

Government and Market Failures
in the Pharmaceutical System:
*Partial Explanations towards
Understanding the Troubling Drug Gap*

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"Universal responsibility is the real key to human survival." (Dalai Lama: 345)

Introduction

Pharmaceuticals are indispensable to health systems; they can complement other types of health care services to reduce morbidity and mortality rates and enhance quality of life at the systems level. From an individual point of view, pharmaceuticals make us feel better when we are sick by either treating existing health conditions or help us when we are well by preventing conditions from happening. Pharmaceuticals, if used appropriately, thus have the power to make our lives qualitatively better and longer. As pharmaceuticals have curative and therapeutic qualities, they cannot be considered as simply ordinary commodities or even basic health inputs for that matter.

Access to medicines has taken a central role in the international policy debate. It is increasingly viewed as a basic human right, which is evident in light of the HIV/AIDS crisis that is devastating populations in the developing world, most acutely in Sub-Saharan Africa where as many as 29 million persons are infected with HIV/AIDS (UNAIDS and WHO, 2002) and as little as 5 to 6 percent of the population currently have access to the medicines they need (Moatti et al, 2002).

Benatar, Daar and Singer (2003) in their call for global health ethics note that "despite spectacular progress in science and technology during the twentieth century, as we enter the twenty-first the world is more inequitable than it was 50 years ago." The example of pharmaceutical access demonstrates this disparity in bold terms and serves a microcosm for broader trends, which are taking place in health care products and service delivery globally. As the former Director of WHO, Dr. G.H. Brundtland reported, "At the beginning of the 21st century, one-third of the world's population still lacks access to the essential drugs it needs for good health. In the poorest parts of Africa and Asia, these figures are even more depressing; over 50% of the population does not have access to the most vital drugs" (Brundtland, 2000). We cannot let these figures startle us momentarily and then retreat into a state of apathy. We need to identify what are the constraints to improving pharmaceutical access globally.

The global pharmaceutical system is unsatisfactory on moral grounds for a long list of reasons. The most compelling one is that access to pharmaceuticals is often a life and death issue and until the global population has equitable and regular access to essential medicines, we are faced with a morally reprehensible situation. We need to develop global pharmaceutical systems that are grounded on principles of fairness and compassion. Fairness requires that pharmaceutical pricing policies of the private sector and governments take into account economic constraints of individuals, particularly the very poorest in the least developed countries where public health insurance cannot guarantee access to pharmaceuticals for the indigent. Compassion requires that our policy directions

cannot be limited to economic arguments and/or incentive structures. We have a moral obligation to be designers of policies that promote compassion globally and take into full account the public health needs of the indigent.

This paper is organized as follows. First, the reasons why the global pharmaceutical system is not equitable are highlighted. Second, some of the government failures found in the pharmaceutical system are identified and discussed. Third, market failures, such as the gap in research and development for drugs for neglected diseases are discussed. Fourth, the issue of intellectual property protection for pharmaceuticals and drug access is discussed primarily in terms of the recent Doha Declaration and the August 30 accord. Finally, the paper draws conclusions based on the above.

As a point of departure, we need to recognize the complexity of the global pharmaceutical system and its interplay with government, the private sector and others, such as international organizations. All have a stake in the pharmaceutical system and are faced with dealing with the agendas of each other as they compete for primacy of their policy agendas in the international pharmaceutical system. The definition of access used in this paper is based on the one put forward by MSH-WHO (2000). Understanding precisely what the term “access” entails is a critical starting point for this discussion and the definition used is accepted internationally. Thus, access includes the following criteria:

- Physical availability – the relationship between the type and quantity of product and service needed and what is available;
- Affordability – the relationship between the products and services and the user’s ability to pay for them
- Geographic accessibility – the relationship between the location of the product or service and the location of the eventual user of the product or service
- Acceptability – This can also be understood as patient satisfaction and is the congruity between the user’s and the providers attitudes and expectations about the products and services and the actual characteristics
- Quality of products and services – cuts across all elements.

