

HEALTH AND THE
INTERNATIONAL ECONOMY

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THE REPORT OF WORKING GROUP 4 OF THE COMMISSION ON
MACROECONOMICS AND HEALTH

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FOREWORD

The Commission on Macroeconomics and Health (CMH) was launched in January 2000 by Gro Harlem Brundtland, Director-General of the World Health Organization. Its mission was to analyse the impact of health on development and to examine ways in which health-related investments could spur economic development. The Commission worked to develop specific recommendations that would save lives, reduce poverty, and spur economic growth through a scaling up of investments in the health sector of developing countries. The final report of the Commission, *Macroeconomics and Health: Investing in Health for Economic Development*, was released in December 2001.

The Commission focused its work on the world's poorest people, in the world's poorest countries. Millions of impoverished people die every year of conditions that are readily preventable or treatable. Technologies exist to avert millions of deaths due to malaria, TB, HIV/AIDS, diarrhoeal disease, respiratory infection, and other killers. These tragic deaths—and the enormous economic and social costs associated with them—reflect the basic fact that essential life-saving health services are out of reach of hundreds of millions of the world's poor. And yet, without extending these life-saving interventions, poverty is likely to be exacerbated and to be passed to the next generation. The economic costs of ill health, the Commission documented, are enormous and pervasive.

The findings of the Commission are both stark and also encouraging. It will take a lot of money and much more political and organizational effort than has been seen in the past generation to accomplish the tasks at hand. Curbing the HIV/AIDS pandemic, or the resurgence of tuberculosis and malaria, or major killers of children such as diarrhoeal disease and vaccine-preventable diseases, will not happen by itself. Yet the task is feasible, with breathtaking achievements possible. The Commission calculates that if the donor countries contribute around 0.1% of their GNP—one penny for every US\$ 10 of income—and if that effort is matched by a suitable increase in effort within the low-income countries themselves, it should prove possible to avert 8 million deaths per year by the end of this decade. As of 2007, the donor contribution would be around US\$ 27 billion per year, or roughly four times the current US\$ 6 billion in official development assistance for health. The reduction in human suffering would be

enormous. The economic gains would also be striking, around the order of US\$ 360 billion per year during the period 2015–2020, several times the costs of scaling up the health interventions themselves, counting both the donor and recipient country efforts.

To arrive at its conclusions, the Commission organized its research and intensive analysis mainly within six working groups, which in turn engaged the energies of a worldwide network of experts in public health, finance, and economics. Each working group held several meetings around the world, commissioned papers, debated alternative approaches, circulated drafts to the policy and scholarly community, and made detailed recommendations to the full Commission in the form of a Working Group Report. Working group members included CMH members, staff of various international agencies, and experts from governments, academic institutions, NGOs, and the private sector. The Working Group Reports, prepared by the working group co-chairs in consultation with the entire working group membership, are a synthesis of the commissioned background papers and the culmination of each working group's detailed review of the literature and intensive deliberations.

The Commission's findings are therefore based heavily on the crucial work of the six working groups, each of which was responsible for taking stock of the existing knowledge base on a particular topic in order to identify implications for policy and for extending that knowledge base as appropriate. The working groups, with their titles, topics, and chairs, are:

- Working Group 1, Health, Economic Growth, and Poverty Reduction, addressed the impact of health investments on poverty reduction and economic growth. Co-Chairs are Sir George Alleyne (Pan American Health Organization, USA) and Professor Daniel Cohen (Ecole normale supérieure, Paris, France).
- Working Group 2, Global Public Goods for Health, studied multi-country policies, programmes, and initiatives having a positive impact on health that extends beyond the borders of any specific country. Co-Chairs are Professor Richard G. A. Feachem (Global Fund to Fight AIDS, Tuberculosis, and Malaria, Geneva, Switzerland) and Professor Jeffrey D. Sachs (The Earth Institute at Columbia University, New York, USA).
- Working Group 3, Mobilization of Domestic Resources for Health, assessed the economic consequences of alternative approaches to resource mobilizations for health systems and interventions from domestic resources. Co-Chairs are Dr Alan Tait (former senior IMF

official) and Professor Kwesi Botchwey (The Earth Institute at Columbia University, New York, USA).

