

DRUG REGULATION IN THE PHILIPPINES

Allan Grand A. Sobrepeña

Graduate Student,
Masters in Public Administration
National College of Public Administration and Governance
University of the Philippines

I. Introduction and Overview

Access to essential drugs is vital for the promotion of better health for the entire population. However, access to these essential drugs are hampered by a number of factors, most notable among which are the uneven availability of essential drugs across different areas and low capacity to pay (Lachica, 2008). Furthermore, “it is argued that the prices of drugs and medicines reduce access to medical care by the poor, reinforces irrational drug use, and imply deadweight losses” (Solon and Banzon, 1999:90).

High prices of drugs are being used as an argument for greater government role in the drugs sector through effective regulation of the drug market. To note, there have been different programs or policies implemented in order for government to have a more active role in drug regulation. The passing of RA 3720 or the “Food, Drug and Cosmetic Act” facilitated for the creation of the Food and Drug Administration (FDA). The FDA was tasked to oversee the implementation of RA 3720, and serve as the central regulatory agency on food and drugs. Executive Order (EO) 851 abolished the FDA and in its place the Bureau of Food and Drugs (BFAD) was created. In the launching of the new BFAD office, then President Corazon Aquino also publicly announced the Philippine National Drug Policy, which shall serve as the blueprint of the country’s drug policies. It has four pillars, Quality Assurance, Rational Use of Drugs, Self- Reliance, and Tailored Procurement (BFAD, 2008).

Another notable legislation is the Republic Act (RA) 6675 more commonly known as the Generics Act of 1988. Although the “tendering of generic products” is considered as a powerful price reduction tool, this has not been the case with the Philippines. It was observed that “through generic competition, price reductions of 75% to 95% were achieved over the initial brand prices” (WHO, 2004:3). For the case of the Philippines, the penetration of generic drugs in the market is only 5% (Institute of Philippine Culture, 2004).

Furthermore, the tapping of the Philippine International Trading Corporation (PITC) to serve as the lead implementing agency in the country’s parallel importation program for pharmaceuticals is another government initiative to improve access to high quality, branded medicines for some of the most common life-threatening ailments. The parallel importation program was initiated in order for low-priced drugs to be able in the local market (PITC, 2008).

The latest addition to the government initiatives is the passage of RA 9502 or the “Cheaper Medicines Act of 2008”. This legislation gives power to the President, upon recommendation of the Health Secretary, to impose a maximum retail price (MRP) over any or all drugs enumerated in the Philippine National Drug Formulary (PNDF) Essential Drug List, or other drugs as identified in Section 23 of the RA.

However, despite the abovementioned government policies with the exception of RA 9502 by virtue of its being newly implemented, drug prices in the Philippines are the second highest in Asia. Furthermore, it was found in the survey that “medicines cost 3.4

to 184 times higher than the international reference prices” (Western Pacific Regional Office (WPRO)-WHO, 2007:3).

The high prices of drugs in the Philippines will serve as the background upon which the analysis of the intricacies of the drug issue will revolve. This paper will provide a quick glance at the pharmaceutical sector at the global level and provide a more in-depth discussion of the pharmaceutical sector in the country.

The paper will try to answer whether drug prices are high as a result of market failures or government failures or a combination of both. Furthermore, the paper will try to explain why drug prices in the Philippines are higher compared to other neighboring countries using market failure particularly monopolistic tendencies of pharmaceutical companies to be specific. It is acknowledged that there are a number of reasons why drug prices are high; however, focus will be given on monopoly and the two reasons that causes monopolistic pricing— lack of competition and patent protection which is said to exacerbate the drug price situation.

From the analysis, the paper will try to draw recommendations that may help relevant stakeholders in coming up with effective decisions. It is envisioned that the paper will at least provide a coherent analysis of the drug issue in the country.

II. Background of the Industry

The Global Pharmaceutical Industry

The global drug industry is valued at US\$631 billion as of June 2007. It is said to be growing at a compounded average growth rate of 7.9% since 2002. Furthermore, the Asia-Pacific/African and Latin American drug markets are growing faster compared to the other regional drug markets (Pharmaceutical and Healthcare Association of the Philippines (PHAP), 2008).

