Health Policy Notes

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"Sustaining the Gains of Effective Regulation for Health"

The Department of Health (DOH), as the lead agency in the health sector, developed and institutionalized the Health Sector Reform Agenda (HSRA) in 1999. The HSRA describes the major strategies, organizational and policy changes, and public investments needed to improve the way health care is delivered, regulated and financed. One of the reform areas in HSRA is health regulation, which has become a major function of the DOH especially after the devolution of health services to the Local Government Units (LGU) in 1991. Other reform areas of the HSRA are hospital reform, public health, local health system, and health financing.

The HSRA identified two policy objectives in its regulatory reforms: (1) improved access to quality low-priced drugs; and (2) improved regulatory and enforcement mechanisms for ensuring quality and safety of health facilities, products, and services. To achieve these goals, three reform strategies were formulated: (1) identify and address the gaps in health regulation, particularly, strengthen the legal mandates for regulation and enforcement; (2) strengthen the capabilities of central office and regional health offices in standards development, licensing and enforcement; and (3) develop new regulatory instruments to promote competition, cost containment, better accessibility and quality assurance in health care markets.

Several initiatives on regulation were then made to implement the HSRA. To improve access to quality low priced drugs, new programs were formulated including the parallel drug importation scheme; DOH Model Botika (Integrated Hospital Pharmacy Program); establishment of Botika ng Barangay and Botika ng Bayan; development of the Essential Drug Price Monitoring System; Pharma 50 program; and Gamot na Mabisa at Abot Kaya Project (GMA 50). To improve the regulatory and enforcement mechanisms of DOH regulatory agencies, the Sentrong Sigla Movement was initiated and various enhancements of the technical and regulatory capabilities of the Food and Drug Administration (formerly known as BFAD) were conducted.

Clearly, the implementation plan of the HSRA made important gains in achieving its objectives but areas for improvement still surfaced. The DOH then continued to enhance its regulatory reforms to better assure quality and affordable health products, devices, facilities and services. In the revised implementation plan for the health sector reform, new strategies were identified including harmonization, licensing, accreditation and certification; developing a seal of approval for quality assurance; pursuing revenue enhancement with income retention for health regulatory agencies; and ensuring access of the poor to essential health products, specifically drugs and medicines. Major accomplishments for these regulatory reform strategies are discussed below.

MAJOR ACCOMPLISHMENTS IN HEALTH REGULATION

The DOH's regulatory agencies are: Food and Drugs Administration (FDA), formerly known as Bureau of Food and Drugs, which regulates food, drugs, cosmetics, drug delivery services, household hazardous substances and toys; Bureau of Health Devices and Technology (BHDT) which regulates medical and radiation emitting devices; Bureau of Health Facilities and Services (BHFS) which regulates health facilities including hospitals, clinics, laboratories and other health service establishments; and Bureau of Quarantine (BoQ) which is responsible for the surveillance and institutes measures to prevent the entry of diseases subject to International Health Regulations and other emerging and re-emerging diseases and health concerns from other countries that may impact on public health in the Philippines.

Several key legislations have been passed in recent years to improve the regulatory and enforcement mechanisms of the regulatory agencies of the DOH. These are the Quarantine Act of 2004; and the Food and Drug Administration Act of 2009. The Bureau of Health Facilities and Services (BHFS) also made significant reform in strengthening its regulatory powers by harmonizing and streamlining its systems and processes that made health regulation more rational and client-responsive. The passing of the Universally Accessible Cheaper and Quality Medicines Act of 2008, on the other hand, improved access to quality low priced drugs.

Access to Cheaper and Quality Medicines

Medicines are important commodity in a well-functioning health system and is an indicator of the quality of health services provided. Accessibility and availability of affordable and effective medicines is therefore one of the government's top priorities.

In a 2006 WHO/HAI survey, access to essential medicine was only 11% and 15% in the public and private sectors respectively. This scenario is worsened as prices of medicine in the Philippines are 3.4 to 184 times the international reference table.

