

World Bank Pharmaceuticals

Ramesh Govindaraj, Michael R. Reich and Jillian C. Cohen

September 2000



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FOREWORD

The timely provision of good quality essential drugs to those in need, and particularly to the poor and the vulnerable, is an important component of the World Bank's mission "... to fight poverty with passion and professionalism for lasting results". Just as schools cannot be effective without appropriate textbooks, even the best health care provision cannot realize its intended results without ensuring people access to the right drugs at the right time.

In recent years, the World Bank, without much fanfare or publicity, has grown to become a significant policy advisor and international financier of drugs, vaccines, micronutrients, and contraceptives in low- and middle-income countries. The involvement of the Bank in pharmaceuticals is embedded in our growing partnership on all aspects of pharmaceutical policy and provision with WHO, UNICEF, UNFPA, FAO, the International Micronutrient Initiative, IFPMA and its pharmaceutical industry members, Medicine-sans-Frontieres (MSF) and other NGOs, and other partners active in this field. While relying on the strategies and policies of our development partners, the Bank did not, so far, have an explicit strategy to guide its policy dialogue and funding in the pharmaceutical sector. The Discussion Paper in front of you, in conjunction with the recently issued Bank pharmaceutical procurement guidelines ("Standard Bidding Documents and Technical Note for the Procurement of Health Sector Goods"), is a first step in this direction, and offers our client countries, development partners, and the staff and managers at the Bank itself a more coherent approach to this often complex sector.

Access by the poorest communities to essential medicines at the right time, the right place, and the right price remains an enormous efficiency challenge for most low- and many middle-income countries. As a key to addressing this challenge, the pharmaceutical strategies outlined in the Discussion Paper highlight the importance of supporting developing countries in their efforts to strengthen their capacities to provide, finance, and regulate pharmaceuticals, and their ability to formulate and implement pharmaceutical policies that emphasize essential drug availability, affordability, and quality using an appropriate mix of public and private sector resources.

Ultimately, of course, these pharmaceutical sector challenges are not mainly economic or technical in nature, but are part of the larger moral and equity concerns which are at the core of the development mandate of the Bank, and which we hope to be able to pursue in close collaboration with our colleagues at WHO, UNICEF, and other partner institutions.

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PREFACE

Pharmaceuticals have a major impact on health, on government and household spending, and on health systems. Despite the fundamental role of pharmaceuticals, there remains a profound gap between the benefit which pharmaceuticals have to offer and the reality that for millions of people -- particularly poor and disadvantaged people -- medicines are unavailable, unaffordable, unsafe or improperly used. This World Bank Pharmaceuticals Discussion Paper provides a pragmatic analysis of some of the causes for this gap and strategic directions to help close this gap.

The strategic directions outlined in this Pharmaceuticals Discussion Paper complement and reinforce the objectives outlined in the WHO Medicines Strategy: 2000-2003 (World Health Organization, Geneva, 2000, WHO/EDM/2000.1). The WHO strategy describes specific objectives, expected outcomes, and progress indicators in the areas of drug policy, access to essential drugs, quality and safety, and rational use of medicines. Both the World Bank and the WHO initiatives rest on a fundamental commitment to work with governments, non-governmental organizations, the private sector, professional bodies, and other key actors to help strengthen the pharmaceutical sector and its ability to contribute to improved health outcomes.

Since 1996, UNICEF, WHO, the World Bank, and, more recently, UNFPA have worked closely together through the Interagency Pharmaceutical Coordination Group (IPC) to develop common policy approaches in areas such as pharmaceutical procurement, to exchange information in critical areas such as drug financing and quality assurance, and to better coordinate support to individual countries. Though some differences in perspective remain, this process has led to greater synergy within the UN family and to complementary efforts, such as this discussion paper.

The current burden of disease falling on the two billion people living on less than one dollar per day undermines both individual well-being and collective economic development. Much of this burden of disease can be reduced by securing the availability, affordability, and rational use of essential drug of assured quality. Yet this aim can not be achieved by governments alone, by individual multilateral organizations working alone, or by any other individual organization. It can only be achieved when committed governments and local organizations are supported by clear, consistency, and mutually compatible approaches by agencies such as the World Bank, WHO, UNICEF, others in the UN family, bilateral donors, and the broader development community. This discussion paper provides an important contribution to this process.

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I. INTRODUCTION

This Discussion Paper was commissioned by the World Bank's Health, Nutrition and Population (HNP) Sector Board in May 1998 as a vehicle for stimulating discussion and debate on the Bank's role in pharmaceuticals,⁴ and as a first step towards articulating a coherent and explicit set of pharmaceutical strategies that are consistent with the HNP sector strategy, regional and country priorities, and the World Bank's broader development goals.

This is an opportune time to reflect on the World Bank's pharmaceutical activities and identify potential strategies. Health systems around the world are challenged by a combination of rising costs, difficult choices between conventional and new drug therapies, and persistent inequities in access to drugs, both geographically and across income groups. Throughout the world, health sector reform efforts commonly involve pharmaceutical issues. Within the World Bank, priority programs, such as HIV/AIDS, tuberculosis, malaria, and tobacco control, all require pharmaceutical support. Recent changes within the Bank also have important implications for pharmaceutical activities (such as the adoption of the Comprehensive Development Framework, the publication of an HNP Sector Strategy, the formation of the HNP Thematic Groups, the implementation of a new Knowledge Management System, and the introduction of new flexible lending instruments). More broadly, there is increased international attention to ways to expand access to both existing and new medicines.

The primary audience for this paper is World Bank staff – task team leaders, analysts, and managers. In addition, we seek, through this paper, to present the World Bank's activities and proposed directions for pharmaceuticals to the Bank's development partners and clients.

This paper is structured as follows. In Section II, we provide a brief outline of the Bank's engagement in pharmaceutical activities, based on our detailed review of all World Bank HNP projects with pharmaceutical components. In Section III, we present five major issues related to pharmaceutical policy in developing countries, with particular attention to issues that are relevant to the World Bank's development goals. In Section III, we present six strategic directions for focusing the Bank's work on pharmaceuticals.

II. THE WORLD BANK AND PHARMACEUTICALS

The Bank began to support direct lending for the HNP sector in the late 1970s.⁵ Today, the Bank is the single largest external source of HNP financing in low- and middle-income countries. In 1999, the Bank had 144 active and 130 completed HNP projects, representing a

⁴ For the purposes of this paper, "pharmaceuticals" refers to all pharmaceutical products, vaccines, contraceptives and medical supplies (but not medical equipment). We also use the term "pharmaceuticals" interchangeably with "drugs" in this paper.

⁵ Stout, Susan, et al. 1997. *Evaluating Health Projects: Lessons from the Literature*. World Bank Discussion Paper No. 356.

total cumulative value of about US \$ 16.8 billion in 1996 prices.⁶ The Bank's activities in the HNP sector are based on the rationale that investments in health, nutrition and population constitute an investment in human capital, and are necessary for enhanced welfare, reduced poverty, and sustainable growth.

Within the HNP portfolio, the Bank has been financing pharmaceutical activities since 1983.⁷ Since that time, the Bank has provided financing for pharmaceuticals in over 100 HNP projects in all six regions. We prepared a database of all 116 World Bank projects that included a pharmaceutical component, for the period 1983 to 1999, based on a detailed review of Staff Appraisal Reports (SARs) and Implementation Completion Reports (ICRs). The database was analyzed to estimate how much and where the World Bank has invested in pharmaceuticals (see Annex 2 for the Executive Summary).

The analysis shows that four types of lending practices apply to pharmaceuticals. These are: (1) HNP projects that finance drug procurement for specific diseases; (2) pharmaceutical stand-alone projects; (3) pharmaceutical components as part of broader health reform projects; and (4) projects linked to non-health-specific activities, such as structural adjustment, critical investment, and private sector investment loans.

The analysis of this sample of 116 Bank-financed projects shows that the estimated lending for pharmaceuticals, as a proportion of total committed HNP lending worldwide, ranges from a lower bound estimate of 12% to an upper bound estimate of 44%. The wide range is due to the lack of specificity in the cost categories used in the Bank's Project Appraisal Documents. The World Bank share in the total amount committed to pharmaceuticals in Bank-financed projects is about 58%, with the balance representing contributions from the client governments and other international donors. The Bank's lending for pharmaceuticals has focused on the procurement of drugs for its client countries, representing about 82% of the total amount allocated for pharmaceuticals. Of the 116 Project Appraisal Documents, 89 specifically mentioned a pharmaceutical component, and 62 stated specific pharmaceutical sector goals. Beyond drug procurement, the Bank's pharmaceutical lending activities included: financing for civil works, such as the rehabilitation of pharmaceutical warehouses and pharmacies (e.g., Bolivia); equipment for drug quality control (e.g., Romania); training of health professionals (e.g., Kenya); and technical assistance (e.g., Nicaragua).