Table 1.Audited Global Market by Region for June 2007

REGION	Moving Annual Total (MAT) June 2007 (US\$)	% Share	MAT June 2006 (US\$)	2002-2006 CAGR (%)
North America	299	47.5	291	8.7
Europe	189	30.0	182	7.0
Japan	56	8.9	57	2.8
Asia-Pacific/Africa	56	8.9	52	11.3
Latin America	29	4.6	28	13.7
GLOBAL MARKET	631	100	609	7.9

Source: PHAP, 2008.

The global pharmaceutical market is currently dominated by the United States with 44.6% of the entire market share, followed by Japan with 8.9% market share. Japan ranks as the 2nd largest country in the world in terms of its percentage share in the global pharmaceutical market. It is followed by Europe's top five countries, France, Germany, UK, Italy and Spain that comprise two-thirds of the European market, cornering 20.7% share of the entire global market.

Table 2. Top Ten Pharmaceutical Market Sizes (2007)

RANK	COUNTRY	MAT June 2007 (US\$B)	% Share
1	US	283.3	44.6
2	Japan	56.3	8.9
3	France	36.2	5.7
4	Germany	33.6	5.3
5	UK	22.1	3.5
6	Italy	21.3	3.4
7	Spain	17.8	2.8
8	Canada	16.0	2.5
9	China	12.1	1.9
10	South Korea	9.5	1.5

Source: PHAP, 2008.

In terms of incomes, the cumulative values of the world's top 20 pharmaceutical companies total US\$ 378 billion representing 60% of the entire global pharmaceutical market. The highest ranking pharmaceutical company in terms of market share is Pfizer with 7.1% share, followed by GlaxoSmithKline with 5.9%, Novartis with 5.2%, Sanofi-Aventis with 5.1%, and AstraZeneca with 4.5%. Johnson & Johnson is number six with 4.4% share (PHAP, 2008).

The Philippine Pharmaceutical Industry

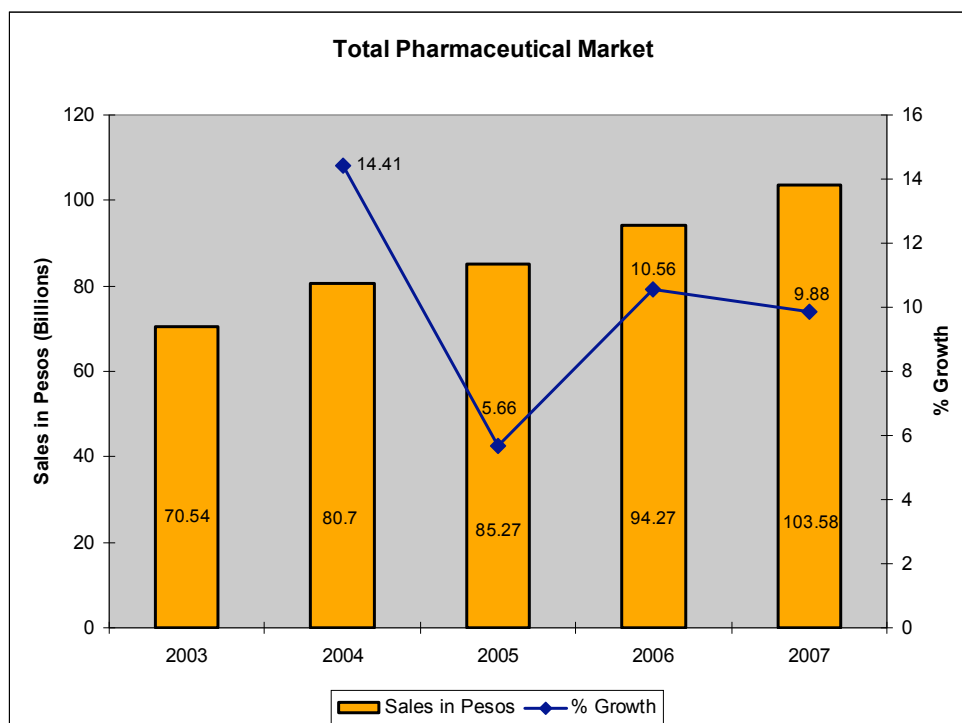
The Asia Pacific pharmaceutical market is led by Hong Kong-China cornering 27.28% market share, followed by Korea, Australia, India, and Taiwan with 19.39%, 15.02%, 12.75% and 6.12% respectively. The Philippines has a 3.93% share in the Asia Pacific market. The Asia-Pacific Market shows high growth rates, even surpassing the global industry average. Due to this, the Asia-Pacific market is being projected as the "new growth hub for the pharmaceutical industry in 2008 (PHAP, 2008: 74-75).