The signing of Republic Act (RA) 9502 or the **Universally Accessible Cheaper and Quality Medicines Act of 2008** in July 2008 made a

significant mark in the goal of reducing prices of medicines. The Act provides that the DOH Secretary has the power to: recommend maximum drug retail prices (MDRP) of drugs and medicines subject to price regulation; include other drugs and medicines in the list subject to price regulation; implement cost-containment measures; impose administrative fines and penalties; deputize government entities; and other powers necessary to implement price regulation. The lists of drugs and medicines that are subject to price regulation includes all drugs and medicines indicated for: treatment of chronic illnesses and life threatening conditions; prevention of diseases and pregnancy; anesthetic agents; intravenous fluids; those included in the Philippine National Drug Formulary; and other drugs and medicines which the DOH Secretary determines to be in need of price regulation.

Pursuant to RA 9502, Executive Order 821entitled "**Prescribing the Maximum Retail Drug Prices for Selected Drugs and Medicines that Address Diseases that Account for the Leading Causes of Morbidity and Mortality"** was then signed in July 2009 that imposed MDRP to retail outlets, public and private, including drugstores, hospitals and hospital pharmacies, health maintenance organizations, convenience stores, supermarkets and the like. The determination which medicines would be imposed corresponding MDRP was premised on the following criteria: (1) conditions that address public health priorities especially those that account for the leading causes of morbidity and mortality; (2) drugs that have high price differentials compared to international prices; (3) lack of market access particularly for the poor; and (4) limited competition with their generic counterparts.

On 24 July 2009, Resolution No. 2009-0001 of the Advisory Council for Price Regulation entitled "**Implementing the Voluntary Price Reduction for at Least Sixteen Molecules (or 41 Drug Preparations)**" was approved wherein multinational companies agreed to lower their prices by 50%. These medicines are for hypertension, diabetes, influenza, hypercholesterolemia, cancer, arthritis, goiter, allergies and infections. The price cuts became effective on 15 August 2009 for the large drugstores and 15 September 2009 for the small and medium-sized drugstores. Surprise inspections including serving of cease and desist orders to erring drugstores where conducted by DOH to monitor implementation. Table 1 shows the voluntary price reduction list for the following active ingredients. To further support the implementation of the Universally Accessible Cheaper and Quality Medicines Act, the DOH has requested the Department of Budget and Management for budget provisions for the creation of a National Center for Pharmaceutical Access and Management as mandated by the same law. As of writing, a notice of organizational staffing and compensation action for the creation of the new office has been released.

Table 1. Voluntary Price Reduction List

Active Ingredient	Dosage Strength and Form	Old Retail Price	*Government Mediated Access Price*
ANTI-HYPERTENSIVE			
1. Telmisartan	40 mg tablet	51.50	25.75
	Telmisartan 40 mg + Hydrochlorothiazide 12.5 mg tablet	50.00	25.00
	80 mg tablet	89.00	44.50
	Telmisartan 80 mg + Hydrochlorothiazide 12.5 mg tablet	89.00	44.50
2. Irbesartan	150 mg tablet	48.76	24.38
	Irbesartan 150 mg + Hydrochlorothiazide 12.5 mg tablet	50.26	25.13
	300 mg tablet	80.00	40.00
	Irbesartan 300 mg + Hydrochlorothiazide 12.5 mg tablet	83.00	41.50
ANTI-THROMBOTIC			
3. Clopidogrl	75 mg film-coated tablet	123.50	61.75
ANTI-DIABETIC/ANTI-HYPOGLYC			
4. Gliclazide	30 mg Modified Release tablet	15.00	7.50
	80 mg tablet	15.00	7.50
ANTI-BIOTIOC / ANTI-BACTERIAL			
5. Piperacillin + Tazobactam	Piperacillin 2 g + Tazobactam 250 mg vial	2175.46	730.20
	4 g + Tazobactam 250 mg vial	4614.00	1270.06
6. Ciprofloxacin	500 mg tablet	83.83	41.91
	500 mg tablet (Extended Release)	99.23	49.62
	1 g tablet	145.10	72.55
	250 mg tablet	65.13	32.57
	2 mg/mL (100 mL) for injection	18984.17	942.00
	2 mg/mL (50 mL) or 100 mg IV infusion (50 mL)	1440.87	720.43
	400 mg (200 mL) for injection	3207.17	1603.59
7. Metronidazole	125 mg/5ml (60 mL) suspension	131.00	65.50
	500 mg tablet	23.50	11.75
	500 mg (100mL) IV Infusion	379.50	189.75
8. Co-Amoxiclav (Amoxicillin + Clavulanic acid)	625 mg tablet	97.75	48.90
	375 mg tablet	79.50	39.75
	1 g tablet	142.25	71.15
	600 mg vial for injection	687.50	343.75
	1.2 g vial for injection	1156.75	578.40
	Amoxicillin 200 mg + Clavulanic	555.50	277.75