Partial Explanations about the Global Drug Imbalance

Global inequities in access to pharmaceuticals are stark between developed and developing countries because of market and government failures and income differences. (Reich 2000, 287(5460):1979-81). People in developing countries make

up about 80% of the population but only represent about 20% of global pharmaceutical sales (MSF, 2001). More specifically, high drug costs, weak or corrupt institutions, contributing to less than effective pharmaceutical purchasing and distribution systems, and the potential consequences of the Trade Related Aspects of Intellectual Property (TRIPS) Agreement all constrain drug access (Henry and Lexchin 2002, 360(9345):1590-5). Inadequate access to essential drugs is not only a concern in less developed countries. In the United States, for example, many seniors and uninsured people cannot afford the drugs they need (Henry and Lexchin 2002, 360(9345):1590-5). Still, the numbers are significantly less than those in developing countries.

While spending on pharmaceuticals represents less than one-fifth of total public and private health spending in most OECD states, it represents 15% to 30% of health spending in transitional economies and 25% to 66% in developing states (Govindaraj, Reich, Cohen, 2000). In most low-income states pharmaceuticals are the largest public expenditure on health after personnel costs and the largest household health expenditure. Family illness, including drugs, is a major cause of household poverty in developing states (Velasquez, Madrid and Quick, 1998). One of the major differences between developing countries and advanced economies is that the majority of pharmaceutical expenditure represents out-of-pocket payments—anywhere from 50% to 90% (Velasquez, Madrid and Quick, 1998). Consider that, along with the point that more than 1 billion persons survive on a dollar a day, and we understand plainly why there is a drug gap (World Bank, 2003).

In Ghana, as an example, despite availability of pharmaceuticals in many health facilities across the country, access to drugs is largely limited due to financial barriers for the majority of the population, particularly the poorest of the poor. As Management Sciences for Health (MSH) has reported, recent data indicate that 40 percent of Ghana's population earns less than the minimum wage and that this is even higher in rural areas¹. As a result the poverty level makes it difficult for patients to purchase drugs. The cost of a recommended adult treatment course for pneumonia of minimum wage earner is two days of wages for drugs from a private pharmacy; one and three-quarters days' wages if at a private health care facility; one and a half days' wages if purchased at a public health care facility²

¹ See MSH "Strategies for Enhancing Access to Medicines (SEAM), Ghana: Key Findings." 2003.

² Management Sciences for Health, Enhancing Access to Medicines (SEAM), Ghana: Key Findings. (www.msh.org) Accessed November 5, 2003.

Government Failures

More government spending on health generally and pharmaceuticals (including infrastructure) in particular is a necessary condition for improving access to pharmaceuticals. The WHO's Commission on Macroeconomics and Health in 2001 found that basic health care spending in the poorest countries would require \$57 billion in 2007. This would be the necessary annual health outlay for both health infrastructures and the care against infectious diseases and nutritional deficiencies (Sachs, 2001). In many of these developing countries, the overall health expenditure may be as little as US\$ 10-12 per person per year (WHO, 2003). Furthermore, in 1999, 39 of 94 reporting countries (41%) had a public drug expenditure of less than US\$ 2 per person per year where many of these countries have large numbers of people living with HIV/AIDS (WHO, 2000). On top of this inadequate percentage of spending on health and drug expenditure, inefficiencies and/or corruption in the prescription, storage and use of drugs in developing countries are such that some countries benefit only \$12 for each \$100 the public sector spends on drugs (World Bank, 1994).

Compounding the problem, health facilities in developing countries are often not located in areas with the greatest patient need, primarily rural areas, but their location is often based on physician choice or political factors, leading to mostly urban facilities. For example, three-quarters of Nigeria's health facilities are in urban areas, where only 30 percent of the population is living. Furthermore, the number of health facilities in 30 Nigerian states can range from one per 200 people in some states to one per 129 000 in others (PhRMA, 2003). Even when there are hospitals and other facilities found in both urban and rural areas of a country their condition is often poor.

