

Philippines Health Policy Note

ON IMPROVING THE POOR'S ACCESS TO AFFORDABLE DRUGS

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List of Acronyms

BFAD	Bureau of Food and Drugs
BnB	Botika ng Barangay (Community Pharmacy)
CBHP	Community Based Health Programs
CGMP	Current Good Manufacturing Practice
CHD	Council for Health and Development
COA	Commission on Audit
COMED	Community Medicine Foundation
CPG	Current Practice Guidelines
CPR	Certificate of Product Registration
DBM	Department of Budget and Management
DILG	Department of the Interior and Local Government
DOH	Department of Health
DOST	Department of Science and Technology
DTI	Department of Trade and Industry
FDRO	Food and Drugs Regulation Officers
HEAD	Health Alliance for Democracy
INAM	Integrative Medicine for Alternative Healthcare Systems
IRA	Internal Revenue Allocation
IRR	Implementing Rules and Regulations
LGU	Local Government Unit
LIKAS	Lingap Para sa Kalusugan ng Sambayan (Care for People's Health)
NCR	National Capital Region
NPF	National Pharmaceutical Foundation
OECD	Organization of Economic Cooperation and Development
OPB	Outpatient Benefit
OTC	Over the Counter
PCSO	Philippine Charity Sweepstakes Office
PDI	Parallel Drug Import(ation)
PHAP	Pharmaceutical and Health Care Association of the Philippines
Philhealth	Philippine Health Insurance Company
PITC	Philippine International Trading Corporation
PLS	Procurement and Logistics Service
PMS	Post-Marketing Surveillance
PNDF	Philippine National Drug Formulary
PPF	Provincial Pharmaceutical Foundation
SONA	State of the Nation Address
WTO	World Trade Organization

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Executive Summary

On Improving the Poor's Access to Affordable Drugs

I. Factors Contributing to Inadequate and 'Irrational' Use of Medicines by the Poor

Fig. 1 clarifies why there is inadequate and 'irrational' use of medicines by the poor:

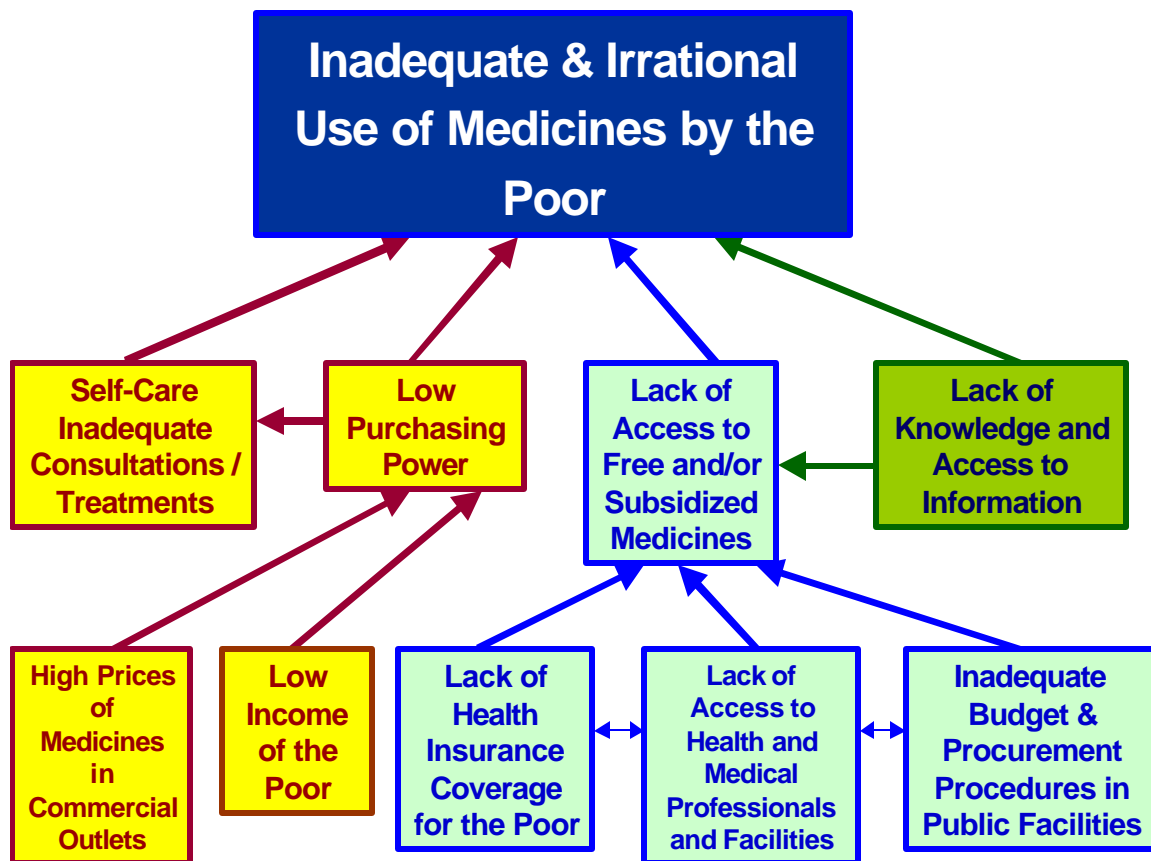


Figure 1: Factors Leading to Inadequate and Irrational Use of Medicines by the Poor

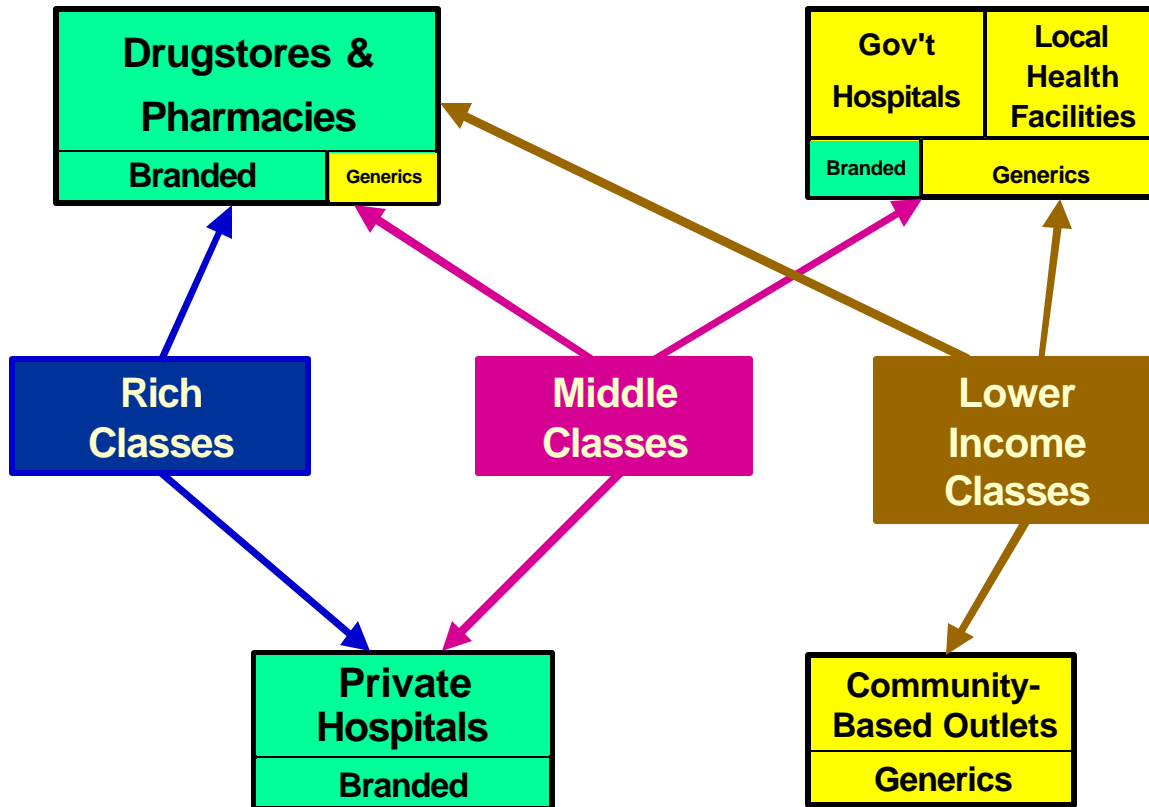
- A. Low income of poor families and high prices of medicines at most commercial outlets reduce purchasing power of the poor with respect to pharmaceutical products, leading to self-medication and inadequate medical consultations and treatments of illnesses.
- B. In addition to the lack of purchasing power of the poor, they further lack access to free and/or subsidized medicines, caused by: a) the poor's lack of access to medical professionals and medical facilities, b) the lack of health insurance coverage for the poor and the indigents, and c) the lack of budget and inadequate systems and procedures for government procurement of drugs and medicines in public facilities.

- C. There is a lack of knowledge and access to information concerning the proper medical treatments and medicines to be obtained for the diseases on one hand, and possible sources of free/subsidized treatments and medicines, on the other.

II. The Segmentation of the Pharmaceutical Market

Fig. 2 shows us the segmentation of the retail market for pharmaceuticals.

Figure 2 Market Segmentation in the Pharmaceutical Market



The dominant market catering to the rich and middle classes is dominated by expensive branded (non-generic) medicines, and is concentrated in commercial drugstores and pharmacies and private hospitals. The poorer folks who are able to find financing or credit, obtain their medicines also from commercial drugstores and pharmacies. Those who can't try to avail of the more affordable or subsidized or free medicines in government hospitals (usually as inpatients), local health centers, a sprinkling of community-based and NGO outlets and even fewer commercial outlets catering to generic drugs. The outlets for this latter market are very inadequate and/or not easily accessible. They lack financing and mass demand, and have poor facilities. The causes of market segmentation and dominance of expensive branded (non-generics) medicines are:

- A. There is inadequate quality assurance due to the limited resources and capacity of the regulatory authority, Bureau of Food and Drugs (BFAD)

- B. This gives the big (monopoly) distributors and manufacturers of expensive branded (non-generic) medicines ammunition to claim to have superior products over the more affordable (generic) medicines. This tendency is strengthened by the high promotion and gift-giving done by these drug companies to physicians and pharmacists. Physicians have become a main force supporting expensive branded (non-generic) medicines.
- C. Competition is not being provided by potentially significant outlets as government hospitals, local health centers, community-based and/or NGO outlets and private outlets concentrating on generics and low income classes.
- D. Consumers, especially the poorer ones, rely completely on the advice of physicians and pharmacists to determine the choices and brands of their medicines. They have no knowledge of the competing products, branded or generic, and the alternative prices they can pay out-of-pocket.

III. Addressing the Problems: Supply Side

- A. Quality Assurance by Bureau of Food and Drugs (BFAD): There has to be political will and commitment of the highest order to ensure quality assurance of pharmaceutical products. Some key recommendations to achieve this are:
 - 1. Outsourcing of product testing to qualified laboratories
 - 2. Implementing strictly full compliance of pharmaceutical manufacturers to current good manufacturing practice (CGMP)
 - 3. Giving investment incentives for medical centers to have capacities for bioavailability/ bioequivalence testing
 - 4. Improving facilities, personnel and systems for product registration, inspections and monitoring needed for quality assurance
 - 5. Increase significantly penalties for producing and marketing substandard drugs and for practices leading to substandard drugs.
 - 6. Delegate punishment functions to police and courts
 - 7. Allow BFAD to increase fines and fees and to retain its earnings conditional on improvement of its performance and conditional on removing its annually allocated budget from the national government
 - 8. Putting BFAD directly under the Secretary of Health for accountability
- B. Ensure Availability of Affordable Quality Generics in Public Facilities
 - 1. Improve public health structures and facilities and access to physicians
 - 2. Accredite only fully CGMP-compliant firms for government procurement
 - 3. Plan and implement pooled bidding of medicines by public entities to achieve economies of scale and reduce corrupt, untransparent practices

4. Shift funds of Pharma 50 intended exclusively for parallel drug imports (PDIs) to a competitive procurement of CGMP generics, imported generics and PDIs
 5. Find additional financing from anti-poverty programs
- C. Improving Availability of Quality Generics in Community-Based (NGO) Outlets
1. Allocate Pharma 50 funds more evenly by reducing allocations to current public-NGO endeavors -- Botika ng Barangay (BnB – community-based drug outlets) and rolling stores outlets -- which are still inadequate in number and which are limited to over-the-counter drugs, cotrimoxazole and amoxicillin (the latter two only in BnBs).
 2. Increase allocations to already existing pharmacies and clinics of community-based programs of the NGO and church sectors. This entails a public-NGO/church partnership and collaboration.
 3. Plan and implement accreditation of BnBs and community-based pharmaceutical outlets for the Philhealth outpatient indigent program.
 4. Link BnBs and other community-based retail outlets to public health facilities and physicians
- D. Encouraging Private Sector in Providing More Affordable Medicines
1. Again government should link private outlets marketing affordable medicines to physicians and public hospitals and centers, and accredit them once the Philhealth outpatient (indigent) program begins.
 2. Once BFAD capacity allows product testing of imported drugs in a massive scale, the government should allow PDIs in the private sector.

IV. Addressing the Problems: The Demand Side

- A. Philippine Health Insurance Corp. (Philhealth) and Social Insurance for Indigents
1. An outpatient indigent program for reimbursement of drugs and medicines for acute illnesses should be introduced by riding on the current Philhealth outpatient program for indigents. Part of the capitation fees should be used (and possibly increased) for reimbursements for drugs and medicines. Accreditation of qualified public facilities, community-based and NGO outlets, and private outlets catering to affordable quality generics is also essential.
 2. A full-blown outpatient scheme for reimbursement of medicines, using the accredited outlets, should be carefully studied and planned in order to use Philhealth's market power to reduce drug prices, and to free Philhealth funds for more reimbursements for the indigents.

B. Generic Drugs and Traditional/Herbal Medication Promotion

1. Once quality assurance is achieved, there should be high promotion of the BFAD seal of good quality and certification of CGMP, especially to physicians and pharmacists. Promotion should also utilize mass media that cater to the low income classes: radio, TV, comics, magazines, tabloids.
2. Once quality assurance is achieved, physicians should be required to prescribe medicines in generic name only, without any branded name in parenthesis.
3. Information centers in public health facilities, community-based health programs, Philhealth counseling structures, and pharmacies / drug outlets should be established to: a) advise the public on the choices of brands and generics, and issues of quality assurance, and b) ensure the patient's subscription to the regimen needed for effective and rational use of medicines.
4. DOH should identify effective traditional and herbal medicines and treatments and institute a regulatory framework to mainstream these medications and practices. Identified good practices should be introduced in public health facilities, which should also provide access to authentic traditional healers. Philhealth should eventually include essential traditional and herbal treatments and medications in its reimbursements.

V. Coordinating and Managing All the Components

In order to prioritize the agenda of this paper and to coordinate and manage all the components of the proposals and recommendations:

1. It is proposed that a point person and special committee or task force be created and given key responsibilities to coordinate and manage the entire set of recommendations across the various agencies.
2. It is proposed that the Secretary of Health be the point person to be given this task, and the current ad-hoc Pharma 50 Committee be expanded to include the Secretary of Health and top persons of BFAD, Philhealth, DILG, DOH drug procurement, representatives of government and district hospitals as well as representatives of local health centers and community-based health programs.
3. This committee should then be given more permanent and broader powers of management and coordination, and should report their monthly progress directly to the President of the Philippines.

On Improving Accessibility of Drugs for the Poor

Panos G. Kanavos, Joseph Y. Lim and Clarence G. Pascual

1. Introduction

Policies to improve the poor's¹ access to affordable medicines and drugs should naturally be part of a comprehensive national development program which includes: 1) a successful economic development strategy that improves people's income and access to resources and 2) a national health care and development program.

The need to subsume programs for drugs and medicines under a broader national health care and health development program cannot be underestimated. Preventive health must be critically linked to curative health. Drugs and medicines are involved in both aspects. They play a secondary role in preventive health (although immunization and health maintenance are important aspects of preventive health), and a key, but, certainly not exclusive, role in curative health.

Although these are important areas that need national attention and resources, this study assumes that the best efforts are already being undertaken², and limits its analysis to the issues directly pertaining to access of the poor to affordable drugs and medicines, including the factors that influence such access.

Section 2 puts forward the argument that pharmaceutical prices in the Philippines are high by international standards and in comparison with both developed and developing countries and reviews the available evidence. Section 3 documents the poor's lack of utilization of medicines and medical services as well as their problematic access to medical facilities and health professionals. Section 4 discusses the pharmaceutical market and the pharmaceutical industry in the Philippines, and provides evidence of its segmentation and the concentration on expensive branded products. Section 5 lays down a (supply and demand) framework used to evaluate the various schemes to improve the poor's access to affordable essential drugs. Section 6 discusses the main issues from the supply side and focuses on quality assurance and the supply of medicines in public facilities, community-based outlets and private outlets. Parallel drug importation is also critically appraised, since it is currently being used by the government in an attempt to reduce pharmaceutical prices in the public facilities. Section 7 discusses the main issues from the demand side, focusing on the need to provide access to physicians and health facilities, the need for a wider insurance coverage for indigents and outpatients, the need for generic drug promotion and generic substitution (of expensive branded medicines), and the need to promote authentic and cost-effective traditional/herbal/ alternative medication and treatment. Section 8 gives brief suggestions on the coordination and management of the various agencies on the various policies and recommendations presented in the paper. Finally, section 9 analyzes briefly necessary improvements in the government's current efforts and provides some international evidence to support our key recommendations.

1 Based on the latest definition of the National Economic Development Authority (NEDA), "poor" families are families with an annual per capita income of less than P13, 915 in 2000. As defined above, the poor account for 34.2% of all families or 5.2 million families in Filipino society.

2 See DOH Health Sector Reform Agenda (1998).

2. High Prices of Pharmaceuticals in the Philippines

Table 1a reproduces the drug prices of various drugs in selected countries from the important study of Balasubramaniam (1995)³. It gives retail prices of 100 units (tablets/capsules) of 16 commonly used drugs with the stated dosages from a survey done in July-September 1995. The table presents generic and branded products so that inter-country comparisons can be done on the same products. There may be problems comparing the generic medicines of different countries, because of differential quality and ingredients, but comparing the same branded products should be more exact since they are the same brand licensed by the same multinational firms.

The study shows that, for most of the selected drugs, the Philippines indeed has higher pharmaceutical prices than most of the countries in the study. Differential movements in exchange rates and domestic costs across countries cannot account fully for the huge gap between Philippine drug prices and the other countries' drug prices. But to deal with this possibility, we calculated drug prices as a ratio to the price of rice (Table 1b). (The prices of rice in current US dollars are given in Table 1a.) The result shows the Philippines still retaining its high drug price status among the countries (although the US and Indonesia show almost equally high drug prices relative to rice prices)⁴.

We further calculated the relative price of pharmaceutical prices to the average of four food items (given in Table 1a as rice, sugar, milk and eggs). This is shown in Table 1c. The Philippines still has very high ratios, but is displaced from the top spot by the US, and is challenged in the second spot by Indonesia. The results here show that while Philippines may indeed have high food (and perhaps general consumer) prices, in purchasing power terms, compared to the other countries, it is not enough to explain the still very high relative prices of drugs and medicines (vis-à-vis food items), which surpass those in the Asian countries in the table and even the relative prices in Germany and the UK.

To further stress the gravity of the problem for the Philippines, we used Balasubramaniam's (1995) figures to further calculate drug prices as a percentage of the monthly⁵ GDP per capita in purchasing power parity (PPP) dollar prices of 1995 (based on the UNDP Human Development Report and shown in Table 1a). This is shown in Table 1d. Philippine drug prices (in comparison to income) are again the highest among all the countries in the table (including the developed countries) for most of the drugs. The ratios given in Table 1d are for the average GDP per capita. Given that the Philippines' income distribution is one of the most skewed among the countries studied (as shown by the Gini indices in Table 1a), this means that the ratios of drug prices to the poor's income would be even much worse for the Philippines. Table 1a shows that only Thailand and Malaysia among the countries in the table have slightly higher (and worse) Gini indices than the Philippines. But both countries have very low drug prices, especially in comparison to average income. All this points to the very serious problem of high drug prices in the Philippines – especially in relation to the lower and poorer income groups.

Finally, the mere fact that the Philippine government has been pursuing a program of parallel drug importation points to the fact that prices of pharmaceutical products in the Philippines are significantly higher than in other countries, especially the ones with similar or analogous per capita income levels.

3 Many other papers cite this crucial survey piece. See Bengzon et al (2000), Lim (1998), Solon and Banzon (1999).

4 Of course comparing drug prices to the price of rice makes more sense for the Asian countries in the table than for the three Western countries.

5 We got the annual GDP per capita figures in 1995 PPP dollar prices in Table 1a and divided them by 12.

3. Determining Access to Pharmaceuticals by the Poor

Although high drug prices is one of the important causes of the poor's lack of access to drugs and medicines, it is not the only factor. Even if drug prices were to be cut in half in the Philippines, the most likely big beneficiaries would be the middle classes and the rich. The poor's lack of access to drugs and medicines also springs from three other sources: first, their problematic access to hospitals, clinics, physicians, other health professionals and health workers, diagnostic centers and laboratories and medical facilities. One should therefore not consider lowering of drug prices as synonymous with improving the poor's access to medicines and drugs. Second, there also seems to be a problem of availability of certain medicines in the Filipino market. Whereas the Philippines has implemented a generics policy, there seem to be considerable problems in the availability generic products and there is no clear assurance of their quality (and this goes for branded products as well). Third, there is an issue with health coverage, as most, if not all poor are either uninsured or under-insured.

