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## IMPROVING ACCESS TO DRUGS

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### ABSTRACT

Although essentially not all therapies need drug intervention, drugs is still an important components in health sector, either in preventive, curative, rehabilitative or promotion efforts. Hence the access to drugs is a main problem, either in international or national scale even to the smallest unit. The problem on access to drugs is very complicated and can not be separated especially from pharmacy management problems; moreover in general from the overall lack of policy development and effective of health policy, and also the implementation process. With the policy development and effective health policy, rational drug uses, sufficient health service budget so a country can overcome the health problems. Besides infrastructures, regulations, distribution and cultural influences; the main obstacles for drug access is drugs affordability if the price of drugs is an important part and determined by many factors, especially the drug status whether is still patent or generics that significantly decrease cost of health cares and enhance the drugs affordability. The determination of essential drug prices in developing countries should based on equity principal so that poor people pay cheaper and could afford the essential drugs. WHO predicts two third of world population can not afford the essential drugs in which in developing countries, some are because of inefficient budget allocation in consequence of drug distribution management, including incorrect selection and allocation and also irrational uses. In part these could be overcome by enhancing performances on the allocation pharmacy needs, including the management of information system, inventory management, stock management and the distribution.

**Key words:** access, drugs, essential drugs, generic drugs

### INTRODUCTION

The fundamental interrelationship between the "state of development" and the "state of health" of a nation and its population has been well known for years. Poor health is not only a component and consequence of poverty but also a cause of it, and hence the main obstacle to sustainable development. The state of health of an individual conditions the person's quality of life, productivity, earnings, and thus all other determinants of living standard. Ill health therefore represents not only sickness but also an economic calamity. The connection between health and nutritional status, for example, has a measurable impact on learning ability and adult intellectual capabilities-which again are long-run determinants of adult productivity and earning capacity.

Although not every treatment needs a drug intervention, drug is surely an essential component in preventive, curative, rehabilitative or promotive

health. Therefore access to drugs is a crucial issue both internationally and nationally. Access to drugs certainly can not be separated from pharmaceutical management system. Despite 50 years development in pharmaceutical products, millions of people in developing countries do not have access to even basic essential drugs and world widely die each year from diseases such as malaria, tuberculosis, and more recently, HIV/AIDS.

Most infectious diseases—which account for death and child mortality in low-income countries—can be controlled with available and affordable medicines and tools, all of which are off-patent.<sup>1</sup> The WHO estimates that one-third of the world's population lacks access to essential drugs. Regrettably, a significant portion of pharmaceutical expenditures in developing countries is wasted due to inefficiencies associated with the management of drug supplies, including inappropriate selection, procurement and rational

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use of drugs. This wastage can be minimized, in part, by improving the performance of pharmaceutical supply chains, including management information systems, inventory control, stock management, and distribution.<sup>2</sup>

An example of a problem in drug management system was ever identified in the Philippines when there was the nonavailability of essential drugs in hospitals. A review of the system showed that the hospitals were individually procuring their drugs and were paying widely varied prices for similar drug items, besides poor quantification of drug needs, poor prioritization of drug purchases, and procurement of drugs not included in the formulary. To address these problems, a pooled procurement system involving all hospitals was introduced and results showed that the prices of drugs were reduced by an average of 54 percent and the revitalization of the therapeutics committees improved compliance with drug therapeutic guidelines<sup>3</sup>. Rational selection of a cost-effective list of drugs requires not only knowledge of drug prices and applications, but also of the health sector's capacity to use those drugs efficiently.

### HEALTHCARE SYSTEM IN INDONESIA

The Indonesia healthcare system is a non insurance-based system, privately dominated, fee for service and heavily relied on market. Findings from a field tested of TRIPs template on WHO's experience in drug policy and price monitoring in 2002 in Indonesia shows that: (1) pharmaceutical consumption data in nominal prices was an aggregate, (2) No report on health insurance plan and how many currently existing insurance scheme is unclear, (3) the structure of pharmaceutical price in Indonesia not price-control based but final price, (4) there is a lack of database and data tracking system in Patent Office.<sup>13</sup>

The decentralization policy in Indonesia together with the pharmaceutical expenditure in public sector, large variations in District Warehouses operational practice as a result of varied organization structure between districts and insufficiencies in budget for drugs which were reflected in the request for national buffer stock resulted in: (1) a considerable variability in commitment, district drug management, budget allocation, patterns of RDU, capability of HR, r/r system and organization structure, (2) insufficient resources to support the EDL concept and RDU policy

and (3) urgent needs of drugs that are still on patent to be used in public health service.<sup>14</sup>