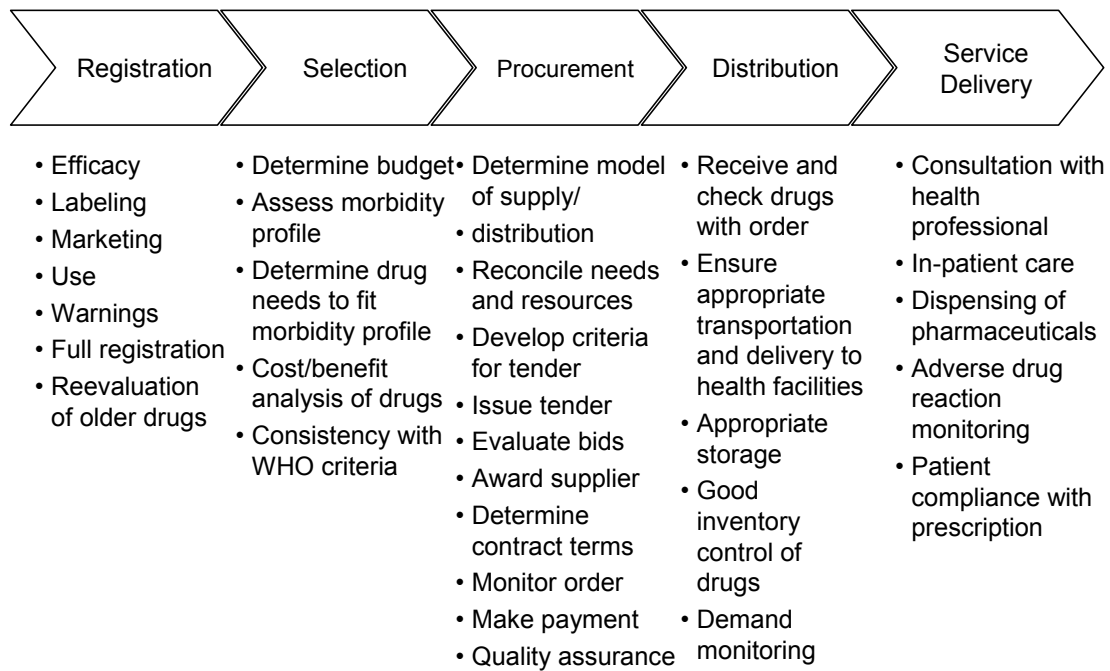
Another potential government failure in the pharmaceutical system is the potential for corruption to be present which in turn can reduce the impact of government expenditures on pharmaceuticals. Oftentimes it is difficult to identify corruption out right given that it is often difficult to disentangle corrupt practices from inefficient ones. However, we cannot overlook the potential for corruption in pharmaceutical systems. Corruption is not limited to any culture and is indeed a global phenomenon affecting both advanced and developing economies. It can, however, be more apparent in the pharmaceutical system of developing countries because while uniformly there is a high degree of government intervention through its regulation and wide information asymmetries between the patient and the physician and between the government and the health care provider, in developing countries, institutional weakness is more common. As a result, there are often poorly defined and documented processes, which comprise the system and limited institutional checks and

balances in many countries. The latter contributes to an environment that can allow corrupt practices to occur without penalty and this has a most deleterious impact on the poor who are most dependent on the public health systems for their drug needs.

Corruption in any one of the critical decision points in the pharmaceutical system can be detrimental to a country's ability to improve the health of its population by limiting access of the population to high quality medicines and thereby reducing the health gains associated with the proper use of pharmaceuticals. The diagram and its description below illustrates critical points in the pharmaceutical system: selection, distribution, procurement, service delivery and use. It is from a study that determined how to improve transparency in the pharmaceutical system in Costa Rica by Cohen, Cercone and Macaya (2002) and emphasizes that a pharmaceutical system is as good as its weakest link.

Drug management arrangements in countries vary with regard to the role of the public and private sectors in financing, distribution, dispensing and use of drugs, and the incentives for efficiency for both the government and the private sector. Pharmaceutical coverage for a country's population involves a highly regulated and technically complex system. This system must ensure demand for medications is met in a timely manner with high quality and efficacious drugs.

Figure 1. Key Decision Points in the Pharmaceutical System's Value Chain



The system must also allocate its limited resources efficiently in order to expand coverage to the greatest number of inhabitants or to uncovered diseases. The varied and highly specialized skills necessary for the functioning of a pharmaceutical system require the oversight and operational infrastructure of several government and private institutions.