- Working Group 4, Health and the International Economy, examined trade in health services, health commodities, and health insurance; patents for medicines and trade-related intellectual property rights; international movements of risk factors; international migration of health workers; health conditions and health finance policies as rationales for protection; and other ways that trade may be affecting the health sector. The Chair of this working group is Dr Isher Judge Ahluwalia (School of Public Affairs, University of Maryland, College Park, USA).
- Working Group 5, Improving Health Outcomes of the Poor, examined the technical options, constraints, and costs for mounting a major global effort to improve the health of the poor dramatically by 2015. Co-Chairs for this working group are Dr Prabhat Jha (University of Toronto, Canada) and Professor Anne Mills (London School of Hygiene and Tropical Medicine, UK).
- Working Group 6, International Development Assistance and Health, reviewed health implications of development assistance policies including modalities relating to economic crisis and debt relief. It focused on the policies and approaches of international developmental agencies. One emphasis was on the appropriate balance between country-specific work and support for activities that address international externalities or provision of international public goods. The Co-Chairs are Mr Zephirin Diabre (United Nations Development Programme, USA), Mr Christopher Lovelace (World Bank, USA), and Ms Carin Norberg (Transparency International, Germany).

It is my great pleasure and honour to introduce *Health and the International Economy: The Report of Working Group 4 of the Commission on Macroeconomics and Health*, and to thank Dr Isher Judge Ahluwalia for this outstanding contribution to the work of the Commission. The Report places the challenge of health policy in low-income countries in the context of globalization. Globalization has many potential benefits for health in low-income countries—to the extent that it facilitates faster overall economic growth in those countries and the faster flow of technologies from rich to poor countries—but globalization also poses some enormous new challenges and threats. First, globalization may well speed up the already burdensome brain drain of skilled health-sector workers such as doctors and nurses from the poor countries to the rich countries. This

brain drain is often abetted by the specific policies of rich-country governments to attract doctors from regions suffering from great scarcities of trained personnel. Second, globalization may speed the transfer of skilled personnel from the public sector to the private sector within the poor countries, again exacerbating the scarcity of doctors and nurses available to attend to the needs of the very poor. Third, globalization could increase the spread of harmful technologies and behaviours from rich markets to poor markets, such as the increased flow of tobacco products to low-income populations who may be unaware of the risks or are not protected by needed public health education and by limitations on advertising and promotional activities of the tobacco industry. Fourth, the construction of a new global intellectual property rights system could threaten the availability of some life-saving drugs to the world's poorest people, by increasing the reach and duration of patent-protection to those drugs, with a result of raising market prices. These problems can be addressed through creative approaches, but they require policy attention and special action. For example, the Report recommends the development of a coherent international framework for *differential pricing* of essential medicines, so that patent protection in the high-income countries can continue to spur innovation while the drugs that are developed under patent protection can also be made available at low cost to the low-income countries. Such practical approaches can allow the low-income countries to reap the benefits of globalization while reducing or eliminating the possible significant harms.

The Commission, together with the working groups' co-chairs and members, gratefully acknowledges the financial and technical support provided by the donor community. In particular, thanks are due to the Bill and Melinda Gates Foundation, the Government of Ireland, the Government of Norway, the Government of Sweden, the Grand Duchy of Luxembourg, the Rockefeller Foundation, the United Kingdom Department for International Development, and the United Nations Foundation.

Jeffrey D. Sachs
Chair of the Commission on Macroeconomics and Health
August 2002

PREFACE

One of the most important developments in the last two decades is the increasing globalization and integration of the world economy. This process has had an impact on almost every aspect of human life. It is well recognized that although globalization has many potentially beneficial effects, it can also have adverse effects, which is a legitimate cause of concern. The Commission on Macroeconomics and Health set up Working Group 4, dealing with “Health and the International Economy”, to examine the impact of globalization and integration of the economies of the world on the health status of the populations of developing countries, particularly the poor in these countries.

Our Report focuses on some of the major issues that arise in this area. Trade liberalization and economic integration has led to a sharp increase in trade in health-related goods and services, amongst other goods and services, and this is likely to accelerate further. However, the successful exploitation of the opportunities to be found in exporting health-related services by setting up health centres of international standard on the part of some of the developing countries leads to a potential duality in which state-of-the-art health care facilities are created for the rich while the public health services actually deteriorate. This is partly because the emergence of high-quality private health care leads to neglect of the public health system in the form of underfunding and a migration of health care professionals from the public to the private system. We have suggested ways in which this problem could be tackled through public–private partnership in certain areas, and a larger and more effective role for the public sector in delivering health.