Therefore, the overall problem in the Philippines seems to be one of (a) poor or non-affordability, (b) poor accessibility, (c) limited availability, and (d) inadequate coverage. In light of the above, one ought to look at the problem in a more holistic way as a health and medical care problem.

This section documents the poor's lack of utilization of medicines and medical services, and their poor access to facilities and health professionals.

3.1 Low Pharmaceutical Use by the Poor

The latest statistics on the poor's expenditures on pharmaceuticals come from a World Bank study ("Filipino Report Card on Pro-Poor Services" (2001)) which is based on a survey conducted by the Social Weather Station (SWS). Table 2a gives the health expenditures of the bottom 30%, middle 30% and top 40% of the population categorized by income. The table shows that the bottom 30% spend the least in all types of health-related activities except for consultation/treatment where they spend on average more than the middle 30%⁶.

Expenditures on pharmaceuticals by the bottom 30% are a fraction of those of the other two income groups: they comprise less than a quarter of the pharmaceutical expenditures of the middle 30% and almost one-fifth of the drug expenditures of the top 40%.

Table 2b gives the mean or average expenditures as well as the median expenditures of each income class. Because of strongly skewed expenditures (even within income classes), we see that for all income classes median health expenditures are much less than mean expenditures. This points to even bigger problems of lack of access to essential drugs and health services, as half of the bottom 30% spend no more than P500 a year for medicines (compared to mean health expenditures of more than P3,000 for the group), and half of the middle 30% no more than P883 annually for medicines (compared to mean health expenditures of more than P11,000 for the group).

6 Consultation/ treatment refers to consultations with health experts (including traditional healers) and treatments by the same.

The problem is further emphasized in Table 2c, which shows that the bottom 30% spend only 3.1% of their total household expenditures on medicines, a very small share given that most of them are not insured, and that their total household expenditures are much smaller than those of the other two groups.

Table 3a shows that there is also a problem of uneven utilization of medicines and health care facilities across the three regions of the country. Residents in the National Capital Region (NCR) or Metro Manila and the rest of Luzon spend much more on medicines, hospital stay and laboratory tests and related services, compared to residents in the Visayas and Mindanao, even if morbidity and mortality data don't show higher illnesses in Luzon (see National Statistics Coordination Board, *Philippine Statistical Yearbook, 2000*).. This may point to regional income disparities and their impact on access to pharmaceuticals and health facilities.

3.2 Lack of Access of the Poor to Physicians and Health Facilities

Access to physicians, other health professionals, and medical facilities is important so that the poor will know:

- 1) whether they need to take medicines or not;
- 2) what is the most appropriate medicine given their condition; and
- 3) in what dosage, frequency, length of time and mixture with other medicines and treatments the medication should be taken.

Despite the importance of access to health care professionals, it appears that the poor in the Philippines cannot or do not avail of their services. Table 4 gives us the usual responses to health complaints of the different income groups by quartile. It shows clearly that the poorest group consults the doctor much less than the richer quartiles. Only 25% of the poorest quartile consult the doctor whenever they have a health complaint, compared to 48% for the richest quartile. The poorest quartile are also much more prone to self-care, or consulting a traditional healer or non-physician health professional (usually midwives). Therefore, it can be argued that, overall, the poor do not get proper medical advice and (pharmaceutical) treatment, especially for conditions where traditional healing may be inadequate.

Table 5 shows further that the utilization of health facilities by the bottom 30% (and also by the middle 30%) and rural population is more skewed towards the traditional healer, local health stations and government hospitals, compared to the richest 40% who use more the private clinics or private hospitals. Table 6 shows that across regions Visayas and Mindanao depend more on traditional healers, local health stations and centers while NCR leans heavily towards private hospitals/clinics. The rest of Luzon and the Visayas use private clinics/hospitals just slightly more than government hospitals while Mindanao uses private clinics/hospitals more than government hospitals.

Table 7 shows people's overall net satisfaction rating of the various health facilities. It is clear that, for all income groups, private clinics/hospitals and traditional healer rate better than local health stations and centers and government hospitals. This clearly shows that the poor, who use more the government hospitals and local health

stations and centers, are perceived to be getting substandard services from these public facilities.

Table 8 gives the net satisfaction rating of the different types of health facilities according to type of service received. It is very clear that, in comparison to private hospitals and clinics, health facilities used more by the poor – the local health stations and centers, government hospitals and traditional healers – rate badly in terms of

- a) the availability of medicines and supplies,
- b) the quality of medicines, supplies and medical facilities,
- c) the number, availability, and competence of health personnel, and their understanding of health issues.

In addition to the above problems, public health facilities (local health stations and centers, and government hospitals) rate badly in terms of

- a) treatment received
- b) non-medical facilities,
- c) waiting time,
- d) paperwork requirements,
- e) convenience of schedule, and
- f) attitude of health personnel, compared to traditional healers and private clinics/hospitals.

All the above point to the perceived inferiority of public health facilities in terms of the availability and quality of medicines, and the overall quality of health care and services provided there. If true, these perceptions may provide some explanation why the poor have more difficult access to appropriate care and quality drugs.

Table 8 also provides good insight into the cost of medicines and supplies, and the cost of treatment as well as the reasons for greater use by the poor of some types of health care facilities and services. One conclusion that seems to be emerging from table 8 is that the poor use traditional healers highly, as opposed to other health facilities, whether public or private, because the former do not entail the high cost of medicines and supplies as well as cost of treatment that the latter do. Furthermore, the cost of treatment and costs of medicines and supplies, flexibility of payment and convenience of location are better in public health facilities and traditional healers compared to private hospitals/clinics. This again explains the higher usage by the poor of the public health facilities and traditional healers. The result is that the poor rely more on public facilities than on private facilities for cost reasons, but the services they get there are perceived to be inferior to those provided by the private facilities (hospitals/clinics). The high reliance on traditional healers may or may not be a good practice depending on the nature of the illness and the quality of the healer (we will discuss more of this later). But the important fact remains that lack of

access to physicians, medical facilities and medicines may lead to under-treatment or no treatment of patients who are poor.

3.3 High Drug Prices Reduces Rational and Effective Use of Drugs and Medicines by the Poor

Hardon (1991) and Tan (1988) point to the inadequate and ineffective use of medicines by the poor due to their high costs. Because of inadequate funds to cover medicines they need, many of the poor who do purchase medicines do not get the proper dosage and do not take the medicines based on the frequency and length of time prescribed by the doctor. Thus, from a medical point of view, there is irrational and improper utilization of drugs and medicines, diminishing their potential health benefits and medical curative value.

Punzalan and Wong (2001) in a study on Capiz, showed that patients who purchased more affordable parallel imported drug were more able to follow the proper dosage and to complete and satisfy the prescribed regimen compared those who purchased local branded products at a higher price. The study concluded that apart from providing higher access to drugs and medicines, lower drug prices would allow the poor to use drugs more rationally and effectively.

This is an important point that incorporates three policy items: first, insurance coverage, which would ensure access to health care professionals; second, compliance with prescribed course of action (including correct dosage, duration, conflict with other medications) and, third, follow-up to monitor the patient's status. On all counts, the poor in the Philippines fare badly

4. The Pharmaceutical Market and the Pharmaceutical Industry

The pharmaceutical market is made up of retail outlets composed of commercial drugstores and boticas, government and private hospital (or clinic) pharmacies. Most drugstores and boticas are owned by the Mercury Drugstore chain, other mini-chains or private individuals. Some outlets are both retail and wholesale outlets serving individual buyers and bulk buyers at the same time. These are what are termed here as retailer/wholesaler. A sprinkling of drugstores and clinics are owned by community-based non-government organizations (NGOs) with community-based health programs. Medicines in public facilities are accessed through government hospitals controlled by the Department of Health (DOH), decentralized district hospitals controlled by local governments, and barangay health centers and rural health units (the two are called local health centers) controlled also by local governments.

The wholesale market is dominated by the Zuellig chain of companies, although there are still numerous wholesalers throughout the country serving the regions and local areas.

Wholesalers purchase their products from drug traders (the owners of the medicines and brands). The drug traders can be pharmaceutical manufacturers themselves or commission the production of their medicines to toll manufacturers. It is the drug traders that need to get the certificate of product registration for their pharmaceutical products. Finally we have the pharmaceutical manufacturers, most of which are multinational firms using their multinational names.

4.1 The Retail Pharmaceutical Market

Table 9 provides a breakdown of the pharmaceutical retail market from 1997 to 1999. It can be seen that branded products dominate the market, accounting for more than 95% of total market sales. However, branded products would include branded generics. Thus, according to Table 9, unbranded generics made up around 4.2% of the drugs market in 1999 in terms of sales. Unofficial estimates claim branded generics make up another 5 to 6 percent of the market, with the entire generics market (branded and unbranded generics) making up 10 to 11 percent of the total drugs market⁷ – with the outlets largely concentrated in government hospitals, district hospitals, local health centers, and community-based program outlets. Recall that the public hospitals and local health centers are supposed to be ill-equipped with medicines and facilities, as a result of the survey in the previous section. It is clear that branded (non-generic) medicines dominate the pharmaceutical market, making up close to 90% of the total. Of this, ethical or prescription-only medicines (POMs) accounted for approximately 79% of the market in 1999 with the remainder being proprietary or over-the-counter (OTC) products (as Table 9 shows).

Most of the drugs were sold in the retail (and retail/wholesale) outlets of pharmacies and drugstores (see Table 9). In 1999, 66% of the P46.2 billion market were sold by retail outlets, and 20% by wholesale/retail outlets, totaling to 86% for the entire drugstore market⁸. Timmons et al (1999) claim that Mercury Drugstore outlets account for 40% to 50% of the total retail market and are still expanding aggressively. This makes them the dominant player in the entire retail drugstore market in the Philippines. Only less than 15% of pharmaceutical sales were made in hospitals in 1999 – 10% from private hospitals and only 4.5% from government hospitals and other public facilities (including outlets of local government units such as district hospitals and local health centers).

There is strong anecdotal evidence of irrational over-purchasing/consumption of some medicines such as steroids, vitamins, antibiotics, analgesics and painkillers (see Hardon (1991) and Tan (1988)). Data on what medicines the poor actually purchase and where they purchase their drugs from are not available but we can at least infer the following from the above:

- 1) The poor would also have to resort to buying mostly branded (non-generics) drugs since the latter comprise around 90% of drug sales;

7 It is also possible that the government hospital market is underestimated since most medicines here are given for free, and therefore may not be included in the retail market calculations. The figures in Table 9 come from the pharmaceutical industry's data and information sources.

8 Sales of retail/wholesale outlets are considered as retail sales in the table.

- 2) They would also be more likely to buy frequently from drugstores since this is where most people purchase medicines; and
- 3) Since they are more exposed to government hospitals and local health stations and centers, it would not be illogical to assume that purchases from government hospitals, district hospitals and local health centers would be more weighted to the poor compared to other outlets. But, given that only 4.5% of drugs are bought from government hospitals and other public facilities, it would be safe to assume that there is either a lack of availability of essential drugs in government hospitals and public facilities, or the poor simply do not purchase sufficient drugs for their own needs, or both⁹.

4.2 Distribution of Drug Outlets, Hospitals, Local Health Centers and Other Facilities

Table 10 shows startlingly that drug sales are heavily concentrated primarily in Metro Manila at the expense of Visayas, Mindanao and the rest of Luzon. Of the P46.2 billion market value in 1999, 47.8% were sold in Metro Manila, 26.3% in the rest of Luzon, while only 25.9% were sold in both Visayas and Mindanao. On the other hand Table 10 shows that only 13% of the population reside in Metro Manila, 43% in the rest of Luzon, and 44% in Visayas and Mindanao.

The explanation for this over-concentration in Metro Manila can be found partly in Table 11 which shows that, compared to its share of the population, NCR captures a bigger share of retail drugstores, private hospitals, diagnostic laboratories and blood banks. The rest of Luzon also captures a bigger share of these facilities than Visayas and Mindanao. Areas outside Manila would be more dependent on government hospitals, hospital pharmacies, barangay health stations and rural health units. The figures for Metro Manila in the all categories are understated since the scale of facilities is usually several times larger in the national capital region than outside the metropolis. This means that in terms of capacity of health facilities, the disparity between Metro Manila and the rest of the country is even starker. Table 11 also shows the lack of private hospitals in the Visayas .

Table 11 shows that for the whole country in 1998, there were 1,097 private hospitals, 616 government hospitals (including both government retained hospitals and district hospitals). There were 11,675 barangay health stations and 2,449 rural health units. There were 1,333 hospital pharmacies. In 1996 there were 1,446 diagnostic laboratories and 104 blood banks, mostly situated in the National Capital Region of Metro Manila.

4.3 Concentration in Wholesale Distribution and Drug Manufacturing

The wholesale drugs distribution is dominated by Zuellig Pharma, who together with its subsidiary Metro Drug Inc. (which is part of the Zuellig group of companies) is the top wholesale distributor of drugs and medicines. This company, together with United Laboratories (the top pharmaceutical manufacturer and trader (in terms of sales) that

9 It is also possible that the government hospital market is underestimated since most medicines here are given for free, and therefore may not be included in the retail market calculations. The figures in Table 9 come from the pharmaceutical industry's data and information sources.

markets its own products), make up almost 80% of the wholesale market (see Timmons et al (1999))¹⁰.

Table 12 gives us the number and distribution of manufacturers, traders, and distributors in the drug industry. As of February 28, 2002, there were 223 drug manufacturers, of which 80 are producers of pharmaceutical products (and the rest mostly producers of medical gases), 360 drug traders, 2,336 drug distributors (of which 1,876 were local wholesalers and 458 importers).

Out of the 80 producers of pharmaceutical products, only 16 were fully CGMP compliant as of April 3, 2002. This raises a key quality problem and contributes to the continuation of the current paradigm, whereby branded products enjoy near-market dominance as generics are frequently not trusted by practitioners and patients alike.

Table 12 further emphasizes the regional imbalance by showing that drug manufacturers, drug traders, drug distributors, and retail outlets are primarily concentrated in Metro Manila and secondarily in regions 4 and 3 (which are satellites of Metro Manila), and 7 (Cebu area) and 11 (Davao area).

Table 13 shows the top 20 corporate groups of drug manufacturers and traders from 1995 to 1999. It can be seen that, in 1999, the top 5 drug companies captured almost 40% of the pharmaceutical market; the top 10 captured around 58% of the market, and the top 20 are firmly entrenched with 79% of the market. This is in agreement with international evidences on patterns of concentration within the pharmaceutical industry at the company level. One should expect an even higher concentration level at the therapy level, where only a handful of products share the market, especially in patent-protected therapy areas¹¹.

It must be pointed out that the top 20 drug companies in Table 13 are all subsidiaries of foreign multinational companies with United Laboratories (UNILAB), the local firm with the biggest market share among the companies shown, being the only notable exception. In recent years, though, UNILAB's market share has declined in favor of the multinational firms¹² as Table 13 shows.

4.4 Wide Price Variations: Symptoms of Market Segmentation

Table 14 provides a price list from a sample of DOH-monitored drugs from commercial retail outlets. One can see the wide variation of prices in the majority of the monitored drugs (standardizing for dosage of a generically categorized medicine). Table 14 also gives us the ratios of highest branded priced drug to the lowest priced drug in the sample, the ratio of average brand price to average generic price, and the ratio of highest to lowest brand prices. One can see that most of the ratios are enormously high even if all the brands and generics are not enumerated in the DOH monitored list. This wide price variations is symptomatic of pharmaceutical market segmentation.

10 There are several chains in the wholesale distribution of drugs and medicines. Zuellig Pharma, Metro Drugs and UNILAB dominate the first level wholesaling as they sell to other wholesalers and retail outlets.

11 Kanavos, P. et al, European Pharmaceutical Research, Development and Innovation: Assessment of the Socio-Economic Benefits of New Drugs, European Commission - Institute for Prospective Technological Studies, Seville, 1998.

12 This accounts for the declining share of the top 5 and the top 10, but non-decreasing share of the top 20.

4.5 Summing it all up

First, the pharmaceutical market in the Philippines can be categorized by segmented markets because of asymmetric information, income disparities and the lack of quality assurance. There is (a) the dominant traditional mainstream market which is dominated by expensive branded medicines. It is comprised of the traditional retail and wholesale distributors ; (b) there is the smaller market for the lower income classes made up of government hospitals, district hospitals, local health centers, some community-based and private outlets, informal traditional healing and herbal markets. This market is smaller because of the low purchasing power of the consumers in this market, poor health infrastructure, lack of availability of physicians in government hospitals and local health centers, and the absence of insurance coverage for the poor and indigents. This smaller market is where the generics and cheaper drugs circulate more and where government procured drugs constitute a significant portion of the supply. This is also the sector which includes subsidized (or free) medicines, though in very inadequate volumes. Because of these inadequacies, the traditional retail and wholesale outlets would have some supply of these generics and cheaper branded medicines (a secondary market for the big distributors) inasmuch as the poor and lower income classes also purchase much of their medicines in the traditional retail outlets.

5. The Framework Used in Evaluating Schemes to Improve the Poor's Access to Affordable Essential Drugs

5.1 The Problem

Sections 1-4 above highlighted a number of problem areas with regards to access to medicines by the poor in the Philippines. In sum, it was shown that

- a) Drug prices in the Philippines are higher than in most countries, including some wealthy OECD countries.
- b) The poor do not enjoy the same access to facilities, doctors and medicines as the wealthier segments of Filipino society do.
- c) The lack of insurance or social protection plays a leading role: leaving the poor and indigent population without any kind of insurance coverage and having to resort to self-healing practices or, if they are fortunate enough to get credit or additional financing, to professional healers.
- d) Survey data show that consumption of medicines by the poor is far lower than that of higher income groups, in absolute terms (by value and volume) and as percentages of their income and expenditure.
- e) Data on the total pharmaceutical market, both in terms of value and volume of medicines purchased by the poor is patchy, and there is little information on utilization and compliance, where most of the evidence is often anecdotal. Only inferences can be made about their needs and actual spending patterns.

- f) The pharmaceutical market is highly fragmented and there seems to be an “addiction” to branded products, which are priced at a premium.
- g) Pharmaceutical manufacturing comprises several companies, however, only 20% of which (16 out of 80) were CGMP compliant, as of April 2002.
- h) Wholesale distribution is (nearly) monopolistic.
- i) Retail distribution is immensely fragmented comprising commercial pharmacies (the majority and dominated by Mercury Drugstore), hospital pharmacies, barangay health stations, rural health units and a few community-based NGO outlets.
- j) It is accepted by most people in the field, including the Department of Health (DOH), that government hospital pharmacies, barangay health stations and rural health units, which are supposed to serve the lower income classes and rural population, are not very accessible, have poor facilities and lack adequate supplies of medicines. Thus, patients either do not take any medication or may have to resort to a more expensive branded product (purchased in commercial outlets), which is paid fully out-of-pocket.

The above observations from the field lead to the conclusion that there are significant problems in the access to medicines by the poor and that serious discontinuities exist in their distribution. Some of these observations point at institutional rigidities or problems, which are reflected by the situation on the field and may impact directly on the ability of the poor to access medications. In particular:

- a) There is a lack of capacity in ascertaining the quality of the medicines due to the limited resources and capacity of the Bureau of Food and Drugs (BFAD) to give the seal of good quality for the produced medicines. BFAD inspects, registers and licenses drug manufacturers. It also registers and licenses drug products. It deals with counterfeit and substandard drugs. Finally, it inspects, registers and licenses drug distributors. There are complaints that licensing of drug products and drug manufacturers as well as product testing take a long time to achieve. Furthermore, only 16 of the 80 (20%) pharmaceutical manufacturers are fully compliant with current good manufacturing practice (CGMP). There are also complaints that culprits responsible for counterfeit and substandard drugs are not properly prosecuted and punished.
- b) Because of the above, the bigger distributors are able to promote their more expensive branded products successfully to the physicians, pharmacists and to the general public, and claim better quality in comparison to the more affordable and what are perceived to be inferior products. The latter include the more affordable generic drugs. This tendency is strengthened by the high promotion and gift-giving done by drug companies of expensive branded products to pharmacists, and especially to physicians. Without interventions to bring about competition against the big distributors and highly promoted branded drugs, the

monopoly power of these big distributors and manufacturers will remain firmly entrenched and established, and pharmaceutical prices of branded non-generics will remain high as they earn high monopoly rents.

- c) The lower priced (mostly generics) drugs do not completely disappear since they cater to a smaller base of poorer customers (who cannot come up with sufficient market demand due to their lack of purchasing power) catered to by government hospitals, local health centers and a few community and private outlets.
- d) Consumers, especially the poorer ones, rely completely on the advice of physicians and pharmacists when purchasing their medications. They have no knowledge of the competing products, branded or generic and the prices they pay out-of-pocket, and are prone to take doctors' advice to purchase the more expensive branded product. This is occurring despite the Generic Drugs Act of 1988, which stipulates that the generic name of the medicine be written in the physicians' prescriptions and that the pharmacists have a list of branded and generic drugs – and their prices – available for the customers. This problem is natural because consumers do not have the medical and chemical knowledge of active ingredients in medicines, and are overwhelmed by the technical names, jargons and appropriate chemical mixtures for medicines. In economic parlance, they need agents to act for them – consumer or health groups, NGOs, sympathetic doctors or pharmacists, qualified public entities or insurance companies with more technical knowledge and clout.

5.2 The Government's Plan/Pharma 50

DOH Plan/Pharma 50 was developed as a result of the President's State of the Nation Address (SONA) to the 12th Congress last 23 July 2001. There she made a commitment to reduce by 50% the prices of drugs and medicines frequently bought by the poor.

An ad-hoc Pharma 50 committee was set up to plan and implement it, chaired by Health Assistant Secretary Rolando Domingo.