As stated in the preceding paragraph, the Philippine pharmaceutical industry has a 3.9% share of the Asia-Pacific market. This is valued at PhP 103.58 billion as of September 2007. Furthermore, the industry has a CAGR of 10%. Of the PhP 103.58 billion, 93% comprise drugs, both prescription and over-the-counter. The remaining 7% are non-drug products, e.g. nutritionals, devices, and cosmetics (PHAP, 2008).

The Philippine pharmaceutical industry is composed of the different drug distributors, wholesalers, retailers, and manufacturers, and of course, the consumers. From 2003 to 2007, it can be observed that there is an increase in the number of both

local and foreign drug companies. However, the increase rate of foreign owned companies are higher. In terms of sales, foreign companies posted PhP 71.12 billion, while local companies were able to sell PhP 32.46 billion (PHAP, 2008).

Figure 1. Philippine Pharmaceutical Market



Source: PHAP, 2008.

Table 3. Number of local and foreign companies established (2003-2007)

COMPANIES	2003	2004	2005	2006	2007
Local	208	210	224	224	240
Foreign	165	171	194	203	231

Source: PHAP, 2008.

Table 4. Comparative Growth Trend: Foreign vs. Local Companies (in Billions of Pesos)

COMPANIES	2003	2004	2005	2006	2007	4-year % CAGR
Local	20.15	23.71	24.43	28.40	32.46	12.67
Foreign	50.38	56.99	60.83	65.86	71.12	9.00
TOTAL	70.53	80.70	85.26	94.26	103.58	10.08

Source: PHAP, 2008.

III. Statement of the Problem

As stated earlier, the Philippines has the second highest drug prices in Asia, second to Japan. Medicines in the Philippines “cost 3.4 to 184 times higher than the

international reference prices” (WPRO)-WHO, 2007:3). Furthermore, Filipino consumers are paying more than twice the price of the same branded off-patent drugs that are being sold in India and Pakistan. As a result of the exorbitant drug prices, there is a “reduced access to medical care by the poor and the consequent irrational drug use, i.e. resulting to ineffective remedies and improper dosages” (Solon & Banzon, 1999; and Kraft, 2006:11).

Table 5. Comparative Trade Prices of Branded Medicines in the Philippines, India, and Pakistan, in Pesos (2005 as base year)

BRAND NAME	MANUFACTURER	PHILIPPINES	INDIA	PAKISTAN	MAXIMUM PRICE DIFFERENTIAL
Fortum 1g inj	Glaxo	980.00	390	304.22	675.78
Ventollin 100mcg inh	Glaxo	315.00	123.31	62.10	252.90
Adalat Retard	Bayer	37.56	1.40	3.63	36.16
Plendil ER 5mg/tab	AstraZeneca	35.93	4.58	7.78	31.35
Lopid 300mg/cap	Pfizer	36.39	12.27	2.72	33.67
Ponstan 500mg/tab	Pfizer	21.82	2.61	1.38	20.44
Voltaren 50mg/tab	Novartis	17.98	0.86	3.70	17.12
Bactrim	Roche	15.55	0.69	1.03	14.86
Diamicron 80mg/tab	Servier	11.46	7.05	4.71	6.75
Immodium 2mg/cap	Janssen	10.70	3.05	1.83	8.87
Isordil 5mg/tab	Wyeth	10.29	0.24	0.22	10.07
Buscopan 10mg/tab	Boehringer	9.61	2.28	0.57	8.92
Lasix 40mg/tab	Aventis	8.99	0.49	1.21	8.50

Note: Maximum Price Differential = highest price – lowest price

Source: WPRO-WHO, 2007.