Another area of concern and importance relates to the strengthening of intellectual property rights. Although intellectual property rights provide incentives for research and development (R&D), which is crucial for making advances into the production of new and improved medicines, strengthening these rights in developing countries may have implications for the price and availability of medicines and other health products in developing countries. This creates a potential conflict between having improved medicines, through R&D encouraged by the patents regime, and providing affordable access to these improved medicines, especially for the poor in developing countries. The growing pandemic of AIDS in

the poor countries of the world has heightened the perception of this conflict. A related concern is the possible loss of access of developing countries to native resources and knowledge for producing traditional medicines, given the limited capability of developing countries legally to protect and commercially exploit plant genetic resources and traditional knowledge. We have examined these issues and suggested appropriate policy responses.

The Report also addresses the problems related to the brain drain of skilled health personnel from the developing countries to developed countries and the issues involved in a larger role for information technology (IT) in the delivery of health care for all and the associated concerns on the regulatory front. In both these areas, we have suggested some policy responses that may help to address genuine concerns.

The economics of health in developing countries, and its interaction with other economic developments, both domestic and international, has not received the attention it deserves; we are conscious that there is a dearth of detailed empirical studies on this subject. We have sought to overcome this limitation by involving experts from different fields. We are thankful to the writers of all the background papers for providing us with the appropriate material to enable us to focus our minds.

We are thankful to Jeffrey D. Sachs, Chair of the Commission on Macroeconomics and Health, for participating in the discussions of our Working Group and contributing to a better understanding of some of the very complex issues studied by us. I would also like to take this opportunity to convey my special gratitude to Jonathon Quick, Director, Essential Drugs and Medicines Policy Department, and his colleagues at the World Health Organization (WHO), without whose cooperation and collaboration we would not have been able to complete this task. John Barton and Keith Maskus deserve a special word of thanks for their contribution to the preparation of this report. I must also thank Rama Goyal at ICRIER for providing editorial assistance and other help in coordinating the work of our Working Group.

Isher Judge Ahluwalia
College Park, Maryland
August 2002

INTRODUCTION

The agreement reached at the conclusion of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) has expanded global opportunities for trade in goods and services, including health-related goods and services. However, the rules relating to the protection of intellectual property, such as patents on essential drugs, incorporated in the Trade-Related Aspects of Intellectual Property Rights (TRIPS) component of the Uruguay Round have raised hurdles for developing countries. The Working Group on Health and the International Economy (Working Group 4, or WG4) was assigned the task of studying the implications of these developments for health, particularly in developing countries.

The Group focused on two principal aspects of this relationship: (1) implications of the increasing liberalization of trade in health commodities and services, including health-related services such as insurance and health-related information technology (IT), and (2) the role of the intellectual property protection, as governed by the rules of the international trading system, in promoting or hindering access to essential medicines in the developing countries, particularly for their poor. This Report presents a synthesis of the tentative findings, based on the papers and background notes that were prepared for the Group and the discussion of the results amongst the members of WG4. The lists of papers and background notes are presented in Annexes 2 and 3, respectively.

The first three chapters are directed at exploring how governments in developing countries can take advantage of the emerging global opportunities through trade in health-related goods and services, while successfully mitigating the associated adverse effects. The subsequent four chapters analyse the impact of globalization and other factors on access to medicines. Chapter 1 presents the major trends in health-related trade. Chapter 2 discusses the principal issues concerning trade in health sector. Chapter 3 sets out the policy priorities and the areas for action. Chapter 4 analyses the effect of TRIPS on access to medicines. Chapter 5 presents the evidence on differential pricing. Chapter 6 spells out a number of options for achieving affordable prices, and Chapter 7 presents the recommendations of WG4 for improving access to essential medicines for the poor.