Pharma 50 is made up of two parts. The first is the continuing short-term strategy (Aug. 2001 – Dec. 2002) of providing a supply of affordable essential drugs in public facilities and alternative outlets. In 2002, P100 million was allotted to government-retained and district hospitals for a year's supply of parallel drug imports (PDIs). Furthermore, the Philippine Charity Sweepstakes Office (PCSO) is providing P60 million of PDIs for local governments. PCSO is also giving P40 million to fund generic drugs to be allocated equally to community-based (NGO) outlets (Botika ng Barangay) and National Food Authority's rolling stores. Procurements for the P160 million worth of PDIs and P40 million worth of generic drugs are to be undertaken by the Philippine International Trading Corporation (PITC) of the Department of Trade and Industry (DTI).

The second part is a set of medium and long-term strategies to commence during the first six months of 2002. The components are:

- a) Develop a reimbursement scheme for medicines with PhilHealth by:
 - i) establishing reference prices for the 100 most commonly claimed drugs and medicines
 - ii) formulating policies on outpatient reimbursement of medicines; and
 - iii) formulating policies that would include indigents and workers in the informal sector in the reimbursement of drugs and medicines.
- b) Reduce and eliminate substandard drugs by improving BFAD's capacity and capability, and by collaborating with the pharmaceutical industry.
- c) DOH will study the possibility of toll manufacturing for selected drugs and medicines. PITC is again being eyed as the agency to be responsible in the toll manufacturing and distribution of selected drugs and medicines to government hospitals.
- d) DOH will work with the pharmaceutical industry and the local retail industry to significantly reduce the prices of essential drugs and medicines.
- e) DOH will continue to monitor prices of essential drugs.
- f) DOH will promote generic drugs and medicines as a continuation of the Generic Drugs Act of 1988.

We will evaluate each of these elements as we analyze and discuss the problems in the following sections.

5.3 Addressing the problem– a framework of analysis

Given the previous discussion and taking into account the objectives of SONA/Pharma 50, we believe that the necessary elements needed to improve the poor's access to affordable drugs and medicines are quite diverse and incorporate both the supply-side and the demand-side. Therefore, to constructively evaluate the strategies to improve the poor's access to affordable essential drugs, we use the following framework of analysis:

I. The supply side:

- a) The need to improve quality assurance in order to eliminate substandard drugs, and to remove once and for all uncertainty about the quality of the more affordable drugs: Related to this is the need to force pharmaceutical manufacturers to follow current good manufacturing practices (CGMP). A stronger quality assurance service and capability should translate into respect and trust for the BFAD seal of good quality. The BFAD seal of good quality for drug products and drug manufacturers has to be strongly promoted and advertised once quality assurance has been achieved.

- b) The need to promote and improve competition in favor of the more affordable quality products and the outlets for the more affordable drugs and medicines: The stranglehold in the production and distribution of highly promoted branded drugs needs to be broken. Potential competition can arise from government hospitals and local health centers as well as alternative private and public retail and wholesale outlets for more affordable quality drugs and medicines. Thus availability of affordable drugs and medicines in government retained hospitals, district hospitals, local health centers, NGO and community-based outlets and private outlets is absolutely essential since these are the outlets of medicines for the poor.
- c) It may be the case that the several alternative sources of drug supply, may either need to come under a common umbrella or be coordinated more effectively in order to ensure maximum coverage and better access. This includes BnB and other NGOs that serve predominantly rural or non-urban populations which are largely low-income.
- d) The need to re-consider the strategy for PDI and examine its viability and added value over the long term.

II. The demand side:

- a) There is a need to improve access of the poor to physicians, quality health facilities and the outlets dispensing more affordable drugs. This is true for the lower income classes in general, and for the population residing in regions outside Metro Manila and Luzon, and in the rural areas.
- b) The need to convince physicians, pharmacists and the general public to promote and support generic products with adequate standards and quality: This is connected to Ia and Ib above.
- c) The need for promotion of generic drug and traditional/ herbal/ alternative medicines: It is essential to go into generic drug promotion and promotion of appropriate traditional/ herbal/ alternative medicines, and educate the citizenry that there are high quality but affordable drugs.
- d) The need to improve information and knowledge of the poor concerning drug prices, where to get affordable drugs, how to avail of these medicines, where and how to avail of subsidies and financing for drug expenditures from the national and local governments as well as the private sector. Promotion and information dissemination concerning affordable drugs, especially generic drugs, can be done intensively in mass media: radio, TV, comics and magazines.
- e) The need to correct irrational use of medicines by policies to reduce over-prescription and overuse of some medicines on one hand, and to advise patients to follow the regimen of their medication, on the other.

- f) The need to empower agents and entities representing the poor so that the latter can avail of the medical and chemical information and knowledge required for the proper selection of medicines and treatments.
- g) One of the potentially more effective entities that could act as an agent for the ordinary folks and at the same time have monopsony power on drugs and medicines (with potential market power to affect total demand for drugs and medicines) is the Philippine Health Insurance Company (Philhealth). Thus, it is important to deal with Philhealth's programs and plans concerning reimbursements of drugs and medicines, as well as its programs and plans for indigents.
- h) Other potential agents for the ordinary folks and poor can be groups of physicians and pharmacists promoting generic (and other affordable) drugs, health/consumer and community groups, public and private information centers.

The reason why the Philippines has one of the highest drug price levels in the world – absolutely and relative to personal income and other goods – would be a combination of the lack of responses to the above needs. Specifically, five related issues especially characterize the Philippine drugs and medicines market:

- the need to provide strong quality assurance for the more affordable drugs;
- the need to convince physicians, pharmacists and the general public to promote more affordable quality drugs, and that they are not inferior or substandard;
- the lack of competition to the big distributors of medicines from outlets catering more to the poor: the government hospitals, the local health centers and the alternative drug outlets;
- the lack of prevalence and presence of agents that would provide control and information to the poor concerning consumer choices on drugs and medicines;
- the lack of universal coverage of essential drugs and medicines in insurance schemes or social programs for the poor.

6. Analyzing the Main Issues: The Supply Side

6.1 The Need to Improve the Regulatory Framework (BFAD): Quality Assurance and Elimination of Substandard Drugs

The need to provide quality assurance and eliminate substandard drugs is a big challenge. It requires not just addressing the essential problems of lack of financial, physical and human resources but also the exercise of political will and drive to give positive incentives to drug producers to produce quality drugs and to prosecute and punish those who don't.

As mentioned earlier, the key institution here is the Bureau of Food and Drugs (BFAD). BFAD is tasked with assuring the quality not only of drugs and medicines but also of food products, cosmetic products, hazardous household substances and medical devices. There is indeed a shortage of personnel, equipment, facilities, and physical infrastructure in BFAD. There is also a lack of capacity as well as a weak institutional and political framework to monitor and punish purveyors of substandard products and practices.

With respect to pharmaceuticals, BFAD undertakes four important regulatory functions:

- 1) Regulation of pharmaceutical products: licensing and product testing of pharmaceutical products and pharmacovigilance (post-marketing surveillance study requirement).
- 2) Regulation of pharmaceutical manufacturers and traders: licensing, inspection of facilities and assurance of good manufacturing practices and storage facilities.
- 3) Regulation of pharmaceutical distributors and retail outlets: licensing, monitoring and inspection of facilities and of the quality of drugs sold.
- 4) Policing and punishing violators: Policing and penalizing establishments or individuals that violate standard rules on quality of drugs, production and storage facilities and other rules on production and distribution of drugs and medicines.

We shall tackle each one of the above.

6.1.1 Regulation of Pharmaceutical Products

The regulation of drug products consists of the following components: a) licensing and registration, or renewal of a drug product, b) post-market physico-chemical testing of samples of drug products, c) bioequivalence testing of drugs under the B prime list, and d) post-market surveillance (PMS) studies for new drugs.

6.1.1.1 Acquiring/Renewing A Certificate of Product Registration

Annex B.1 in Appendix B lists the requirements for initial acquisition or renewal of a certificate of product registration (CPR). This is the stage where paperwork is voluminous and waiting time is longest. Processing time for CPRs for new products or brands take around eight months to a year. Renewal of CPRs, which is required every two or five years (depending on the size of the payment for the license), takes at least one month.

The requirements include technical specifications and procedures to be used, results and analyses of tests (assay) of substance and stability

tests, satisfaction of labeling requirements, and plastic container requirements. For imports, a certificate of free sale from the country of origin, and a certificate of good standing as drug manufacturer in the exporting country (both authenticated by the Philippine consulate) are required.

The Problem

There are at present only 12 full-time evaluators of the documents and 6 supervisors, all stationed in the BFAD office in Alabang right outside Metro Manila. Without any prioritization or rejections, the number of CPR applications and renewals number at least 600 to 700 a month. The human and physical resources of BFAD are simply unable to cope with these numerous applications. One way of coping with the problem is currently being undertaken by implicit rules that discourage applications to overcrowded sectors of expensive branded medicines. The division handling CPR has prioritized the applications to generic drugs with price 50% or less than the market price, and drugs which have 20 or less competing producers. This has cut down applications to around 400 per month but this is still more than the staff can handle. There are more than 17,000 registered products and each one has a manual file. Submitted papers have to be matched with the correct file and this can be quite an arduous task.

Given that the processing time is from 8 to 12 months for new certification and one month for renewal, much of the waiting time is made up of queuing time and backlog.

Recommendations

Message 1: Long Approval Times

It appears that BFAD has a tremendous workload which results in long waiting times for product authorization and approval and can lead to serious bottlenecks in the market. Some solutions to the long approval times are:

- a. Make a formal rule to discourage applications in overcrowded sectors catering to expensive branded medicines. Formalize current practice of restricting applications only to: 1) generic drugs whose prices are significantly lower than the market price, and 2) drug products which have 20 or less competitors.
- b. Disallow two-year renewals of CPR, and institute only the five-year renewal of CPRs. This means that the pharmaceutical companies or traders should pay a larger licensing or user fee to cover five years. This will significantly reduce the number of applications for renewals.
- c. Computerize much of the needed information in the manual files, and computerize the matching and validating processes as well as some of the analysis of indicators.
- d. Streamline the procedures, reduce unnecessary documents, paperwork and operations.
- e. Increase personnel and space for the evaluation and paperwork.
- f. Increase licensing and user fees to reflect at least all the costs of processing and validating (including computerization, personnel, space, etc.) payable by manufacturers / traders to BFAD with the submission of the dossier for product approval.

Operationalisation requirements

1. Additional information technology (IT) systems and computerization with additional workforce can be completed within a reasonable time frame
2. Additional financing would have to be identified to support the above activities
3. There is a need to institute a user fee tariff to reflect the actual work performed for each product application type

6.1.1.2 Physico-Chemical Testing

There is currently no pre-market BFAD testing of drug products acquiring or renewing a CPR (including imported drugs satisfying the certifications described previously), although the drug manufacturer or trader has to submit the results of its own tests. A post-market physico-chemical test of a sample of drugs specified in Annex B.2 is done by BFAD. Government-procured drugs as well as parallel drug imports (the latter usually lack the certifications required for imports) are first required to be tested by BFAD before they are distributed to the government

hospitals and other public facilities. Other drugs that are tested by BFAD are those suspected to be substandard or counterfeit based on samples taken by inspectors in the field as well as those brought by complaining consumers.

The physico-chemical analyses carried out by BFAD include: visual (physical) examination, assay of substances and ingredients, dissolution tests, microbiological tests of syrups and liquids, and sterility tests for injectibles.

The Problem

In March 2002, 557 sets of samples of drugs were sent to BFAD for testing. Because of the high number of holidays during this month (Holy Week), only 63% of the tests were finished. Testing of samples is prioritized according to the following criteria, in descending order of importance: 1) tests for substandard drugs, 2) tests for PITC-procured parallel drug imports, 3) tests for government procured drugs; and 4) others. It is estimated by BFAD laboratory personnel that tests for PITC parallel drug imports take around 14 to 15 days, while those for government-procured drugs take around one month. Other tests would obviously take more than a month. A test for one set of samples for a particular drug takes a maximum of two or three days. Thus the entire period for drug testing is made up mainly of queuing and waiting time. There is therefore a lot of potential to improve and shorten product testing time. There are only nine analysts in BFAD's main laboratory in Alabang, Rizal. It is estimated that an analyst can finish 3 samples a day.

Recommendations

There is, of course, the possibility of conducting these tests outside BFAD. BFAD has identified for this purpose eight laboratories. Officially drug traders can send their drug samples to the 8 laboratories for testing. This, however, is not being done because there is no memorandum of agreement accrediting these laboratories and unifying the testing fees. It is strongly recommended that this be done immediately since this is the more affordable and reasonable way of dealing with the current problem. It is also very probable that there are other qualified laboratories. For example, the laboratory of the Department of Science and Technology (DOST) is not included in the list of eight.

Message 2: Reducing product testing time

- a. Outsourcing of product testing to the 8 accredited laboratories, as international practice from other regulatory agencies suggests, so that BFAD can concentrate on its main job as a regulatory authority reviewing the evidence. The current BFAD lab can continue its role as one of the network of laboratories, or, indeed, act as a supervisory agency that reviews the performance of the accredited laboratories and inspects on a regular basis their activities.
- b. Identify other laboratories qualified to do the physico-chemical tests for at least a cluster of drugs and medicines, and add them to the accredited laboratories.
- c. The accredited laboratories will examine samples on behalf of BFAD and will appropriate the fees payable for sample testing. The fee structures for the various types of tests will have to be unified across laboratories. In this way, the accredited laboratories can sustain their activities financially. BFAD will act (a) as a collector of fees and samples; (b) the samples will subsequently be given to a laboratory randomly selected (samples should not have labels containing the name of the brand or manufacturer or trader or distributor); (c) lab reports back to BFAD within an agreed-upon short time period; (d) BFAD will then review all the available evidence, which includes sample test results.

Operationalisation

1. Identify laboratories, expedite the process of accreditation, develop capacity, ensure labs have adequate staff levels;
2. Develop a protocol of collaboration and memorandum of agreement between BFAD and affiliated labs;
3. Develop fee schedules for sample testing that will be standardized for each type of test.

6.1.1.3 The Lack of Bioequivalence Tests

BFAD has initially required bioavailability/bioequivalence testing for drugs in the B prime list. The order and the list of drugs in the B prime list are given in the bureau circular shown in Annex B.3. These are the drugs that need to prove the correctness of their formulation in terms of delivery to and absorption of the medicines in the human body. BFAD has accredited five medical centers for bioequivalence testing.

The Problem

But these centers can only undertake bioequivalence testing for rifampicin (a medicine for tuberculosis), and so only this drug is required to be tested for bioequivalence. Aside from the lack of facilities and capacity, bioequivalence tests are very expensive (a bioequivalence test for rifampicin costs around P800,000) and, according to BFAD, may lead to

the closure of some generic drug producing companies. A bioequivalence test may take from 4 to 6 months.

BFAD, since June 1999, has waived the test for the other medicines and instead is requiring a dissolution profile. See last part of Annex B.3 -- BFAD Bureau Circular No. 13-A s. 1999.

Bioequivalence testing is important to prove that generic drugs have similar rates and extents of absorption as the innovator medicines. The test compares bioavailability of the drug being tested on (according to BFAD's rule, at least 18) normal subjects with the bioavailability of the innovator drug. For better statistical significance, some experts suggest a minimum of 30 patients for the bioequivalence tests. This test is vital if we want to prove that generic medicines are as effective as branded, non-generic medicines. This protection of consumer welfare far outweighs the high cost of the test.

Recommendations

Message 3: Bioequivalence

It is suggested that the following be undertaken:

- a. Require a phased implementation of bioequivalence testing, giving priority to safeguarding the effectiveness of life-saving drugs (e.g. cardiovascular medicines, anti-infectives, etc). BFAD should strictly enforce this implementation.
- b. Develop capabilities of medical centers to undertake bioequivalence testing; these should be accredited institutions that may be subject to random inspections.
- c. If needed, the government can give positive incentives for this:
 - i. no import duties on equipment,
 - ii. giving investment taxation incentives to this priority area (e.g. tax holidays, accelerated depreciation),
- d. But requiring bioequivalence tests for the drugs in the B prime list would be necessitated, and a strict scheduling of this should be set up;
- e. Producers of generics drugs with the same formulation (or mixture) of active and inactive ingredients should be allowed to share costs of one bioequivalence study.
- f. Develop a protocol and time frame for examining generic drug applications and incorporating the bioequivalence test in the generic drug applications .

Operationalisation

1. Identify medical centers, expedite the process of accreditation, develop capacity, ensure labs have adequate staff levels.
2. Develop a protocol of collaboration and memorandum of agreement between BFAD and accredited medical centers.

6.1.1.4 Lack of Clinical Post-Marketing Surveillance (PMS) Studies

Clinical testing of new drugs and medicines involves what are called Phases 1 to 4 tests on patients taking the medicines. Phases 1 to 3 in general test the efficacy and safety on patients of the new drugs. These tests are quite expensive and require sophisticated testing devices. BFAD therefore requires only the results of tests of Phases 1 to 3 derived from foreign countries for new drugs being introduced in the market. But producers of these new drugs are required to do the Phase 4 post-market surveillance (PMS) study to be done in three years (with at least 300 patients) or with 3000 patients, whichever comes first. This study aims to

confirm the efficacy and safety of the drugs and to ascertain any adverse effects of the new drug that are unique to Filipino patients.

The Problem

Many companies have not complied with this PMS study requirement as they claim not being able to find enough samples. Finding samples will not be too difficult if doctors and nurses make it standard practice to regularly report adverse and side effects and the lack of efficacy and safety of certain drugs. With this good practice, it would be easier to undertake the PMS tests. DOH should therefore undertake initiatives to force physicians and nurses to earnestly follow this practice (which are required but not implemented) and to facilitate the flow of information to the drug companies. The drug companies will also have to be forced to comply with the PMS study requirement.

Overall, it is a fact that testing for medicines in the Philippines is concentrated on physico-chemical testing rather than on clinical testing (including bioequivalence tests). In the long run, it is imperative that clinical testing be incorporated in the process of quality assurance for drugs and medicines in the country, including the capability to undertake Phases 1 to 3 of clinical testing. This is important for the promotion of more affordable generic drugs to prove their efficacy, quality and safety. If the capacity and the practice of clinical testing is not instituted, the Philippines will further lag behind other countries in terms of medical technology and in terms of providing quality and affordable medicines to its citizenry.

The Philippines also has a lot of potential to come up with its own new drugs based on its many herbal and traditional treatments. In the long run, it may lead to the lowering of drug prices in the country (witness the prevalent use of *lagundi* and *sambong* as cheaper but effective bronchodilator and diuretic, respectively). The capacity to bring these traditional/ herbal medication and treatments more accessibly to the general public by converting them into capsules, tablets, syrups or tea may be beneficial. A special framework and evaluation process would be required for these alternative medications.

Recommendations

Message 4: Post-marketing surveillance

The effectiveness of new medications needs to be checked a few years after their first marketing authorization for serious adverse effects amongst the population and to monitor the effectiveness of the approved medication.

- a. It is the responsibility of BFAD to enforce existing post-marketing surveillance regulation.
- b. It is the responsibility of manufacturers to collect, analyze and submit all the necessary information and studies to BFAD.

Operationalisation

1. DOH should make sure that physicians, both in primary care and in hospitals, and pharmacists in the community should report any adverse effects and non-efficacy of medicines reported by patients.
2. Unless post-marketing surveillance studies are submitted by manufacturers of original products, their license will not be renewed for a second five-year period.

Message 5: Alternative therapies

A framework should be set up that evaluates and licenses alternative (herbal, natural and traditional) substances; this may be the responsibility of BFAD, although not the same section that gives licenses to CPR mentioned earlier. Much will depend on what each new remedy will claim to do.

6.1.2 Regulation of Drug Manufacturers and Drug Traders

Annex B.4 gives us the requirements for a license to operate as drug manufacturer and drug trader. Apart from the paper requirements listed in Table B.4, drug manufacturers and traders are inspected once before licensing and after by irregular spot checks, especially concerning their building space, equipment and laboratory facilities, and storage facilities.

The Problem

In 1998, BFAD ordered that drug manufacturers comply with the guidelines for current good manufacturing practice (CGMP). The deadline was supposed to have been on January 1, 2000. Because most firms could not comply

in 2000, and used the financial and economic crisis as reason for the lack of financial capital, the firms have been given reprieves by BFAD repeatedly. The latest reprieve is up to June, 2002 (and BFAD is inclined to give more reprieves in the future).

As of early April, 2002, 16 out of the 80 pharmaceutical firms have been 100% compliant with the CGMP guidelines¹³. The situation is, nevertheless, more complicated. For example, a plant may produce three pharmaceutical products. It may be compliant with CGMP guidelines for one of the products but not for the other two. In this case the firm is CGMP-compliant only with respect to one of the products – and is not a fully CGMP-compliant firm.

Many firms find it difficult to comply with CGMP guidelines because of financial constraints for additional and improved buildings, equipment and other facilities. CGMP requires dedicated facilities and equipment, which means a drug product should have a one-to-one correspondence with its building, equipment and facilities. Different products should not be sharing a building, equipment or set of facilities.

CGMP compliance substantially increases the quality of medicines produced. It is therefore urgent that CGMP compliant firms be given positive incentives and those not complying be punished and penalized. A strict rule might be to close down all non-complying firms after a certain date. This is recommended after a grace period has been determined. If applied now, only 16 pharmaceutical firms will survive, and there might be concerns that this number will not provide enough competition and capacity for the industry. A compromise would be to stop immediately giving reprieves and to impose very heavy penalties and fines for non-compliance. Another penalty would be more stringent inspections and product registrations and product testing for non-compliant firms. Positive incentives for CGMP compliant firms can also be given. One most useful incentive would be to limit bidders for government procured drugs and producers of drugs reimbursable by Philhealth to CGMP compliant firms. (These positive incentives of course would be implemented by DOH and Philhealth, respectively, and not by BFAD.)