Active Ingredient	Dosage Strength and Form	Old Retail Price	*Government Mediated Access Price*
	acid 28.5 mg/ 5mL (70 mL) suspension		
	Amoxicillin 125 mg + Clavulanic acid 31.25 mg/ 5mL (60 mL) suspension	378.00	189.00
	Amoxicillin 250 mg + Clavulanic acid 62.5 mg/ 5mL (60 mL) suspension	648.50	324.25
	Amoxicillin 400 mg + Clavulanic acid 57 mg/ 5mL (70 mL) suspension	940.50	470.25
	Amoxicillin 400 mg + Clavulanic acid 57 mg/ 5mL (35 mL) suspension	523.75	261.90
ANTI-NEOPLASTICS / ANTI- CANCER			
9. Bleomycin	15 mg vial/ampul for injection	9750.00	3520.00
10. Carboplatin	10 mg/mL (15 mL) vial or 150 mg for injection	3610.00	1805.00
11. Cisplatin	50 mg powder vial for injection	2804.00	1125.00
12. Cyclophosphamide	50 mg tablet	33.50	17.50
	200 mg vial for injection	698.95	175.00
	500 mg vial for injection	649.00	324.50
	1 g or 1000 mg vial for injection (no innovator locally)	1155.00 (most expensive brand)	577.50
13. Etoposide (No innovator locally)	100 mg tablet	1130.00 (most expensive brand)	565.00
14. Mercaptopurine	50 mg tablet	79.00	39.50
15.Methotrexate sodium (No innovator locally)	2.5 mg tablet	23.00 (most expensive brand)	11.00
	50 mg/2mL vial for injection	612.00 (most expensive brand)	306.00
16. Mesna	400 mg ampul for injection	369.00	166.67

Source: National Drug Policy/ Pharmaceutical Management Unit-50

Expansion of distribution networks

Botika ng Barangay (BnB) and Botika Ng Bayan (BNB) were established to provide the market with low-cost essential drugs and medicines. BnBs can offer up to 40 essential medicines and are allowed to sell 8 prescription preparations. All the medicines sold in various BnB outlets nationwide have passed through the quality control and product registration standards of the FDA. A comparison of the prices of these medicines as against the leading drugstore chain's lowest selling price is on the average 62% cheaper based on 2001 prices. The current target is to establish one BnB for every three adjacent barangays. In a recent GTZ-European Commission study conducted, BnBs assessed that have been operating for at least two years, 85% remain functional serving around 500 patients per month per outlet. Last 24 September 2009, the 15,000th BnB was inaugurated in the municipality of Cabatuan in Iloilo.

The DOH together with the Philippine International Trading Corporation (PITC) established the BNB project to set up a nationwide network of privately-owned and operated accredited pharmacies that sell low-priced parallel imported or generic drugs with the aim of competing with commercially priced drugs and medicines in the market. There are 1,971 outlets all over the country as of August 2009.

In 2008, the P100 Project was also launched to allow the sale of a list of prescription drugs that are packaged in complete treatment courses for P100 or less. Medicines available under the P100 Project include Amlodipine 5mg (12 tablets for P100.00); Felodipine 2.5mg (7 tablets for P100.00); Felodipine 5mg (5 tablets for P100.00); Felodipine 10mg (3 tablets for P100.00); Simvastatin 20mg (18 tablets for P100.00); Atenolol 50mg (14 tablets for P100.00); Ascorbic Acid 500mg (30 tablets for P100.00); Omeprazole 20mg (15 tablets for P100.00). For antibiotics, only one drug package is prescribed and dispensed for a complete regimen. For chronic or maintenance treatment, a maximum of 1 to 1 ½ month supply is prescribed and dispensed. This also makes the P100 project a tool in helping curb irrational drug use. Currently, there are seventy DOH hospitals and sixteen LGU hospitals that sell P100 drugs.