Considering the big discrepancies in prices of drugs, what could be the problem? The Philippines has quite a number of legislations that seek to influence the prices of drugs— Generics Law and the Cheaper Medicines Act of 2008, and yet drug prices remain to be high. The Generics Act that sought to provide an alternative to branded medicines has only a 5% market penetration (Institute of Philippine Culture, 2004). Furthermore, the Philippine government has tapped the PITC in coordination with the Department of Health (DOH) and the BFAD, to spearhead the parallel importation program of the government, another measure to lower drug prices, but still, it was not able to influence market prices of drugs.

IV. Theoretical Considerations

One then is made to ask whether the issue with the drug regulation in the Philippines is a result of market failure particularly the monopolistic tendencies and

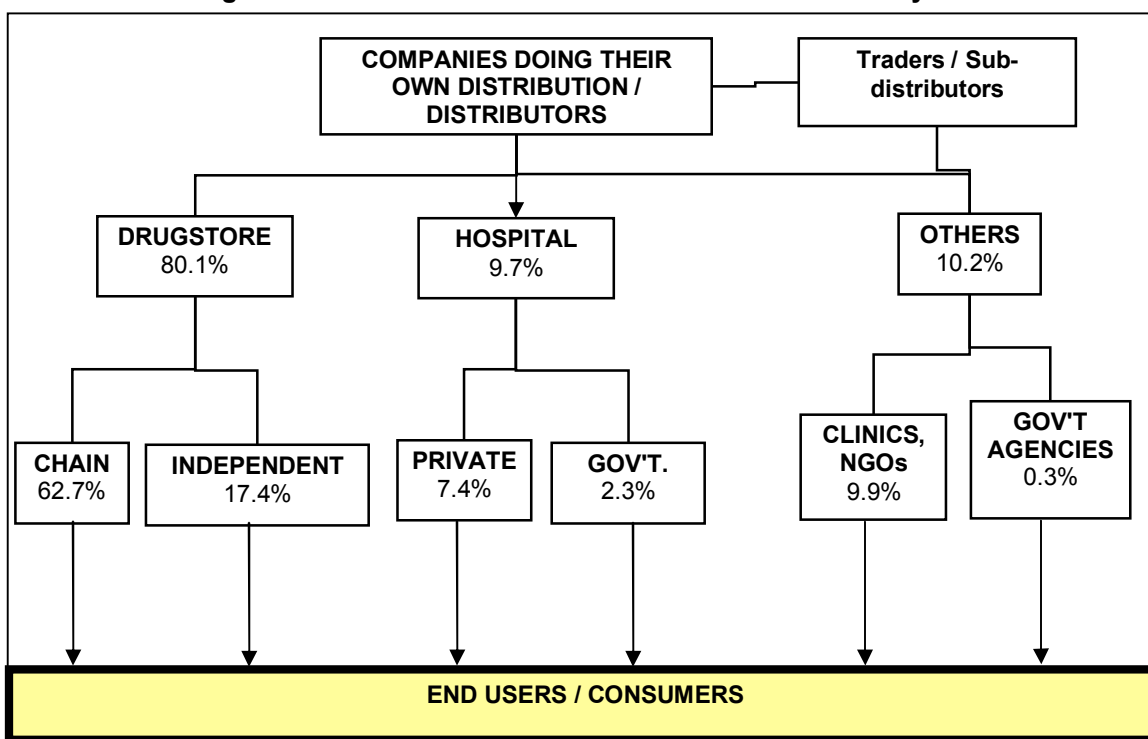
structures of the Philippine pharmaceutical industry? Or is the fault solely the government's, as a result of lack of capacity in the implementation of the different programs? Or worse, could it be that it is a conglomeration of both market failure and government failure?

Market Failure

In its simplest sense, market failures occur when individuals or firms in pursuit of their self-interest, cause inefficiencies and inequities in how the market operates. This paper will look at monopoly, a form of market failure to explain the issue of high drug prices in the Philippines. As Solon and Banzon (1999:90) claim, "the prices of drugs and medicines are considered to be at levels that produce inequities as well as inefficiencies".