Registration, the first decision point in the pharmaceutical system, evaluates a drug's efficacy against a specific disease and the potential side effects. The process also determines the restrictions of labeling, marketing, use, warning and prescription requirements for the drug. The primary role of the registration process is a regulatory one. **Selection**, the second decision point, focuses on covering the population's morbidity profile efficiently. The Essential Drug List establishes a country's priority areas of treatments and usually aims to cover the most common diseases. This area of activity requires the appropriate technical skills to be able to select which drugs will cover the most prevalent or highest priority, diseases in the most cost-effective way. This entails current knowledge of clinical studies, adverse drug reactions, morbidity profile shifts, and cost studies. The primary role of the selection process is a prioritizing one.

Procurement is the principal interface between the public system and the suppliers of drugs. The procurement process' focus is to acquire the appropriate volume and quantity of drugs for the population in the most cost-effective manner. This process involves inventory management, aggregate purchasing, and the establishment of bidding contests, technical analysis of offers, allocation of resources, payments, receipts of drugs purchased and quality control checks. The primary role of the procurement process is one of purchasing and resource allocation. **Distribution** in the pharmaceutical system must ensure drugs are allocated and transported to and stored appropriately at all points where drugs will be dispensed to treat disease. This system involves several levels, such as central warehouse, regional warehouse, pharmacy and service floor. Information must flow through the system to control inventory movements and deposits. In addition, the system must have storage facilities, including refrigeration units, to guarantee the integrity of the drugs. The distribution process is one of transportation, storage and inventory control. And lastly, **Service Delivery** is the interface between the health care system and the patients covered. This area is staffed with physicians, pharmacists and nurses to guarantee diseases are identified and treated effectively. This is the point at which patients should experience the benefits of the entire system. Here physicians prescribe, pharmacists dispense and nurses administer drugs to treat patients. Therefore, the primary focus of the area of service delivery is the effective treatment of disease. Each one of these core decision points needs to have robust institutions and good policies and practices to contribute towards

the availability of quality essential drugs at a reasonable price. This in turn can significantly reduce morbidity and mortality rates and contribute towards greater public trust in government services.

Market Failures

In a perfect world, the pharmaceutical market would work effectively and efficiently. That is to say, the market would be subject to price competition, comprehensive and accurate information that is available for all, an adequate supply of drugs, and consumers are able to make informed and beneficial choices between competing products, and no barriers for product entry into the market. However, there is significant evidence of market failure in the pharmaceutical system because it cannot be understood as a typical market. First of all, a consumer does not typically make choices about their pharmaceutical needs. Their health care provider prescribes a medicine for them and may not always act on the best interest of the patient but due to self-interest. This is the classic principal-agent dilemma. Second, there are information asymmetries between the consumer and the health care provider, the health care provider and the manufacturer, as well as between the manufacturer and the government. Third, the presence of patent protection means that there are market monopolies for products, which prevents price competition in the market until the patent expires and generics are able to compete.

The imperfections of the market are evident when we pay attention to some descriptive numbers. There is an 80/20 distortion in the global pharmaceutical market. Even though developing countries represent about 80 percent of the global population, they represent a relatively small proportion of the global pharmaceutical market in value about 20 percent of the global value, thus providing limited market incentives for the development of new drugs specific to disease of those countries (including many tropical diseases). Since 1973, more than twenty-five new infectious diseases have emerged, all requiring treatment with pharmaceuticals. Some like HIV/AIDS are global in their scope and are particularly devastating. Other diseases like cholera, tuberculosis, and malaria are mainly disease burdens of developing states. As will be discussed later, the TRIPS Agreement could exacerbate the control of these and other diseases by maintaining high prices for new drug therapies instead of allowing the production of generics that could effectively initiate price competition in the market.

There are also contradictory trends in health research and development. Global expenditure on health R&D has increased significantly and continues to rise. In 2001, an estimated US\$70 billion was invested globally in health R&D, with the U.S. private sector alone accounting for just under half of the spending (MSF,

2001). An analysis of drug development outcomes over the past 25 years shows that only 15 new drugs were indicated for tropical diseases and tuberculosis (MSF, 2001). These diseases primarily affect poor populations and account for 12% of the global disease burden. In comparison, 179 new drugs were developed for cardiovascular diseases, which represent 11% of the global burden of disease. Finally, out of the 1393 new drugs approved between 1975 and 1999, only 16 (or just over 1%) were specifically developed for tropical diseases and tuberculosis, diseases, which account for 11.4% of the global disease burden.