A central issue that features throughout the discussion in this Report is the tension between equity and efficiency, both static and dynamic. In

the context of health services, the key question that underlies much of the discussion is whether trade liberalization could have adverse distributional effects on the poor, and whether the long-run efficiency and resource gains from such liberalization could offset the short-run costs in terms of equity. In the context of access to medicines, the discussion highlights the conflict between dynamic efficiency arising from monopoly rights as an incentive to innovate and the need for equity arising from higher prices of medicines under a patent regime. The discussion outlines a number of redistributive and complementary policies for addressing the equity concerns, while also pointing out the political economy constraints to implementing such policies and recognizing that many of the distributional and equity issues would exist—and in fact do exist—even in the absence of trade and investment liberalization of health services or patents. Highlighting the need to address the underlying economic conditions that are at the root of this tradeoff between efficiency and equity, the Report outlines policies and priority areas for action.

I. KEY FEATURES AND TRENDS IN HEALTH-RELATED TRADE

The health care sector is among the most rapidly growing sectors in the world economy. The size of this sector is estimated at about US\$ 3 trillion in the Organisation for Economic Co-operation and Development (OECD) countries alone and is expected to rise to US\$ 4 trillion by 2005 (Zarilli and Kinnon, 1998: p. 55; UNCTAD, 1997).¹ Health and related services have become increasingly tradable due to a variety of economic, social, technological, and global institutional factors, although the sector is also subject to a wide range of tariff and nontariff protection for health-related commodities and inputs across developing countries (see Woodward, 2001; Simon et al., 2001). In recent years, there has been significant growth in trade and investment opportunities both within the health services sector and in related services, such as health insurance, across developed and developing economies.

The increased trade in health-related goods and services is reflected in the growing cross-border delivery of health services through the movement of health care providers and consumers and through and electronic means. The number of companies engaged in joint ventures and collaborative arrangements in the health sector has also grown. Other major aspects of globalization of health include the increased cross-border exchange and dissemination of information, education, and training in the health sector, and the growing presence of international companies offering private health insurance in overseas markets.

I.1 TRADE IN HEALTH SERVICES

The General Agreement on Trade in Services (GATS) characterizes services as being traded via four modes of supply: consumption abroad, movement of persons, commercial presence, and cross-border supply. These four modes also apply to the case of international trade in health services.

Trade through consumption abroad—that is, movement of patients to receive treatment in overseas markets—is driven by differences in cost, quality, and availability of treatment across countries as well as factors such as natural endowments; the availability of alternative or traditional medicines and treatment procedures; and cultural, linguistic, and geographic proximity between countries. For instance, patients from devel-

oped countries such as the United States and the United Kingdom get heart bypass surgeries or transplants in high-quality corporate and super-specialty hospitals in developing countries such as India at one-fourth or one-fifth of what it would cost them in their own countries (Zarilli and Kinnon, 1998: Chapter 13). There is also consumption abroad in health education and training services²—that is, there is also trade in health education and training services, whereby students from developing countries go to developed and other developing countries for medical education and training purposes.

Numerous studies have discussed the significance of cross-border movement of consumers in health services trade, particularly between neighbouring countries and within regional trading blocs, and the associated benefits in terms of cost, quality, and improved access to health services (see, for example, Chanda, 2001, for WG4; Warner, 1997; and Freeman and Frenk, eds., 1995). Rahman (2002) finds that an estimated 50 000 patients come from Bangladesh each year seeking treatment in Calcutta and other Indian cities, and that Bangladeshi patients spent some US\$ 1.4 million in India in 1998–1999, mostly for specialized treatment concerning heart diseases, cancer, and kidney diseases. Given the escalating health care costs and ageing populations in developed countries, and given also the likelihood of increased portability of health insurance following deregulation of the insurance sector in many countries, there is considerable scope for expanding consumption abroad in health services.