What makes the pharmaceutical industry monopolistic? To better understand this, it is essential to know how drugs reach the consumers.

Figure 2. Market Structure of the Pharmaceutical Industry



Source: PHAP, 2008.

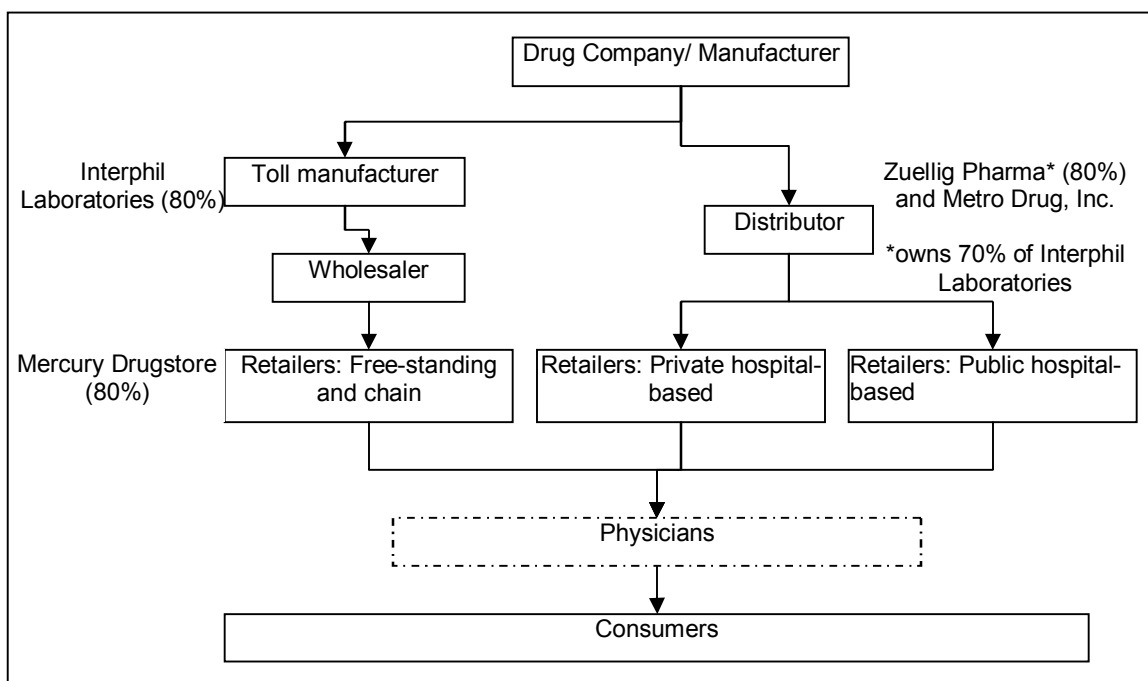
Looking at the market structure, it can be seen that drugstores are the main vehicles for drugs to reach the consumers. As much as 80.1% of drugs are coursed through drugstores, while 9.7% of drugs are distributed by hospitals, and 10.2% are distributed by other means. 62.7% of the drugs distributed in drugstores are found in chain drugstores, e.g. Mercury Drugstore, while 17.4% are distributed in independent

pharmacies. Of those distributed in hospitals, 2.3% are given by government hospitals, while the remaining is from private hospitals.

Juxtaposing the previously cited data, of the top 20 companies in the Philippines, 16 are foreign owned and they have a combined sales value of PhP 58.23 billion or 81.87% of the share of foreign companies. 80% of the toll manufacturing of these foreign companies is handled by Interphil Laboratories (Kraft, 2006). “Since most products are imported, the transfer price or profit share of the exporting company accounts for half of the landed cost of the drug products” (Lachica, 2008:3).