In the past five years, the Bank has become involved in non-lending activities in the pharmaceutical sector. These have included policy dialogue with governments on developing national drug policies (e.g., Egypt) and drug pricing strategies (e.g., Ecuador and Macedonia). The Bank has also become active in partnership efforts. For example, it has been engaged in efforts to coordinate its pharmaceutical activities with those of other UN agencies through the

⁶ This information was obtained from the database maintained by the Human Development Network at the World Bank, Washington, DC.

⁷ The first project with pharmaceutical financing was the Peru Health Project in 1983.

Interagency Pharmaceutical Coordination (IPC) Group.⁸ The World Bank, the Pan-American Health Organization (PAHO), and the Inter-American Development Bank have declared pharmaceuticals a priority area in the health sector as part of their “Shared Agenda.” The Bank is also working with the private sector to expand access to existing and new essential drugs and vaccines for HIV/AIDS, malaria, TB, hepatitis B, and H. Influenzae.

Our analysis of the World Bank’s pharmaceutical lending indicates that:

- A major portion (82%) of the Bank’s pharmaceutical lending sector is directed towards pharmaceutical procurement. Less attention has been given by the Bank to establishing a policy dialogue with client countries or with the private sector – particularly at county level.
- Bank projects for pharmaceutical procurement often disregard important policy questions, such as the sustainability of the drug procurement and supply system, the impact of lending for procurement on local capacity building, and the impact of the Bank’s procurement activities on the pharmaceutical market in the client country.
- Even when lending for drug procurement is a significant component of an HNP loan, the loan does not include systematic assessment of the pharmaceutical system, despite recognition of linkages among different elements of the pharmaceutical supply chain. Pharmaceutical procurement is also sometimes undertaken in the absence of a policy framework for pharmaceuticals, or without appropriate linkages with the broader health care system in the country.
- On-going monitoring of the pharmaceutical components of HNP projects has been limited – perhaps due to the lack of funds for effective supervision and the limited pharmaceutical expertise within the Bank. Poor monitoring has limited the ability of managers to make necessary adjustments during project implementation.
- Adequate attention has not been given to institutional analysis or to political analysis of pharmaceutical policy, including building consensus for proposed reforms.⁹
- Country-specific studies on pharmaceuticals can serve as an important knowledge base for future lending, but not enough attention has been given to such assessments as part of Analytic and Advisory Work (AAA).

⁸ Members are the World Bank, WHO, UNICEF, and UNFPA.

⁹ Project completion reports have indicated the importance of having a political environment that is conducive to the realization of public health goals (e.g., Brazil and Nigeria). The HNP Sector Strategy Paper also noted the need for an analysis of the political economy of health.

III. PHARMACEUTICAL POLICY IN DEVELOPING COUNTRIES

Pharmaceutical technologies make a vital contribution to health. Access to essential drugs is fundamental to the good performance of health care delivery systems.¹⁰ In addition to their roles in preventing and treating disease, pharmaceuticals serve other social, psychological, and political functions.¹¹ One study identified 27 “latent functions” of pharmaceuticals,¹² including symbolic and social functions in patient-doctor interactions as well as broader political and economic roles in society. These multiple functions of pharmaceuticals contribute to the complex nature of decisions over pharmaceutical policy. Both the market and the state play important roles in the provision, financing, and regulation of pharmaceuticals, and finding the right balance between state and market is often difficult for policymakers.

Below we present five major pharmaceutical policy issues¹³ that are relevant to the World Bank’s development activities. These five issues inform our recommendations on the Bank’s strategic directions for the pharmaceutical sector. We exclude from this discussion those aspects of pharmaceutical policy that are beyond the scope of the Bank’s current HNP sector activities (such as issues of industrial organization and market concentration). These five pharmaceutical policy issues also represent broader health system concerns, and are of critical importance for Bank Task Team Leaders and managers who plan and oversee HNP projects.

1. Significant Public and Private Expenditures: Pharmaceuticals represent a significant proportion of government and private out-of-pocket expenditures in many developing countries, and provide a motivation for health sector reform.

Pharmaceutical expenditures in developing countries represent between 10-40% of public health budgets,¹⁴ and between 20-50% of total health care expenditures,¹⁵ compared to an average of 12% in OECD countries.¹⁶ If expenditures on salaries are excluded, then pharmaceutical expenditures often dominate the public health budgets in developing countries.

¹⁰ WHO, 1978. *Declaration of Alma Ata: Report on the International Conference on Primary Health Care*. Alma Ata, USSR.

¹¹ Geest, Sjaak van der, et al. 1990. “Planning for Essential Drugs: Are we Missing the Cultural Dimension?” *Health Policy and Planning* 5:182-185; Reich, Michael R. 1987. “Essential Drugs: Economics and Politics in International Health,” *Health Policy* 8, p. 45.

¹² Smith, Mickey C. 1983. *Principles of Pharmaceutical Marketing*, Philadelphia: Lea and Febiger, p. 112.

¹³ Although the five issues discussed here may also apply to vaccines, a detailed discussion of the issues relating to the vaccine market in developing countries is beyond the scope of this paper.

¹⁴ Govindaraj Ramesh, G. Chellaraj and C.J.L. Murray. 1997. “Health Expenditures in Latin America and the Caribbean,” *Soc. Sci. Med.* 44(2): 157-169. World Bank. 1993. *World Development Report 1993: Investing in Health*, New York: Oxford University Press.

¹⁵ WHO. 1998. *Health Reform and Drug Financing: Selected Topics*, Geneva: Action Programme on Essential Drugs (WHO/DAP/98.3), p. 9. Brudon, Pascale. 1997. *Comparative Analysis of National Drug Policies in Developing Countries*, Geneva: Action Programme on Essential Drugs (WHO/DAP/97.6), p.114. Patel, Mahesh S. 1983. “Drug Costs in Developing Countries and Policies to Reduce Them,” *World Development* 11(3), 197.

¹⁶ Julio Segura, J. in F. Lobo and G. Velasquez (eds.). 1998. *Medicines and the New Economic Environment*, p. 46, Madrid: Editorial Civitas.

Pharmaceutical expenditures in developing countries involve substantial private, out-of-pocket, payments by individual patients, with the poor spending a disproportionate share of household income on the purchase of drugs¹⁷ (sometimes more than twice as much as the richest 10% of the population spends¹⁸).

The policy implications of these large public and out-of-pocket expenditures are many. Governments are concerned about the total resources being spent on pharmaceuticals as well as the allocation of these resources.¹⁹ In addition, governments have difficulties in assessing the value of pharmaceuticals and the proportion of health budgets that should be allocated for pharmaceuticals. Governments are also under pressure to spend financial resources efficiently for pharmaceuticals, but, at the same time, have to ensure that pharmaceutical resources are distributed equitably. Governments must decide how to allocate resources between expanding access to new, more expensive drugs versus improving access to existing drugs. Governments with a local pharmaceutical industry face the dilemma of “make or buy?” Often, a politically strong domestic industry will persuade a government to purchase locally manufactured pharmaceuticals, even if it is more costly than purchasing imported drugs. These decisions have important implications for pharmaceutical industrial policy and for health care policy.

The substantial public and private out-of-pocket expenditures on pharmaceuticals provide a motivation for health reform in many countries. One direction has been to encourage the private sector to play a more active role in pharmaceutical activities – as shown by the privatization of pharmaceutical warehousing and distribution facilities and by the introduction of patient co-payments for pharmaceutical products. This trend highlights the importance of understanding the evolving roles of public and private actors in the pharmaceutical sector and how those roles influence the goals of health reform.

