Position Paper on HB Entitled: An Act Regulating the Prices of Drugs and Other Pharmaceutical Products, Creating for the Purpose the Drug Prices Regulations Board and Instituting Further Measures to Lower the Cost of Medicines

Office of the World Health Organization in the Philippines

I. Current Industrial Situational Analysis

The total value of global pharmaceutical product was estimated to be 320 billion US dollars in 1999. And the growth rate of the pharmaceutical industry is around fourfold as compared to the over-all rates in the GDP. The average real growth rate of pharmaceutical production was 14.9% per annum as compared to the GDP annual growth rate increase of only 3.6% per annum\(^1\).

On the total global consumption however, 15% of the world’s population who live in high income countries purchased and consumed about 90% of total medicines by value, leaving only around 10 percent to the rest of the developing and underdeveloped nations. This data is a strong indication that there is a limiting factor on the access of the essential drugs and medicines on the population in these countries. In fact around 50% of the world’s population lack access to essential medicines.

One of the major factors for the poor access to medicines is cost. In many countries, drug prices are too high in relation to their local purchasing powers.

Drug prices are high for four primary reasons. Firstly, rigorous standards to protect the public from poor quality, unsafe and inefficacious drugs require manufacturers to invest in expensive research and development programs. The drugs that therefore pass the standards would then be priced so that a sufficient return of the investment is achieved. The costs would then include the costs of the drug itself, the costs of the research projects that failed, the cost of promotion, investment in future R and D and a yield into the stockholders dividends\(^2\).

Secondly, there are certain factors which tend to create monopolies. One, patent protection and the quality of drugs that are attributed to it. Products that improve health are relatively inelastic commodities and strong demand enables the patent holder to command a high price.

Third, third party payers, rather than the patient pay for drugs, thus making the consumer less price sensitive, and fourthly, since the consumer has no real understanding of the product, he or she tends to judge the quality and efficacy of the drug price on the basis of price: a higher price is almost synonymous to quality, and a lower price to substandard medicines.

\(^1\) The World Medicines Situation, WHO, 2004
\(^2\) Dukes, M.N.G., et. al., Drugs and Money, WHO regional Office for Europe, 2003
There are two general ways of controlling the prices of medicines. First is obtaining the best possible price through the selection and purchasing process and second is to ensure price regulation throughout the supply chain, from the level of the manufacturer down to the patient.

On price regulation, WHO Member states have regulated producer prices, retail mark-ups, wholesale mark-ups, retail plus wholesale mark-ups, producer price plus retail mark-ups. Table 1 below shows the number of WHO Member States which have been applying price controls. It can be seen from this data that there is a greater proportion among middle and high-income countries that exercise price controls. Table 1.

### Table 1.
**Price regulation according to countries’ level of income, 1999**

<table>
<thead>
<tr>
<th>Level of Income</th>
<th>None</th>
<th>Producer price only</th>
<th>Retail mark-ups</th>
<th>Wholesale mark-ups</th>
<th>Retail and wholesale mark-ups</th>
<th>Producer price + retail mark-ups</th>
<th>All</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low-income</td>
<td>20</td>
<td>2</td>
<td>8</td>
<td>0</td>
<td>6</td>
<td>1</td>
<td>2</td>
<td>39</td>
</tr>
<tr>
<td>Middle-income</td>
<td>30</td>
<td>4</td>
<td>7</td>
<td>4</td>
<td>12</td>
<td>4</td>
<td>4</td>
<td>65</td>
</tr>
<tr>
<td>High-income</td>
<td>4</td>
<td>4</td>
<td>0</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>4</td>
<td>18</td>
</tr>
<tr>
<td>Total</td>
<td>54</td>
<td>10</td>
<td>15</td>
<td>7</td>
<td>20</td>
<td>6</td>
<td>10</td>
<td>122</td>
</tr>
</tbody>
</table>

*Source: World Drug Situation Survey (1999)*

### The Anatomy of a Drug Price

The price paid for a medicine is made up of a number of price components, including the Manufacturer’s Selling Price (MSP) and all costs of freight, import tariffs, taxes, mark-ups distribution and dispensing fees.

The data provided by the Pharmaceutical Research Manufacturers of America revealed that costing was distributed as follows:

1. Research and Development 15%
   - The cost for research and development is further divided into:
     - a. Clinical Evaluation 40%
     - b. Basic research 27%
     - c. Development of Production Process 19%
     - d. Implementing Regulatory requirements 7%
     - e. Others 7%

2. Tariffs. Average tariff adds 23% to the price of active ingredients and over 12% to the price of finished medicaments.

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3 Worlds medicines situation, 2004
3. Add-ons. Add-ons comprise about 50% to 80% of price of medicines. Table 2 below shows the add-on cost for medicines in 10 countries.