Furthermore, at the wholesale distributor level, Zuellig Pharmaceuticals, Inc. together with its subsidiary Metro Drug, Inc. distributes around 80% of the drugs sold in the market. The remaining 20% is marketed or distributed by the manufacturers themselves or through small distribution firms (Kanavos, P. J. Lim, and C. Pascual, 2002; and Lachica, 2008). “The manufacturer pays 5 to 30% of total annual sales distribution fee to the distributor” (Esguerra & Oprecio, 2004:7). Interesting to note is that Zuellig Pharmaceuticals, Inc. owns the majority of stocks of Interphil Laboratories totaling 70%.

Figure 3. Market Structure of the Drug Industry with Emphasis on Market Control



Source: Lachica, 2008. Modified and updated to include 2008 figures.

What can be inferred from the above statements is that, in essence, despite the increasing number of players in the pharmaceutical sector, only a few have control of the majority of the market. The issue that arises out of this arrangement is that at the manufacturing level, the pharmaceutical industry is controlled by foreign-owned corporations, while the toll manufacturing and distribution is being controlled by only a

few players, the biggest of which is Zuellig Pharmaceuticals, Inc. and Interphil Laboratories.

At the drugstore level, majority (62.7%) is owned by chain drugstores. Mercury Drug, Inc. dominates the retail market, cornering 80% of the total sales of drug retailers (Esguerra & Oprecio, 2004). Furthermore, at the retail levels, particularly on chain drugstores, prices are marked up by 7-15%, while private hospital pharmacies mark up prices by 15-30%. The dominance of a few players in the pharmaceutical market increases the market power of these companies in dictating drug prices.

Patent protection further increases the likelihood of high drug prices. Similarly, the quality of drugs attributed to it also increases the likelihood of monopolies. (Office of the WHO-Philippines, undated). Although “patent protection is recognized as instrumental in promoting the invention, development and marketing of new drugs, by providing incentives for research and development”, it has also added to the apparent monopoly of the pharmaceutical industry. The patent holder by virtue of the protection afforded to his product, is “granted exclusive right to manufacture the product or use the process, thus granting monopoly rights on the holder” (Kraft, 2006:12).

The Philippines, as a signatory to the World Trade Organization Trade Related Aspects of Intellectual Property Rights (WTO-TRIPS), it still provides flexibilities in trade in health, in this case pharmaceuticals.

Article 8 of the agreement states that members are given flexibility in adopting or amending their laws especially in relation to protecting public health and nutrition. TRIPS in this case is not limiting as other may claim. It further provides for mechanisms to safeguard the aforementioned public interests. Parallel importation as well as the limited exceptions to exclusive rights, compulsory licensing and protection of data (non-exclusivity).

“Parallel importation is the importation of a patented product from a country where it is marketed either by the right holder or with his consent. The rights of the right holder are deemed to have been exhausted or used in another country so that imports from that country are permissible” (Kraft, 2006:13).

The Philippines has adopted this safeguard mechanism. However, it has not to a certain extent affected drug prices in the greater drugs market. According to Kraft (2006), even if drugs acquired through parallel importation have relatively lower prices, if these are coursed through the dominant single wholesaling and distribution company, in this case Zuellig Pharma, it would erode the price reductions since there are mark-up costs being placed by Zuellig Pharma. Furthermore, if these same drugs are coursed through Mercury Drug Chain, this will further erode the price reductions.

The problem with this situation lies in the dilemma that if the drugs are coursed through government hospitals, these hospitals have a low share of 2.3% in the drug market as opposed to the 62.7% share of Mercury Drug.

A Special Case of Government Failure

The government failure aspect of the drug issue lies in certain government policies initiated which did not have impacts on the industry they sought to affect. Parallel importation alone is not enough to affect drug prices. As stated in the preceding paragraphs, even if prices of drugs under parallel importation are cheaper, the mark-ups in the distribution and retail level will erode the lower prices. As such, parallel importation needs a vehicle wherein it can market the drugs imported with no mark-ups so as not to increase the price. Coursing it through hospitals will not be as effective as coursing it through independent retailers who have a higher market share compared to government hospitals.

Furthermore, even government itself instead of facilitating the smoother transactions in parallel drug importation has in fact even facilitated for hindering parallel drug importation. RA 8203 or the Special Counterfeit Drug Law of 1997 was a domestic drug regulation that served as a non-tariff barrier. Its Implementing Rules and Regulations that “unregistered imported drug products that have counterpart registered brands in the Philippines shall be considered as counterfeit” (Kraft, 2006:15).