2. *Inadequate Regulatory Capacity: Governments in developing countries commonly lack adequate institutional capacity to regulate pharmaceutical activities effectively.*

The institutional capacity to regulate pharmaceuticals varies widely across the world, and particularly in developing countries.²⁰ Developing country governments have difficulty in assuring the quality of pharmaceuticals in the public sector and on the private market. Governments confront problems of counterfeit drugs and poor manufacturing processes, as well as difficulties in the regulation of prescribing practices and informal sales of drugs. Recently, public agencies in developed countries (such as the US FDA and the EU pharmaceutical regulatory agencies) and

¹⁷ WHO. 1998. *Health Reform and Drug Financing: Selected Topics*, Geneva: Action Programme on Essential Drugs (WHO/DAP/98.3).

¹⁸ See, for example, Medici, Andre. 1998. *O Sus e a Politica Hood Robin de Saude*, Mimeo. Washington, DC: Inter-American Development Bank.

¹⁹ Fairness in financing has been recognized by WHO as an important determinant of health systems performance in the recently published World Health Report, 2000.

²⁰ Jayasuriya, D.C. 1985. *Regulation of Pharmaceuticals in Developing Countries*, Geneva: WHO.

international agencies (such as WHO, UNICEF, and the World Bank) have sought to help developing countries improve their quality assurance standards and systems and their overall regulatory capacities.

Government efforts to regulate the pharmaceutical sector have sometimes been counterproductive. Some government policies have created new inefficiencies and bureaucratic problems. Policies to promote the domestic drug industry have led to conflicts between industrial and health policy objectives,²¹ and to the creation of highly inefficient public-sector production units.²² Price control policies have been particularly controversial. For example, it has been suggested that India's pharmaceutical price control policies in the 1970s and 1980s contributed to decreases in investment, productivity, capacity utilization, R&D, and overall profitability.²³

Cumbersome registration requirements and, in particular, significantly different regulatory requirements across developing countries²⁴ make the registration of new products by the international pharmaceutical industry a less attractive proposition in these countries. Non-registration of these products further hampers access to essential medicines in developing countries. These problems are being addressed, to some extent, by international drug regulatory harmonization initiatives, such as the International Conference on Harmonization (ICH). The ICH focuses on Europe, Japan, and the United States, but has been used as a model for harmonization initiatives among developing countries, such as Mercosur.²⁵

3. *Inadequate Access to Essential Drugs: The inefficient use of pharmaceutical resources in many developing countries substantially reduces access to essential drugs and potential health benefits.*

A significant portion of pharmaceutical expenditures in developing countries is wasted due to inefficiencies associated with the management of drug supplies, including drug selection, procurement, distribution, and use.²⁶ To enhance the efficiency of pharmaceutical resources and expand access to essential drugs, countries have been encouraged to develop and implement policies for essential drugs. Since the first WHO Model List of Essential Drugs was published in 1977, over 140 countries have adopted national essential drugs lists. Despite this progress, many developing countries are still struggling to assure access to essential drugs. The WHO estimates that one-third of the world's population lacks access to essential drugs (this estimate

²¹ Danzon, Patricia. 1997. *Pharmaceutical Price Regulation: National Policies versus Global Interests*. Washington, DC: American Enterprise Institute Press.

²² WHO. 1998. *Health Reform and Drug Financing: Selected Topics*, Geneva: Action Programme on Essential Drugs (WHO/DAP/98.3).

²³ Mathur, R.S. 1984. *Industrial Drug Policy: The Indian Experience*, UNIDO, ID/WG.502/7 (Spec.), June. Narayana, P.L. 1998. *The Indian Pharmaceutical Industry: Problems and Prospects*, NCAER, India.

²⁴ PAHO. 1998. Conference on Harmonization of Drug Regulations.

²⁵ Argentina, Brazil, Paraguay, and Uruguay are members of Mercosur.

²⁶ World Bank. 1994. *Better Health in Africa: Experiences and Lessons Learned*. Washington, DC: World Bank.

has remained unchanged since the mid-1980s).²⁷ The proportion reaches 50% in the poorest parts of Africa and Asia.²⁸

Significant problems also exist in pharmaceutical procurement and distribution systems. The causes of these problems include market failures (such as insufficient drug information) and government failures (associated with limited management capacity, weak management information systems, and poor warehouse and storage systems). The problems are compounded in some countries by widespread corruption in public sector procurement and distribution systems,²⁹ including in the health sector. The inefficient use of resources in public procurement and distributions systems represents an important motivation for health sector reform efforts.

A number of strategies can improve the efficient use of pharmaceutical resources and expand access to essential drugs.³⁰ These measures include: a) strengthen the state's capacity to use the international market and achieve more efficient procurement of essential drugs; b) improve the state's capacity to manage the national pharmaceutical system (for example, through improved warehousing and distribution systems and better control of corruption); c) focus on mechanisms to maintain effective supplies (such as better drug financing,³¹ price regulation, and greater price competition); and d) improve the rational use of drugs by health workers and consumers (for example, through social marketing programs). In addition, governments could be encouraged to reduce public sector pharmaceutical production. Annex 1 provides a review of eight World Bank policy papers on these topics, with a summary of their analyses and recommendations.

4. *Limited Access to New Drugs: There is limited funding for new pharmaceutical products in developing countries, resulting in limited access for groups who might benefit therapeutically. The limited access is compounded by the tendency for pharmaceutical companies to set prices close to developed country prices.*

The international pharmaceutical market is becoming increasingly globalized. Multinational companies make decisions about the launch price of a new product, based on multiple factors, including cross-national price comparisons, the potential for parallel trade, prices for competing products, probable market sizes, and the protection of intellectual property. If there is a limited market for a new product in developing countries, then a company tends to launch the product worldwide within a narrow price range that is consistent with the market environment in developed countries. The limited sales in developing countries (often to elite urban purchasers) will be within that price range.

²⁷ WHO. 1985. *The World Drug Situation*. Geneva: WHO.

²⁸ Scholtz, Michael. 1999. "International Trade and Public Health: WHO's Role," Presented at Conference on Increasing Access to Essential Drugs in a Globalized Economy," Amsterdam, 25-26 November.

²⁹ World Bank. 1997. *Helping Countries Combat Corruption: The Role of the World Bank*. Washington, DC: World Bank.

³⁰ Reich, Michael R. 2000. "The Global Drug Gap," *Science* 287:1979-1981.

³¹ Examples might include the development of larger risk pools and increased prepayment, with appropriate targeting programs to protect the poor.

When prices for newly introduced pharmaceuticals are set at levels close to developed country markets, developing countries confront major budgetary problems for those products. Some developing countries have decided to procure new drug therapies, despite the high cost. For example, Brazil committed about one-third of its federal drug budget in 1999 on anti-retroviral drugs for HIV/AIDS.³² These expenditures place enormous pressure on already fragile public sector health budgets in developing countries.

The effects of globalized product patents on developing countries are controversial and uncertain. Globalized product patents could expand access to drugs, if firms introduce new products into developing country markets after legal assurances of adequate patent protection. Similarly, patent protection could provide an impetus to foreign direct investment and technology transfer, as well as R&D investments (both local and foreign) that are relevant to developing countries. However, globalized patent protection could reduce access, if patented products are marketed at high monopoly prices in developing countries. The patent issue remains a source of persistent controversy between developed and developing countries, as reflected in the recent debate over parallel trade and compulsory licensing for pharmaceuticals.³³

A number of strategies have been proposed to expand access to new drugs.³⁴ Three of these strategies are: a) use the market to purchase new drugs (as Brazil has done for anti-retrovirals), either at international market prices or through a tiered pricing approach; b) use legal mandates to expand access to new drugs (as proposed with compulsory licensing and parallel imports, as allowed under the Trade-Related Aspects of Intellectual Property Rights, or TRIPS, Agreement); and c) use munificence to expand the donation of new drugs, through programs initiated by pharmaceutical manufacturers or by private foundations (for specific diseases or for specific products).

5. *Limited Incentives for New Drug R&D: Developing countries represent a relatively small proportion of the global pharmaceutical market, providing limited market incentives for the development of new drugs specific to diseases of those countries (including many tropical diseases).*

While the global market for pharmaceuticals is large and rapidly growing, developing countries account for a small proportion of the total market value. It is estimated that developing countries in 1998 accounted for about 20% of global pharmaceutical sales of US \$ 302.9 billion (at ex-

³² Cohen, Jillian Clare. 2000. *Public Policies in the Pharmaceutical Sector: A Case Study of Brazil*. LCHSD Paper Series No. 54, Human Development Department, Washington, DC: World Bank.