13 Of course one can get in and out of the list of CGMP firms depending on the results of the latest inspection.

Recommendations

Message 6: Good Manufacturing Practice

- a. Only 20% or 16 out of 80 local pharmaceutical manufacturers are fully CGMP compliant; some firms may be compliant for only part of their manufacturing lines;
- b. BFAD has given a reprieve until June 2002 for all firms to become CGMP compliant; it needs to enforce this as strictly as possible by making an announcement that no further reprieves will be given and that violators will be either shut down or will go out of business because nobody would want to procure from them. A possible compromise (in case political will is not enough to immediately close the firms) is to impose stiff fines and penalties for non-compliant firms from July to December, 2002, and then promise and undertake closure after this.
- c. Government should continue procuring from CGMP compliant firms only (namely those which are CGMP compliant for all their production lines)
- d. Facilities should be inspected routinely, more often, randomly, and without warning.

Operationalisation

1. It may be the case that if non-CGMP compliant facilities will be shut down, this may result in temporary unemployment, but we estimate that those laid off will be absorbed by CGMP compliant facilities before long.

6.1.3 Regulation of Drug Outlets and Drug Distributors

The Problem

Annex B.5 gives us the checklist of requirements for drug outlets, and Annex B.6 those for drug distributors. The main problem here is the lack of inspectors to inspect drug outlets and drug distributors. (In the current setting, the inspectors also have to inspect medical device and cosmetic distributors). There are around 23 inspectors for the Metro Manila area and less than 100 inspectors for all the other regions (with some regions having only 5 or less inspectors). Table 12 shows us that there are more than 18,000 retail outlets and 2,300 drug distributors for the whole country as of end of February, 2002. The huge numbers make it difficult to achieve BFAD's target to have the inspectors visit every retail outlet and drug distributor at least once a year.

Aggravating the problem is that the inspectors in the region (food and drugs regulation officers – FDROs) are under the regional directors and they get other assignments from the regional directors. BFAD thus has very limited control over these inspectors.

Still, the importance of the inspectors cannot be overestimated. Aside from inspecting the retail outlets and drug distributors to find out whether there is a pharmacist present and to check the quality of storage facilities, they are the country's main means for monitoring that the drugs being sold at the retail outlets are not substandard, expired or counterfeit. The inspectors are supposed to get samples of suspected drugs at the retail outlets for testing at BFAD's main laboratory. Table 15 gives us the number of punished drug outlets and drug distributors in 2001, most of which were due to the absence of a pharmacist or the detection of expired, substandard or counterfeit drugs. The numbers actually punished (closure orders executed) seem to be very few compared to the high base of retail outlets and distributors.

Aside from the inspectors, BFAD's main office can send a 'flying squad' to the establishments of violators based on information they have acquired. Possible 'turfing' problems arise whenever local government officials and regional directors are angered by the 'flying squad's' lack of communication and information concerning their 'raid'.

Recommendations

Message 7: Regulating distributors and retail outlets

1. Wholesale and retail inspections should not be the responsibility of the regulatory authority (BFAD), but of the respective Public Health Department(s) within the DOH and/or the local government.
2. BFAD needs to become less involved in the operation of pharmacies and distributors and focus on its main business, which is the approval of safe and efficacious drugs.
3. However, BFAD should intervene when a counterfeit or substandard case has been uncovered by public health inspectors. BFAD's role comes in due to: a) the need for product testing of suspected substandard drugs, b) the need to recommend punishment of the violators.
4. It is recommended that the current FDROs be transferred and re-integrated into public health departments to be jointly managed by DOH and the regional governments.
5. These inspectors will have to devote full-time work in wholesale and retail inspection activities. More full-time inspectors will also have to be recruited.
6. Spot checks and surprise inspections need to intensify and, in fact, become the norm rather than the exception.
7. Wholesale and retail facilities should become accustomed to this new reality and be given a time period to comply fully with what the law specifies.
8. Beyond that transition period, violators should face criminal prosecution and very heavy fines.

6.1.4 Punishment of Violators

The Problem

Once a violation of BFAD's regulations has been detected, determined and confirmed, the pertinent case and documents are sent to the legal division of BFAD. There are only five plantilla for lawyers. Currently there are two full-fledged lawyers and two barristers. Obviously, this is inadequate for the proper disposition of the cases. According to the legal division, priority is given to cases involving substandard drugs.

Another problem is that fines and punishment are too lenient. Fines for violative or substandard drugs and other violations range from P1,000 to P5,000. There is of course the possibility of temporary or permanent closure of the establishment, recall of the drug products and a revocation of the CPR or license to

operate. Only selling of counterfeit drugs carry substantial fines – from P100,000 to P500,000. Total fines collected by BFAD in 2001 totaled P419,000.

Recommendations

Message 8: Dealing with violators

1. Violations should be considered a crime and violators should face criminal prosecution, heavy jail terms and very heavy fines
2. There should be increases in penalties and fines especially for:
 - producing and/or distributing substandard and expired drugs
 - incorrect storage and handling practices of drugs and medicines
 - dispensing dangerous drugs without prescriptions
3. BFAD should in principle not be responsible in pursuing and punishing violators; this is a police and courts issue.
4. BFAD and the field inspectors should report violators to the police.
5. Prosecution should be done by the courts under the direction of the Department of Justice (DOJ)
6. If violations become a police matter and the police is credibly involved, then potential violators may be deterred.
7. BFAD needs to institutionalize a partnership and collaboration between its 'flying squads' that raid outlets of counterfeit and substandard drugs and the police.

6.1.5 Sources of Additional Financing

The Problem

BFAD's budget for the latest fiscal year was P140 million. This has been increased to P186 million for the next fiscal year (2003) as part of Pharma 50. The additional money should be able to finance some of the recommendations made in the preceding sections.

BFAD also can become more financially viable in the long run since it collects fees for product registration, license to operate, product testing and fines from violation.

Annex B.7 gives us the fees for product registration, licenses to operate and testing fees. In 2001 BFAD was able to make from P40 million to P50 million from these fees. It had to remit the money to the national treasury and got part of it back only after significant delays. Fees were raised on November 15, 2001, sometimes more than double, and BFAD is optimistic that it can increase its total collection of fees and fines this year to between P150 million and P200 million. There is a bill in Congress seeking to allow BFAD to retain its entire collection of fees and fines. This measure can make BFAD financially viable and self-sustaining. We recommend that BFAD be allowed to increase its fines (especially for selling substandard drugs) and retain its revenues and this be continued in the future subject to its improved performance in terms of: 1) reduced processing time and increased quality of service in product registration, and issuing licenses to operate to drug manufacturers, drug traders, drug distributors and drug outlets, 2) reduced processing time and increased quality in physico-chemical product testing, 3) significant advances in bioequivalence and clinical testing of drugs, 4) significant increase in CGMP compliant firms, and 5) increased detection and punishment of those involved in substandard drugs and violators of other BFAD regulations.

The Commission on Audit is important in ascertaining that the funds are properly utilized and disbursed by BFAD. The Secretary of Health and the task force or committee we suggest to coordinate all the policies recommended in this paper (see Section 8) should be the main ones to evaluate the performance of the agency, and recommend corresponding actions to the Secretary of Health and to the President of the country.

In exchange, we recommend that the national government need not allocate any budget for BFAD. This will in effect be a cost saving mechanism for the national government.

Recommendations

Message 9: Financial sustainability of BFAD

BFAD should be allowed to increase its fines (especially for selling substandard drugs) and retain its revenues from fees. This should be subject to demonstration of improved performance vis-à-vis the agency's various areas of competence. In exchange, there should no longer be an allocated national government budget for BFAD.

6.1.6 The Need for Political Will and Calculated Response to the Quality Assurance Problem

The Problem

But perhaps more than additional funding, the importance of quality assurance and the elimination of substandard drugs in reducing drug prices should be emphasized to the highest officials of the country so that they will deliver the political weapons and leadership needed to achieve this fully and in the shortest time possible. In line with this, the highest officials of the country, once convinced, should decide on the best set of actions in terms of leadership and management, organizational and institutional accountability and responsibility to ensure accountability, transparency and efficiency from BFAD.

Recommendations

Message 10: The position of BFAD

1. The topmost echelons of the country's leadership should be convinced that quality assurance of pharmaceutical products is imperative to reduce their prices and to promote generic medicines for the poor.
2. The role of BFAD, as an agency safeguarding food and drug safety, places it in a unique position among governmental agencies. In this light, BFAD should be an independent agency of the DOH, directly under the Secretary of Health and accountable, through him or her, to the Office of the President and Congress.

Operationalisation

The administrative/legal requirements to move BFAD directly under the Secretary of Health are minimal.

Even if BFAD doesn't improve overnight its capacity and delivery of quality assurance, there are already many things that can be done now. First, the DOH, government hospitals, local governments, Philhealth and NGOs already have enough experience with local generics and the more affordable drugs. They definitely have knowledge which manufacturers produce good quality products and offer affordable prices. Together they can limit their procurement or, in the case of Philhealth, reimbursement to CGMP-compliant firms and their quality products. A formal or informal arrangement among these entities will give them monopsony power and thus force non quality-compliant firms to shape up. A list of quality generic drugs and their producers should be widely promoted and circulated.

6.2 The Need to Increase Availability of Affordable Quality Drugs in Public Facilities

We have seen that government hospitals (including national government retained hospitals and local government controlled district hospitals) and local health centers (made up of barangay health stations and rural health units) cater more to the poor and lower income classes. But at the same time, their facilities and the availability of drugs and services are inadequate and often substandard in the perception of the users (as survey results in section 3.2 showed). These are also the outlets where medicines are given free or at subsidized rates either to inpatients or outpatients. Sadly, the needed drugs and medicines are not adequately available in these centers. Table 9 shows that drugs from government hospitals account for only around 5% of the entire drugs market¹⁴, even if this small share already amounted to more than P2 billion in 1999.

Thus perhaps the single most important component of the holistic approach we are taking in this study is ensuring the availability of essential quality generics and other affordable drugs in these public facilities. Availability of essential drugs goes hand in hand with the availability of physicians, health professionals, medical facilities and equipment, and the accessibility of hospitals, clinics and health centers to the low-income groups.

Ensuring all this requires: 1) enough infrastructure, health professionals and equipment for these facilities, 2) adequate and timely budget for the procurement of drugs and medicines, and 3) an efficient and transparent system of procurement and distribution of quality and affordable drugs.

The first point we have already discussed in the very beginning of the paper. Access of the poor to physicians, government hospitals and local health centers, and the quality of diagnostic and medical facilities and equipment in these centers are absolute necessities before the poor can have easy access to drugs and medicines. Later sections will show that NGO and private outlets for generic drugs become successful only if they are critically linked with physicians, health professionals and workers as well as health facilities promoting generics. Public health facilities too will face a higher demand for medicines from the poor if the latter can easily find doctors to diagnose and prescribe for them, if there are volunteer health professionals and health workers to educate, monitor and remind them to follow their regimen, and if there are accessible diagnostic and medical facilities to detect their illnesses and cure their diseases in conjunction with the medicines. In this respect, perhaps the most essential elements needed to improve the poor's access to affordable drugs are outside the scope of this paper, for the accessibility of hospitals, local health centers and physicians, and the quality of their services and facilities should really be part of the broader health sector plan and reform agenda. But this limitation has to be well understood and cannot be underestimated. One cannot expect recommendations in this paper to succeed if the centers that cater to the poor are too few and have inadequate facilities, physicians, health personnel and services. The absorptive capacity of these centers, even if one pours in as many medicines as possible, may not yield the higher accessibility we desire. Thus increasing the supply of drugs and medicines must be matched with absorptive capacity and the appropriateness of the centers and outlets to the drugs being distributed, as we shall point out time and again.

14 Again it must be pointed out that this amount may underestimate the free medicines being dispensed in the public facilities.

6.2.1 Government Procurement at Various Levels: DOH Central Office, Government Retained Hospitals, Devolved Hospitals and Local Health Centers

There are numerous studies on the procurement of drugs and medicines, including studies for the World Bank and Management Sciences and Health, Inc. (MSH). Thus, although they may be very important considerations and essential to the success of increasing accessibility to affordable drugs, we will not repeat many of the suggestions for improvements in the system of procurement, bidding, paperwork, length and terms of delivery, funds audit, work and systems audit, etc. But we cannot overemphasize the need to eradicate corruption, under-the-table-deals and inefficiencies that lead to shortages in needed medicines, substandard quality of the medicines, and higher drug prices in public facilities.

What we will cover in this paper are what we feel are policies that are connected to the other parts of our paper – especially those that relate to the quality of drugs and medicines, and means to lower their prices in the public facilities.

Because of devolution (starting in the early nineties), the Department of Health (DOH) has retained control of around 72 government-retained hospitals made up of regional hospitals and specialized hospitals, with total bed capacity of around 24,000. The rest, which are made up of around 575 district and other local hospitals and with total bed capacity of around 27,000, have been devolved and are now controlled by their respective local governments. Barangay health stations and rural health units (numbering more than 11,000 and 2,000 respectively) are also being managed and controlled by the local governments.

The Problem

Devolution has made important changes in terms of national government control on drugs and medicines. The budget, requisition and monitoring of government-retained hospitals remain with DOH and the Department of Budget and Management (DBM). The DOH still retains central procurement for anti-tuberculosis, vaccines, micronutrients and medicines from special programs. For the other medicines, government-retained hospitals procure them on their own based (in consultation with DOH) on a budget derived from DBM. For the other devolved hospitals and local health centers, the local governments procure the medicines using their own health budget funded from the internal revenue allocations (IRA) from the national government and supplemented by locally generated revenues. Thus, overall there has been a devolution of district hospitals and local health centers and a consequent decentralization in the procurement and monitoring of drugs and medicines since the early nineties. This has led to some unevenness in the availability of drugs and medicines at the local levels. Timmons et al (1999) report that in 1997 a study of a sample of local governments yielded huge variations in the share of the local health budget for drugs and medicines. The percentages for the various local governments ranged from 4% to 82%. There are no systematic studies on whether these variations correspond to differential needs in the areas, or to different priorities of the local governments.

Whether before or during devolution, the procurement and distribution of drugs and medicines to government hospitals and local health centers have been plagued with charges of inefficiency, lack of transparency and corruption, not to mention inadequate funds and budget. Thus, it is important that all the past studies and recommendations on government procurement and systems to check pilferage, wastage, overpricing and low quality of drugs and medicines should be carefully studied and the recommended improvements adopted (see references for some of these studies).

In addition, to further encourage transparency and good practices as well as to avoid pilferage and wastage, we recommend that the Commission on Audit check and monitor drug purchases and distribution at the DOH central level, in the government-retained hospitals and in the local governments. Again past and future studies on this issue should be used to generate systems and procedures.

Recommendations

Message 11: Government procurement

1. In order to ensure availability of medicines in government retained hospitals, the latter should comply with procurement guidelines, submit requests on their expected needs and also be encouraged to bid collectively in order to have more price-negotiating power. This would be the process more transparent and would also ensure accountability.
2. For district and local hospitals, directly under the control of local authorities, the latter should be made accountable to the central government for decisions they make regarding pharmaceutical procurement, to the extent that the latter delegates a budget to the former for that purpose. That can be done through more auditing and monitoring by the Commission on Audit (COA). Should shortages in the local facilities continue, these would have to be justified and discussed with the relevant stakeholders and with the Department of Interior and Local Government (DILG).
3. Budgeting for pharmaceuticals should be needs-based and local authorities would need to make the funds available without consideration for political patronage. Thus, past studies recommending accountability and elimination of corrupt practices should be adopted.

6.2.2 Improvements to Assure Quality of Generic Drugs

Our main recommendations concern how to improve the quality of procured drugs and medicines and how to lower the wholesale prices (and therefore reduce the retail prices) of drugs and medicines in the public facilities.

The Problem

Interviews with senior clinicians in two big government hospitals based in Metro Manila revealed that many of the government doctors in administrative positions as well as members of the therapeutic committees believe that at least some of their generic drugs are inferior to the branded ones. It is difficult to determine whether these are biased views against generic drugs, or reflect the actual inferior quality of particular generic drugs from some accredited suppliers or the deficiencies in the quality assurance of the procurement processes or deficiencies in storage facilities of some government hospitals, or a combination of these.

Thus we propose that government procurement be used to enhance quality assurance, especially for generic drugs. We propose that only CGMP firms be accredited for government procurement, apart from the other financial requirements and past history of the supplier. If the existing CGMP firms are not able to provide all the required procurements, then the accreditation committee should consult with BFAD and prioritize firms that are almost CGMP compliant (such as preferring those that are 90% compliant as opposed to those only 60% compliant).

We also recommend adopting a system of good monitoring of the quality of various drug manufacturers based on their delivered stock. Clark et al (1994) noted that there was no system to monitor suppliers' performance. They proposed a computerized database with a critical supplier information system.

Finally, as we mentioned earlier, all government procured drugs and medicines are tested by BFAD. To ensure quick testing and quality assurance (a lengthy test period may bring many of the purchased drugs closer to expiry), we recommend the national government, government-retained hospitals and local governments come up with a memorandum of agreement with the eight identified qualified laboratories to act as additional facilities to do the product testing, using fees comparable to those of BFAD's. Even if BFAD reforms don't come about immediately, government procurement can go ahead and have the medicines tested in accredited laboratories.

The above rules (accrediting only CGMP firms, monitoring suppliers' quality and accrediting other laboratories for product testing) should encompass not only DOH and government-retained hospitals but also devolved hospitals and local health centers. This may require two different administrative orders – one coming from DOH for itself and government retained hospitals and the other from the Department of Interior and Local Government (DILG) or Office of the President for the local governments.

Recommendations

Message 12: Improving the quality of generic medicines

1. Only CGMP firms must be accredited for government procurement, apart from the other financial requirements and past history of the supplier. CGMP should ideally apply to the entire production line of each firm. Should that be difficult to achieve in the medium-term, then lower standards should apply, which the DOH and BFAD need to review on an annual basis.
2. A system of good monitoring of the quality of various drug manufacturers based on their delivered stock should be adopted. This would involve a database easily accessible.
3. BFAD has a key role to play in ensuring that generics are of good quality; this reverts back to the previous section about BFAD's regulatory capacity and testing procedures.
4. There is an active role for the government in terms of campaigning actively and in favor of generics; the target should be clinicians as well as the public. This is in line with the 1980s adopted generic policy. (See later section on 'Generic Drug Promotion')
5. Pharma 50 funds earmarked for parallel imports should instead be used in a competitive bidding of CGMP generics, imported generics and parallel drug imports targeted for public health facilities.

6.2.3 Improvements to Reduce Drug Prices in Public Facilities

With respect to ways to reduce the wholesale prices of drugs and medicines, it is worthwhile to discuss two opposing tendencies in government procurement of drugs and medicines. First more centralization is advantageous because of economies of scale and monopsony power. As orders are pooled, the bargaining power of the pooled government agencies as single procurer becomes stronger. Also bigger sales lead to bigger discounts.

The Problem

But the question arises, why is pooling of orders not done by government hospitals, especially those adjacent to one another? The answer of course is that the composition and timing of the required drugs and medicines may be very different from one hospital to the other. Furthermore, personal relationships and preference for certain suppliers are harder to translate into winning bids for these preferred suppliers if many entities are involved in the bidding. The first reason is understandable and calls for flexibility in orders and bulk buying. The second is harder to justify and may reflect corrupt practices that actually lead to shortages,

lower quality and higher-priced medicines¹⁵. It seems that an improvement over the current very decentralized system is called for.

Timmons et al (1999) points to a study by Admadini (1996) which showed that drugs purchased by local governments with no price ceilings or price controls had resulting bid prices which were way above average international prices. In contrast, the bid prices for ten drugs procured by DOH's central procurement body (Procurement and Logistics Service – PLS) were much lower than those procured locally and lower than the average international prices for the ten drugs. This shows that central or pooled procurement of drugs has a price reduction advantage.

Recommendations

Because of this, we propose that a list of commonly used essential drugs be drawn up (say 100 drug items by generic name and formulation). Government-retained hospitals will be asked to give projections of their annual demand and requirements based on this list. DOH then consolidates these to determine the total amount of drugs to be bought by the entire system. The Department of Budget and Management (DBM), together with DOH, then does a central computerized bidding on the drug items with the CGMP and financially capable firms that are allowed to bid. The winning bidders can then be asked to follow a schedule for the deliveries of the drugs and medicines to the final users of the medicines (DOH central office and the government-retained hospitals). The winning bids can have regional variations depending on transportation, storage and handling costs.

Flexibility can be achieved by allowing the government hospitals to do exchanges of medicines with other government hospitals (with set procedures and documentation) and additional purchases. These additional purchases, however, will have to be made from the winning bidder for that drug or medicine, at an allowable margin above the winning bid (since these are unplanned and unscheduled orders). This allowable margin can be part of the process of the centralized bidding. (i.e., part of the considerations in the awarding of bids can involve the bidding firms' bid of allowable margins for unscheduled orders).

Obviously this suggestion requires capability, capacity, transparency and efficiency in the entity that will be responsible for the bidding, as well as a foolproof computerized bidding system. We recommend that a full-blown study and pilot testing of this be made. The government should seriously identify which entity will be best qualified to undertake the centralized bidding. The selection will be based on capacity, track record, transparency and system of accountability. Possible candidates are PLS, PITC and the Department of Budget and Management (DBM). It is clear that whichever is chosen will have to improve their current capacity and system of accountability. There have been various pilot testing and experimentation of pooling of orders by regions and we recommend incorporating the recommendations from these studies. If a national centralized bidding process is not feasible, we encourage a combination of initiatives to pool

¹⁵ Preference for certain suppliers due to reasons such as quality assurance and low prices should actually encourage pooling of orders.

orders from different hospitals and local governments together, whether by region or specialization of hospitals and clinics. Again these need more in-depth studies and pilot testing.