Similarly, the policy issuances of the Department of Health (DOH) at times are not in accordance to pending legislations that seek to lower drug prices. In an official statement of the DOH, it was calling for the removal of the generics only provision of the Cheaper Medicines Bill. It cites several survey studies conducted by the Social Weather Station (SWS) saying that since more Filipinos are already buying generics drug (from 47% in 2003 to 54% in 2006), a generics only provision is no longer necessary. Furthermore, DOH also asserts that 45% of Filipinos now believe that medicines are now cheaper as opposed to 7% who said the same in 2001. Lastly, the DOH says that 6 out of 10 Filipinos in the D and E classes have access to and have brought generic drugs.

What this implies is a disjoint in policies or directions that the legislature and the DOH are taking. The DOH as the lead agency in terms of public health must at all times try to coordinate with members of the legislature. The pronouncement made by the DOH makes their motives questionable. In the heat of the Cheaper Medicines enactment into law, one can always conjecture that DOH wants to remove the generics only provision. The statement of DOH saying that “thrust of the DOH is for all Filipinos to have access to safe and quality medicines whether generic or branded as long as they are affordable” is replete with innuendos that non-generic drugs are of better quality. It must be remembered that the generics only provision of the bill will sort have “turn the tide”, wherein prior to the Cheaper Medicines Act, it is the branded medicines that were given primacy and the generic drugs are only an option. With the passage of the Act, it would be the other way around.

V. Recommendations

Despite the different issues confronting the regulation of the Philippine pharmaceutical sector, there are also notable gains that the government has achieved. The President in seeking to reduce drug prices as well as to increase accessibility initiated the National Drug Policy- Pharmaceutical Management Unit (NDP-PMU 50) or the Pharma 50. It is a multi-stakeholder initiative of both private and public stakeholders.

This program has seen notable gains and needs to be continued, if not strengthened. Pharma 50 needs to be strengthened since it is complementary to the Botika ng Barangay. These two programs may just well answer the issue of drug prices since; there is now a working program that ensures that affordable and quality drugs are available. The Botika ng Barangay serves as the retail outlet of the government's parallel drug importation initiatives. The barrier imposed by mark-ups will now be greatly diminished. Initial success as shown by the increase of "BnBs nationwide from 4,738 in 2005 to 7,437 in 2008", must be sustained (NEDA, 2008:1).

Another recommendation is the stricter monitoring and implementation of the Cheaper Medicines Act since it has provisions that need closer monitoring for them to be effective among which is the generics only provision of the Law.

Furthermore, the President must exercise the power afforded to her to set the maximum retail price (MRP) of medicines upon recommendation of the Health Secretary. The President must at least immediately impose the MRP of essential drug products especially for those that are the most used drugs in the country like the calcium antagonists which are prescribed for hypertension, the antibiotics, and those that are needed for nutrition like micro-nutrient drugs for children and pregnant women.

In addition, BFAD, being the lead agency in drug regulation must have the capacity to perform its job efficiently and effectively. It is therefore recommended that the Senate Bill (SB) 2645 or the BFAD strengthening bill which seeks to strengthen the regulatory capacity of BFAD by establishing adequate testing laboratories and field offices, upgrading their equipment, augmenting their human resources, and giving it the authority to retain its income.

Strengthening the regulator will ensure that quality testing and certification of drugs are done in a fast and effective manner thereby reducing the transaction costs that drug manufacturing companies may incur due to delays and lack of testing equipment of the BFAD.

Having an effective and holistic drug policy indeed is essential. More than having the necessary legislation and laws, it is also important that mechanisms to spur competition are present, as in this case, the Botika ng Barangay, and the parallel drug importation program of the government. The best way to deal with monopolistic tendencies of the drug industry does not rest entirely upon setting up price control mechanisms; rather, it rests in setting up the right competitive environment for the sector.