Health services are also traded via the movement of health personnel, including doctors, nurses, paramedics, technicians, consultants, health management personnel, and other skilled professionals. This movement, along with consumption abroad, constitutes the bulk of trade in health services today. Such flows have been abetted as well as discouraged by host and source countries through a variety of immigration and labour market regulations. The driving factors for such trade are two: first, low wages, poor working conditions, and low standards of living in source countries, where working conditions are so discouraging that health care workers leave such countries for better conditions in other countries that need health care services; and second, demand-supply imbalances in the health sector between home and host countries—that is, the normal motivation for trade. The majority of cross-border flows of health care providers are from developing to developed countries and between developing countries in some parts of the world. Chanda's background paper for WG4, as well as Zarilli and Kinnon (1998), Cohen (1997), and several earlier studies on migration have discussed the nature and extent of

these flows in the health care sector and the attendant benefits as well as concerns. Although the GATS framework addresses cross-border mobility of service providers, including health care professionals, under the movement of natural persons mode of supply, there is as yet little liberalization in this area.³

Because of the increasingly liberal attitude of countries towards foreign direct investment and towards collaboration with foreign companies in the form of joint ventures, alliances, and management tie-ups, the existence of commercial presence in the health sector has grown in importance. A commercial presence includes the establishment of health care facilities, including hospitals, clinics, diagnostic and treatment centres, and nursing homes in markets other than a country's own market. Many regional health care networks and chains have also been established in recent years following strategic alliances, mergers, and acquisitions in the health sector.⁴ This reflects a growing recognition of the significance of the commercial presence in health services for upgrading infrastructure and raising the standards and quality of health care and also for the emergence of new forms of business organization in this sector. There has also been some diversification of commercial presence into allied areas such as medical education and training as well as hospital administration and management. With mounting pressures on public resources in countries round the world, the commercial presence in health services is likely to become an important means of generating resources for supplementing public sector investment in health care.

Cross-border supply in health services occurs in the context of telemedicine or traditional cross-border delivery of medical samples and diagnosis. The importance of this means of trade has grown in recent years with advances in information and communication technologies. Several studies, including Chanda's background paper prepared for WG4 and the paper by Zarilli and Kinnon (1998), provide evidence on the provision of telediagnostic, telepathological, surveillance, and consultation services across health care establishments in different countries. Mathur's background paper for WG4 discusses the potential of IT for revolutionizing health care design and delivery by influencing wide-ranging aspects of health care, from the development of new medicines based on biotechnology to distance supervision of patients, from data collection and dissemination and the transfer of medical information and documents to the functioning of health insurance companies and health care administration. Recent reports by the US government and by Canadian business associations also highlight the growing significance of telehealth services and the

emerging opportunities for integrating information and communication technologies into health care delivery. In recent years, there is also growing recognition of the scope for outsourcing related services such as medical transcription and billing services to developing countries (see *The Economist*, 5 May 2001). With further advances in telecommunication technologies and declining costs of electronic delivery, the scope for trade in health and related services trade via cross-border supply is likely to increase.

1.2 TRADE IN HEALTH INSURANCE SERVICES

Investment opportunities and new technologies have expanded opportunities for trade in health insurance services, although there has been no substantial opening up under any agreed multilateral rules of GATS.

The bulk of trade in health insurance services occurs in the form of commercial presence or foreign direct investment whereby health insurance companies set up operations or make equity investments in other countries (see Mattoo, 1998). International companies are increasingly turning towards developing and emerging country economies for providing private health insurance to tap their profitable markets with their large uninsured populations. This trend is likely to grow. The rising incomes in these economies, particularly for some segments of the population, create an effective demand for private insurance. The glaring inadequacies of the existing public health systems further create demand for private health care and private health insurance even among those segments of population where normally such insurance would not be affordable. These developments have increased the overall availability of health care facilities, and to some extent, reduced pressure on publicly owned facilities, while they may have at the same time contributed to the emergence of dual market structures in these economies.

It is important to recognize that the privatization of health insurance is a part of the process of liberalization in developing countries in their quest for faster growth and integration into an increasingly interdependent global economy. The globalization of health insurance services is also likely to receive an impetus from liberalization commitments in this sector under the World Trade Organization (WTO) negotiations on services, although, to date, there is no evidence of the WTO's catalytic role in this regard, as pointed out by Lipson's background note for WG4.

The emergence of private health care services in developing countries is, in part, a response to the poor state of public health care services. The latter in turn is due partly to the overall resource constraints of the gov-

ernments in developing countries and a lack of political commitment to invest in health, and partly to their dual inability to (1) control the inefficiencies and rising costs of operating public health systems, and (2) charge users what it costs to provide these services. The introduction and expansion of private health insurance is in turn linked to growth in private health care. The degree of private insurance depends on the state of the national health care system, market opportunities, the extent of market access permitted for private health insurance companies, and the regulatory environment.