³³ For example, a major debate occurred in South Africa, in the context of limited access to HIV drugs, over whether South Africa's Medicines and Related Substances Act is TRIPS compliant (specifically Section 15(c), which authorizes parallel trade and compulsory licensing).

³⁴ Reich, Michael R. 2000. "The Global Drug Gap," *Science* 287:1979-1981.

manufacturer prices).³⁵ At the same time, developing countries represented over 85% of the global population.³⁶

This market structure has important implications for R&D investments on new drugs. Most major research-based multinational pharmaceutical companies focus their R&D strategies (and marketing efforts) on the 80% of the global market in the wealthier countries plus the middle-class market in some developing countries.³⁷ The pharmaceutical industry's R&D investment decisions are based on the expected present value of net returns. This focus on the health needs of the richer countries is economically rational for most private companies, since the market for their products in developing countries is limited.³⁸ Without a reasonable chance of having a market for their products, pharmaceutical companies are reluctant to invest in research needed on diseases that predominantly affect developing countries. One assessment of 1,233 new drugs that reached the market between 1975 and 1997 found only 13 products that were approved specifically for tropical diseases.³⁹

An analysis of the pharmaceutical industry and health needs in developing countries concluded that a redirection of industry research efforts would require a substantial portion of the investment to be paid from sources outside the industry.⁴⁰ Policy mechanisms to redirect R&D on yet-to-be-developed drugs include⁴¹: a) public subsidies (“push” strategies, such as grants through the US National Institutes of Health and the UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases); b) public-private partnerships for R&D on specific diseases or types of products (such as the Medicines for Malaria Venture); c) protection of product patents (as provided by the TRIPS agreement); and d) guaranteed markets for future products (“pull” strategies, such as purchase funds proposed for vaccines on malaria, AIDS, and tuberculosis).

This brief review of five major pharmaceutical policy issues in developing countries reflects the existence of significant market failures and government failures. There exist critical opportunities to help pharmaceutical markets work better and improve the regulatory and managerial capacity of governments. We address these issues in the paper's next section, which proposes six strategic directions for the World Bank's pharmaceutical activities.

³⁵ SCRIP. 1999. *Pharmaceutical Issues in Perspective*. January, p.30.

³⁶ World Bank. 1999. *World Development Indicators*, Washington, DC: World Bank.

³⁷ Schweitzer, S O. 1997. *Pharmaceutical Economics and Policy*, New York: Oxford University Press. p. 6.

³⁸ Comanor, William S. 1996. “Annex 4: The Pharmaceutical Industry and the Health Needs of Developing Countries,” in: Ad Hoc Committee on Health Research Relating to Future Intervention Options, *Investing in Health Research and Development*. Geneva: WHO (Document TDR/Gen/96.1), p. 211.

³⁹ Pécoul, Bernard, Pierre Chirac, Patrice Trouiller, and Jacques Pinel. 1999. “Access to Essential Drugs in Developing Countries: A Lost Battle?” *JAMA* 281:361-367.

⁴⁰ Comanor, William S. 1996. “Annex 4: The Pharmaceutical Industry and the Health Needs of Developing Countries,” in: Ad Hoc Committee on Health Research Relating to Future Intervention Options, *Investing in Health Research and Development*. Geneva: WHO (Document TDR/Gen/96.1), p. 212.

⁴¹ Reich, Michael R. 2000. “The Global Drug Gap,” *Science* 287:1979-1981.

IV. STRATEGIC DIRECTIONS

The World Bank's Key Development Themes

The World Bank is seeking to implement five key development themes. The themes are based on the Bank's mission to "fight poverty with passion and professionalism for lasting results," and are consistent with the goals of the 1997 Strategic Compact and the 1999 Comprehensive Development Framework. The five themes can also serve as a guide to the Bank's pharmaceutical activities.

- 1) **Organize the World Bank as a Knowledge Institution:** This theme reflects the Bank's stated intention of becoming a clearinghouse for information with an active exchange of knowledge and evidence-based learning across Bank and other projects, by bringing together "vibrant communities of practice to facilitate learning, problem solving, and mutual support among its members."⁴²
- 2) **Strengthen public-private collaboration in World Bank operations:** This theme reflects the Bank's commitment to re-focus the development agenda with "increased attention to social and environmental sustainability" by "responding to the changing roles of the public and private sectors."⁴³
- 3) **Emphasize systematic evaluations of the political economy and institutional factors in the World Bank's client countries:** This theme affirms the Bank's project experiences, which have consistently shown that "efforts to improve sectoral policy must recognize the complexity of the decision making environment in which they are taking place" and must involve a "detailed analysis of incentives and institutions, and a careful political analysis of organizations and interest groups."⁴⁴
- 4) **Help the World Bank's client countries strengthen their financial and regulatory capacities:** This theme reflects the World Bank's thinking that while "private investment is the key to economic growth," such a policy "prior to establishing an effective regulatory and competition framework can be a recipe for disaster."⁴⁵
- 5) **Encourage strategic partnerships with the World Bank's development partners, based on the relative strengths of individual institutions:** This theme reflects the Bank's stance that since it shares "a social, structural, and human agenda with regional

⁴² <http://wbIn0023.worldbank.org/KMS/kmmuse.nsf>

⁴³ World Bank. 1997. *World Bank Strategic Compact*, Washington DC: World Bank.

⁴⁴ Stout, Susan, et al. 1997. *Evaluating Health Projects: Lessons from the Literature*. World Bank Discussion Paper No. 356, p. 29.

⁴⁵ World Bank. 1997. *World Bank Strategic Compact*, Washington, DC: World Bank.

banks, members of the UN system, and other partners in development,” there is a need for greater “cooperation, transparency, and partnership” among these institutions, particularly given the “lessening resources for overseas development assistance and budgetary restraints on [international] agencies.”⁴⁶

Strategic Directions for Pharmaceutical Activities

Based on these five development themes, we propose six strategic directions to give greater structure and focus to the World Bank’s pharmaceutical activities. The strategic directions are also based on the pharmaceutical policy issues discussed above (Section III) and on our assessment of the Bank’s pharmaceutical activities in all HNP projects (Section II and Annex 2).

Proposition 1: Strengthen Policy Analysis and Dialogue

The Bank should support policy dialogue with client governments for sustainable pharmaceutical reform.

The Bank has been more reactive than proactive in initiating and sustaining a policy dialogue on pharmaceutical reform with its client countries, and has tended instead to focus on short-term imperatives, such as the financing of public sector pharmaceutical procurement. We believe that it is critical for the Bank to engage borrowers in a policy dialogue on pharmaceuticals within the broader context of health reform. This is important because of the influence of pharmaceuticals in the public and private health sectors in developing countries, and their substantial impact on the health of the poor. The Bank should take a leadership role in designing innovative strategies to expand access to these products among the world’s poor.

Pharmaceutical policy reforms are controversial because they change the costs and benefits that accrue to different stakeholders, including domestic and international pharmaceutical producers, physician groups, and developed country governments. These stakeholders tend to be relatively well organized and adept at seeking to influence public policy. The intended beneficiaries of the reform (particularly patients), on the other hand, tend to be poorly organized, and their voices are often not heard in the policy process.⁴⁷ The Bank should support policy dialogue that gives adequate consideration to the interests and capacities of different groups, including patients.

The policy dialogue could address the formulation and implementation of comprehensive national drug policies,⁴⁸ or focus on specific sub-components, such as the financing of

⁴⁶ See World Bank. 1999. *Comprehensive Development Framework*, Washington DC: World Bank.

⁴⁷ For details of this collective action dilemma, see Olson, Mancur. 1965. *The Logic of Collective Action*, Cambridge, MA: Harvard University Press.

⁴⁸ WHO defines a National Drug Policy (NDP) as a “formal policy document that expresses and prioritizes the goals set by the government for the pharmaceutical sector, and identifies the main strategies for attaining them”. It provides the framework within which the activities of the pharmaceutical sector can be

pharmaceuticals, management of drug supplies, pharmaceutical pricing, or selection of drugs to be included in national essential drug lists and/or reimbursement packages. The focus should be on addressing market failures, fostering effective public-private collaboration, and improving the regulatory capacity of governments – and, where possible, assuring that the best treatments are available to patients. The World Bank should use its global experience, as well as its partnerships with members of the Interagency Pharmaceutical Coordination group (IPC) and the private sector, in advising client countries about pharmaceutical “best practices,” based on empirical analyses and benchmarking of actual implementation.