In the meantime, as these recommendations are being studied, we also recommend that the government come up with a list of wholesale prices for essential and commonly used drugs, based on quotations from the wholesalers. This price list would be a useful source of information for various endeavors (Philhealth reimbursement, comparison with government winning bids, calculating retail mark-ups, etc.) which will yield more competitive and transparent processes.

For the local governments (who control the district hospitals, field hospitals and local health centers), it is recommended that they be encouraged to participate in the centralized or pooled bidding in order to reduce their prices for drugs and medicines. Alternatively, a more stringent approach would be that once the centralized or pooled bidding processes for DOH and retained hospitals are actually functioning, an administrative order will force them to participate in the centralized or pooled bids, or to follow the reference pricing derived from the central or pooled bidding.

Message 13: Reducing drug prices in public facilities

- a. Central computerized bidding for the entire network of government-retained hospitals may lead to better price deals and savings for the system.
- b. Local governments should be encouraged to participate in the centralized or pooled bidding in order to reduce their prices for drugs and medicines.
- c. DOH should come up with a list of wholesale prices of medicines based on generic and therapeutic categories.
- d. Pharma 50 funds earmarked for parallel imports should instead be used in a competitive bidding of CGMP generics, imported generics and parallel drug imports targeted for public health facilities.

Operationalisation

- 1. The first recommendation above would require capability, capacity, transparency and efficiency in the entity that is chosen to do the centralized bidding, as well as a foolproof computerized bidding system.

6.2.4 Finding Additional Funds for Health Services and Resource Allocation

The Problem

It is well known that even if procurement procedures are greatly improved, there will most likely still be a shortage of drugs and medicines in the public facilities. This is not only a problem of lack of money for drugs and medicines but a problem in general of shortage of funds for more hospitals and health centers, more facilities and equipment in these centers, and most importantly providing access to well-paid physicians (and other health professionals). As we have said and will be repeating often, absorptive capacities of government hospitals for drugs and medicines and accessibility of the poor to these drugs and medicines precisely depend on these factors.

Thus the government, if serious in this endeavor, should be able to cough up the needed financing for these urgent needs. We recommend that the anti-poverty program of the government be very active in identifying budget sources and donors' money to improve health facilities, health resources and supplies (including physicians and medicines), especially in poorer regions and areas.

There has to be a progressive scheme where more impoverished areas get more funding for health facilities, health personnel and medicines. Currently, revenue capacity is higher with richer local governments, and infrastructure (including health infrastructure) is biased to urban and metropolis areas.

All of this again requires a lot of political will and drive to reduce poverty with the health sector as a critical focus.

Recommendations

Message 14: Additional funds and Resource Allocation

1. Scarcity of resources means that there will be unmet needs.
2. For urgent needs, the anti-poverty program of the government should be very active in identifying budget sources and donors' money to improve health facilities, health resources and supplies (including physicians and medicines), especially in poorer regions and areas.
3. A needs-based resource allocation formula needs to be set up, such that poor provinces facing large health-related needs are provided with the necessary funds.

6.3 Parallel Drug Imports (PDI)

Parallel drug importation is the importation of branded drugs under patent, exported from another country, even as the same products are licensed and being produced

by locally based subsidiaries. PDI of course will bring benefits to the country only if the prices of the parallel imports are substantially below the prices at which the locally produced medicines are being sold in the country.

PDI is currently being undertaken by the government to increase the stock of affordable medicines in the public facilities, especially government hospitals and local governments. Parallel-imported pharmaceuticals are sold in government facilities (hospital pharmacies) only and we have not been able to confirm rumors that such medicines may one day be on sale by commercial pharmacies. We asked the National Drug Policy office and the DOH that handle the issue of parallel drug importation about this matter but the response was that some discussions had occurred between the government and some wholesalers but no definite arrangements were drawn up. Therefore we assumed that for the duration of the PDI program, parallel importation will be conducted only by a governmental agency (in this case, PITC).

6.3.1 PDI Phase One: The First Two Shipments of PDI

6.3.1.1 Description of the Scheme and Policy

In 2000, the national government and DOH amended the implementing rules and regulations (IRR) of the Counterfeit Drugs Act so that drugs with the same brands registered and produced in the country can be 'parallel imported' from another country, as long as they pass the quality assurance of BFAD. (See Annex C.1 of Appendix C for Administrative Order 85). The first shipment of 8 parallel imported drugs worth P1.5 million was undertaken in November 2000, and the second shipment of another 8 parallel imported drugs worth P20 million was undertaken in February 2001. PITC was tasked to find the imported branded products, and it decided on imported brands from India. The patents on all parallel imported substances had expired, but the parallel imported product was the originator branded product. BFAD was asked to hasten the testing of the drugs and certify their meeting of quality standards. The drugs were sold to 30 voluntarily participating government hospitals, which were able to retain the mark-up between the PITC selling price and the retail price sold in the government hospital, in order to improve their stock and inventory of drugs and medicines.

PITC was given the sole responsibility of importing the PDIs because the government wanted to ensure control of the quality and prices of the shipments, as well as ensure that proper procedures were undertaken in the supply sourcing. The most important consideration was a uniform retail price at the hospital outlets, which could not have been achieved if procurement was decentralized to private wholesalers/importers. Similarly, government hospitals were the only ones chosen for the outlets again so that the government can control the flow of supplies and the retail prices of the PDIs. Including private players would have increased the difficulty of coordinating, monitoring and ensuring the desired quality standards and uniform prices. Including private participants, however, may be experimented with in the next phases of PDI (see below). We will offer a

critique of the PDI distribution to government hospitals and exclusive importation and distribution by PITC in later sections.

Table 16 gives the list of eight parallel imported drugs for the first and second shipments. The table includes the PITC selling price, the suggested DOH hospital price, and the current local market price of the branded products. One can see that the price reductions for the 8 drugs were indeed substantial, if compared to Mercury drugstores' retail prices. One can also see that the 8 drugs were essential drugs which we have identified in Annex A.1.

6.3.1.2 Results of the First Two Shipments of PDI and Problems With Implementation

A closer look at Table 17 shows that the government hospital outlets for the second shipment of PDIs were heavily concentrated in Metro Manila, with 15 hospitals located in Metro Manila, 6 in the rest of Luzon, 5 in Mindanao and 4 in the Visayas. We assume that this allocation bias is most likely due to the experimental nature of the first phase wherein government hospitals were included in the program on a voluntary basis. The Manila hospitals would have an upper hand since they are bigger and would have bigger budgets and greater capacity to order.

The first phase of the PDI implementation was plagued by resistance from the local pharmaceutical industry. This is reflected in the court suit brought by the Pharmaceutical and Health Care Association of the Philippines (PHAP) against the government on at least four counts:

- a) The exemption of PDIs from some documentation requirements (e.g., the paper certifications from the exporting country required for all imported drugs – see Table B.1) gives special preference to PDIs over locally produced drugs.
- b) The PDI medicines were not subject to the detailed requirements of generic labeling required for local drugs as stipulated in a DOH administrative order.
- c) The PDI medicines violate the exclusive rights of trademark and licensing of multinational brand products that are being produced in the Philippines.
- d) The government is establishing a monopoly for PITC in the wholesale distribution of PDI drugs.

The first two charges are relatively minor. PDIs are bought from wholesalers of the exporting country and not from the drug manufacturers or traders of the branded medicines. Thus, the marketing chain makes it difficult to produce the required documents for imported drugs (see Table B.1). To compensate for this, AO 85 (Annex C.1) requires BFAD testing

of PDIs for quality assurance before they are brought into the country. The third charge is the most serious, as it questions the whole logic of parallel imports and views it as a violation of the exclusive licensing of brands and exclusivity of rights to produce and market branded products. The fact that the suits were not brought before the WTO is admission that the WTO rules are silent and not contrary to parallel imports¹⁶. It is important that the government wins this case, in order to keep open an alternative channel of more affordable drugs for the future. The fourth charge is also serious, and the government is seriously considering and negotiating with some private distributors on the possibility of private wholesale distribution of PDIs. But this can only be feasible if BFAD develops the capacity to test these PDIs en masse. Institutionalization of the outsourcing of product testing is therefore essential.

Utilization of the parallel imported medicines was very low. Table 17 shows the utilization of the second shipment of PDIs as of October 31, 2001 (eight months after the shipment). One can see the very low utilization across all imported medicines, with an average utilization rate of only 12.5% for all medicines in all the 30 hospitals. A look across hospitals though shows a very uneven utilization of the PDIs with some hospitals achieving more than 50% utilization and one hospital achieving 80% utilization. The high users of PDIs, though, were those hospitals that were not given large quantities of the imported medicines. It seems that the absorption capacity for the imported medicines, relative to the amount distributed, was very low.

A more detailed investigation into the matter, through interviews in two main hospitals in Manila and PITC officials among others, revealed the following problems which may have been responsible for the low utilization:

1. The second shipment of PDI had to use up an allocation of P20 million. This, in turn, had to be divided into only eight medicines and distributed to only 30 hospitals. Initially, there were more medicines on the list. But this was trimmed down as the task force committee for the PDI found that many of the Indian counterparts had different strengths or formulations compared with the ones in the Philippine National Drug Formulary (PNDF). Thus many hospitals were forced to accept many thousands of medicines without consideration of their absorptive capacities. A look at Table 17 shows that those with very low utilization rates had been 'dumped' with too many PDI medicines. A visit to two participating government hospitals in Metro Manila (St Lazaro and Jose Reyes) at the end of March 2002 revealed that most of the medicines are still unused. The hospital pharmacists are looking for

16 The US drug manufacturing group PHARMA originally threatened to put the Philippines in the blacklist due to the PDIs, but this did not push through.

other government hospitals to give the medicines to before they expire.

2. Hospitals (responsible for purchasing and using the PDI drugs) were not consulted on what drugs they needed and the corresponding projected demand for each drug. This relates not only to the actual product but also to the strength and dosage. The choice of drugs and their quantities were decided at the very top at the DOH level by the task force committee for PDI. It is not known whether any consideration was given to actual clinical needs, in terms of ensuring that a certain strength/dosage would be purchased rather than anything that would be available at the time.
3. The suggested retail prices set by DOH and PITC in Table 16 contained 30% mark-ups over the PITC prices. The PITC prices also were based on unknown mark-ups over the imported prices (plus transportation and handling costs). This retail price was compared to the Mercury drugstores' retail prices for the same medicines and strengths. The policy of the task force committee was that as long as the suggested retail prices for the PDIs were substantially lower (at least 30% lower) than the prices in Mercury drugstores, then the PDIs would be approved. There are two problems with that logic. The first is that Mercury drugstore prices were compared with those of the parallel-imported drugs. This would still mean that consumers might have to pay high prices compared with available generics, which are in general priced lower than branded products, even those which are parallel-imported. The second and more important problem was that parallel-imported medicines were sold only in hospital pharmacies, (using as benchmark a discount off the Mercury price), and were thus directly competing with the generic medicines, which are by definition used in hospitals and hospital pharmacies. The issue, of course, here is that generic medicines are not always available in hospital pharmacies and clinicians are not always convinced of their effectiveness. By introducing parallel-imported drugs in hospitals only, the government seemed to be doing the following: (a) antagonizing its own generic drug policy, and (b) accepting indirectly that generics are not up to standard, instead of intensifying its campaign to increase their use. We estimate that the proportion of outpatients that switched to parallel-imported drugs purchased from a hospital pharmacy instead of going to a neighboring commercial pharmacy to purchase a branded product, must have been very small. The government hospital clientele is also mostly poor, who tend to use generic drugs more. The PDI should have been introduced to the

hospitals only if its price was lower than the local generic drug being used by the hospital. Indeed, we saw one such case, namely a branded (PDI) Indian Adalat, versus an equivalent imported generic, nifedipine. Nevertheless, this seemed to be the exception rather than the rule. A visit to one of the biggest Metro Manila government hospitals participating in the PDI program revealed that the acquisition cost of the local generic drug for cotrimoxazole 200 mg. SMG +80 mg. TMP, 60 ml suspension is P10 while the PITC selling price for the same dosage and formulation of Septran is P61.45. (See Table 18). The retail price at the hospital of the same medicine is P13 while the suggested PDI retail price of Septran is P79.90. A similar story can be told when one compares the prices of the local generics for cotrimoxazole 800 mg and 400 mg tablets with the prices for the PDI Bactrim of the same dosages. This same problem which we shall discuss later of using Mercury drugstores' prices to compare with PDI prices persists in the current shipments of PDI under Pharma 50. We feel this problem reveals a fundamental flaw in the strategy of PDI in its first and current phase, for the PDIs are being used as competitors not to the expensive branded medicines (as it was originally intended), but to local generics. (Note also in Table 18 that the hospital had very many excess quantities of most PDI medicines, and PDIs of Nifedipine (Adalat) and Cotrimoxazole suspension. (Septran) are near expiring.)

4. There was very weak social marketing of the PDIs, especially in relation to making them the competitors of expensive local branded medicines. According to a DOH informant, the social marketing phase was weakened by the aforementioned legal suit since the judge did not want to have the pros and cons of the case discussed publicly since it is subjudice. Even if the promotion of PDIs was not explicitly banned, DOH decided to move with extreme (and many feel over) caution, and hardly any promotion was made. It is often told that many government doctors in government hospitals selling PDIs did not even know there were PDIs available in-house.
5. Many doctors, including those in government hospitals, doubt the quality of Indian parallel-imported drugs, even though these drugs have the same formulation and seal of the same multinationals as the local branded medicines. This despite the fact that BFAD is testing the PDIs before they are allowed entry into the country. The reason for this may be continued skepticism about quality assurance in general but it may also relate to advertising campaigns by

local subsidiaries of multinational pharmaceutical companies.

6.3.2 PDI Phase Two: Pharma 50

Pharma 50 and the Department of Trade and Industry (DTI) envision the continuation and strengthening of PDI as the main short-run strategy to reduce essential drug prices in compliance with President Arroyo's SONA promise. A total of P100 million -- P25 million per quarter for four quarters -- has been allotted for PDI for the whole of 2002. An additional P60 million from the Philippine Charity Sweepstakes Office (PCSO) is also being used for purchase of PDIs by local governments. The Department of Trade and Industry (DTI) and DOH are pushing and promoting PDIs among local governments and convincing them to purchase these from PITC.

Administrative Order No. 69 (Annex C.2) gives us the PDI guidelines for Pharma 50. The main procedures of parallel importation for the government hospitals are the following:

- a) Pharma 50 and DOH give a shopping list of drugs to the government and district hospitals and ask them to identify their essential drug needs. From this survey, the list of PDIs and their quantities is determined. This procedure is obviously in reaction to the problem of lack of consultation and oversupply in the first phase of PDI.
- b) DOH prepares purchase orders (PO) for the drugs to be parallel imported and submits this to PITC.
- c) PITC submits samples to BFAD.
- d) BFAD tests and releases test results.
- e) PITC orders, imports, relabels (complying with the Generic Law) and repacks the medicines.
- f) PITC completes delivery to government and district hospitals.

One of the big changes in Pharma 50 (as opposed to the two earlier shipments of PDIs) is the expansion of the list of drugs from 8 to more than 40. Another is consulting with government hospitals on the essential drugs they need. This latter was done in light of the low utilization rate of the drugs in the first two shipments of PDI. Furthermore, the hospital outlets have been increased from 30 in the first two shipments to around 76 government and district hospitals.

As of this writing (early April, 2002), PITC has ordered the third shipment of PDIs, consisting of two quarters worth of PDIs (P50 million), for delivery to government hospitals. Table 19 gives us a list of the PDI drugs being ordered for the third shipment, including the PITC price, the suggested retail price, the market price and the price savings. Most drugs in the list again conform to the identified

essential drugs listed in Appendix A.1. The only PDIs not in Appendix A.1 are the anti-epileptic and anti-psychotic drugs.

The requirements of Pharma 50 for the PDIs are:

- a) The drugs must be off-patent (to avoid intellectual property rights issues with the multinational firms and, particularly, the US)¹⁷;
- b) The drugs are needed to treat the leading causes of morbidity and mortality;
- c) The drugs must be top selling drugs; and
- d) There must be a wide price differential with the local counterpart brand.

One can see in Table 19 that most of the drugs still offer substantial savings, compared to Mercury drugstores' prices. (One of the criteria of choosing the PDIs is that the average price reduction for all the PDIs, compared to the Mercury outlets' prices, should be at least 50%, consistent with the President's SONA promise.) Another thing to notice in Table 19 is that the mark-ups in general are lower than in the first two shipments. This has two opposite effects. It reduces the costs of the drugs at the hospital retail level, but it also reduces the amount that the hospital can retain.

Finally Table 20 identifies the 76 government and district hospitals that are targeted as the retail outlets of the PDIs, and their allocation in terms of value of PDI drugs from the P100 million being provided by the national government. The allocation is more or less based on each hospital's bed capacity. One can see that Metro Manila hospitals are getting 31.37% of the total allocation, an amount bigger than its share of the population (given in Table 10). The other regions are getting smaller shares, especially compared to their population share. This lopsidedness may just be a reflection of the lopsided distribution of government-retained hospitals and the bigger bed capacities of Metro Manila hospitals.

6.3.3 Evaluation of the PDI Strategy and key messages/recommendations

The PDI strategy has demonstrated above all, that popular branded and essential drugs can be sold at much more affordable prices than those sold in traditional retail outlets. This should signal to local pharmaceutical suppliers, distributors and retailers (particularly the latter, since we don't know what their margins are and what discounts they receive) that the government can find alternative sources of affordable medicines for the general public and for the poor.

¹⁷ WTO is still quiet with patented products, and there are academics and activists [e.g. Oxfam] who actually support PDIs being used to compete with local patented products, for this, together with compulsory licensing, would be the most effective ways of bringing prices of patented drugs down.

It should also convince the general public that quality medicines need not be expensive and that high drug prices are not synonymous with quality drugs.

For parallel drug importation to be beneficial on welfare grounds it should result in lowering the prices of pharmaceuticals in the importing country. Of course, a key concern about parallel trade is who benefits from its conduct¹⁸ and, in particular, what benefit accrues to the agency that pays for pharmaceutical benefits (payer) or to the final consumer who may be paying, fully or partly, out-of-pocket. We explore these questions but the relevance of parallel trade in this section implies that its conduct clearly has a potential welfare effect because of price differentials.

The Problem

However, the low utilization rates in the initial phase of PDI (plus the fear that this possibility might be repeated in this phase) and the small market share of PDIs (a total of P160 million for Pharma 50 in a more than P50 billion¹⁹ drug market) make its impact very limited. Very few people, even physicians, are aware of the strategy, let alone convinced that it poses anything of a threat to expensive branded medicines.

Equally important is a fundamental flaw in the logic of PDIs and its current strategy. The rationale for the PDI strategy is: given that people (especially physicians) prefer expensive branded medicines over more affordable generic drugs, and since it may take time for quality assurance and the regulatory framework to substantially improve, an interim strategy would be to introduce parallel drug imports to compete with the more popular but more expensive branded medicines. This logic would be correct if PDIs were introduced precisely in the market where expensive branded medicines dominate, and which is comprised of the mainstream, traditional retail outlets of drugstores, pharmacies and private hospitals. In order for this to happen, some regulatory interventions may be needed in order to provide incentives for retail outlets to stock and sell PDI drugs. This may prove difficult, expensive and counter-productive given the drugstore chains' agreements with pharmaceutical companies. An alternative would be for private wholesalers who also have retail activities to be allowed to do PDI.

The current strategy fails to see that one of the main reasons for high drug prices in the Philippines is market segmentation where the dominant retail market (drugstores, pharmacies, private hospitals) generated by the demand of those with purchasing power is concentrated on expensive branded medicines. The smaller market for those without purchasing power (the lower middle class and the poor) is concentrated in government hospitals, district hospitals, local health centers and a few NGO and private outlets where the more affordable generic drugs are more in demand. The lack of access of the poor to medicines is brought about by: 1) their lack of purchasing power and access to physicians and other facilities, and 2) the

18 Kanavos, P., Mossialos E., Outstanding regulatory aspects in the European Pharmaceutical Market, *PharmacoEconomics*, vol. 15, No. 6, pp. 519-533, 1999.

19 Even if we just use 10% of the pharmaceutical market as base (to make up for the irrational and overuse of some pharmaceutical items), this is still P5 billion. P160 million out of P5 billion is still only 3% of the entire market.

lack of availability of quality generic drugs in government hospitals, district hospitals, local health centers and NGO outlets where the drug prices are usually lower and subsidized for the poor.

The more rational approach therefore would be to improve the poor's access to quality generics (either local or imported) in the public facilities and NGO outlets. PDIs should supplement drugs in the public facilities only if they are cheaper and/or of higher quality than the generic drugs. PDIs, on the other hand, should give expensive branded medicines stiff competition if private importers and wholesalers are encouraged or given positive incentives to distribute them in the private retail outlets.

Instead PDIs are being promoted in the public facilities that already provide (albeit inadequately) more affordable generics to the lower income groups. The current push of DTI to promote PDIs to local governments reinforces this wrong approach. Thus, it is possible that, even if successfully promoted, these PDIs will be competing with the already more affordable local generics, rather than compete with their more expensive branded local counterparts. Branded medicines are being promoted among a clientele that is already used to generics products. The value-added of PDIs in the public facilities is that, given a lack of available essential generic drugs, PDIs can be supplements and additions to the supply. But the question should be asked: why only PDIs? Why not a competitive acquisition of additional medicines – local and imported generics as well as PDIs – based on their prices and their quality?

