula down to 1980 levels.

The different countries in this group use price control schemes to avoid steep increases, but also utilize with success a national basic framework (Costa Rica) or legislation on essential and generic drugs (Colombia) as a complementary market regulation strategy. In addition, in Colombia massive purchasing through cooperatives set up by health schemes in a number of cities has made it possible to enhance negotiating power with manufacturers and thus obtain much lower prices that make the best use of scarce resources.

3. Free market schemes

The legislation of eight countries in the Americas provides for free fixing of drug prices with profit margins that are either agreed with the sector or left freely to the play of supply and demand (Table 5). The majority of these countries have only recently adopted free market practices.

Table 5

Free market schemes for drug prices
in countries of the Americas, 1994

Country competent authority	Price to the pharmacy (producer's margin)	Price to the public (pharmacy margin)
Argentina	Pharmaceutical wholesalers' margin 60%	Pharmacy margin 25%
Bolivia	Producers or importers apply 30% to pharmacies. Domestic producer 35%	
Chile	Market	Market
Dominican Republic	Importers' and retailers' margin of 40% to 33%	Pharmacies' 30% margin
El Salvador	Market	Market
Guatemala	Market	Market
Peru	Importers and retailers fix prices "by blocs".	The Ministry of Health fixes prices at state health centres and posts (generic)
United States	Market	Market

Source: Survey by PAHO/WHO representatives in the Americas; Alifar; P. Lobato, *op. cit.*

Reasons for changing the scheme

In the countries concerned, there is no unanimous assessment of the pricing scheme which prevailed before the change to the present scheme. Whereas Bolivia and Guatemala consider that it provided stability and acceptable supplies of products, even though they were limited, Peru found that prices rose, though to a lesser extent than under the present scheme. In the Dominican Republic, it was possible to control any abuse in the form of price increases and there was no effect on availability.

Characteristics of the present scheme

Producers or importers fix the selling price to the public. In the United States, health cover schemes which combine public and private financing components cover part of pharmaceutical costs: Medicare does not assume drug costs outside hospitals although proposals have been made to include them. Medicaid covers the cost of pharmaceutical products prescribed. The Maximum Allowable Cost (MAC) scheme was set up in 1975 with the aim of making increased use of generic drugs and achieving decreases in public spending on pharmaceutical products; it restricted refunds for products without patents to the lowest price at which the product could be widely and permanently found on the market. This is the maximum allowable cost (MAC) for this product.

This scheme has resulted in a temporary reduction in spending levels due to the increases in prescription costs incited by suppliers as well as the increase in the states' service payments to pharmacies. Between 1982 and 1988, the cost per prescription rose at an annual rate of 11.1 per cent, while the overall price index rose by 3.8 per cent (Schondelmeyer and Thomas, 1994: 92).

Results of free schemes

For some countries (Guatemala, Peru), prices have increased over and above the exchange rate or the consumer price index, have been subject to erratic fluctuations (Bolivia, Guatemala) or lack transparency, in addition to encouraging self-medication (Chile) due to the excessive promotion encouraged by competition, and only the Dominican Republic shows stability, even though there has been an increase in the smuggling of drugs.

In Guatemala, greater variety of products and prices is seen as an advantage, while in Bolivia the scheme is perceived as not having yielded any benefits.

At the present time the United States health system is being reviewed, especially as far as control of spending is concerned because higher prices account for 97 per cent of increased expenditure. Partly as a result of this situation, there is discussion of the possibility of imposing price controls on pharmaceutical products by setting up a review body to monitor prices and annul patents if excessive increases are proved. This announcement alone incited the industry to slow down the rhythm of price increases. Another line of action being discussed by the Clinton Administration is the promotion of use of generic drugs, which at present account for 33 per cent of all prescriptions dispensed in the United States, but only amount to 8 per cent in terms of value.

In other countries where there is a free market for the fixing of drug prices, concern at exaggerated increases has led to the implementation of strategies such as the creation of information centres for those prescribing and for the public regarding appropriate drug options (Guatemala), the definition of essential drugs programmes, particularly in the public sector (Bolivia), or the promotion of generic products, also within the public sector (Peru). In Argentina, in order to curb excessive increases, import obstacles have been lifted and tariffs reduced with a view to broadening the supply available (González, 1994: 149).