The policy content would vary, depending on the level of economic development and the structure of the health care and pharmaceutical systems in the client country. Broadly speaking, the evidence suggests that increasing access to good quality and cost-effective essential drugs is the top priority in low-income countries, improving the efficiency of pharmaceutical spending is the main concern in middle-income countries, and balancing health sector and industrial priorities is a core concern in countries with a substantial domestic manufacturing capability. Cost-containment is a common theme in all countries.

The use of the Bank’s new flexible lending instruments should be explored to support the policy dialogue with client countries. For example, Adaptable Program Loans (APLs) could be used to motivate client countries to adhere to a framework for pharmaceutical reform that is mutually agreed upon by the borrowers, the World Bank, and other development partners, while allowing governments greater flexibility and control over the reform process. Learning and Innovation Loans (LILs) could be used to finance evidence-based research in areas where not enough is known regarding what does or does not work, prior to choosing a policy option. The Bank is still in a learning mode in terms of what its role should be in supporting pharmaceutical reforms, and which activities and strategies its investments should focus on. As a result, experimentation and learning are both necessary.

Effective donor coordination, at both the global and country level, is likely to enhance the impact of pharmaceutical policy dialogue. Expanding the Bank’s role in pharmaceutical policy dialogue will also require the development of greater in-house expertise in this area. We recommend that the Bank hire more pharmaceutical experts, particularly in the regions that have significant pharmaceutical portfolios. HNP Task Team Leaders would also benefit from training focused on pharmaceutical issues relevant to Bank operations, possibly in collaboration with the World Bank Institute. Finally, better use needs to be made of short-term consultants with pharmaceutical expertise, ensuring that they are closely involved in every step of a Bank’s project cycle when significant pharmaceutical lending is involved, and that their reports are widely shared across Bank projects.

coordinated, and includes drug legislation and regulation, essential drugs selection, drug registration, pricing policy, and public sector procurement.” For further information on NDPs, see Brudon, Pascale. 1997. *Comparative Analysis of National Drug Policies in 12 Countries*, Geneva: Action Programme on Essential Drugs, WHO (WHO/DAP/97.6).

Proposition 2: Institutionalize Sub-sector Assessments and Project Evaluations

The Bank should promote comprehensive assessments of pharmaceuticals during project development in the HNP sector (particularly when the pharmaceutical components constitute a significant proportion of the HNP project lending), and a continuous and systematic evaluation of the Bank's pharmaceutical portfolio.

This paper's analysis demonstrates that the World Bank has not approached pharmaceuticals in a systematic way in its existing health portfolio. Regardless of the main focus of HNP projects – whether it be specific diseases or comprehensive sectoral reform – pharmaceuticals have remained an afterthought. Assessments of the pharmaceutical sector are not a regular feature of country-specific HNP sector studies. Furthermore, the monitoring and evaluation of pharmaceuticals components is weak.

We recommend that an assessment of the pharmaceutical sector⁴⁹ be an integral part of the AAA in situations where significant pharmaceutical lending is anticipated in HNP projects. These evaluations should include an analysis of the poverty focus as well as the institutional and political context of suggested pharmaceutical reforms. Applied political analysis at the project appraisal stage can help identify potential risks to project components.⁵⁰ In this context, we recommend that appropriate linkages be established with the Poverty Reduction and Economic Management (PREM) network's broader efforts to strengthen institutional and political analyses in Bank projects. Even in cases where a pharmaceutical component is not planned at the beginning of the HNP project, we believe that an assessment of pharmaceuticals may be useful in developing the HNP project, as well as in planning future pharmaceutical components. Strengthening the Bank's approach to pharmaceutical issues will require additional staff expertise, through hiring and training, as noted above.

There is also a need to ensure that the knowledge gained from each project is widely shared across different regions and countries, through access to formal publications and informal documents. A possible mechanism to disseminate relevant information on pharmaceuticals is to use the Bank's web-sites (HD Net and regional web-sites) more effectively, and establish linkages with web-sites in other international agencies and public and private sector institutions. The Bank also needs to establish an integrated, Bank-wide database to track pharmaceutical activities on an ongoing basis, by building on the audit method and project database developed as an input into this paper (see Annex 2).

Finally, we recommend a strengthening of the ongoing monitoring and evaluation of pharmaceutical components within broader HNP projects, with the development of appropriate

⁴⁹ See Management Sciences for Health. 1997. *Managing Drug Supply*, 2nd Edition. West Hartford, Connecticut: Kumarian Press, Chapter 4, for details on what a pharmaceutical assessment entails.

⁵⁰ Reich, Michael R. 1996. "Applied Political Analysis for Health Policy Reform," *Current Issues in Public Health* 2:186-19.

tools to undertake such evaluations.⁵¹ Although funding for the supervision of Bank projects is limited, we believe that monitoring and evaluation could be improved within existing resources and through better coordination of activities with partners at the country level.

Proposition 3: Control Corruption

The Bank should support control of corruption, greater transparency, and increased accountability in its pharmaceutical lending activities.

The World Bank has begun to address corruption issues directly since the establishment of the Corruption Action Plan Working Group in 1996. There is now a Bank commitment to “mainstream” anti-corruption activities in all World Bank projects through an explicit consideration of corruption in the Country Assistance Strategy (CAS), AAA, and the lending program.⁵² To date, however, there has been relatively little attention to corruption-related issues in the HNP sector. We believe that the pharmaceutical sector is a logical place for these activities to begin, and that the Human Development Network (HDN) needs to work more closely with the PREM network to further anti-corruption efforts in HNP projects.

The pharmaceutical sector has a high potential for corruption, because of the degree of regulation and because procurement features prominently in the sector and typically involves significant amounts of money. For example, high rents can accrue from the illegal sale of publicly procured drugs; the drug selection process and the awarding of contracts are susceptible to manipulation; and the institutional capacities of many drug regulatory agencies are limited. Corruption in the pharmaceutical sector not only means inefficiencies and wastage in the health system, but can result in serious health risks for the population. A recent study undertaken by the World Bank’s Operations Evaluation Department (OED) showed that corruption is a major determinant of project outcomes in the HNP sector.⁵³

One of the outcomes of the Bank’s intensified corruption activities has been the development of general procurement guidelines intended to mitigate corruption in all Bank-financed projects. These guidelines, along with the recently revised World Bank Standard Bidding Documents and Technical Note for the Procurement of Health Sector Goods⁵⁴, can help ensure that the procurement of pharmaceuticals, contraceptives, and vaccines through Bank-financed projects are done in a fair, transparent, and competitive way. The Bank has also, on occasion, resorted to sanctions to counteract corruption, such as declaring mis-procurements or canceling pharmaceutical procurement contracts. In addition, the Bank has attempted to reduce

⁵¹ One such tool is a modified participatory methodology that has been used successfully by the World Bank in recent evaluations of Bank-financed pharmaceutical procurement in Tanzania, Kenya, and India.

⁵² One of seven action items as articulated in the World Bank “Anti-Corruption Plan” 1999.

⁵³ Stout, Susan, et al. 1997. *Evaluating Health Projects: Lessons from the Literature*, World Bank Discussion Paper No. 356.

⁵⁴ The project design and procurement planning considerations outlined in the technical note should prove useful to Bank Task Team Leaders, by guiding them through the entire process of pharmaceutical procurement. New provisions in the revised guidelines, such as the recommendation on the pre-qualification of suppliers, should also help in streamlining Bank-financed procurement.

corruption in loan disbursements by making payments to governments through special accounts or against statements of expenditures.

The Bank's efforts to combat corruption in the pharmaceutical sector must go further than current practices. For example, the Bank should explicitly raise the issue of corruption in its dialogue on pharmaceutical policies with client countries and also link this issue with lending for pharmaceuticals. In countries seeking assistance from the Bank for anti-corruption programs, efforts should be made to promote fairness and transparency in all government pharmaceutical procurement procedures in the Bank's client countries. A system of independent audits, and various security management initiatives,⁵⁵ could support this effort. The Bank could also encourage drug regulatory agencies to institute appropriate information disclosure policies. Another potential area of intervention is a review, and appropriate modification, of the incentives facing individuals involved in pharmaceutical supply and logistics systems, in order to encourage more professional and ethical conduct.

Proposition 4: Promote Selectivity in Procurement Lending

The Bank's lending for pharmaceutical procurement should be restricted to projects that promote policy and systems development and target the poor.