### ACCESS TO DRUGS

The issue of "access to drugs" cannot be isolated from overall deficits in development policies, health policies and systems, and implementation processes. It is a complex issue that includes the price of drugs but also goes far beyond that. Usually the combination of appropriate development and effective health policy, best practices in the health system, a rational use of drugs, and adequately funded health services can handle most of the health problems in any country. The most important obstacle to access is affordability but legal, infrastructural, distribution and cultural factors are also serious impediments. The influence of each of these factors is different from country to country, just as frequencies of diseases also vary greatly.<sup>6</sup>

Furthermore expenditures for pharmaceuticals have risen dramatically, especially for the elderly, as new treatments have appeared for the chronic diseases and conditions that affect this growing population. Many options have been considered for making pharmaceuticals more affordable, i.a. discounts from pharmaceutical manufacturers, subsidy supplemental insurance policies that will cover medications as well as legislation allowing drug purchase at reduced cost<sup>7</sup>. The effect of this spending on pharmaceuticals is greatly undermined because (1) inappropriate drugs are purchased and prescribed; (2) governments and consumers pay higher than necessary prices for drugs due to suboptimal and intransparent purchasing practices instead of tenders; and public facilities are hampered by shortages, theft, and spoilage.

#### – Price and affordability

Price is an important part of affordability. Drug prices depend on many factors, but one of the most important is whether the drugs are *proprietary* (still new and under patent) or *generic* (not under patent, and therefore sold at a price closer to the cost of production). Survey in 36 countries found that in some developing countries retail prices were higher than in developed one, and differences in retail prices of proprietary drugs were much wider than those of generic equivalents as well as retail prices of multisource drugs in developing countries than in developed one.<sup>8</sup>

Bringing these drug alternatives to consumers can significantly reduce overall health care costs, and increase access to life saving medicines that are just as safe and effective as their brand-name counterparts. This is an especially important source of drug savings, because a growing number of important brand-name medications coming off patent. Yet there are still obstacles to getting greater savings from generic drugs: (1) Approval times for generic drugs because companies need to prove that their products contain the same active ingredient, are manufactured to the same quality standards, comply with good manufacturing practices, have similar labeling, and is bioequivalent to the brand-name drug. -- a long process that adds to the costs and delays the availability of these low-cost alternatives; (2) Opportunities to improve consumer knowledge and safe use of generic drugs from surveys have indicated that many health practitioners and patients are not aware that generic drug alternatives are available, or that the generic alternatives act the same way as the brand-name drugs -- that they are just as safe and effective -- and they may also be concerned about the state of scientific knowledge about generic drugs, and want assurances that the science base is strong.

Essential medicines should be priced in developing countries based on the principle of "equity" that means from the point of view of the community and the individual, the price of a drug is fair, equitable and affordable, even for a poor population and/or the health system that serves them. Equity pricing is based on the principle that the poor should pay less for, and have access to, essential medicines.

The first approach to improve affordability is to decrease drug costs by developing strategies so as to reduce source prices paid to producers and importers, namely by means of collecting information on drug prices and sources, negotiating for favorable prices, tendering for generic drugs and by therapeutic class, controlling price directly through cost-plus pricing, reference pricing, or other forms of price control as well as producing locally. The second approach concerns private sector drug distributors, and aims to reduce the mark-up on price between the supplier and the consumer by (1) removing import and value added taxes; (2) minimizing the number of distributors and limiting their margins; (3) moving from pharmacy charges (dispensing margins) based

on a fixed percent of drug costs to the more current system of a fixed professional fee.

#### – Improving Access to drugs

The initiative on Improving Access to safe and effective, low-cost drugs in order to make them much more affordable for millions of people and therefore make a big change in the nation's public health should better include the following components: (1) Increase of resources devoted to improving access to generic drugs, (2) Reduction of the time and cost of generic drug approvals and (3) Enhancement of public education and scientific study of generic drugs.<sup>9</sup>

Increasing access to medicines for populations in developing countries and for the poor in middle income countries certainly requires an understanding of the medicines life cycle. Each step of this cycle creates its own constraints to access of drugs for the most vulnerable people.

The efforts to improve access to drugs should:<sup>10</sup>

1. Deliver benefits through a decentralized, pluralistic market structure that encourages meaningful competition in order to preserve patient choice, improve quality and encourage innovation.
2. Prioritize any assistance toward beneficiaries with the greatest economic and medical need in order to focus limited funds.
3. Expand eligible beneficiaries' choices of quality health plans and benefit packages that include prescription drug coverage.
4. Improve patient care by promoting strong incentives for the discovery and development of innovative new prescription drugs, and to ensure that the new tools of biotechnology are applied as quickly as possible to create medicines for the huge unsolved medical problems.
5. Ensure that the cost of drug coverage does not jeopardize the financial security of those entities administering programs.
6. Avoid interfering with existing coverage and payment rules for the types of drugs currently covered by existing programs.