Price Monitoring

With the passing of the Universally Accessible Cheaper and Quality Medicines Act of 2008, the need to monitor medicine prices and inventory of all drugs from manufacturers, traders, distributors, wholesalers and retailers is therefore necessary to make a more informed policy making. The Electronic Essential Drug Price Monitoring Scheme or e-EDPMS is a price monitoring system that establishes a standard system and procedures for collecting, submitting, processing, and analyzing prices and inventories of drugs through electronic means. Enforcement of this policy, i.e. collection and submission of data, is expected to start every 31st of December starting 2009.

Restructured Health Regulatory Agencies

One of the major reforms in health regulation is the passing of RA 9271 or the **Quarantine Act of 2004**. The old quarantine law, RA 123 of 1947, creating the quarantine practice for the country has become outdated in relation to current public health practices, disease prevention and control methods, technological advances and legal terminology. The implementation of the Quarantine Act of 2004 strengthens the regulatory facility of the BoQ with the category of a line bureau and has a nationwide scope of functions and international commitment in accordance with the International Health Regulations of the World Health Organization.

With the Quarantine Act of 2004, BoQ conducts surveillance and institutes infection control measures to prevent the entry and spread of infectious diseases; provides technical assistance and supervision, consulting and advisory services on health and sanitation programs in its area of responsibility; conducts medical examinations of aliens/foreigners for immigration purposes; provides vaccination requirements for international travels; and ensures maintenance of sanitary environment. BoQ is also authorized to use at least fifty percent of its income to substantially support the various quarantine operations in light of the modernization program in addressing the change in trends due to globalization and volume of travel and trade.

Another major reform in health regulation is the passing of RA 9711 or the **Food and Drug Administration Act of 2009** which increases the BFAD's manpower compliment and renames the Bureau into Food and Drugs Administration. The Act aims to enhance and strengthen the administration, technical capacity, monitoring, regulatory coverage, and coherence of the FDA in the regulation of establishments and products under its jurisdiction.

The Act will create four centers per major product category: the Center for Drug Regulation and Research (to include veterinary medicine, vaccines and biological); the Center for Food Regulation and Research; the Center for Cosmetics Regulation and Research (to include household hazardous/urban substance); and the Center for Device Regulation, Radiation Health and Research. At least one testing laboratory each in Luzon, Visayas and Mindanao will be established with state-of-the-art laboratory equipment and personnel complement.

Also, with the passing of the Universally Accessible Cheaper and Quality Medicines Act, FDA is authorized to retain all the fees, fines, royalties and other charges they collect. The income retained will be used in its operations like upgrading of its facilities, equipment outlay, human resource development and expansion among others to improve its service delivery.

With the issuance of AO 2007-003, or the "**Policies and Guidelines Governing the Registration and Licensing of Establishments Dealing with Medical Devices**", BHDT acted as the technical arm of the BFAD on matters relative to the registration and licensing of establishments dealing with medical devices. This is to address the enhancements made by science and technology and the efforts being made to rationalize and streamline the operations and capacities of DOH.

Currently, ASEAN countries are looking for integration measures on the regulatory systems and processes for medical devices and equipment. These processes include a common submission dossier for product approval; an abridged approval process for medical devices which Regulatory Authorities (RAs) of benchmarked countries or regional RAs have already approved; a harmonized placement of medical devices into the ASEAN market based on common product approval process; and a formalized post marketing alert for defective or unsafe medical devices and equipment.

With the passing of the FDA Act, BHDT will be part of the new FDA and shall be called **Center for Device Regulation, Radiation Health and Research**. With the new set-up, BHDT envisions a more client responsive processing of product registration and licensing of medical device establishments through online registration, extensive market surveillance, and shorter processing time.

Harmonization and Streamlining of the Regulatory Systems and Processes

The harmonization and streamlining of the regulatory systems and processes is a strategic approach to improve the supply side of the health system to derive customer trust and satisfaction from the services provided. In the process, human resources for health would be rationalized and dedicated to more productive activities.