The financing of recurrent expenditures is restricted by World Bank guidelines, and is only permissible under specific conditions. These general guidelines have been adapted to pharmaceutical lending in the form of recommendations that World Bank financing for pharmaceutical procurement occur only for: a) the control of specific diseases; b) as an integral part of an overall national drug policy; or c) as part of a cost recovery or other drug financing program (see Denis Broun, 1994, in Annex 1). The implications of World Bank financing of procurement for pharmaceuticals have been debated within the Bank and outside.

While these guidelines may be a reasonable starting point, we recommend that the World Bank consider lending more selectively for drug procurement. In our view, the Bank should finance drug procurement to expand access to essential drugs and new drug therapies, only in situations where the lending is linked to institutional development, capacity building, and specific poverty alleviation initiatives in client countries, with explicit performance standards and agreed-upon timetables. In other words, pharmaceutical procurement loans should be used to establish and strengthen procurement and distribution infrastructure, set up logistical, management support and quality assurance systems, and train individuals, rather than merely to satisfy current demand.

Furthermore, when a decision is made in HNP projects to finance pharmaceutical procurement, it is critical that a serious commitment be made to "getting it right." Precisely defined, procurement could be considered as one step in the process of ensuring that good quality cost-

⁵⁵ For a description of some of these measures, such as independent inventory counts, consumption comparisons, and the use of unique identifiers for drug supplies, see Chapter 39 of *Managing Drug Supply*.

effective commodities are available to support health sector services. In this procurement planning process, procurement follows from selection – the informed determination of the most suitable items to obtain for the health system – and precedes the distribution of the products to the dispensing unit and subsequent rational use by the consumer. Underlying the whole process is the national legislative and regulatory framework. World Bank project experience has shown, however, that the objectives of procurement are successfully met only when careful attention is paid in the design of the project to a much broader range of activities. These activities include: the selection of pharmaceuticals, issues relating to the manufacture of goods to be purchased for the project, appropriate delivery to and storage within the recipient health system, and stringent monitoring and assurance of quality through inspection and product testing, in addition to the transparent, fair, and cost-effective management of the purchasing of goods. Central to the process is management and direct oversight of all the stages encompassed by this broader procurement definition.

The Bank has taken a step in the direction of operationalizing these concepts by the publication in May 2000 of the revised Standard Bidding Documents and Technical Note for the Procurement of Health Sector Goods. These revised procurement guidelines, which were prepared through an active collaboration between the Human Development and Operational Core Services Networks, should be of significant benefit to World Bank Task Team Leaders in planning and supervising projects that include lending for pharmaceuticals procurement.

Finally, we would strongly recommend an ongoing monitoring and evaluation of procurement loans, using objective assessment criteria, to ensure that they are being used in a way that is consistent with the Bank's mandate of poverty alleviation, Bank guidelines, and HNP sector and pharmaceutical priorities, in addition to project objectives. In particular, monitoring and evaluation should focus on financial and institutional sustainability of Bank investments in pharmaceuticals. The Bank should maintain an accurate and user-friendly database on the drugs, sources, and quantities purchased through Bank projects and the prices paid.

Proposition 5: Expand Access to Drugs through Public-Private Collaboration

The Bank should promote public-private partnerships to expand access to traditional and new essential drugs for the poor, and encourage governments to use the private sector as a technical resource.

The Bank should take a leadership role in designing innovative strategies to expand access to drugs that will significantly improve the welfare of the world's poor. These strategies will depend on public-private collaboration. For example, the Bank and the private sector have collaborated in single-drug donation programs in some of the Bank's client countries (illustrated by the Mectizan Donation Program). These programs are a concrete example of effective public-private sector collaboration for specific diseases, and can make a significant contribution to welfare of the poor. Donation programs, however, do not offer a long-term solution to the problem of expanding drug access for the poor.

An alternative strategy is to develop "pull" mechanisms that can create incentives for the pharmaceutical industry to enter under-served markets, by assuring that a paying market for these drugs will exist. These mechanisms include the establishment of loans, contributions to global funds, and other mechanisms that would reduce market uncertainties and thereby persuade companies to enter. The Bank could also examine strategies to implement tiered pricing for new drugs, in ways that would expand access to drugs for poor people in developing countries.

A recent example of a "pull" strategy is the Global Alliance for Vaccines and Immunization (GAVI), created by WHO, UNICEF, several bilateral agencies, the William H. and Melinda Gates Foundation, and the World Bank. Under the auspices of GAVI, the Gates Foundation is providing US \$750 million over five years to capitalize a Global Children's Vaccine Fund (CVF), which will be used to purchase new vaccines (such as the Hepatitis B and *Hemophilus Influenzae* B vaccines) for some of the world's poorest countries. We believe that the Bank needs to broaden the scope of such initiatives to encompass cost-effective essential drugs (both traditional and new essential drugs) that are currently inaccessible to poor people in developing countries.

The Bank has a comparative advantage in addressing economic and market incentive issues that constrain drug access compared to other development institutions involved in pharmaceutical activities. The Bank is a major lender for health, has regular communication with the Ministries of Health and Finance, and also has credibility with the private sector. The Bank, in collaboration with the International Finance Corporation (IFC), can thus help create better understanding between the public and private sectors about their respective constraints and priorities, and facilitate the identification of common priority areas.

The Bank should also encourage governments to use the private sector -- both for-profit and non-profit -- as a technical resource in appropriate areas. For example, developing countries could benefit from the R&D-based pharmaceutical industry's considerable experience with

quality assurance systems. At a national and sub-national level, developing countries could benefit from a more effective integration of the pharmaceutical services provided by private health care providers and non-governmental organizations with those provided by the public health system. Also at the national level, countries would profit from greater involvement of the private sector, possibly through contracting arrangements, in areas such as drug supply management and drug quality testing.

Proposition 6: Create Incentives for New Pharmaceutical R&D

The Bank should expand its efforts to promote incentives for pharmaceutical R&D targeted at critical diseases of the poor.

The Bank has recognized the importance of addressing market failures that have limited the development of products for critical diseases of the poor in its client countries. In the past, the Bank made efforts, with some success, to subsidize pharmaceutical R&D on new products for tropical diseases. An important example is the support provided by the Bank to the UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases (TDR). TDR helped develop 24 tropical disease drug products from 1974 to 1995; 14 were still in trials in 1995, and 10 were in clinical use.⁵⁶

More recently, the Bank has placed high priority on the development of medicines for malaria and on the development of an HIV/AIDS vaccine. An example of this commitment is the Medicines for Malaria Venture (MMV), which brings together public sector organizations (including the World Bank) and pharmaceutical companies under the umbrella of the WHO. Another example is the International AIDS Vaccine Initiative (IAVI), which has raised about \$75 million from various sources (including support from the Bank), towards the \$350-500 million target in its Scientific Blueprint for AIDS Vaccine Development. The Blueprint charts the course for the development of an AIDS vaccine for developing countries that would be inexpensive to manufacture, easy to transport and administer, stable under field conditions, and require few inoculations.

The Bank has also participated in initiatives proposed by other development partners. An example is the initiative proposed by Medecins Sans Frontieres (MSF) to promote orphan drugs laws that identify tropical diseases as “orphan” diseases, and provide incentives through public subsidies (such as tax credits and marketing monopolies) to encourage investments by drug companies in these diseases. The WHO Stop TB Initiative has called for the establishment of a global fund to purchase fixed-dose anti-tuberculosis combination drugs for developing countries. A similar purchase fund has been proposed to encourage greater private sector investments in R&D for malaria, tuberculosis and AIDS vaccines.

⁵⁶ UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases. 1995. *Tropical Disease Research, Progress 1975-94, Highlights 1993-94*. TDR Twelfth Programme Report. Geneva: TDR.

We recommend that these efforts be studied by the Bank to explain both the successes and the failures, and to design innovative strategies for a broad initiative to encourage investments in R&D for the most important diseases of poor countries. The Bank should examine how it can work proactively with the private sector to foster the development of medicines for the critical diseases of the poor. The Bank should also consider providing support, through HNP projects, to developing countries that are attempting to increase investments in domestic pharmaceutical R&D targeted at neglected diseases.