<table>
<thead>
<tr>
<th>Country</th>
<th>Add-on cost (%)</th>
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<tbody>
<tr>
<td>Sr Lanka</td>
<td></td>
</tr>
<tr>
<td>Kenya</td>
<td></td>
</tr>
<tr>
<td>Tanzania</td>
<td></td>
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<tr>
<td>South Africa</td>
<td></td>
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<tr>
<td>Brazil</td>
<td></td>
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<tr>
<td>Armenia</td>
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<tr>
<td>Kosovo</td>
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<tr>
<td>Pune, India</td>
<td></td>
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<tr>
<td>Nepal</td>
<td></td>
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<tr>
<td>Mauritius</td>
<td></td>
</tr>
</tbody>
</table>

Add-on cost is one of the major components of a medicine price and it varies from country to country and from one product to another. The study conducted by Laing and presented on the Figures below show this wide degree of variation.

4 Worlds Medicines Situation
The figures above would show that add-on cost placed on medicines is of substantial matter. The biggest proportions are the wholesale and retail mark-ups. VAT and other taxes generally comprise the third biggest component of a drug price.

On the other hand, the draft paper prepared by Libby Levison on Investigating Price Components: Medicines Costs between Procurement and Point of Delivery, defines the stages of the pharmaceutical chain and the prices of medicines that goes through it.

Stage 1: Manufacturers Selling Prices (MSP) or Cost, Insurance and Freight (CIF).
For locally produced medicines the stage 1 is the MSP, for imported medicines, stage I is the MSP plus the insurance and international freight.

Stage 2. Landed Price
The landed price includes all other price components that are incurred in the procurement of medicines and their delivery to the procurement office. These include banking fees of foreign currency purchases, inspection charges, customs clear and transportation.

Stage 3 Wholesale Selling Price
This is based on the landed price and includes either the wholesaler’s or health center’s additional expenses: storage, handling, overhead expenses and profit margins.

Stage 5. Dispensed medicine price
This already includes the stage 4 price plus any dispensing fees and any sales taxes (such as VAT).
The Drug Atenolol (a preparation for hypertension) was studied along this concept in Malaysia at both the levels of the retail pharmacies and dispensing doctors. This study shows that the major part of a drug price is incurred in Stages I and 4. Tariffs and taxes however can also affect the cost of a medicine substantially.

II. General Comments to the Bill

The cost of drugs and medicines is one of the most important barriers to health care. Both prescribers and end users and even government policy makers have a very little insight into the actual cost of medicines, thus the market is not cost-driven. This lack of awareness has to some extent allowed the excessive prices of medicines in the market.

Often it is far from clear up to what extent the prices of the new preparations really reflect the cost of their development, production and marketing, but it is clear that in many cases the manufacturer will attempt to set what is generally known in commercial circles as “the highest price that the market will bear”.

Price Control Measures

In many countries as discussed above, price control measure is one of the mechanisms to contain the prices of drugs and medicines. The proposed bill in this instant case intends to do the same by fixing the Maximum Retail Price (MRP) of certain formulations.

6 Laing, Richard, Price Availability and Affordability of Medicines (International Comparison of 29 Surveys), WHO, 2005
7 Dukes, MNG, et. al., Drugs and Money, WHO Regional Office for Europe, 2003
Foremost, the government must consider the price components of medicines in this country to be able to determine the basis of the MRP. Second, the basis must be supported by valid data and methodology of computation. Also, the government may consider the other parts of the drug component which will be subjected to control. Of primordial significance is to decide whether the control must be placed at the level of the manufacturer or importer or at the level of the wholesaler.

**What is a Fair Price?**

The most difficult step in developing any price control system is the establishment of a “fair price”. The pharmaceutical market is not usually transparent, especially for medicines patented by Multinational Corporations. There are however methodologies that have been developed to arrive with what are fair prices both at the level of manufacturers and exporters and at the level of the wholesaler and the pharmacy.\(^8\)

Price Control Mechanisms at the Level of the Manufacturer/Exporter

1. **Cost-plus system**  
The cost-plus approach allows a certain profit margin at the level of the manufacturers and exporters. It however involves complicated calculations with respect to the cost of production. In such case, the pricing authority, or the “Regulatory Board” as provided for in the proposed bill needs extensive and reliable information about the costs and margins of the companies.

2. **Profit Ceilings**  
Under this system, a ceiling on the return on capital (sometimes on sales) for the company as a whole is set. An example of this is the Pharmaceutical Price regulation Scheme in the United Kingdom (PPRS) in which the government negotiates with individual pharmaceutical companies on the amount of profit that can be had through selling their products to the National Health Service. The greatest difficulty in this approach is also on the non-transparency of multinationals in disclosing both the cost and the earnings.