With the previous regulatory scheme, separate licenses for hospital ancillary services were a prerequisite to obtain a license to operate for a hospital. The hospital has to transact with different regulatory offices in the DOH to secure licenses for these ancillary services. This scheme incurred costs and an excessive amount of time for the hospitals.

The issuance of Administrative Order (AO) 2007-0021 entitled **Harmonization and Streamlining of the Licensure System for Hospitals** in June 2007 paved the way for the harmonization and streamlining of the licensing system for hospitals. Two policy directives were formulated to achieve this: (1) establishment of the one-stop-shop licensure system for hospitals; and (2) decentralization of the licensing process to the Centers for Health Development or CHDs.

- ***One-Stop Shop Licensure System for Hospitals***

  The main feature of the system is the issuance of a single license to operate (LTO) for the hospital including its ancillary services and other facilities. These ancillary services and facilities include clinical laboratory, HIV testing, drinking water analysis and drug testing; blood bank, blood collection unit and blood station; dialysis clinic; ambulatory surgical clinic; pharmacy; and medical x-ray facility; but excluding hospital-

based medical facility for overseas workers and seafarers; hospital-based drug abuse treatment and rehabilitation center; facility using radioactive material that are currently regulated by the Philippine Nuclear Research Institute; and performance of kidney transplantation.

With the one-stop shop licensing system, initial LTO is issued within thirty calendar days after the official receipt of a complete application and compliance with the standards and technical requirements had been demonstrated during inspection. Automatic renewal of LTO is done every year and is issued immediately or not later than five working days after the submission of a notarized affidavit stating that the hospital has complied with licensing requirements and that there are no changes in the status of the LTO.

A one-stop shop secretariat was created at the DOH central office composed of technical persons from BHFS, BHDT and FDA. Another secretariat was also created for the CHDs.

- ***Decentralization of the Regulatory Functions to the CHD***

To further streamline the regulatory process, the hospital licensing system also decentralized the issuance of initial LTO and renewal of LTO to the CHDs. However, the BHFS, BHDT and BFAD have oversight, supervisory and monitoring functions over the CHDs with regards to the regulation of hospitals including its ancillary services and facilities. Technical assistance is also provided by these regulatory agencies to increase CHD capacities.

Two other AOs were issued to strengthen the licensure system. These are AO 2007-0022 and 2007-0023 that states the violations and schedule of fees for the one-stop-shop licensure system for hospitals respectively.

Further streamlining measures were adopted with the issuance of AO 2008-0027 or the One-Stop-Shop System for the Regulation of Medical Facilities for Overseas Workers and Seafarers, Non-Hospital Based Dialysis Clinics, Non-Hospital Based Ambulatory Surgical Clinics with Ancillary Services.

Development of Quality Seals for Health Facilities, Products and Services

The strategic approach to increase demand for health care is the development and implementation of a "seal of approval" system, with quality seals as indicators to influence consumer behavior.

The unified seal of approval system for health products, devices, facilities and services is currently ongoing. Funding for technical assistance for the development of an overall framework for the seal of approval for the three regulatory bureaus (BFAD, BHFS and BHDT) was approved by the World Health Organization in the 1st quarter of 2008.

BoQ developed the Quality Seals for Food Service Establishments within the perimeter of airports and seaports.

FDA developed a Seal of Approval System (SAS) that combines the requirements for an LTO and certificate of current Good Manufacturing Practice (cGMP) for the production of pharmaceutical products which is in harmony with the guidelines in the ASEAN region. Last September 2008, twenty-eight companies compliant with the cGMP were awarded quality seals or certificates that proved they are of international standards.

Institutionalization of Cost Recovery and Revenue Enhancement Mechanisms

Income retention and fiscal autonomy, with the appropriate control and auditing system, is expected to result in better performance of the health regulatory bureaus.

The BoQ has restructured its regulatory fees in 2005 and is mandated to retain and utilize at least 50% of its income by virtue of RA 9271 of 2004.