Conclusion

This paper proposes six directions to provide a new strategic focus to the World Bank's pharmaceutical activities. These directions should be connected to performance-based criteria for evaluation. Each proposition constitutes a recommendation or a new initiative. This would require reorienting existing financial and human resources within the Bank to support these interventions, and making more effective and coordinated use of external resources. We believe that by re-focusing the World Bank's efforts on these strategic directions in pharmaceuticals, the Bank could significantly enhance its impact on access to pharmaceutical in client countries, with important positive consequences for health system performance, for public health objectives, and for overall development goals.

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Annex 1

Major World Bank Documents on Pharmaceutical Activities

The World Bank began lending for pharmaceuticals in 1983, but these activities have been conducted without an explicit operational policy on pharmaceuticals as guidance. *Operational Policies* (OPs) are “short, focused statements of policy that follow from the Bank’s Articles of Agreement, the General Conditions, and policies approved by the Board. These policies establish the parameters for the conduct of operations; they also describe the circumstances under which exceptions to policy are admissible and spell out who authorizes exceptions.”⁵⁷ In contrast, *Good Practices* (GPs) contain “advice and guidance on policy implementation; for example, the history of the issue, the sectoral context, analytical framework, and best practice examples.”⁵⁸

The World Bank has published a number of policy papers and reports on pharmaceuticals, but these are not considered operational policy. Good practices and implicit policy, then, guide much of the Bank’s pharmaceutical activities (as well as other activities in the HNP sector). This annex reviews eight key documents and their central messages.

1. *Pharmaceuticals in the Third World: An Overview* (1986) by Karen Lashman

This is the first Bank paper that includes a detailed analysis of pharmaceuticals, and identifies some strategic policy directions, such as those related to local manufacturing. Many of the policies proposed in this paper are reflected in later Bank reports.

For Lashman, major pharmaceuticals-related problems in developing countries are: shortages in basic medicines among the poorest groups in the population; inadequate pharmaceutical budgets which are used inefficiently; and, a mismatch between drug consumption and needs. In view of these weaknesses, she addresses the question of whether health status can be improved without increasing expenditures. Lashman concludes that this is possible; developing countries can meet their essential drug and vaccine needs by altering existing demand patterns and enhancing the efficiency of the selection, procurement, supply management and distribution process.

To help make the Bank’s client countries more “market wise” in their drug supply decisions, Lashman examines the economics of local production. Based on extensive interviews with a sample of pharmaceutical manufacturers, Lashman concludes that given economies of scale and technological needs, local production does not make economic sense for most countries. Exceptions are countries with large local markets and the technological capacity to produce raw materials (e.g., China, India, Thailand, Egypt, Brazil, Mexico, and Argentina).

⁵⁷ World Bank. 1999. *World Bank Operational Manual*. Washington DC: World Bank.

⁵⁸ *Ibid.*

2. *The World Development Report (WDR): Investing in Health* (1993)

The 1993 WDR provides a comprehensive analysis of the HNP sector, with a particular emphasis on the role of the government and the market. The WDR also promotes competition in health services, provision, and insurance.⁵⁹ The WDR includes the first major statement on pharmaceutical policy of the World Bank. It recommends:

- Essential drugs policies, through the prioritization of medicines appropriate to each country's epidemiological needs;
- Improved methods of drug and vaccine procurement, through the better selection of products and competitive purchasing methods; and,
- Enhanced drug prescription and consumption habits, through better training and information.

The WDR understands pharmaceuticals primarily as an input into the health system,⁶⁰ and makes the case for governments to develop public policies and implement programs to improve efficiencies in the selection, acquisition, and use of drugs. The WDR generally argues that governments should intensify their regulatory role and reduce their involvement in the production and direct provision of drugs. The WDR positions pharmaceutical policy within broader development objectives for the HNP sector, and identifies a number of specific policy mechanisms; however, it does not provide guidance on implementation, or operational implications of the proposed policy directions.

3. *Drug Policy Issues in Sahelian Countries* (1993) by Rene Vaurs and others

This paper examines pharmaceuticals issues regionally, emphasizing deficiencies in the availability, affordability, and quality of drugs. The recommendations proposed in the report can also be applied to most developing countries, as all of them are in line with standard Bank positions: (1) better needs estimation; (2) no state production (in most cases); (3) cost-effective purchasing techniques; (4) better distribution systems; (5) simplified pricing systems; (5) secure public financing; and, (6) effective management structures (e.g., legislative, consultative, and administrative structures).

The paper is the first Bank document to address the processes and politics of formulating and implementing a national drug policy (NDP). Vaurs and others admit that implementing an NDP can result in strong opposition and will require large consensus-building and behavioral changes. Even so, they recommend that the Sahelian countries plan to implement comprehensive NDP by the year 2000.

4. *Better Health in Africa (BHA): Experience and Lessons Learned* (1994)

⁵⁹ Stout, Susan, et al. 1997. *Evaluating Health Projects: Lessons from the Literature*. World Bank Discussion Paper No. 356, p. 33.

⁶⁰ The alternative "systems view" depicts pharmaceuticals, not only as complements, but also as substitutes for other health inputs, such as physician services and hospital-based interventions.

This book highlights the importance of essential drugs for health gains in Africa. BHA emphasizes that many of the pharmaceutical markets in Sub-Saharan Africa are inefficient, mainly because of a lack of information, inadequate financing mechanisms, and poorly managed drug supplies. Based on data from WHO and the Bank, the report shows that there is significant wastage of financial resources. It estimates that for every US \$100 spent on pharmaceuticals, only US \$ 12 are spent on real drug needs. This finding supports one of the report's central messages: governments must reduce the amount of waste found in the drug supply distribution network so that coverage of essential drugs can be expanded without straining health budgets.

5. The Procurement of Pharmaceuticals in World Bank Projects (1994) by Denis Broun

This paper focuses on the Bank's financing of drug procurement. World Bank financing of recurrent expenditures is restricted by several guidelines (see World Bank Operational Manual, Section 1.21.1985), and is only permissible under specific conditions. Broun points out that if pharmaceuticals are considered as recurrent public expenditure, then financing drug procurement falls outside of the World Bank's development mandate.

Broun proposes three conditions, consistent with World Bank guidelines, which could justify lending for pharmaceutical procurement. They are: a) if an HNP project (or sub-component) addresses a particular disease; b) if an HNP project has activities related to the pharmaceutical policy of a country; or c) if an HNP project supports the start-up of a cost recovery, or other type, of drug financing program. This paper includes an annex, which details all the HNP projects that have included pharmaceuticals components. Our initial assessment suggests that the three conditions articulated by Broun are general enough that any of these (or other) projects could be justified on this basis.

Broun then develops three policy recommendations which, in his opinion, should be applied to all procurement lending. First, drug procurement should be accompanied by institutional and human capacity building, in order to create a sustainable pharmaceutical system. Second, Bank procurement should be limited to essential drugs (it is not clear whether Broun is suggesting that they should be essential drugs according to the WHO list or that of individual countries). And, third, pharmaceuticals be procured under generic or an international non-proprietary name (INN). As discussed later, our evaluation of Bank projects involving pharmaceuticals suggests that these recommendations are not always adhered to in the Bank's pharmaceutical projects.

6. Getting the Most out of Pharmaceutical Expenditures (1994) by Helen Saxenian

This paper focuses on the central theme presented in the WDR 1993: how can governments increase efficiencies in the pharmaceuticals market. Saxenian presents seven major pharmaceutical expenditure policies which countries use to "rationalize" drug expenditures in terms of impact, administrative costs, relevance to different types of health care systems, and levels of development. The policies are: (1) essential drug lists; (2) competitive procurement

methods; (3) generic drug substitution; (4) influencing provider and consumer behavior through education and incentives; (5) the promotion of essential drug use in the private sector; (6) price controls; and (7) user fees.

The paper concludes that developing countries have a menu of pharmaceutical policy choices available. The choice a government makes depends on its health objectives and the characteristics of its pharmaceutical market. Saxenian argues that by formulating sound policy, a government can increase the efficiency of pharmaceutical expenditure, and generate savings, which, ideally, can be used to increase the access of the population to essential drugs.

7. The Pharmaceutical Industry in India and Hungary: Policies, Institutions, and Technological Development (1997) by Greg Felker, Shekhar Chaudhuri, and Katalin György, with Melvin Goldman

The paper emphasizes how government policy has had an impact on the pace and type of industrial development. Through different strategic choices, the government and industry in both India and Hungary supported applied research and process technology, rather than pharmaceutical product innovation.