References:

- Cayetano, Pia. 2008. Sponsorship Speech on BFAD Strengthening.
<http://www.senatorpiacayetano.com/psc/allthebills.php?recordID=83>
- [DOH] (2008) Joint DOH-DTI-IPO-BFAD Administrative Order No 2008-1. The Implementing Rules and Regulations of RA 9502 other wise known as the “Universally accessible cheaper and quality medicines act of 2008.
- [DOH] Department of Health. (2005). Administrative Order No 2005-0031. Guidelines and Procedures for the Principal Issuance of the Principal Certificate of Product Registration.
- _____ (2004). Administrative Order No 144 s. 2004. Guidelines for the Establishment of Botika ng Barangays and Pharmaceutical Distribution Networks.
- _____ (2004). Administrative Order No 145 s. 2004. Revised policies and Guidelines for the Institutionalization and Decentralization of the Department of Health Drug Consignment System.
- _____ (2004). Department Memorandum No 118 s. 2004. Botika ng Barangay Performance Monitoring Reports and Routine Schedule of Submissions.
- [DOH] Department of Health. (2008) Official Statement on Cheaper Medicines Bill.
<http://www.doh.gov.ph/node/1819>
- _____ (December 2005) Essential drug price monitoring system. National Drug Policy.
- Esguerra, V. & J. Opreco (2004) Drug industry and parallel imports. UPSE: unpublished undergraduate thesis.
- Kanavos, P., J. Lim and C. Pascual. (June 2002) On improving the poor’s access to affordable drugs. Philippine Health Policy Note. World Bank.
- Kraft, A. (2006) Competition, promotion, and the prices of drugs and medicines, Public Policy 3(3):90–106.
- [NEDA] National Economic and Development Authority (2008) Bringing Cheaper Medicines to Filipinos, DevPulse XII (12):1-2.

Institute of Philippine Culture (undated) The Prices People Have to Pay for Medicines in the Philippines. Ateneo de Manila, Philippines.

Lachica, J. (2008) Improve access of the poor to quality and affordable essential drugs. Health Policy Notes, 1(6):1-6).

Office of the World Health Organization in the Philippines. (Undated). Position Paper on the HB Entitled: An Act Regulating the Prices of Drugs and Other Pharmaceutical Products...and Instituting Further Measures to Lower the Costs of Medicines.

[PHAP] Pharmaceutical and Health Care Association of the Philippines (Nov 2008) Philippine Pharmaceutical Industry Fact Book. 7th Edition.

[PhilHealth] Philippine Health Insurance Corporation (2008). Stats and Charts 2008.

Lachica, J. (2008) Improve access of the poor to quality and affordable essential drugs. Health Policy Notes, 1(6):1-6).

Ramos, J. (2006) Pharmaceutical policies for affordable access. Presentation given at the Asian Institute of Management, Makati City.

Ratanawijitrasin, S. & E. Wondemagegnehu (2002) Effective drug regulation: A multicountry study. WHO.

Republic Act No. 9502. Universally Accessible Cheaper and Quality Medicines Act of 2008.

Republic Act No. 6675. Generics Act of 1988.

Solon O, Banzon E (1999) Competition, promotion, and the prices of drugs and medicines, Public Policy 3(3):90–106.

[WPRO-EDM] Western Pacific Regional (June 2005) National drug reimbursement price standard in Japan. Essential Drugs and Medicines Policy, IV (1): 2.

_____ (2005) Regional strategy for improving access to essential medicines in the Western Pacific Region 2005-2010.

_____ (2007). Cheaper Medicines Bill in the Philippines, Essential Drugs and Medicines Policy. VII (1):2-4.

_____ (October 2002) User friendly computer assisted drug registration system. Essential Drugs and Medicines Policy I (2):6.

[WHO] World Health Organization (2004) equitable access to essential medicines: A framework for collective action, WHO Policy Perspectives on Medicines No 1: 1-6.

_____ (1997) Comparative analysis of national drug policies.

_____ (2000) WHO medicines strategy 2000-2003, WHO Policy Perspectives on Medicines No 1: 1-6.

_____ (2004) World Medicines Situation. WHO Geneva.

_____ (Jan 2006) TRIPS, intellectual property rights and medicines, Briefing Notes: 1-4.