BHFS in 2006 started to implement a rationalized schedule of fees for the regulation of health facilities. BHFS also continues to implement the provision of the Hospital Licensure Act that allows the hospital licensing agency to retain funds collected from permit to construct, registration and LTO fees for hospitals and other health facilities covered by the Act. Fee restructuring policies for certain services rendered by BHFS for health facilities and services were also issued through AO 2007-001 (Revised Schedule of Fees for Certain Services Rendered by the BHFS and CHD in Relation to the Regulation of Health Facilities and Services and validity Period of LTO, Accreditation, Authority to Operate, and Clearance to Operate for Certain Health Facilities and Services) and AO 2008-007 (Schedule of Fees for the Licensure of General Clinical Laboratories and the Registration of Special Clinical Laboratories).

FDA and BHDT will also re-structure their own regulatory fees based on actual administration costs. The Food and Administration Act of 2009 seeks to make the FDA into a financially autonomous institution and gave authority for it to retain all its derived income in addition to its annual budget.

THE CONTINUING CHALLENGE

Availability and acceptability of generic products and low-priced medicines

Access to affordable medicines for diseases that account for the leading causes of morbidity and mortality is critical to improve the health and productivity of Filipinos, prevent impoverishment of families due to high cost of health care and thereby achieve the Millennium Development Goals and National Objectives for Health. The recent price reduction of medicines is a big step in achieving these goals. However, there are other factors that affect access to affordable medicines. One is the

availability of affordable medicines in pharmacies especially government hospitals. Second is consumer awareness and usage of generics.

In a recent drug pricing survey for drugstores, it was found out that pharmacies have fewer stocks of cheaper alternatives than branded items and that some outlets tend to carry branded items more than the cheaper alternatives. In the same study, it was also observed that branded products were much more frequently purchased than generic counterparts and in some instances highest priced medicines are the most saleable ones.

Drugs and medicines are imported from countries like Pakistan and India while some are made locally. One factor that affects consumer's choice is the belief that drugs from developed countries like the US and Sweden are of superior quality than others. Although this may not always be true, this has an effect on why generics are not preferred by some consumers.

Pharmaceutical distribution network problems

The government target is to have one BnB outlet for every three adjacent barangays. Currently, there are about 15,000 BnB outlets nationwide distributed in 42,008 barangays. This means there is around one BnB outlet for every 2.8 barangays which is more than the targeted number. But where are these BnBs located? From the table below, hard-to-reach areas like those in the Autonomous Region of Muslim Mindanao has the least number of BnB outlets. Lanao del Sur, one of the poorest provinces in the country with 1032 brangays, has only17 BnBs.

Table 2. Number of BnB Outlets per Region, August 2009

CHD	Total Number of BnBs Established from 2003-2009
CHD I – La Union	1061
CHD 2 – Cagayn Valley	379
CHD 3 – Central Luzon	1675
CHD 4a – CALABARZON	1330
CHD 4b - MIMAROPA	844
CHD 5 – Bicol	350
CHD 6 – Iloilo City	1569
CHD 7 – Cebu City	653
CHD 8 – Tacloban City	807
CHD 9 – Zamboanga City	565
CHD 10 – Cagayan de Oro City	985
CHD 11- Davao City	635
CHD 12 – Cotabato City	357
CHD CAR	436
CHD NCR	594
CHD CARAGA	367
Autonomous Region of Muslim Mindanao	277

Source: National Drug Policy/ Pharmaceutical Management Unit-50

BnB outlets are set-up on the initiatives of the CHDs or community organizations and LGUs. Barangays with local government and community support and with at least 15,000 population can establish a BnB outlet. However, the Pharmacy Law requires one pharmacist for every drugstore and DOH AO 144 s. 2004 states that BnBs should be monitored by a supervising pharmacist to promote rational drug use. This poses a problem in setting up more BnB outlets as pharmacists in the country are very few and some of them are not willing to work in hard-to-reach areas.

For the P100 project, only seventy DOH hospitals and sixteen LGU hospitals are currently selling P100 treatment packages. The project provides quality medicines at affordable price and should therefore be available in all hospitals, both public and private.

Irrational drug use

There is still no concrete framework that addresses irrational drug use. Initiatives such as the P100 Project and disallowing doctors to dispense medicines are just but a few strategies in rationalizing drug use. Interventions that address client behaviors regarding drug use, self-medication and overuse of over-the-counter drugs are still inadequate.