3. **Comparative pricing Systems**  
In comparative pricing systems, the prices of identical or similar products marketed in certain other countries are compared to the prices of products on the domestic market. Examples of countries which have used this system are Portugal, Romania and the Netherlands. **Other countries require companies, when bringing new products to the market, to supply information on the prices of these products in selected foreign countries.** In The Netherlands, maximum permissible prices of pharmaceuticals are set by calculating an average price on the basis of comparable products in Belgium, Germany, UK and France. Medicines are considered comparable when they have the same active ingredient. Prices are compared at the pharmacy buying level, net of Value Added Tax. This

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\(^8\) Dukes, MMNG, et.,al., Drugs and Money, WHO Regional Office for Europe, 2003
system has been implemented in 1996, and prices of pharmaceuticals in that country have fallen to an average of 20%.

4. Price Negotiation Models

As mentioned, the customer in the pharmaceutical industry is not cost-driven for varied reasons. One, as has been mentioned, price is considered as a function of quality and efficacy. Second, the decision making is usually lodged on the doctor, and third, health insurance pays for their medicines. Because of these factors, the consumer or the individual patient is in a too weak position to enter into negotiation.

Institutional buyers therefore, such as the government, hospitals and insurance systems have more technical expertise and authority to negotiate. In most European countries, virtually no market for pharmaceuticals exist outside the social health care system and often pricing authorities can refuse to admit a drug to their re-imbursement system if the price of the drug is considered too high.

Price Controls at the Level of the Wholesaler and Pharmacy

A mechanism for price control at the wholesaler and pharmacy levels is the limitation of distribution margins

The costs associated with the distribution of drugs consist of the mark-ups of the wholesalers and the pharmacies. Margins at this level can represent more than 40% of the price ultimately paid. This strategy therefore involves limiting both the wholesale and retail margins.

There are two mechanisms for limiting the wholesale margin. One is to allow the wholesaler a maximum margin for its services and second is to set a maximum for the price at which the wholesaler can sell a product to the pharmacies. An example of this system is in Romania where a maximum is set for the total distribution mark-up, with subsidiary provisions, setting a maximum margin for the wholesaler and a minimum margin for the pharmacy with the total mark-up.

On the other hand, limiting pharmacy retailing margins may take the form of setting a fixed percentage mark-up from the wholesale prices of medicines.

Supporting Provisions

The proposed bill however as it is alone, is not sufficient to effect a price control mechanism. As discussed above, all the proposed mechanisms and systems would be primarily dependent on reliable and valid data. The data needed in order to develop and monitor drug policies must therefore relate to a whole series of issues and actors. Important variables that must be considered include various aspects of prescribing,
dispensing, consumption and the ultimate consequences in terms of health and finance. Facts and figures on pharmaceutical expenditures, utilization, manufacturing costs, and health and economic outcomes must be considered. Also, the methodology by which the data shall be obtained must be fully considered.

The determination of the “right” or “fair” or “proper” price however, primarily relies on the transparent disclosure by the players in the pharmaceutical industry (the manufacturers, wholesalers and distributors) of the price components that they incur in the manufacture and distribution of their products. A provision must therefore be provided to this effect.

**Other Cost Containment Measures**

The determination of the basis of the medicines cost may demand considerable resources and systems, particularly technical systems. Thus absent such established systems, other strategies or mechanism for cost containment may be applied. The following mechanisms are recommended aside from Price Controls.

1. Reimbursement systems through the creation of positive list and reference pricing.
   A list of medicines eligible for re-imbursement is called a positive list. In the Philippines the Philippine National drug Formulary (PNDF) is used as a positive list, such that drugs which are not found in the PNDF are generally not reimbursed by Philhealth.

   On the other hand, reference pricing has already been widely used in many countries. It is a means of setting limits to the reimbursement level of a drug by making use of the existence of equivalent drugs in the market. In the light of the current prices of similar drugs, a single “reference price” is fixed which authorities regard as acceptable for funding. If the price of any product is higher than the reference price, public payment of re-imbursement will only be granted up to the level of the reference price and the difference will have to be paid for the patient (co-payment).

   Reference price systems serves three purposes: 1) they are a tool to induce both physician and patient to choose cheaper medicines within a therapeutic group, thus decreasing the costs for society; 2) they stimulate the suppliers of more expensive medicines within a group to lower the prices and 3) they make both prescribers and patients more aware of possible alternatives to the drugs which they might in the first instance be inclined to choose, thus increasing the transparency of the of the pharmaceutical market.

2. Generic Substitution and Parallel Imports

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9 *Ibid, p 15*

10 *Ibid., 38*
Generic substitution is defined as the process through which governments seek to reduce costs by stimulating the prescription and dispensing of generally cheaper generic medicines. Parallel Importation on the other hand (as that already implemented by PITC) is a system by which drugs are obtained in bulk from a foreign country where the sales price is much lower and importing is independently “parallel” with the official agent of the manufacturer.