A number of issues should be addressed to ease the process of production and commercialization:

- Even under a regulated marketing framework and prices, importation visa and production authorization, increasing competition is a key feature of pharmaceutical markets. Countries'



internal markets are limited (with limited scale savings), access to raw materials is difficult and access to new technologies is limited. To become competitive, developing countries and their industries should address the above mentioned issues on a case by case basis.<sup>11</sup>

- Lately, low quality drugs have been either produced locally or even imported from developed countries. Up to 7% of the drugs sold in the world are considered as counterfeited or of low standard productions. Therefore the strengthening of drugs authorities and drugs inspection networks is a necessity to accompany the globalization and contribute to quality insurance. Developing countries, in partnership with pharmaceutical industries, international organizations and developed countries should develop strategies to minimize this growing phenomena.
- Some developing countries still have high rate of taxes on drugs and medical supplies, most of the time in contradiction with priorities and objectives of health policies. Essential drugs special pricing, reevaluation of the tax and tariff system while preserving fiscal and budget balance may be considered.
- Insurance covering access to pharmaceuticals is still the privilege of the wealthiest groups of population, when a national social insurance does not exist.
- Training and access to independent and ethical information to develop rational prescriptions habits, for the only information available from pharmaceutical representatives does not provide the knowledge about best therapeutic practices, cost/efficiency and frequently lack the necessary objectivity and comprehensiveness.
- To promote rational use of drugs and thus minimize drug resistance, transfer of competencies/training/equipment should be organized through private and/or public organizations.<sup>8</sup>

FDA Requirements for Generic Drugs.<sup>11</sup>

- Similar active ingredients and similar labeled strength as the brand-name product.
- Similar dosage form (for example, tablets, liquids) which must be administered in the similar way.
- Bioequivalency to the brand-name drug.
- Similar labeling as the brand-name drug.

- Complete documentation of drug's chemistry, manufacturing steps, and quality control measures.
- Specifications of raw materials and finished product according to the Pharmacopoeia.
- Potency and stability up to the expiration date on the label.
- Compliance with regulations for good manufacturing practices and description of facilities used to manufacture, process, test, package, and label the drug.

#### Problems associated with public health care

Although public health care saves millions of lives from premature death due to disease and injuries, several problems still remain:<sup>12</sup>

- *misallocation* of public resources (spending scarce resources on health interventions of *low cost-effectiveness* while underfunding critical and highly cost-effective health interventions)
- *inequity* (government spending for basic health services for the poorest goes disproportionately to affluent segments of society)
- *inefficiency* (health systems are often poorly structured and badly led).

The key role for the pharmaceutical industry is to discover, develop, produce, and market innovative products to prevent and cure diseases, to ease suffering, and to enhance the quality of life. Intellectual property rights are the lifeline of the research-based pharmaceutical industry and are vital to sustain continued R&D into new treatments. In view of the substantial investments as well as the high risk of failure, the research efforts are of course primarily focused on diseases with potential for an adequate return on investment. New mechanisms are therefore needed to foster research on diseases of poverty. When ability to purchase drugs is low, it is often not profitable for drug suppliers to offer their products at all, especially for proprietary drugs. However, some generic drugs with important benefits for people living with HIV are also inconsistently available even when they appear on the WHO's Essential Drugs list. Another gap in coverage comes from the fact that some generic drugs of great benefit to people living with HIV are not on the WHO Essential Drugs list.

The impact of patent protection on patients' access to treatment in developing countries is at

times exaggerated: Although about 90% of the drugs on WHO's model list of essential drugs are available off-patent, over a third of the world's population still has no access to these drugs. As essential drugs for the management of HIV/AIDS and drug-resistant forms of TB are patent-protected, innovative and unorthodox solutions must be found to improve poor people's access to these treatments. The challenge is to integrate the emerging global health system of intellectual property rights into a workable solution to make treatments available to poor people. TRIPS (Trade Related Aspects of Intellectual Property Rights) aims to strike such a balance by providing intellectual property protection and allowing countries the flexibility to ensure that treatments are available for the poor in situations of national emergencies, such as the HIV/AIDS pandemic.

Providing treatment for all HIV/AIDS and malaria patients will continue to be beyond the means of governments in developing countries. Substantially expanding access to essential medicines, including antiretrovirals, will require additional domestic and international financing for the purchase of the drugs as well as a significant investment in building effective health and supply systems.<sup>13</sup>

**– Problems associated with access to HIV drugs**

Living with HIV infection is complicated with various symptoms and medical conditions, many of which are manageable with drugs. Drug access issues related to HIV infection are especially complex because HIV gradually destroys the body's immune system. When this defense system is weakened, even relatively weak invaders may cause diseases that would otherwise be rare. The most important classes of drugs are (1) anti-infective agents for opportunistic infections; (2) anti-cancer drugs; (3) palliative drugs and (4) antiretrovirals to limit the damage to the immune system.