In the current Pharma 50, there is a lack of initiative to address the inadequate supply of affordable but quality generic drugs in the public facilities which are catering more to the poor (and instead PDIs are being promoted in these same public facilities). The programs in Pharma 50 that involve the promotion of generic drugs are in the Botika ng Barangay and rolling stores programs, which are limited to over-the-counter drugs and two antibiotics (cotrimoxazole and amoxicillin). A bigger program for Philhealth reference pricing for drugs would concentrate on CGMP generics, but this program has not even been pilot tested yet and so is not expected to take off in the near future. The potential of generic drug promotion for a Philhealth outpatient program is also a bit into the horizon, as discussed in the relevant section.

In this regard, the criticism of the current PDI approach by such nationalist health groups as the Health Alliance for Democracy (HEAD – see their newsletter *Pulso ng Bayan*, April-June, 2000) as being only a palliative and not addressing the issue of a national drug industry, hits the nail right on the head.

Recommendations

We recommend that private importers and wholesalers eventually be allowed to undertake importation and distribution of PDIs according to the requirements of AO 85. This means that AO 85 itself will have to be amended to allow private sector involvement. They can target their sales to the private sector or public sector, as long as they compete according to BFAD rules and government procurement procedures.

However, this will be feasible only if BFAD is ready to test the imports in a systematic and timely manner. This can only be achieved if outsourcing of product testing is immediately institutionalized .

The implication of all this is that the exclusive importation and distribution of PDIs by PITC will have to end. This of course doesn't mean PITC should stop importing and distributing PDIs. It simply means that it will have to compete with other wholesalers and distributors. Competition might reduce the mark-ups of PDIs (this, however, does not necessarily follow) and make them even more attractive to consumers, if promoted correctly and incentives are given to private retailers to dispense them. It is reported that foreign retail distributors – Watson and Hi-Mart – are interested in entering the business of PDIs, and are negotiating with the government. If it allows this, government must gather enough political will to counter the wrath of the multinational companies, and most likely, the US. It would also help greatly if the court case by PHAP against the government is resolved speedily in favor of the government.

We also recommend that future allocations for PDIs in Pharma 50 (after the third shipment which is currently being undertaken) be allotted instead and targeted to quality CGMP generics (whether local or imported) for distribution in government hospitals, local health centers and NGO outlets. PDIs can be allowed if their prices and quality are better than those of local or imported generics. In other words, future allocations of funds in Pharma 50 should be used in the competitive procurement of affordable drugs for the public facilities and NGO outlets where CGMP and imported generics as well as PDIs compete in terms of price and quality.

Overall, it must be said that the Pharma 50 strategy of employing PDI will not, in the short term, achieve President Arroyo's SONA goal of reducing essential drug prices by 50%, especially if we interpret this as making affordable drugs available to the majority of the masses. As we have explained before, the PDI market currently being formed by Pharma 50 will only make a small dent in the overall market of essential drugs. But the lessons learned in this experience should spur us to tackle more holistically and more rationally the problem of low accessibility to affordable drugs.

Message 15: Parallel Imports

Given the government-led activity that has already taken place on parallel drug imports, we feel that the following need to be taken into consideration:

1. Parallel importation can lead to lower prices of branded medicines; in order to achieve lower prices of branded medicines, parallel-importation must be a significant source, therefore providing a credible threat to local subsidiaries' market shares for the same products.
2. Conducting parallel imports means relying on several exogenous factors that are beyond the government's control; the government might want to relinquish its exclusive role and encourage PDI by private wholesalers, who would then absorb the risk of the entire process.
3. One significant risk factor is the future response of multinational subsidiaries in the exporting country, which may enforce mechanisms not to allow its imports to countries where the multinational would have a corresponding (sister) subsidiary. Thus, parallel imports altogether may provide only a short-term relief measure in terms of meeting its objective in lowering prices in the medium- to long-term.
4. The international experience (particularly from Europe, where parallel imports are allowed and encouraged by governments in high-price countries), suggests that PDIs cannot be the epicenter of national policy in attempts to reduce pharmaceutical prices. Even in countries where PDIs are actively encouraged with incentives provided to pharmacies, their total share in the pharmaceutical market, does not exceed 5%, whereas it may be higher in a given product market.
5. Extending the scheme of PDIs would only make sense if private distributors were encouraged to import and if retailers had enough incentive to dispense them. This poses two regulatory challenges: 1) at the level of BFAD, to be able to apply the same approval criteria for private distributors as it does for PITC in a speedy manner (which would also include sample testing of imported batches), and, 2) at the DOH level, to regulate the behavior of pharmacies and provide the relevant incentives for them to be willing to dispense PDI drugs. We fear that, for various reasons, neither of the above challenges might be met in the short- to medium-term.

6.4 Increasing Drug Availability in NGO/CO Outlets

Pharma 50 has begun in 2002 a program to channel drugs and medicines to Botikang Barangay (BnB) outlets. BnB outlets are a joint venture with seed capital from the national government, a local government and an NGO or community organization (CO) merged to operate a retail outlet for drugs and medicines. Administrative Order No. 70 of January 2002 governing the licensing of BnBs is given in Appendix D. This retail outlet would be less than a full-fledged drugstore or pharmacy since it would be handling not the entire range of drugs but only over-the-counter (OTC) drugs and two antibiotics (cotrimoxazole and amoxycillin). Because of this BnBs are able to waive the Pharmacy

Law wherein a pharmacist is needed to be in charge of the retail outlet every time it is open. Instead, a supervising pharmacist is required without having to be always present in the outlet. BnB outlets, however, will have to satisfy the other BFAD requirements for retail outlets.

Currently there are two main sets of NGOs/COs participating in the program, namely, the Health Plus and Botika Binhi outlets. Botika Binhi outlets are carryovers from the past BnB program of DOH. Health Plus (formerly called Famus) is the group of outlets supported by the National Pharmaceutical Foundation, which is supported and funded by GTZ Foundation.

Currently, there are around 300 BnB outlets. The target is 800 outlets by the end of 2002. P20 million worth of drugs are to be distributed to the 800 BnB outlets with PCSO providing the money. PITC is again charged with the procurement of the medicines. The medicines will be exclusively generics, except those which do not have generic equivalents.

Pharma 50 also has obtained P20 million for drugs to be distributed in rolling stores ('Gloria Labandera'). Rolling stores are also government-private joint ventures and carry only the two herbal medicines *sambong* (diuretic) and *lagundi* (bronchodilator). There are plans to expand this to more OTC drugs. Because only OTC drugs are involved, rolling stores are able to waive the Pharmacy Law and other BFAD requirements for retail drug outlets. At present there are only 41 rolling stores all based in Metro Manila. The plan is to create more rolling stores in the provinces as well.

To improve the performance of the BnB and rolling store programs, the following problems should be correctly tackled:

6.4.1 Lack of Absorptive Capacities of BnB Outlets and Rolling Stores

The Problem

One big problem of the BnB program is that there is P20 million for drugs, an amount which is too big for the present number of BnB outlets, which have sales more or less of around P5,000 per outlet per quarter. Given that the drugs will come in the second semester (after orders and procurement by PITC), absorptive capacities will be only P10,000 per outlet for the rest of the year. With 800 outlets, maximum absorptive capacity may only be P8 million. The National Pharmaceutical Foundation in charge of Health Plus outlets already has a revolving fund for drugs and medicines amounting to P26 million. Furthermore, since there are only 300 BnB outlets, it is not clear if the additional 500 outlets can sprout on their own within the next few months. These outlets require counterpart capital from the local government and NGO or CO. They also have to satisfy BFAD requirements for retail outlets and the requirements in AO 70.

The lack of absorptive capacity in rolling stores is even more severe, given that there are at present only a few rolling stores in Metro Manila. The large money

poured into this program may be potentially controversial as some could view this as politicking for the 2004 elections.²⁰

Pharma 50 may have to put more effort into the planning and setting up of BnB and rolling store outlets. Guidelines and effort are currently being put in place to set up more BnBs and more rolling stores. But this may not be achieved in the short run. Thus even if money has been allotted for drugs and medicines for these alternative outlets, an increase in their number and absorptive capacity may not come about very soon. There is little planning for the new 500 BnB outlets and the hundreds of new rolling stores that are needed if the P20 million is to be absorbed. Setting up alternative drug outlets should be a medium to long term strategy, and should include plans, targeting private partners and organizations, and identifying sources of funding for the capital and operating costs. Also, absorptive capacities of these outlets will not increase unless accompanied by increased access to doctors and health facilities. A visit to the Council for Health and Development – the central office of Community Based Health Programs (CBHP) – revealed that drug outlets and clinics of CBHP are successful partly because of the existence of volunteer doctors and health professionals and health workers supporting and promoting these outlets. Section 6.4 also documents the success story of a private drug outlet promoting generic drugs due to its association with a physician dispensing generic drugs.

Health Plus retail outlets also usually situate themselves near local health centers and clinics where physicians and facilities are present in order to get a critical mass of demand for medicines.

In short, new BnBs and rolling stores with enough absorptive capacity will not automatically come about in a span of a few months. Pouring P40 million worth of drugs now to these outlets (many of whom do not yet exist) may be a bit premature. Pharma 50 can help these BnBs by linking them with government doctors so that increased demand for their drugs and medicines will be obtained. When the Philhealth indigent outpatient program takes off, they can also be accredited for Philhealth reimbursement as long as they subscribe to Philhealth guidelines and reference pricing. But these things will take some time to happen.

It is therefore recommended that only a maximum of P5 million out of the P20 million be allotted to drugs for BnB outlets from now until the end of 2003. Only as much as P1 million should be reserved for the rolling store program for the same time period. Allotments in future years for BnB outlets and rolling stores can of course be continued depending on the success of the program.

The rest (P34 million -- P15 million from the BnB fund and P19 from the rolling store fund) should go to existing national and local community health programs which have local or community (BFAD-registered) drugstores or pharmacies and clinics. The project team can identify several entities that have grassroots outlets for drugs and medicines. The mainstream churches of the various religious denominations would have a string of affiliated hospitals, clinics and

20 These stores used to be called 'Erap' stores during the term of ex-President Estrada, and now they have changed the name to 'Gloria Labandera'.

drug outlets catering to the lower income classes. The Community Based Health Program (CBHP), Community Medicine Foundation (COMED), Council for Health Development (CHD) and the INAM (Integrative Medicine for Alternative Health Care Systems) networks have community health and medical program chapters throughout the country and these would have grassroots outlets for drugs (such as clinics, community drugstores or pharmacies). There are local and regional groups that cover whole provinces (such as the LIKAS [Lingap Para sa Kalusugan ng Sambayanan] network in Sorsogon). It is recommended that DOH reach out to such national and regional health and medical groups which have local chapters and drug outlets throughout the country.

One parallel approach for the government is to accredit already existing community-based pharmacies and clinics as BnBs. An additional advantage of reaching out to already established people-based clinics and drug outlets catering to the poor and low income groups is that a wider array of essential drugs can be distributed since these outlets, if they are clinics or BFAD-registered pharmacies, are licensed to dispense prescription drugs over and beyond cotrimoxazole and amoxicillin.

Drug outlets of existing community-based health programs, as mentioned earlier, would also have the advantage of having volunteer physicians, health professionals and health workers associated with the clinics or pharmacies. This would ensure higher demand and absorptive capacity and, especially for affordable generic drugs. It is high time that the government becomes a partner to community-based health programs and NGOs since they have a pool of volunteer physicians, health professionals and health workers as well as a network of clinics and drug outlets. These networks and pool of human resources could easily become a significant dispenser and distributor of affordable medicines to the lower income classes. (When the Philhealth outpatient indigent program takes off, the drug outlets of these programs should be allowed to be accredited by Philhealth, if they subscribe to Philhealth guidelines and reference pricing.)

Of course this approach of dealing with community health programs will need intense consultations with the grassroots organizations on their drug needs. It also necessitates creating an efficient system and procedure of procurement, distribution and remittance of proceeds from the drug sales.

If the churches, NGOs and civil society groups do not have the capacity to absorb P34 million then the excess money should be pooled with the money originally intended for PDIs and channeled to government hospitals and local health centers. The total pool should be used to finance the drug needs of these hospitals and health centers in a competitive bidding of generic drugs and PDIs, based on price and quality (as we explained earlier). To assure absorptive capacity for these medicines, the money can be tied to the outpatient indigent program which will be discussed in the section on Philhealth, and to programs to improve facilities and access to physicians in the health centers and provincial/field hospitals.

Recommendations

Message 16: BnB outlets, rolling stores & other Community-Based Outlets

A role is envisaged for BnB outlets, rolling stores and community-based health program outlets.

- a. All the above can contribute significantly towards improving drug access to the poor and their activities need some coordination; our feeling is that each one does not know what the others are doing;
- b. Establishing adequate BnBs and rolling stores with enough absorptive capacity will not automatically come about in a span of a few months.
- c. Pouring P40 million worth of drugs now to these outlets (many of whom do not yet exist) may be a bit too soon.
- d. The government should target existing community-based, NGO-based and church-based outlets for some of their Pharma 50 medicines financed by PCSO, and originally targeted for the BnBs and rolling stores.
- e. Pharma 50 can help these BnBs by linking them with government doctors so that increased demand for their drugs and medicines will be obtained.
- f. When the Philhealth indigent outpatient program begins and takes off, community-based outlets and BnBs can also be accredited for Philhealth reimbursement as long as they subscribe to Philhealth guidelines and reference pricing.

Operationalisation

Given the above, the following are recommended:

1. Only a maximum of P5 million of the P20 million be allotted to drugs for BnB outlets from now till end of 2003.
2. Only as much as P1 million should be reserved for the rolling store program for the same time period.
3. Allotments in the future years for BnB outlets and rolling stores can be continued depending on the success of the program. The rest (P34 million -- P15 million from the BnB fund and P19 from the rolling store fund) should go to existing national and local community health programs which have local or community (BFAD-registered) drugstores or pharmacies and clinics.
4. It is recommended that DOH reach out to national and regional health and medical groups (CBHP and INNAM networks) which have local chapters and drug outlets throughout the country.
5. If absorptive capacities of the churches, NGOs and civil society groups are not enough to use up P34 million then the excess money should be channeled to drug needs of government hospitals and local health centers and pooled with the money originally intended for PDIs. The total pool should be used to finance the drug needs of these hospitals and health centers in a competitive bidding of generic drugs and PDIs, based on price and quality.

6.4.2 Ensuring BnBs Do Not Become Local Monopolies and Making Sure BnB Mark-Ups Will Not Remain High

The whole rationale for BnBs is that with inadequate supply of affordable drugs in the grassroots, NGO outlets can be alternative outlets for affordable medicines. It must be emphasized that district hospitals and local health centers usually dispense free or subsidized medicines. NGO outlets only take care of the shortages in the area and also service areas that cannot be reached by the district hospitals and local health centers. The current BnB guideline requires BnB outlets to be at least 50 meters from the nearest drug outlet. The NGOs or COs that are co-owners of the BnB supposedly have their own constituents in the community. The decision then to open a BnB should be dictated by the presence of demand in the area. There should be in principle no conflict between district hospitals and local health centers on one hand, and BnBs, on the other.

The Problem

It should therefore be made clear from the outset that BnBs should not question the role of district hospitals and local health centers in providing free or subsidized medicines, generics or PDIs, and that they should not consider these a threat to their own market. There has to be a clear signal to BnBs that they are not being given monopoly power to sell generics in the local areas. The idea is to increase the supply of affordable drugs from all possible sources.

The National Pharmaceutical Foundation (NPF) in charge of Health Plus outlets currently procures its generic drugs and medicines from CGMP firms and does its own quality testing. They put a 10% mark-up on the wholesale price of the drugs they sell to the Provincial Pharmaceutical Foundation (PPF), which acts as the storage center and distributor of the drugs and medicines in the local area. The PPF then sells the drugs and medicines to the BnB outlet with another mark-up of 41%. The BnB outlet is allowed to mark-up their price by another 30%. Thus, once the medicines reach the consumer, she/he is paying 81% mark-up over the wholesale price. It is not clear whether this mark-up rate is high or low compared to the mark-ups of the other outlets (especially those with a chain of wholesale distribution from Metro Manila to the local areas).

The significant mark-ups (up to 81% over the wholesale price) or protection given the PPF and the retail outlets is justified using the classic 'infant industry' argument. Hopefully, there will be a clear timetable to reduce the mark-ups at the provincial and retail levels as the local units become more efficient and competitive. This would substantially lower the prices at the grassroots. Table 21 gives us the items that Health Plus outlets carry and their retail prices compared to Mercury Drugstore prices and other branded generics products prices. The table shows Health Plus products prices as still being cheaper than the other prices in the second to fifth price columns of the table (but some of the prices for Mercury outlets are those for branded medicines).

It would, however, be more worthwhile if the prices were compared to prices of outlets serving the poor, such as those of government hospitals, local health centers and other NGO outlets. Again we must be conscious of the segmented market situation in the Philippines. The last three columns were added by the team. The Health Plus retail prices for cotrimoxazole were still cheaper than those for the PDIs, but, when compared to the government hospital JR Reyes Memorial Medical Center, and the clinic price of Council for Health Development (CHD), we find the antibiotics prices (for cotrimoxazole and amoxicillin) slightly more expensive in Health Plus outlets. For the OTC drugs, Health Plus prices are quite competitive with the government hospital and NGO/private outlets. This shows that, indeed, BnB outlets do provide more affordable medicines when compared to mainstream outlets. They provide a big service towards improving the poor's access to drugs and medicines. But there is still the potential to lower prices in alternative outlets if only they can become efficient and viable.

Recommendations

Message 17: The role of BnBs

1. BnBs should not question the role of district hospitals and local health centers in providing free or subsidized medicines, generics or PDIs, and they should not consider these a threat to their own market.
2. There has to be a clear signal given to BnBs that the program is not giving them monopoly power to sell generics in the local areas. The idea is to increase the supply of affordable drugs to people who need them.
3. The significant mark-ups (up to 81% over the wholesale price) or protection given the PPF and the retail outlets are justified using the classic 'infant industry' argument. It is hoped that a definite timetable is derived to reduce the mark-ups at the provincial and retail levels as the local units become more efficient and competitive.

6.4.3 Exclusive Wholesale Procurement and Distribution by PITC

The Problem

As in the PDI program, the current schemes of BnB and rolling stores give to PITC the exclusive right to do wholesale procurement and distribution of medicines to the NGOs/COs. This may appear a bit strange, since many of the NGO outlets had been and are procuring their generic medicines directly from local suppliers. But the decision to centralize procurement and distribution in PITC is understandable since decentralized procurement by the NGO outlets may be hard to monitor and check, especially if the seed money comes from the government. As in the PDI program, it may be more manageable if orders are taken from participating units, and a central body does the consolidation,

purchasing and distribution. In the Pharma 50 schemes, consolidation is done by DOH, and the central procurement and distribution by PITC. The fact that procurement and distribution was given to PITC is an implicit admission that the central procurement of DOH (by PLS) is inadequate to cope with the procurement and distribution needs of Pharma 50.

For the BnB scheme, the NGOs/COs are supposed to give to PITC their desired retail prices for the desired drugs, and PITC will try to find suppliers with wholesale prices matching these retail prices.

Recommendations

The above however may lead to some demands to ensure that PITC's sole franchise for procurement and distribution of Pharma 50 medicines be done in a transparent and accountable fashion. To tackle this, the following are recommended:

1. There should be a requirement on PITC for a standard, transparent accounting and reporting of cost of materials, shipment, handling and insurance and other costs. A maximum allowable mark-up (say from 10% to 15%) for PITC should be specified and announced beforehand. These requirements are justified since government money is being used.

2. Alternatively, there could have been an open bid among wholesalers (including PITC) in the centralized procurement and distribution of PDIs and generics products under the Pharma 50 schemes. A transparent accounting, reporting and a pre-announced fixed mark-up should also be required for the winning bidder. The advantage of private generics (and PDI) drug wholesalers becoming involved in government procurement is that they can also promote the products among physicians and pharmacists since they have the facilities and personnel to do this. They should however follow government guidelines and procedures in procurement and distribution and government pricing policies.

Pharma 50 also has a plan for PITC to be the responsible agency in the toll manufacturing of drugs and medicines for DOH. Although toll manufacturing has been successfully implemented in other countries (e.g., Thailand), we recommend that this strategy be postponed until the current plans and policies to promote improved competition of generics and other affordable drugs have been fully and successfully implemented. Hopefully the situation will improve, and the need for the government to subcontract drug production and distribution will no longer be necessary. In the meantime, prioritization dictates that we start with the most essential reforms documented in this paper. As it is, these are daunting and challenging enough.

Message 18: Exclusive Wholesale Procurement and Distribution by PITC

The following recommendations are proposed, which can be justified since government money is at stake:

1. There should be a requirement on PITC for a standard, transparent accounting and reporting of cost of materials, shipment, handling and insurance costs and other costs.
2. A maximum allowable mark-up (say 10% to 15%) given to PITC should be specified and announced in advance.
3. Alternatively, there could be an open bid for wholesalers (including PITC) to win the centralized procurement and distribution of PDIs and generics products for the Pharma 50 schemes. A transparent accounting, reporting and a pre-announced fixed mark-up should also be required for the winning bidder. The advantage of private generics (and PDI) drug wholesalers becoming involved in government procurement is that they can also promote the products with the physicians and pharmacists as they have the facilities and personnel to do this. They should however follow the government guidelines and procedures in the procurement, distribution and pricing policies.