Recently, non-essential health products are growing rapidly and are easily available in the market. Examples of these are products that allegedly improve functions of the liver, kidney, heart and eyes. Although these products are registered with the FDA as food supplements, its advertisement is implying that these products are all you need to prevent organ malfunction.

Enforcing the new provisions of the health regulatory agencies

Private hospitals are reported to have been losing money due to the MDRP system. Reports surfaced that several of these private hospitals are increasing their fees to recoup their alleged losses. Increasing hospital fees will defeat the purpose of reducing high out-of-pocket payments by lowering drug prices or it would cancel out the saved money from buying low priced medicines to paying high priced hospital fees.

Regulation of health facilities in the country is limited to the licensing of individual facilities. As such, there is a lack of government control on the costs of health services being provided by the private health sector. This may lead to increased health care cost which would further decrease social protection.

Limited funding and human resources have also made it difficult for the regulatory agencies to fulfill their functions. Although FDA, BoQ and BHFS already started practicing income retention, the needed human resources is still lacking to execute its functions and needed reforms. There are several government

agencies tasked with the development of health professionals (i.e. Professional Regulation Commission, various medical and health boards), but no single agency is responsible for over-all coordination. Each of these agencies has its own direction and regulatory functions resulting to overproduction of some types of health professionals and underproduction of others.

A quasi-judicial powers or "police" power to strictly enforce laws is also lacking. This encourages hospitals or other health facilities to operate without license.

RECOMMENDATIONS

Increase acceptability and availability of quality and cheaper medicines.

1. Intensify promotion of generic products both to doctors and consumers. A study should be conducted on consumer behavior regarding their drug of choice. This will help answer why branded brands are still saleable despite the cheaper alternatives. Establish public-private partnership and initiate price watch advocacy where comparative prices of generic medicines would be published regularly for the public's information.
2. Assure availability of generic and other low-priced drugs especially in government hospitals through increased parallel drug importation and local manufacturing. A study should be conducted to determine the stocking pattern of pharmacies to know the reasons of low stocking of generic products or low-priced medicines.
3. Explore alternative ways to expand BnB outlets in hard-to-reach areas.
4. Expand P100 project to all LGU hospitals and even private hospitals.
5. Strengthen the issuance of quality seals to inform consumers on the quality of the drugs. Enhance FDA's capacity and capability in ensuring quality products by complying with ISO 17025 and WHO Good Laboratory Practice; by passing proficiency testing conducted by internationally recognized accreditation bodies among others.

Institute and operationalize framework to curb irrational use of drugs.

1. Establish a framework for addressing irrational drug use. This may include regulating the sale of OTC drugs in sari-sari stores or small outlets; reclassifying OTC drugs that may actually need to be prescribed because of its side effects; regulating the sale of non-essential drugs; monitoring doctors buying from medical representatives and doctors dispensing drugs; use of standard treatment guidelines; supervision and monitoring of medicine use practices in health facilities; consumer education and empowerment.

Enforce the implementing guidelines for the restructured regulatory functions of the DOH agencies (BHFS, BHDT, BoQ, and FDA)

1. Strengthen the control of regulated product advertisements and promotions to reduce the risk of misleading and biased promotional information reaching consumers and professionals.
2. Regulate hospital fees to ensure that health care services are accessible financially to the population, especially those who belong to the lowest income group.
3. Regulate the industry as opposed to mere regulation of individual health facilities. With these, there shall be

   fewer opportunities for circumvention and the health cost becomes controlled. Also, with this measure, the quality of health facilities and services shall improve as well as the competitiveness, efficiency and productivity of the industry.
4. Fast track provisions of the FDA Act of 2009. Among its provision is the creation of four centers including the Center for Device Regulation, Radiation Health and Research; and the creation of at least one testing laboratories in Luzon, Visayas and Mindanao that will transfer some of Central Office functions to the Regions.
5. Lobby for the passage of Senate Bill 3016 which seeks to enhance the regulation of health facilities.
6. Create a body that will coordinate the functions of government agencies tasked with the development and regulation of health professionals.

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