Medicins Sans Frontieres has identified three basic gaps in the drug development process. They are as follows. Gap 1: basic research is published but pre-clinical research does not begin; Gap 2: validated candidate drugs do not enter into clinical development because of strategic company choices; and Gap 3: new or existing drugs do not reach the patients. The pharmaceutical industry justifies its research decisions and the high cost of its products by pointing to the time, risk, and cost associated with new drug development (Henry and Lexchin 2002, 360(9345):1590-5). While valid points, we need to critique the amount of time, the level of risk and the exact costs that go into drug development. For example, in early 2001, the 20 top-grossing pharmaceutical companies in the world were surveyed about recent drug development activity; the survey found that private sector investment in this field was minimal, although some activity was observed (MSF, 2001).

Pharmaceutical Patents and Access to Drugs: Are They Mutually Exclusive?

One of the major points of discussion and debate in the international pharmaceutical policy sphere is the costs/benefits of the Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement. The TRIPS Agreement is arguably a product of the forces of globalization, at least those associated with international trade. The term "globalization" is used almost to the point of overuse in policy discussions today without much careful consideration of the fact that it is a loaded term that, importantly, can refer to both positive and negative trends worldwide. As Stiglitz notes, "protestors see globalization in a very different light than the treasury secretary of the United States, or the finance and trade ministers of the most of the advanced industrialized countries. The differences in views are so great that one wonders, are the protestors and the policy makers talking about the same phenomena?" (Stiglitz 2003, 9)

From a practical point of view, globalization can mean the imposition of standards and designs that may be in appropriate and/or vastly different from local ones. In this case, oftentimes there is a push-pull dynamic between global and local standards which may lead to very different results depending on the

incentive structure and institutions the individual must navigate. Dani Rodrick argues that multilateral institutions, like the World Trade Organization, thus need to encourage a greater convergence of policies and standards “deep integration” only among those countries that are willing to do so in order to reduce tensions from the differences in national standards. They also must allow for selective disengagement from multilateral standards for countries that need breathing room to satisfy domestic requirements that are in conflict with liberalizing trade (Rodrick 1997, 82). This argument is pertinent to the exigencies of the TRIPS Agreement and its potential threat to public health policies and institutions among members of the WTO.

Under the Rawlsian veil-of-ignorance, how would we want to structure intellectual property rights for pharmaceuticals? On the one side of the debate, the pharmaceutical industry argues that extensive protection of these rights is essential to generate income to recoup from research costs to ensure a continuing supply of new drugs. But, practices, such as “ever-greening” to extend patents are common and continue to prevent market competition (Henry and Lexchin 2002, 360(9345):1590-5). The recent report by the Commission on Intellectual Property Rights clearly states that intellectual property rights are instruments of public policy and that “there are no circumstances in which the most fundamental human rights should be subordinated to the requirements of [intellectual property] protection” (Henry and Lexchin 2002, 360(9345):1590-5).

Main Obligations Pursuant to TRIPS

The TRIPS Agreement extends patent protection to a lengthy period of twenty years (prior to TRIPS, even the United States, which has had a robust patent regime for pharmaceuticals, had a shorter period for the patent life—seventeen years). The TRIPS Agreement includes and surpasses most of the past provisions of the international agreements on the protection of intellectual property rights (Schott 2000, 115). It requires each member state to maintain sufficient procedures and remedies within its body of domestic law to ensure protection of intellectual property. These procedures and remedies must also be made available to foreign right holders.

The TRIPS Agreement provides minimum standards for intellectual property law and the procedures and remedies that should be available so rights holders can enforce their rights effectively. It includes in Part I, the general provisions, Part II, the specialist patent provisions, Part III, enforcement provisions, and the transitional arrangements are defined in Part IV of the Agreement. The main rule of TRIPS for patents is that they should be available for any invention, whether product or process, in all fields of technology without discrimination. Inventions covered under the patent law have to meet the criteria of novelty, inventive step

and industrial applicability. Member states are required to make the granting of a patent dependent on adequate disclosure of the invention. The minimum obligations for pharmaceuticals are these: pharmaceutical products and microorganisms are patentable for up until twenty years from the date the inventor files for the patent application. Second, there is no discrimination permitted against patent rights for imported products. Third, exclusive marketing rights are granted until patent expiry; and, there is a transitional period of one year, which can be extended up to ten years for developing countries without pharmaceutical product patents (Redwood, 1995).