6.5 Increasing Private Outlets for Affordable Medicines

We have discussed the role of segmented markets in the problem of drug and medicines in the country. Note that the segmentation is not complete. Due to inadequate facilities and physicians as well as lack of supply of medicines in the public facilities, the private sector also sells more affordable branded and generic drugs to the low income group as a secondary market.

There are initiatives from enterprising and pro-poor pharmacists and physicians to cater to the low-income market since they are able to make some profits for themselves. A visit to New Glorious Pharmacy in the middle of a busy market place in Paco, Manila revealed that the pharmacy has been relatively successful since the late seventies due to:

- 1) 75% of their customers are patients coming from physicians (uncle and cousin of the pharmacist owner of the drugstore) whose clinic is located in the same building as the pharmacy. The pharmacy-physician tie up and link provides a healthy business for both with low-income groups as their customers and patients.
- 2) The pharmacy is located in a very busy market area (with many competing drug stores) where a conglomeration of potential low-income customers exists.
- 3) The pharmacist-businesswoman takes special care to canvas various wholesalers, and choose the affordable branded and generic drugs to carry in the pharmacy in line with the demand and prescriptions of the affiliated physicians.

The experience of New Glorious Pharmacy and the continued existence of community-based retail outlets for generic drugs show that it is, in some areas and circumstances, financially viable to operate outlets for affordable drugs and medicines, especially with the active participation of physicians and pharmacists. These outlets would grow naturally as the promotion and reputation of generic drugs grow. We tackle this in a later section.

Recommendations

Message 19: Increasing private outlets for affordable medicines

Outlets such as the New Glorious Pharmacy, that dispenses exclusively generics should be promoted and the government can help in this. The turning point will be when the Philhealth indigent outpatient program is introduced; when that occurs, these outlets could be prioritized in terms of accreditation for Philhealth reimbursement.

7. Analyzing the Main Issues: the Demand Side

In tackling the issue of the poor's access to affordable drugs and how to reduce drug prices, both supply and demand considerations must be taken into account. It is tempting to tackle the issue just on the supply side by pouring medicines into outlets without looking at the demand and promotion of the drugs, and how the poor will access these drugs.

In the Pharma 50 program, the supply side is running ahead of demand side policies. The third shipment of PDIs for two quarters has already been ordered and is expected to arrive soon. P100 million from PCSO has already been allocated: 1) P60 million for PDIs for local governments, 2) P20 million for generic drugs in BnBs, 3) P20 million for generic drugs in rolling stores.

Policies on the demand side consist of the following:

- Philhealth outpatient and indigent programs for drugs and medicines;
- Philhealth reference pricing for drugs and medicines; and
- Generic drug promotion.

With the exception of generic promotion, the other two policies are still on the drawing board and, unlike the supply-side policies, seem to be lagging behind, both in planning and implementation. With regards to generic promotion, it appears that considerable problems exist at various levels (manufacturing, prescribing, dispensing, use). It is therefore not surprising that many of the problems we encountered in our previous discussions involved oversupply or lack of absorptive capacities of the centers that are sources for the supplies of medicines.

7.1 Creating Demand by Providing Easier Access to Physicians and Public Facilities

At the risk of over repetition, it must be stated that perhaps the most important but also the most ignored task (perhaps because it is also the most difficult) is to provide the

poor easy access to physicians and to government hospitals, district and field hospitals, barangay health stations, rural health units. Needless to say, the public health centers should be well-managed and have proper facilities, and staffed with adequate numbers of health professionals and health workers. This is more than just a motherhood statement. We have seen how NGO outlets, like CHD, and drugstores promoting generic drugs, like New Glorious Pharmacy, became successful because they have physicians and/or health workers and health facilities associated with the centers.

Obviously this must be complemented with facilities and outlets that offer affordable drugs and medicines, some subsidized and some given free. These outlets cannot succeed without the physicians to prescribe the drugs and medicines, facilities to detect and diagnose diseases, and health workers to ensure that patients follow the correct regimen of their medicines. It is a sad fact that most physicians can earn money only by serving those with purchasing power. It is also a sad fact that health facilities are inadequate and ill-equipped and ill-managed.

In this respect, the program to improve the poor's access to drugs and medicines can only be significantly successful only when the entire health care system and health infrastructure is already in place and working satisfactorily.

7.2 PhilHealth and Drug Prices

Phase II of Pharma 50, implementation of which was to commence in the first semester of 2002, involves the development of medium and long term strategies to sustain the availability of low priced drugs and medicines to the poor. Among the mechanisms identified by the Plan is the development of a reimbursement scheme for medicines by PhilHealth, namely, a reference price scheme for the 100 most commonly used or reimbursed drugs and medicines. As the country's major provider of social health insurance, PhilHealth's potential contribution to the goal of lowering drug prices and improving access by the poor extends beyond the reference price scheme to providing insurance coverage to the poor, bargaining for lower prices for drugs and health services based on acceptable standards, promoting rational and cost-effective drug use, and providing a sustainable source of income stream for the public health system to ensure availability of affordable health services.

This section deals with PhilHealth's drug payment policies in so far as they contribute to achieving the goals of Pharma 50. It does not deal with issues related to the overall design of social insurance such as expanding the membership base, improving the design, delivery and utilization of benefits, strengthening the capacity of the corporation to deliver services, developing alternative provider payment mechanisms, and enhancing the financial sustainability of social insurance. These topics are adequately tackled in the policy note – Making Health Policies More Pro-Poor by Almario and Weber (2002). We touch on some of these only to highlight the implications on drug cost and utilization.

Social insurance is a force to be reckoned with in the drug market. As a large buyer of medical care, PhilHealth can use its monopsony power to bring down prices of drugs and health services. Financial leverage is enhanced by its access to information on quantity and prices, which are necessary in setting optimum prices. A social insurance program with market power and a strong administrative capacity is therefore a powerful ally of government in (indirectly) exerting control over drug prices. Moreover, social insurance

has powerful tools at its disposal to influence the behavior of health professionals and patients. Lower drug prices do not always lead to reduced drug budget for the system. Because of the tendency to over-prescribe and prescribe expensive medicines total drug costs may not go down even with lower prices. Thus, an important goal of social insurance is to promote rational and cost-effective use of drugs. Options include caps on volume and value of reimbursable drugs, the use of drug lists, essential and generic drugs, drug utilization review, prospective payment mechanisms and so on.

Finally, social insurance is an effective way to finance drug expenditures. In developing countries like the Philippines, the bulk of drug expenditures is privately financed, with the poor oftentimes unable to access badly needed medicines (see section 3). At the household level, drugs often represent the largest portion of out-of-pocket health expenses. A major goal of social insurance is to eliminate out-of-pocket drug costs especially of poor households. In sum, the potential role of social insurance in lowering drug prices and improving access by the poor includes price control, promoting rational, cost-effective use of drugs, and financing health expenditures of the poor. Achieving these objectives requires financial and organizational resources as well as the development of appropriate drug payment policies.

7.2.1 Reference Pricing

Pharma 50 identified the reference pricing scheme for drug reimbursement by PhilHealth as one of the medium term strategies to reduce drug prices. This strategy relies on the use of PhilHealth's monopsony power in the local drugs market. With total drug reimbursements of P2-3 billion a year (or 5-7% of the total pharmaceutical market), PhilHealth is an important player in key market segments, such as inpatient care. Spent mostly on ethical drugs sold by hospitals, this amount represents 30 percent of drugs sold in private and public hospitals. The challenge is to develop mechanisms that will allow PhilHealth to effectively wield market power and exert downward pressure on drug prices and improve access by the poor.

Reimbursable drugs are currently limited to inpatient drugs. Only drugs essential in the management of illness are reimbursed. To be reimbursable, a drug must be prescribed in generic terminology and must be listed on the Philippine National Drug Formulary (PNDF) or PhilHealth's Positive List. The PNDP is a list of over 500 substances found to be effective and reliable in the treatment of over 85% of all illnesses in the country. The Positive List contains 35 drugs approved by PhilHealth's Health Technology Assessment Committee for treatment of hypertension, urinary tract infection and pneumonia, but which have yet to be included in the PNDP. To be reimbursed, a drug must be found in either the PNDP or the Positive List. To contain costs and encourage rational use of drugs, PhilHealth sets a ceiling on drug payments depending on case type and hospital level. The number of units per item of drug is limited although there are no corresponding limits on the amount for each drug.

The Problem

To reduce drug costs, PhilHealth has been working on a drug reference price scheme since 2000 for the top 100 drugs claimed by patients based on a sample of NCR claims. Under the scheme, PhilHealth reimburses the cost of a drug only up to the reference price. The reference price for a drug is an average of four prices: the average price of the equivalent generic products of CGMP companies arrived at through a nationwide survey of actual prices of four outlet types (government hospital, private hospital, Mercury outlet, and another private pharmacy) in each of the 16 regions, MIMS prices and international prices. While PhilHealth reimburses drugs consumed in in-patient settings, it must take into account prices in pharmacies outside of hospitals since many patients especially those using public hospitals or public centers buy their medicines from these sources (since many medicines are unavailable in the public facilities). The reference prices will be updated quarterly using the ratio between the survey price, which are gathered every year, and MIMS prices published quarterly.

The rationale for a reference price scheme can be found in the wide variation of drug prices in the local market between different brands and even among generic drugs. Table 24 presents the low and high prices of selected dosages of the top 20 drugs reimbursed by PhilHealth in the National Capital Region (NCR). Consider a 500-mg capsule amoxicillin. The highest amount reimbursed (P252) was over 100 times the lowest amount (P2.35). Or take a 750-mg vial of cefuroxime. The highest price claimed was P662 – eight times the lowest.

Reference pricing offers several advantages. Price information generated provides a benchmark against which to compare actual claims, facilitating detection of fraudulent claims. To the extent that prices of drugs are distributed over a wide range of values, it could lower drug costs. In market segments where PhilHealth is a significant player, it could exert downward pressure on prices. Finally, it provides patients an incentive to seek the cheapest drugs in order to maximize the support value of insurance.

Reference pricing refers to setting an across the board maximum reimbursement price in a tightly or broadly defined therapeutic class. Usually the criteria for defining a class are scientific, namely, similar products are grouped together. In the case of PhilHealth, a maximum reimbursement price is set for the top 100 drugs, without a notion of grouping present, each of which may be available in at least 4 different prices depending on the outlet type. PhilHealth may use this methodology internally for setting a fair reimbursement price. But it should scrutinize and not take into account outliers of the type described in the amoxicillin case. In this respect, PhilHealth can also set the rules of the game to pharmacies, by indicating what is fully reimbursed and what requires a copayment²¹. Regional variations because of transportation costs, etc. would have to be considered by allowing an acceptable corridor around the target price. However, if PhilHealth is interested in controlling drug costs even more in the

21 Copayment refers to the amount, over and beyond that reimbursed by Philhealth, which is shouldered by the patient.

generic segment, then it can proceed with the classification of drugs in therapeutic clusters.

The effectiveness of reference pricing as a tool to lower drug prices depends on the share of the market covered by the system. It is effective in reducing prices of drugs covered by the system, but prices of other drugs may or may not increase depending on the response of manufacturers, doctors and patients. Manufacturers whose products are priced above the reference price may or may not lower prices to the reference level depending on the expected impact on sales and profits. They can recoup their losses by increasing prices of drugs not covered by the system or raising promotional efforts for these drugs. Those with products priced below the reference price will try to raise their prices to that level.

One concern with reference pricing is that it may raise the out-of-pocket drug expenses of members. Where drug availability is a problem, search costs (e.g. transportation and time consumption) could raise the total price of the drug and result in larger out-of-pocket expenses for patients. More importantly, reference pricing could in the short run hurt patients of private hospitals where they do not have the option to buy medicines from sources other than the hospital pharmacy²². To maintain margins, providers would simply charge patients the difference between the hospital price and the maximum reimbursement price resulting in higher out-of-pocket cost to inpatients. Thus, reference pricing may not be suitable for inpatients in hospitals.

Recommendations

Three recommendations follow from the above analysis. First, reference pricing as envisioned by PhilHealth is a sort of ‘average pricing’ wherein the reference price is a weighted average of average prices. As envisioned, the resulting reference price is a hypothetical price not really corresponding to a particular drug found in the market. PhilHealth can use this methodology internally and, perhaps, only once in order to determine the level of variation in drug prices across the country. It can subsequently determine an anchor reference price with a variation corridor around it to reflect transportation costs to different parts of the country. The anchor price will be the reimbursed price that PhilHealth will pay pharmacies putting a claim and can be adjusted for the location of the pharmacy that puts the claim.

The next stage/phase, once the market has learned to work with this methodology, would define therapeutic clusters of products and determine a reference (reimbursable) price for the entire cluster. The approach would require a listing of, say, CGMP firms producing the drug in the particular clustering and their prices for the drug. A reference price for the particular cluster is set corresponding to the price of a particular firm satisfying the quality, price and availability requirement. This type of reference implies that information also be derived on the availability of the drugs of various CGMP firms. The

22 Even if a law or rule mandates that hospitals allow patients to purchase their medicines outside the hospital, the practical application of this, however, is quite limited, especially in emergency situations when the drugs are needed immediately.

aforementioned scheme can be facilitated by using the winning bids of the DOH and government hospitals as a basis for setting reference prices. Of course sufficient markups to cover distribution costs and a reasonable profit margin for distributors should be allowed. This calls for close coordination between PhilHealth and DOH, and for both to work closely together on each other's reference pricing. This process can also include private pharmacies once PhilHealth is in a position to offer an outpatient drug benefit of some sort to its enrollees.

Second, given the monopoly situation in private hospitals which serve 80 percent of PhilHealth beneficiaries reference pricing should apply only to outpatient drug reimbursements if and when PhilHealth begins to cover outpatient drugs. As far as in-patient drugs and medicines are concerned, PhilHealth should explore prospective payment mechanisms. This issue is discussed elsewhere but its implications on drug use should be emphasized: prospective forms such as case payment or capitation discourage unnecessary prescription by imposing a budget constraint on the provider. In contrast, fee-for-service payment, because it allows mark-ups on drugs, encourage over-prescription and prescription of more expensive drugs.

Third, there is a need to look closely into the issue of availability of essential drugs across the country to determine the extent of the problem, identify bottlenecks in distribution and access, and propose solutions. This calls for policies discussed in the supply side section of the paper.

Message 20: On PhilHealth Reference Pricing

1. A reference pricing system (RPS) can be done in two phases:

Phase 1 – Average pricing by generic category and dosage

Phase 2 – Clustering by therapeutic category
2. We recommend RPS to be implemented first on outpatient programs for drug reimbursement. Reference pricing for inpatients should be postponed until:
 - Private hospitals begin to stock more affordable medicines (including generic medicines)
 - A better system ensuring patients' rights to procure medicines outside the hospitals is in place

7.2.2 Covering Outpatient Drugs for Indigents and for All Members

It is an uncontestable fact that high hospital care and medicinal costs deter the poor and other users from effective medical and health care. Drugs and medicines take up 60 percent of the average hospital bill so that high drug prices

are a real deterrent to the poor's access to health care. Social insurance can improve access to health care by reducing if not eliminating the burden imposed by the high cost of drugs. Still another reason for covering outpatient drugs is that it saves on cost in the long run. Effective early treatment of acute illnesses, such as malaria and pneumonia, and routine treatment of chronic illnesses, such as diabetes, reduces costly care for complications and hospitalizations. It discourages unnecessary hospitalizations just to avail of drug benefits.

Discussion has begun on the desirability of covering outpatient drugs. In terms of implementation, two issues are crucial: first, specifying the conditions for coverage; and second, developing a system to track prescriptions, reimburse expenses, and mechanisms of drug supply to ensure the availability of drugs at health centers serving PhilHealth patients. As far as conditions for coverage are concerned, PhilHealth is considering reimbursing outpatient drugs for acute illnesses such as TB, urinary track infection (UTI), and pneumonia to name the more common conditions. Drugs for chronic illnesses are not programmed for inclusion in the outpatient reimbursement of medicines so as to minimize moral hazard problems.

Reimbursing outpatient drugs will involve a network of accredited pharmacies and hospital pharmacies. As in most insurance schemes, a PhilHealth member with a doctor's prescription obtained from a health facility of choice gets the prescribed drugs from an accredited pharmacy which then reimburses the cost of drugs from PhilHealth. Hospital pharmacies, especially those in the public sector, can be encouraged to set up a revolving fund from drug reimbursements as a way of ensuring steady supply of drugs. As the problem in district hospitals may be availability of generics, it is hoped that the revolving fund provided by PhilHealth can provide a buffer, so that better procurement can take place, which, in turn can increase availability of medications in these outlets. Improved availability of essential generic drugs in public health facilities would greatly enhance their credibility to the public.

As earlier mentioned PhilHealth can consider using reference pricing for reimbursing outpatient drugs. This would have the benefit of minimizing PhilHealth's own drug cost, and give a much-needed boost to demand for quality generic drugs, especially if the reference prices are based on prices of generic drugs. Assuring the availability of the supply of medicines at the reference prices can easily be achieved by accrediting only government and private hospitals and local health centers as well as retail outlets that agree to sell the drugs in the reference price lists according to the reference prices. If the reference prices are based on generic drugs, this would bias the accreditation to government hospitals, local health centers, NGO outlets and other outlets catering to generic drugs. These are precisely the outlets aimed at the lower income classes. With this type of accreditation (which ensures that the outlets agree to the reference prices), it would easier to implement a no-copayment condition for indigents and not fear that they will be turned away at the retail outlets.

If mainstream outlets are to participate in the outpatient drug reimbursement program they would have to be given incentives to dispense (and before that to stock) generics. Incentives may relate to the pharmacy reimbursement method by PhilHealth, in that the margin for dispensing a generic is

at least as high as the margin for dispensing a branded, otherwise pharmacies will not be interested and will continue dispensing the branded, knowing that they will receive the reference price from PhilHealth and the difference between the reference price and the market price from the consumer as a co-payment. This would not necessarily solve the problem of generic supply, or better access to medicines for the poor. Alternatively, PhilHealth can devise some sort of reimbursement mechanism whereby it takes into account the high prices of branded products and reimburses branded products depending on the level of medical necessity. Thus, an absolutely-must-have antibiotic will be fully reimbursed whereas something classed as a “comfort drug” will carry a lower reimbursement rate, with the consumer bearing the difference. This strategy will result in price reduction in the consumers’ eyes, whereas PhilHealth will actually be reimbursing market prices. Both require knowledge of each drug’s list price.

In any case, although we highly recommend an outpatient reimbursement program for drugs and medicines, we also propose a thorough and comprehensive planning and analysis of the logistical and administrative requirements of the scheme (see above), as it is not quite clear what strategy needs to be implemented in order to guarantee access to the poor as well as safeguard the rights of current middle-class PhilHealth insures. Because it will take time to develop and implement an outpatient drug reimbursement scheme for all members, PhilHealth may consider coming up with an outpatient drugs program exclusively for indigents members. A short-term solution is to ride on the current outpatient benefit program for indigents (OPB)²³. The capitation fee per member could be raised to cover the cost of drugs with the additional money placed in a revolving drug fund at the local government unit (LGU) level. Use of the fund may be tied to procurements of generic drugs or PDI drugs as discussed earlier, but in any case should augment the drug procurement funds of LGUs. PhilHealth can allow reasonable mark-ups as incentive to LGUs. To assure increased participation of the indigents the outpatient program should have a no-copayment requirement for indigent members. In the medium-term, it may be desirable to provide indigent members an outpatient drugs package that is more generous than what is available to non-indigent members. Drugs for symptomatic care of selected acute illnesses or drugs for a limited list of chronic illnesses may be considered for reimbursement, but only for indigent members.

23 See Almario and Weber (2002) for a more detailed description of this program. In this program, Philhealth and the local government jointly pay the full premium of P1200 for an indigent member endorsed by the local government. The local government gets P300 back (as capitation fees) for an outpatient benefit package for the indigent member using the local public health facilities. In the current scheme, free medicines is an optional part of the outpatient benefit package for the indigents.

Recommendations

Message 21: On an Outpatient Program for Drug Reimbursement

1. PhilHealth should continue developing a strategy and program to include outpatient drugs as part of the standard benefit package. For this purpose, a thorough and comprehensive planning and analysis of the logistical and administrative requirements of the scheme is needed so as to guarantee access to the poor as well as safeguard the rights of current PhilHealth insurees.
2. To encourage private pharmacies to join the outpatient program, PhilHealth should develop an incentive scheme to promote generic dispensing. One option is to ensure that the reimbursements provide higher margins for generic drugs relative to branded drugs. Alternatively, PhilHealth can create a sort of multi-tiered reimbursement scheme wherein drugs are reimbursed according to medical necessity, with the most essential drugs being fully reimbursable.
3. PhilHealth should cover outpatient drug costs of indigent members as soon as possible. A short-term option is to expand the current outpatient benefit package for indigents to explicitly include drugs and medicines.
4. The outpatient indigent program for reimbursement of drugs can be expanded by accrediting public facilities, community-based and private outlets using CGMP generics. An initial reference price system can be experimented with (allowing enough margins for the generic medicines). These accredited pharmacies and outlets can be the seed outlets for the bigger and full-blown outpatient program for reimbursement of medicines to be developed at a later stage.
5. It may also be desirable to extend a more generous drug benefit package to indigent members once the regular outpatient drug benefit package is in place.

7.3 Generic Drugs Promotion

This section discusses the demand side aspects of the generic drug strategy as a major means to lower drug prices and promote greater price competition.

The Generics Act of 1988, passed unanimously in Congress, promotes generic prescribing and dispensing in the country. The act provided for mandatory use of generic names on labels, advertising materials and prescription slips. It emphasizes the need for pharmacists to provide information to clients on generic drugs and their prices, established incentives for manufacturers of generic products, provides for public and professional information on Generics Law and the rational use of drugs. In the face of strong industry and professional lobbying, compromises were inevitable. While it requires doctors to write generic names of drugs, it also allows them to place their choice of brand names in parentheses on prescriptions. It provides for penalties to doctors violating the law, although these are rarely used if at all. The law does not provide for mandatory substitution and contains no provision on price controls.