Proper use of most drugs for HIV requires training and information for doctors, nurses, pharmacists, and other care providers. It also requires knowledgeable clients since most of health care takes place in the household rather than in hospitals or clinics. When the need to care for people living with HIV is acknowledged, the question of providing the services and goods to deliver care becomes part of the political

**Table 1.** Global frequency rates of HIV-related opportunistic infections and malignancies

Infection or malignancy	Average frequency
Oral candidiasis	53%
Pneumocystis carinii pneumonia (PCP)	24%
Tuberculosis	22%
Oesophageal candidiasis	21%
Cytomegalovirus disease	21%
Kaposi sarcoma	15%
Toxoplasmosis	11%
Cryptococcosis	9%
Cryptosporidiosis	8%
Herpes zoster	7%
Systemic herpes simplex	7%
Mycobacterium avium complex infection	4%
Salmonella septicaemia	4%
Histoplasmosis	4%

Table adapted from WHO's "Standard treatments and essential drugs for HIV related conditions: Access to HIV-related drugs" (DAP/97.9)

agenda and addressed as part of the national strategic planning process.

Drug selection is a task that must include the Ministry of Health, NGOs providing care, groups of people living with HIV involved in care, doctors and the private sector. Decisions will be based on: (1) the frequency of HIV infection in the population and of specific diseases and symptoms among people living with HIV/AIDS; (2) the efficacy and safety of different treatment options; (3) other benefits that the drug might provide, in addition to the primary user; (4) availability and cost of the drug and (5) availability of diagnostic, treatment and storage facilities and relevant trained staff.

In many developing countries the high cost of the new antiretroviral (ARV) drugs has been a near-unbreachable barrier to governments struggling to care for their HIV-infected population and infrastructure improvement can be a major expense -- and it often entails much more than a more efficient distribution system. Enhanced laboratory capability is essential to follow the patients' prognosis. Frequently the initiative

behind ARV programs grew out of the activities of organizations and support groups for people living with HIV.<sup>14</sup>

Strategies to increase financial resources for HIV-related drugs include: *public financing; health insurance; financing by NGOs; donor financing and development loans.*

Whereas action to promote access through private and NGO sectors includes:

- organization of group purchasing arrangements by groups of people living with HIV and supply of priority HIV-related drugs by existing NGO essential drugs supply services.
- involvement of local pharmacy and of licensed drug sellers associations in promoting safe dispensing and appropriate advice, especially for specialized HIV-related drugs.
- strengthened regulatory control of drug registration, quality assurance and drug outlets.
- initiation of local partnerships with industry to self-regulate drug promotion, oversee quality in the distribution chain, and ensure availability of priority drugs.

## CONCLUSIONS

The issue of “access to drugs” cannot be discussed in isolation from overall deficits in development policies, health policies and systems, and implementation processes. As a rule, the combination of appropriate development policy, effective health policy, best practices applied in the health system, a rational use of drugs, and adequately funded health services can handle most of the health problems in any country. A drug supply system as a part of supporting health system should be managed in an integrated way considering it as part of a larger socio-cultural, political and economic context and environment. For a new system to be sustainable active consolidation is a must and new structures and processes need to be kept alive, to be implemented and to become established, to avoid falling back into old patterns.

The most important task and ultimate responsibility of government is the definition of a country's health policy framework and the adoption of an appropriate health system. The national fight for better health must be fought on at least three different fronts, namely (1) use non-health interventions to provide health benefits, such as by providing clean water,

improving sanitation, offering better primary education, and improving governance and basic infrastructure; (2) deliver medical interventions, such as vaccines and drugs, medical examinations, tests, and treatment—especially to poor people; and (3) deliver non-medical health interventions, such as training of medical personnel, building of better health information systems, and strengthening of systems for procuring and storing.

Essential drug list has been designed to facilitate the rational selection and use of drugs based on evidence-based treatment guidelines. It enables health authorities to focus expenditure on medicines likely to produce the most health benefits in a population. Reliable health care systems with trained staff as well as a minimal health care infrastructure help ensure that drugs are prescribed and used safely, and that compliance with drug regimens to avoid the serious potential of drug resistance is monitored. Sustainable financing is crucial to ensure a functional and reliable health care system as well as effective distribution of drugs. Political commitment is required to meet the health care needs of all citizens and not just those of the affluent urban segment. Essential drugs have a profound health impact, increasing the effectiveness of health systems as well as the cost effectiveness of pharmaceutical expenditures. Although the concept of essential drugs was already established many years ago, it is not fully implemented in many developing countries.

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