In view of the real and perceived unbalances expressed in the TRIPS Agreement, in November 2001, the Doha Declaration on TRIPS and Public Health was passed partially as a means to mitigate complaints from developing countries and health activists regarding the exigencies of the TRIPS Agreement. The Declaration was not coincidentally passed a few months after the September 11 terrorist attacks in the United States and the anthrax scares that had rippled through the United States and caused even the then Health Secretary Thompson to declare that he was prepared to break patent protection on ciproflxin. The Declaration boldly asserts that “...We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health...We affirm that the Agreement can and should be interpreted and implemented in a manner supportive of a WTO member’s right to protect public health and, in particular, to promote access to medicines for all.”

Doha was partially an effort to interpret article 31(f) of the TRIPS Agreement, which states that compulsory licensing shall be “predominantly for the supply of the domestic market.” That means, under WTO rules, countries with a public health crisis are able to forgo patent law and issue a compulsory license to a local manufacturer. But, given that the majority of developing countries lack the domestic capacity or technical expertise to manufacture on-patent pharmaceuticals, the interpretation of what this terminology means is crucial for ensuring access to medicine for the poor in many developing countries and the profit margins of the pharmaceutical industry. As such, the Doha Declaration includes the now well-analysed Paragraph 6, which recognizes the limitations of the terms of compulsory licensing for member countries of the WTO, particularly the least developed countries that cannot turn to local producers for the manufacture of medicines and calls for an expeditious solution to the problem.

The long-negotiated agreement on the Doha Declaration on Trade Related Aspects of Intellectual Property Right (TRIPS) Agreement and Public Health in August 2003 suggests a means for selective disengagement by permitting those countries that do not have the capacity to manufacture medicines to still use compulsory licensing by contracting out agreements with firms in other

countries. This unleashes the potential for more competition in the pharmaceutical market, more drug supply for those in need. For now, this provision has been cited as a means to increase the supply of antiretroviral therapy globally. The Government of Canada has taken the lead among the OECD countries, pursuant to this accord, to reform its domestic intellectual property law in order to permit the generic production of antiretroviral therapy as an example for export to countries in need.

Despite the seemingly positive outcome in August among negotiators who debated the reach of the Doha Declaration for well over one year and half, the accord is not without its limitations. There are a number of administrative procedures, such as requiring both the importing and exporting countries to issue compulsory licenses, ensuring that the WTO is involved in the overseeing of the procedures, and other stipulations contained in the accord that could effectively limit its application in countries. In addition, many developing countries do not have the necessary administrative infrastructure and know-how to make use of the compulsory licensing provision. Irrespective of these potential constraints, the accord sets an important precedent of ensuring that international trade law does not ignore the importance of public health necessities. Patients are taking precedence over patents. It provides, however imperfectly, the potential for countries to disengage from the exigencies of the TRIPS Agreement. Its true value will be made evident as soon as countries begin to exercise their rights to invoke this provision.

Conclusions

In this paper, both market and government failures that contribute in part to the acute drug gap in the world are highlighted. In addition, patient purchasing power is another major factor that can explain in part why there are such disparities between the “haves” and “have-nots” in terms of drug access. Thus, a broader policy objective of poverty reduction obviously could contribute to improving access to pharmaceutical.

But until then we are faced with a morally unacceptable drug gap today particularly given the life-saving and life-enhancing properties of pharmaceuticals. As much as 60% of deaths each year in developing countries are related to common diseases that could have been treated by inexpensive drugs (MSH). The drug gap could be lessened considerably if the requisite financing, technical support and political will exists. Increased international assistance to ensure public health systems have the requisite resources, use of interim measures such as voluntary licensing agreements and tiered pricing schemes, and ultimately deeper technology transfer, all are examples of policy initiatives that can help improve drug access for the poorest of the poor. Those of

us who are among the privileged rich that can afford to pay for our medicines or have sufficient pharmaceutical coverage through third party payers need to ensure that international health policy sufficiently addresses the needs of the poorest of the poor.

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