The generic drug strategy has met mixed success. The biggest gains are in the public sector where compliance is fairly high. Executive Order No. 49 reinforces the Generics Act by requiring that only drugs in the essential list of the drug formulary be passed in audit by the Commission on Audit. Public sector demand for generic drugs has been responsible for the development of small but growing local generics industry. Generic prescribing in the public sector appears to be the rule rather than the exception²⁴. It is in the private sector where prescribing habits of doctors have hardly changed: only about a third say they would advise generics to their patients. In its early years, the Generics Act succeeded in raising public awareness of generic drugs and increasing information provision to the public by drugstores and other outlets. Nevertheless, acceptance of generic prescribing and dispensing has gradually eroded and there is a need to revive the program.

Past evaluations²⁵ indicate that the generics policy has stalled on several fronts (related to one another): weak reliable quality assurance capacity, lack of professional and public acceptance, absence of economic incentives to underpin generic prescribing and dispensing. An earlier section discussed the issue of quality assurance capacity. This section emphasizes the issues of professional and public acceptance, and economic incentives. It should be said from the start that promoting generic drug use is a long-term strategy. In the short-term, adoption of key policy reforms in themselves difficult to do should provide a measure of success.

Lack of support from doctors, pharmacists, and other allied professionals is a major weakness of the current generics program. Doctor's endorsement of generics is key to increased generic drug use. Without doctor's prescription and instruction to patients, only highly educated and well-informed patients are likely to patronize generic drugs. Generic prescribing in the public sector appears to be the rule rather than the exception, no small achievement of the generic drugs policy. This is significant considering that public facilities cater to the bottom 40 percent of the population.

The Problem

It is in the private sector, which generates the bulk of the demand for drugs and medicines, where a lot of work needs to be done. Opposition by doctors to the generic drugs law revolves around three concerns: infringement of exclusive right to prescribe, lack of scientific evidence of bioequivalence, and perceived poor quality of generic products. Recall that doctor's opposition to the law was accommodated by allowing them to write the brand name of the drug in parentheses below the generic name. This provision cancels the mandate to prescribe in generic name only. Another accommodation was the law's silence on mandatory substitution, although this can be interpreted as allowing but not mandating substitution. Concerns about the quality of generic products are valid issues that must be addressed although it is also important to put these in proper perspective. Definitive quality assurance by government is the most effective way to counter doctor's negative attitude towards the generic drugs policy. Once this is achieved, there should be all-out promotion of generic medicines, concentrating on the quality assurance and the integrity of BFAD seal of good quality.

24 Although informal talks with doctors and pharmacists in government hospitals reveal a pervasive impression that some generic drugs are inferior to branded ones.

25 Policy Review and Program Evaluation of the Generics Law and National Drug Policy: Final Report and Conference Proceedings, edited by Amelia Perez Varela, UP College of Public Administration and the Department of Health, 1997.

While substitution is not mandatory, the law by its silence allows pharmacists to substitute a prescribed drug by a generic equivalent. Next to generic prescribing, substitution is critical to the success of the generic drug law. Close to 80 percent of total drug sales are sold at retail drugstores. Promoting substitution, however, faces a number of obstacles. In the absence of a policy to regulate drug prices and distributors' and retailers' margins, government cannot provide financial incentives to encourage substitution (e.g. higher margins for generics relative to branded products). The demand created by social insurance combined with specific drug reimbursement policies will provide a powerful incentive for substitution.

Public support of the objectives of the Generics Law is not lacking. What is needed is information to translate this support into action. This calls for sustained information and education campaign for the consuming public, doctors and other health professionals, government officials responsible for procuring drugs, and so on. These materials must be designed to meet the specific needs of each user group. There is need, for example, for adequate and proper information at the local government level on the Generics Law, about generic drugs and the National Drug Formulary (PNDF). While quality assurance policies are still being undertaken, there are already promotions of quality generics (such as those produced by CGMP firms) which can be done. Information and education campaigns for generic drugs and their quality assurance should include the media most used by the lower income classes. This includes radios, television, comics, magazines and tabloids.

Government should also consider setting up information centers on generic drug use. This includes guidance and provision of information concerning generic substitution. This includes explaining the choices available to drug consumers for a particular drug prescribed by a physician. The Generic Drug Act requires drug outlets to have a shopping list of generically equivalent drugs. This list, however, may be difficult to use for a layman not used to the quality issues and possible generic substitution of drugs. It would help if pharmacists in the pharmacies help drug consumers to pick the right brand or generic drug to purchase, but this is usually not done. Thus there is a need to create a national system of drug 'counseling' made up of a coordinated network of public and NGO information centers. Information to help generic substitution of expensive branded (non-generic) medicines should also include information on choices based on therapeutic categories of medicines and alternatives within these therapeutic categories. This would be consistent with our suggestion in the reference pricing system to eventually include clustering medicines based on therapeutic categories. But of course, going from generic to therapeutic categorization is a big step and requires major work and careful analysis.

These centers should not only provide technical information on generic substitution but also emphasize rational drug use, especially the need to follow the frequency, dosage and regimen set by the physician. To ensure wider reach and more effective information dissemination, government hospital staff and barangay health workers should be mobilized for the purpose. Community based health organizations should be made part of this effort to take advantage of their links to hard-to-reach segments of the poor and disadvantaged population as well as their intimate knowledge of community values and practices. Overall this network of centers should be coordinated in a systematic fashion and tied into the generic drug promotion in mass media.

As part of efforts to expand social insurance benefits, PhilHealth intends to offer soon outpatient preventive health services, including counseling service (e.g. lifestyle modification). Drug counseling could be incorporated in PhilHealth's counseling service

which would include providing patients information on rational and generic drug use, substitution possibilities, and reference prices.

Part of the information and education campaign is the regulation of advertising and promotion activities especially those that promote irrational drug use. Advertisements and promotional materials must not only adhere to the use of generic names and labels but must also guarantee rational drug use and promote quality. Regulating the quality of the message contained in advertisements and promotional materials requires clearly defined standards especially with regard to quality and rational use issues and also more personnel than is currently available at BFAD.

Local demand for generics is concentrated in the public sector, which accounts for less than 10 percent of the market. Drug procurement at the national level and in DOH retained health facilities largely complies with Generics law and EO 49. This is discussed in more detail in the section on procurement. Significant gains in boosting demand for generic drugs can be realized at the local government level. LGUs should be provided with the necessary tools and administrative structures in procuring the right kind of drugs at the lowest prices. A successful outpatient indigent program (such as the one proposed by PhilHealth) will have a significant impact on the demand for more affordable medicines.

PhilHealth holds the biggest potential for leveraging public procurement to promote generic drug use. Backed by a multi-billion peso drug budget, it has the financial muscle to steer the market towards greater use of generic products. The inclusion of outpatient drugs in PhilHealth's benefit coverage should greatly enhance its leverage in the drug market. Towards this end, PhilHealth requires the use of generic terminology among accredited professionals and institutions, government and private, in all their hospital charts and prescriptions. It also requires a functioning therapeutic committee and encourages the development of prescribing guidelines. Only drugs listed in the PNDF may be charged to the capitation fund related to the outpatient consultation and diagnostic package offered to participating LGUs. As discussed above, the development of a reference pricing scheme for outpatient drugs, the adoption of Current Practice Guidelines (CPGs) for common illnesses and a shift to prospective payment mechanisms are expected to positively influence drug utilization and eventually drug prices.

The other entity (that is integrally linked to PhilHealth programs for indigents) that can significantly affect the supply and demand for generic drugs and medicines is the government itself, with DOH, government-retained hospitals, district and field hospitals and local health centers providing the current biggest set of outlets for generic drugs. Availability, quality and affordable prices should be assured in these outlets. Once this is achieved, these public outlets for drugs and medicines should be promoted by the education and information campaigns. This could be the beginning of the financial viability of these public outlets of generic drugs and medicines.

By generating strong competition for the supply of generic medicines and by using the market power of both the national government and PhilHealth, we would effectively curtail the potential danger of prices of generic medicines going up as their demand goes up (and as manufacturers and distributors initially might exploit the wide price differentials between branded (non-generic) medicines and generic medicines). The PhilHealth outpatient indigent program also provides a strong safety net for the poor against this possibility as the program would provide free generic medicines to the poor.

Through increased access to physicians and public facilities, through PhilHealth outpatient and indigent programs, and through generic drug promotion via information and education campaigns, demand generation for affordable drugs from the lower income classes – which have little purchasing power individually but potentially large economic demand en masse – would provide the needed boost for the generic drug industry and provide the major means to ensure affordable medicines in the country.

Recommendations

The Philippine experience with implementation of a generic drugs policy underlines the need for a sustained long-term approach. To sustain gains in this area, we recommend the following: first, try and amend the legislation to include only generic names, whilst the government takes active steps to ensure better quality of generics as proposed above. Related to this is the need to enforce the law properly.

Second, government needs to undertake sustained information and education campaign that address the specific needs of stakeholders: doctors, pharmacists, patients and procurers in government and in public health facilities. Greater attention must be given to the need to equip LGUs with the tools and information to allow them to procure essential generic drugs.

Third, create a national system of drug “counseling” made of a network of public and NGO information centers. This may be coordinated with the outpatient counseling services to be offered by PhilHealth, which we proposed, should also cover drug related issues such as rational and generic drug use, substitution possibilities, and prices.

Fourth, wholesale and retail margins should be made more transparent. While this may be difficult to do given current market circumstances, the entry of PhilHealth in the outpatient market offers an opportunity to influence retail margins and prices especially for outpatient drugs. If and when PhilHealth introduces an outpatient drug benefit, then by default the margins of wholesalers and retailers will have to become more transparent. As mentioned in the previous section, PhilHealth can consider alternative schemes relating to wholesale and retail margins at least for the part of the market that it will be responsible.

Message 22: Generic Drug Promotion

1. Quality assurance for pharmaceutical products should be achieved. Only CGMP firms should be producing generic medicines.
2. Once quality assurance is achieved, there should be high promotion, especially to physicians and pharmacists, of the BFAD seal of good quality and certification of CGMP.
3. Promotion of generic drugs should also utilize mass media that cater to the low income classes: radio, TV, comics, magazines, tabloids.
4. Government procurement and PhilHealth reimbursement should favor CGMP-manufactured generics.
5. Information centers in public facilities, community-based health programs and pharmacies/drug outlets for generic medicines should be promoted in order to:
 - advise low-income users of medicines on the choices of brands and generics
 - explain issues concerning quality assurance and CGMP
 - ensure the patient's subscription to the regimen for effective and rational use of medicines
6. PhilHealth counseling would also be a source of information for:
 - rational generic drug use
 - substitution possibilities
 - accredited outlets for generic medicines
 - reference prices for outpatient drug reimbursement
7. Once quality is assured, the Generics Law should be amended to require prescribing in generic name only, without the branded name in parenthesis.

7.4 Promotion of Authentic and Cost-Effective Traditional, Natural, Herbal, and Alternative Medication and Treatments

The Problem

Inasmuch as the poor already are more prone to go to traditional healers and utilize traditional and herbal medication (see section 3), it would be in their best interest to encourage and continue the correct practice of authentic and cost-effective traditional and herbal treatments and medication. The identification and promotion of such practices

would also be beneficial as it distinguishes good traditional and herbal practices from the ineffective, inadequate or incorrect ones.

It would also be good to introduce good practices of authentic natural or alternative medication or treatments that are cost-effective and more appropriate for the treatment of certain illnesses or ailments of the poor (e.g. reflexology, acupuncture, acupressure, some homeopathic therapies).

To do the above would require much work and would need clear policies and continuing studies on:

available traditional/ herbal/ natural/ alternative medicines / preparations and their efficacy in the treatment of corresponding ailments or illnesses

regulatory requirements for their marketing and distribution.

Once the above structures are in place, the recommendations below can be implemented:

Recommendations

Message 23: Promotion of Traditional, Herbal, Natural and Alternative Medication

DOH has to continually identify herbal/ traditional/ natural/ alternative medicines / preparations that are cost-effective in the treatment of certain ailments and diseases;

DOH and DTI have to put in place a clear and effective regulatory framework for the marketing, promotion, distribution and practice of traditional medication and treatment

The government and local governments should continue and expand current efforts to train and educate medical and health professional in the respective public facilities on the identified authentic and cost-effective practices.

It is also proposed that public health facilities identify authentic traditional healers in their localities, and work out an arrangement of referrals and linkages with these traditional healers, based on the identified set of medication and treatments.

Once these practices are institutionalized in the public health facilities, and partnership and linkages between public health facilities and traditional/herbal healers become prevalent, it is recommended that some of these medications and treatments be reimbursable by PhilHealth, especially in its outpatient indigent program.

Establish linkages and partnerships with community-based health programs and other health NGOs that are utilizing these practices and treatments.

8. Coordination and Management of the Different Components

The Problem

The recommendations laid down in this paper involve different policies to be implemented in different entities and agencies of government: BFAD, PLS, government and district hospitals, local health centers, local governments, PhilHealth, PITC, community-based health groups and NGOs, the pharmaceutical industry, etc. If the government is serious and gives priority to the problem of improving the poor's access to affordable medicines, the institutional mechanism and linkages for coordinating, managing and putting pressures to the various agencies will have to be in place.

Recommendations

Message 24: Coordination and Management of the Entire Set of Recommendations

1. It is proposed that a point person and special committee or task force be created and given key responsibilities to coordinate and manage the entire set of recommendations across the various agencies.
2. It is proposed that the Secretary of Health be the point person to be given this task.
3. It is proposed that the current ad-hoc Pharma 50 Committee be expanded to include the Secretary of Health and top persons of BFAD, PhilHealth, DILG, government drug procurement, representatives of government hospitals and community-based health programs.
4. This committee should then be given more permanent oversight functions with broader powers of management and coordination, and should report their monthly progress and courses of action directly to the President of the Philippines.

9. Summarizing the Government's Past and Current Efforts and Lessons from International Experience

9.1 On Generic Drugs Promotion

This paper has argued that the government should reconsider generic drugs policy as the overarching framework for improving access by the poor to drugs and medicines. The government had actually taken this approach when it enacted the Generic Drug Act in 1988. However, despite some achievements in terms of increasing (inadequately) the use of generic drugs in public facilities, this has not resulted in lower drug prices or increased access of the poor to affordable medicines. As discussed critically in this paper, for generic drugs policy and promotion to succeed, government must do three things: 1) ensure high quality assurance in the pharmaceutical market, 2) improve availability of inexpensive quality generic drugs in public facilities and community-based NGO outlets, which are

more affordable to the poor, and in commercial outlets, which are more accessible to the general public, and 3) raise the poor's effective demand for drugs through social insurance. It is precisely in these areas where the efforts of the government have been wanting and why pharmaceutical prices are incredibly high in the Philippines and why the poor have very limited access to affordable medicines.

Specific measures to achieve these ends have been enumerated above. How feasible are these policy recommendations? The experience of other countries shows that the successful implementation of these policies have contributed to improving access to drugs and medicines by the poor. A few examples are discussed below.

9.2 On Quality Assurance

We have recommended that, to encourage manufacturers to meet CGMP requirements, BFAD should be stricter in implementing its own directives and public sector drug procurement should be limited to products of CGMP certified firms. Thailand provides a good example of the use of CGMP certification as a means of ensuring quality of locally produced drugs. A study conducted by the Thai FDA in 1991 revealed that GMP-certified manufacturers had lower incidence of substandard drugs compared to non-GMP-certified ones. The proportion of GMP-certified drug factories in Thailand has since increased from 30% in 1989 to currently 73% (126 out of 173 private drug manufactories) as of 2000. This was accomplished through technical cooperation, public relations, public education and economic measures.²⁶ While GMP certification is done on a voluntary basis, only GMP-certified firms are allowed to sell drugs to public hospitals, providing significant incentive for certification. Despite the success of its voluntary scheme, the Thai government recently proposed compulsory GMP certification.²⁷

9.3 On Parallel Drug Importation

As far as improving the availability of inexpensive drugs is concerned the Philippine government has lately emphasized parallel importation of off-patent branded drugs for distribution in public health facilities and the expansion of the government-initiated network of village-level semi-drugstores, *Botika ng Barangay*, which carry generic drugs. In this respect, we have argued for less emphasis on parallel drug importation in public facilities even as we recommend opening the activity to the private sector as soon as the capacity for quality assurance of bulk importation of medicines is achieved. Meanwhile, government should focus on promoting generic drugs.

Indeed, there is evidence that parallel imports have a moderating effect on drug prices. Maskus (2001)²⁸ present evidence from the Swedish experience. In Sweden, for example, parallel drug imports rose between 1996 and 1998 by which time it reached 6%

26 Hanvoravongchai, P., Kanavos, P., State Roles in Drug Financing: The Thai Experience, International Journal of Health Services.

27 Bengzon, Margaret A., Balancing the Scales: A Review of the Pharmaceutical Markets of the Philippines, Thailand and Australia, Ateneo School of Government, February 2000.

28 Maskus, Keith E. Parallel Imports in Pharmaceuticals: Implications for Competition and Prices in Developing Countries, Final Report to the World Intellectual Property Organization, April 2001.

of total sales, 16% of sales of the 50 top selling drugs. For certain products in which imports were concentrated, the latter accounted for as much as 54% of sales.

The same study found that the impact of parallel imports on price changes was significant, albeit confined to a select segment of the market. Over the period 1994-1998, average prices for products in which parallel imports took place rose by less than 2.9% while those for non-PI products rose by 7.6%. The impact on specific products where imports were concentrated saw prices decline by 4.4% over the same period on a weighted basis while the rest of the market saw a 3.6% increase. But as mentioned earlier, the beneficial price effect is limited to a select list of blockbuster drugs and the price impact on the entire drug market moderate. The point is that for parallel imports to be effective it must target products in which there is high local demand and must account for a significant share of these product markets. The financial and logistical requirements especially in distributing and marketing parallel imports call for active participation of the private sector.

Lower prices in themselves do not ensure the poor's access to drugs and medicines. Geographical access to drugs and medicines is just as critical an issue and which the government is addressing through the BnB program. The limited reach of this network, notwithstanding current plans to increase the number of outlets and infuse substantial financial resources, means that government should consider channeling currently available resources to existing national and local community health programs which have local or community (BFAD-registered) drugstores or pharmacies and clinics.

9.4 On Health Insurance

Finally, the third pillar of a revived generic drugs policy is ensuring the poor's access to drugs through social insurance. In particular, this means covering the outpatient drug needs of indigent members immediately and regular members subsequently. There is no doubt that social insurance could play an important role in improving the poor's access to drugs. The issue is to what extent social insurance can be made available to the poor given the limited resources of the state. This is particularly true in developing countries like the Philippines where health insurance coverage is rather limited ranging from 10% in Sub-Saharan Africa, 27% in Asian, 45% in Latin American and the Caribbean, to 57% in the Middle East. It is only in developed market economies where coverage is close to 100%.²⁹

Still, there are a few examples of successful social insurance in developing country settings. The Costa Rican Social Security Fund (CRSS), for example, covers about 80% of health expenditures. Drug availability in CRSS pharmacies is high and drugs are provided free of charge. They are prescribed and dispensed according to generic name and are almost always found in the CRSS formulary.³⁰ Thailand is another success story in this respect with 80% of the population coverage by some form of health insurance. Through greater reliance on capitation system, social insurance in Thailand has encouraged responsible and cost-effective prescribing habits, including generic prescribing.³¹ Where national insurance mechanisms are not deemed feasible, other

29 WHO. Health Reform and Drug Financing: Overview of Experiences, Options and Priorities for Action, Geneva: WHO, 1997.

30 Ibid.

31 Bengzon (2000).

developing countries have experimented with small scale community-based and private schemes as a means of providing drugs and health care to the disadvantaged segments of the population. Community-managed pre-payment schemes in Guinea-Bissau ensure health care and drug provisions in rural communities. Despite problems of drug availability, these schemes were deemed instrumental in raising the quality of health service.³²

Examples of social insurance playing a significant role in lowering drug prices can be found in developed economies where population coverage is high providing the state monopsony power in the drug market. In many of these economies, social insurance is combined with use of an essential drugs list, generic drug policy, pricing policy (including reference pricing), public information and education campaigns, and a strong regulatory framework.

Australia's Pharmaceutical Benefit Scheme (PBS) provides 139 drugs free of charge to Australians. Accounting for 80% of prescription drug sales, it wields effective monopsony power over the market.³³ Drugs undergo strict screening processes before they are included in the list while prices are negotiated between government and manufacturers. An IMS study in 1990 showed that the ex-manufacturer prices of 53 of the 80 largest selling products in Australia were 69% of the European Community (EC) average and 60% of the world average. Prices of 20 of the 24 largest selling products in Australia were 55% of the EC average and 48% of the world average. More recent data (1995) showed that unweighted average of top selling drugs in Australia was 71% of OECD prices while the weighted average was 54% of OECD prices. While the price differential between Australia and other countries have narrowed over the 1990s, these remain substantial. Without implying that the same range of saving can be realized elsewhere, the Australian experience nevertheless shows that social insurance besides providing a means to finance drug expenditures can play a role in reducing drug prices.

The potential of the Philippines for increased health insurance coverage for the poor is not too bad given the large reserves currently enjoyed by Philhealth (see Almario and Weber (2002)). It is the planning of the program, ensuring the availability of the medicines in affordable (reference) prices and providing the right governance and political will that comprise the big challenge.

32 WHO (1997).

33 Bengzon (2000).