Chapter 3

Generic drug programmes

As mentioned in connection with the various strategies for the control of price increases, generic drugs are an expedient in this respect for several countries in the Americas. Table 6 shows the countries which have specific legislation on generic drugs and it will be noted that the results vary even though the lower price aspect is always present.

Table 6

Countries with legislation on generic drugs and the results

Country	Results
Argentina	Partial prescription in certain provinces
Brazil	No clear policy
Colombia	Favourable impact on market regulation
Costa Rica	Lowers prices which allow the introduction of more sophisticated drugs while reducing costs
Dominican Republic	Limited application
Ecuador	Lower prices
Guatemala	Lower prices
Mexico	Public sector utilizes 50%
Panama	Lower prices. Lack of confidence among the medical fraternity regarding quality
Peru	Modest. Campaign only since 1991 and solely in the public sector

Source: Survey by PAHO/WHO representatives in the Americas; Alifar, P. Lobato, *op. cit.*

Conclusions

1. Economic theory and drug prices

The special characteristics of drugs as consumer goods and the structure of the market made up of innovating companies and producers mean that traditional economic theory does not suffice to explain satisfactorily the process of price formation in this field.

Consequently, one analytical framework which takes into account such special characteristics and encompasses the many different cases that are to be found in practice in the special case of pharmaceutical prices is that of "managed prices" applicable both to cases where prices are fixed by companies or by government bodies.

In a market economy, it is normal that innovating companies, operating according to a rationale of profitability, should endeavour to recover investment in research and development and earn profits, thus increasing the final price of drugs. However, drugs are not common and everyday goods, they are related to public health and constitute "meritorious goods" for which some degree of state intervention is desirable and even advisable.

One of the areas most apt for state intervention is research and development into new molecular entities which meet a country's health needs and whose cost is absorbed socially without any excessive impact on the final price of drugs, thus allowing access to such drugs by all income levels.

2. Price fixing schemes

The American continent shows a wide range of options for drug price control schemes, even though countries have recently been moving away from total State intervention schemes towards other schemes with greater market liberalization.

According to the information compiled for this report, three major schemes can be identified: firstly, total state intervention, in which an official body (usually the Ministry of Health or the Ministry of Development) fixes the final selling price for all drugs on the basis of the production costs incurred by the manufacturer.

The second "intermediate" scheme combines two options: in the first, which can be called "mixed", some drugs are under total control in the same way as above and the prices of other drugs are freely fixed by manufacturers; in the second option, called "monitored freedom", the producer fixes the price, but it is subject to monitoring by the state, which can change the price and annul increases that are not fully justified.

The third price fixing scheme is total freedom for producers to determine prices.

The conclusion to be drawn from the analyses contained in this document is that the schemes at the two extremes present complications and difficulties that do not make them the best options for the elaboration of drug price policies. Among the main problems of total control schemes are the following:

- proliferation of procedures and paperwork
- real or artificial scarcities of products as a result of the manipulation of companies' profitability
- proliferation of licence registration for products that are not ultimately put on sale
- tendency towards "political" manipulation of controls
- administrative incapacity of governments bodies to monitor.

Total freedom schemes, on the other hand, show:

- trend towards overall price increases for drugs, with the resulting effects on the overall price level, individual and public sector budgets
- wide variety of prices for the same product and lack of transparency in the flow of information to consumers
- tendency to promote drugs to an excessive degree.

Consequently, intermediate price control schemes, combining administrative control and free market elements, appear to be the most appropriate for a drugs policy that aims to ensure the availability of brand-name drugs, price stability for consumers, and efficient procedures on the part of the authorities responsible for regulation.

Nonetheless, the elaboration of an optimum strategy has to be completed by the development of essential and generic drugs programmes, which have shown their merits in achieving objectives of efficiency and equity in countries that have integrated them.

Lastly, it should be emphasized that pharmaceutical companies consider the use of their trademarks to be extremely important, sometimes more so than their patents. The cost of patents is high, however, and must be included in the estimates when a country is drawing up its global drugs strategy, especially bearing in mind that the new World Trade Organization, stemming from GATT, obliges signatories to adopt the patenting of medicinal products.

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