8. Patents and Pharmaceutical Drugs: Understanding the Pressures on Developing Countries (1990) by Julio Nogues

This paper emphasizes why patent protection is important for the research and development based pharmaceutical industry, given market competition. This paper explains pressures developing countries must address to meet international standards of intellectual property rights. The argument Nogues makes may be even more forceful today, given the TRIPS Agreement, and the creation of the World Trade Organization (WTO).

Conclusions

This review leads to two important conclusions. First, World Bank publications have focused mainly on what the Bank should be doing in pharmaceuticals, with a number of common themes. These themes typically refer to pharmaceutical policy choices that could improve the efficiency of expenditures on pharmaceuticals.

Second, Bank publications on pharmaceuticals have provided very limited attention to evaluation of actual interventions. Some assessment of project impacts can be found in internal Bank documents and consultant reports, which are prepared during project life cycles. But these reports are usually restricted to project team leaders and receive limited dissemination even within the Bank. As a result, we know relatively little about the impact of the Bank's pharmaceutical lending.

Annex 2
Financial and Policy Audit of World Bank's Pharmaceutical Lending*
By Eduardo Sabaté, MD, MBA, MPH (1), Asma Balal, MBA, MS (2), Michael Reich, PhD (3)⁶¹

Executive Summary

Purpose

The aim of this study is to assess the amount of committed lending by the World Bank for pharmaceutical activities. We examined project documents for Bank loans on health, nutrition, and population (HNP), and other development loans, with designated lending to pharmaceuticals, from FY1983 to FY1999. The study also examined the policies associated with these loan commitments. The findings are based on 116 Project Appraisal Documents (PADs) retrieved from the World Bank's Lending Operations database.

Methods

The accounting method employed for the study emphasizes accuracy in cost classification. Budgeted allocations were placed in specific cost categories only when they were explicitly defined in the PAD. The categories were defined on the basis of area of investment (pharmaceutical, nutrition, water and sanitation, other health, and non- health). Each area was further classified into two main components (commodities and non-commodities). In ambiguous cases (where the stated amounts belonged to more than one type of activity or multiple areas of investment), the amount was placed in a "non-defined" category. This method offers important advantages of reliability, transparency, verifiability, and sensitivity. In addition, this accounting method provides the basis for creating a database that could become an effective management information system for the Bank's pharmaceutical activities.

Findings

The World Bank contributed about 58% of the total amount committed to pharmaceuticals in the 116 projects worldwide in the database, with the balance representing contributions from the client governments and other international donors. The Bank contributed a total of \$6.39 billion to the 116 projects and at least \$759 million (11.87%) was committed to pharmaceutical activities. This figure is a lower bound estimate and *underestimates* the World Bank's actual

* **A copy of the full report on this background study for the World Bank Pharmaceuticals Discussion Paper can be obtained from:** Dr. Ramesh Govindaraj, Pharmaceutical Specialist, Health, Nutrition and Population Department, Human Development Network, G3-048, World Bank, 1818 H Street, NW, Washington DC 20433. E-mail: rgovindaraj@worldbank.org

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lending. It represents the minimum amount of pharmaceutical lending, because it does not include pharmaceutical activities in the “non-defined” category.

The amount in the “not-defined health” category represents 34.06% of the total loans of all international donors worldwide. A sensitivity analysis cannot be conducted by donor, because the “non-defined health” account was not analyzed by donors in this study. However, if we assume that the pharmaceutical amounts lumped with non-pharmaceutical lending are distributed across different donors proportionately to their contribution to the total project, and if we assume that the total non-defined health account represents pharmaceutical lending, then the World Bank’s lending for pharmaceuticals would represent 44.41% of its total contribution to the projects in the database. This figure is an upper bound estimate and *overestimates* the World Bank’s pharmaceutical lending.

This detailed analysis of 116 Bank-financed projects over 1983 to 1997 shows that the Bank’s committed lending for pharmaceuticals, as a proportion of total committed HNP lending worldwide, ranges from a lower-bound estimate of 12% to an upper-bound estimate of 44%. The wide range is due to the lack of specificity in the cost categories used in the Bank’s Project Appraisal Documents (and the resulting high amounts in the category called “non-defined health”). This careful financial audit of 116 Bank projects was unable to confirm or reproduce the recent estimate of 17% of total HNP committed lending for pharmaceutical activities.⁶²

The main pharmaceutical activity financed by the World Bank loans is procurement of commodities and represents 82.12% of the total amount allocated for pharmaceuticals. However, funds allocated for procurement of pharmaceutical commodities were explicitly defined in most of the PADs (e.g., essential drugs, vaccines, contraceptives) whereas the pharmaceutical funds for institutional strengthening and civil works were generally lumped with other health activities and were thus placed in the “non-defined health” category.

Out of 116 PADs, 89 categorically mentioned having a pharmaceutical component. 62 PADs stated specific pharmaceutical sector goals. Only 42 projects reported specific conditions attached with pharmaceutical lending.

Limitations

A significant limitation of the study is its inability to give the exact amount of pharmaceutical lending, due to the lack of detailed cost reporting in PADs for the pharmaceutical sector. The World Bank does not have a standardized cost accounting system that could be consistently applied across all pharmaceutical loans. The loan amounts were lumped across activities as well as areas of investment, thus making it impossible to determine the exact amount of pharmaceutical lending. The most common examples of lumping between pharmaceutical and

⁶² Falkenberg, Torkel and Goran Tomson. 2000. “The World Bank and Pharmaceuticals,” *Health Policy and Planning* 15:52-58.

other health activities were: drugs and medical supplies (commodities); construction of health posts and drug warehouse (civil works); medical equipment and vehicles used for drug distribution and vaccine equipment (equipment); and drug policy development and other technical assistance for health (institutional development). This weakness in the accounting system led to a total 'non-defined health' amount of \$8.88 billion worldwide (out of total projects of \$27.29 billion).

Another limitation relates to the World Bank's lending database, which is set up to perform the keyword search only in the abstract of the PAD. Thus, if the project has a pharmaceutical component but it is not mentioned in the abstract, then that report will not be retrieved by the search system. This limitation might have led to the omission of PADs that included pharmaceutical components.

Recommendations

We recommend that the World Bank take the following steps:

- Define a set of cost accounting categories that are consistent across projects and that reflect the World Bank's focus within the pharmaceutical sector
- Improve the level of detail on pharmaceutical sector reporting
- Develop mechanisms to ensure consistency in description of pharmaceutical activities and reporting of committed loan amounts for pharmaceuticals

Pharmaceutical Lending by Source

	All sources			World Bank		
	Intl.*	Local**	N/D	Total	IBRD	IDA
Worldwide	63.68%	19.42%	16.90%	57.80%	19.18%	38.62%
Africa	55.00%	13.30%	31.71%	45.73%	13.91%	31.82%
East Asia	94.85%	2.87%	2.28%	89.43%	13.16%	76.27%
Europe	79.96%	19.84%	0.20%	79.96%	71.24%	8.72%
Latin America	32.28%	53.74%	13.98%	32.28%	27.41%	4.87%
ME & NA	55.91%	13.62%	30.47%	55.91%	44.22%	11.69%
South Asia	78.32%	19.65%	2.03%	70.38%	0.00%	70.38%

Relative Share of Pharmaceutical Lending

	Bank's contribution to pharmaceuticals/Bank's contribution to HNP project			Bank's contribution to pharmaceutical commodities/ Bank's contribution to pharmaceuticals		
	Total	IBRD	IDA	Total	IBRD	IDA
Worldwide	11.87%	10.86%	12.45%	88.85%	72.96%	96.74%
Africa	13.98%	33.81%	11.13%	65.34%	0.00%	93.90%
East Asia	18.00%	4.89%	33.55%	100.00%	100.00%	100.00%
Europe	18.10%	20.55%	9.17%	100.00%	100.00%	100.00%
Latin America	4.67%	4.40%	7.14%	100.00%	100.00%	100.00%
ME & NA	11.57%	14.35%	6.67%	100.00%	100.00%	100.00%
South Asia	11.01%	0.00%	11.12%	96.77%	N/A	96.77%

* International: Includes international donors such as The World Bank, UNFPA, USAID, CIDA, KfW etc.

**Local: Includes government, states, local NGOs, beneficiaries etc.

Note: These figures do not include those pharmaceutical amounts that were lumped with other health components and placed in the “non-defined” health category.



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