3. Professional Interventions and Strategies for Influencing Demand

The objective of this strategy is not primarily to contain costs but to influence demand and optimise rational prescribing and use. The relevance to expenditure is that, by optimizing rational prescribing and drug use, direct waste (over-use of drugs) is prevented, and the treatment becomes more cost-effective. The promotional efforts of the industry that is directed through professionals and he consumers themselves must be countered by the government. The mechanisms can include, the provision of independent drug information, drug formularies, and therapeutic guidelines.

III. Comments to Specific Provisions of the Proposed Bill

1. The use of the term “regulated drugs” must be qualified since the term “regulated drug” has been defined under the Dangerous Drugs Act of 1972 as:

"Regulated drug," which includes self-inducing sedatives, such as secobarbital, phenobarbital, pentobarbital, barbital, amobarbital and any other drug which contains a salt or a derivative of a salt of barbituric acid; any salt, isomer or salt of an isomer, of amphetamine, such as benzedrine or Dexedrine, or any drug which produces a physiological action similar to amphetamine; and hypnotic drugs, such as methaqualone or any other compound producing similar physiological effects;

2. Powers of the Board

a. Price controls involve not only the setting of the initial current price of a drug, but also the regulation of price increases and sometimes also the power to reduce existing prices which have been found to be excessive. These functions may therefore be included in the Powers of the Board.

b. The “when public interest so requires” is not necessary. The government’s responsibility to control the prices of medicines must alone be based on the fact that the people has the fundamental right to health, and the control in the prices of medicines is an important mechanism by which this right can be achieved. Further the clause would also invite the danger of other sectors questioning on what could be the criteria as determinant to “public interest”.
c. The basis for the determination of a ceiling price must be backed up by scientific data and methodology and the mechanisms for review must be properly defined in the IRR.
d. Item (b). The Board shall have the power to include formulations in the List of Regulated Drugs. There are two points that must be considered here:
   - A list of essential drugs and medicines called the Philippine National Drug Formulary already exists. This has also been used as the basis for government purchasing and re-imbursement by the Philhealth. Since all the essential medicines are already contained in the PNDF, the drugs listed therein may already be the subject of price control;
   - Technical competence in the development of the list may become an issue here. The PNDF has gone through a rigorous study by a scientific committee to determine what is to be included as essential drugs. The preparation of a drug list with regulated prices alone and which is not based on what is essential may confuse prescribers and end-users and may cloud the use of the PNDF.

e. Item (c) must be clarified. This provision seems to encroach on the distribution systems which to our opinion are purely a strategy of the producer or distributor. If the intent of this provision is for the government to ensure low prices in bulk purchases, price negotiations with the innovator companies may be considered instead.

3. Section 8 may include the other cost-containment measures prescribed above. The proposed amendments of the Generics Act as provided for in the proposed Bill may not necessarily influence the prices of medicines. Further there is a danger to the qualification provided in paragraph (b) thereof, such that the insertion of the “no substitution” and the provision of criteria 1-3 may cloud the intent of the Generics Act. The main intention of the Generic Act is for all physicians to prescribe and use generic drugs, and therefore is not subject to any qualification. It is not therefore necessary to amend these particular sections of the Generics Act.

4. Section 10 fixes the maximum retail price for drugs and medicines. The 15% ceiling provided must be based on valid data.

5. Section 11. List of Regulated Drugs. As mentioned, there is already an existing list of essential drugs and medicines known as the PNDF. The medicines that are listed here, since they are the medicines considered essential, may already be the ones that will be subjected to price control.

6. Section 12. Information to be furnished by Manufacturers or Importers. As mentioned above, more than any other information, it is necessary that the
government can have the authority to compel drug manufacturers to disclose the components of the drugs and medicines they produce. Such disclosure must be included in this Section.

IV. Conclusions and Recommendations

Price Control is one mechanism by which the government can pursue to reduce the cost of essential drugs and medicines. However, to be effective and sustainable it must be pursued along with other programs. The following are thus recommended:

1. If price regulation is to be pursued, the government must give the highest consideration on the importance of accurate and scientific data, and ensure that the methodologies employed in the gathering, collection, and analysis of the data is devoid of biases.

2. A provision mandating manufacturers and other players to disclose the price components of their products must be provided to enable the determination of the “right” or “fair” price;

3. The Department of Health may be required or an independent group may be commissioned to develop a cost-effective mechanism for price control, based on the attendant factors of the pharmaceutical industry in the Philippines and on the established models of price control in other countries, and,

4. Consider other alternatives of cost-containment, such as reference pricing, restrictions on advertising and promotion, enhancing generic competitiveness and developing incentive systems to increase use of generic medicines.