In addition to direct trade in health insurance services, there are also emerging forms of trade in areas related to health insurance, such as in claims processing and health insurance-related administrative services, which are being increasingly delivered across countries via the Internet. Overall, growing trade and foreign direct investment in health insurance services reflects the privatization and deregulation of health care and health care financing around the world.

1.3 TRADE IN EMERGING AREAS FOR HEALTH AND RELATED SERVICES

More recently, trade and foreign direct investment have grown in health-related educational services, where trade is taking the form of commercial presence, electronic delivery, consumption abroad, and movement of professionals. Joint ventures and alliances are being formed between medical schools, universities, and training institutions across countries. Several primarily developed countries, such as Australia and New Zealand, are undertaking major initiatives to attract medical students from developing countries. With advances in information and communication technology, there is also considerable scope for cross-border distance education in the health sector. Mathur's background paper for WG4 discusses emerging trends and opportunities in e-business in health care delivery and administration. These include the use of IT for risk assessment and trade in health care databases by health insurance companies.

Another important emerging area is that of home-based health care services, including assisted living care for disabled and elderly individuals and services for persons with chronic health conditions or those recovering from surgical procedures. Given the percentage of ageing population in the developed world, this is one of the fastest growing areas of trade. Royall (2000) notes additional opportunities in areas such as distance consulting, particularly in specialty care, traditional healing and alternative medicines, spa and rehabilitation services, and health tourism. Wilder's

background paper for WG4 points to opportunities for increased trade in complementary or alternative medicinal and herbal products. Other emerging areas for globalization in health-related services include database and information dissemination services; clinical, investigation, diagnostic, and specialized services; and consulting services associated with maintenance and management of health care delivery.

2. MAJOR ISSUES CONCERNING TRADE IN THE HEALTH SECTOR

The liberalization of trade in health-related goods and services raises certain concerns that essentially centre around five major issues:

1. implications for public–private balance in health care;
2. implications of health insurance liberalization;
3. implications for availability and allocation of human resources, including issues such as brain drain, capacity building, training, and technical expertise;
4. regulatory issues and concerns, both domestic and international; and
5. other apprehensions about globalization.

Each of these issues is important in assessing the potential tradeoff between medium-term developmental and social objectives, on the one hand, and immediate opportunities for breaking the vicious circle of poverty and poor health, on the other, and for understanding the ways in which these considerations can be addressed. In the discussion of each of these issues, the conflict between short-run equity considerations and long-run efficiency gains emerges clearly. This Report attempts to identify appropriate policies that can minimize costs of managing the tradeoff and help maintain a balance between these competing objectives.

2.1 IMPLICATIONS FOR PUBLIC–PRIVATE BALANCE IN HEALTH CARE

Globalization of the health sector through increased trade and investment flows in health care provision as well as financing is likely to affect the very structure and composition of services in the health sector. In particular, by expanding the scope for profits through trade and investment opportunities, increased trade has the potential of shifting the focus of health care services in developing countries towards the rich and foreign patients and aggravating the existing dualism that exists between the public and private health care segments in these countries. For instance, trade in health services in the form of consumption abroad could result in the creation of a higher-quality, expensive segment that caters to wealthy nationals and foreigners alongside a low-quality, resource-constrained segment catering to the poor. It is arguable whether this is likely to lead to diversion of resources from public health care towards this sector or to greater focus in the public health system on providing services for the

poor. There is also the problem of skilled human resources being attracted away by the private sector and the concomitant problem of increased costs for those resources in both the private and public sectors. Janjaroen and Supakankunti (2000) cite evidence from Thailand where corporatization of the health sector and its opening up to foreign direct investment have led to outflows of professionals from the public health care system to the private sector, with the consequent adverse effect on the distribution of human resources between urban and rural regions. Similar concerns about liberalization of trade and investment contributing to dualism in the health sector have been voiced in other developing countries, such as India and Bangladesh.

In the context of IT and its role in health care, Mathur's background paper prepared for WG4 notes the possible diversion of scarce resources in less-developed countries to private investments in IT. The study also indicates that the use of IT in health care could raise the costs of health care delivery, which may not be commensurate with the associated benefits, thus adversely affecting equity and distributional objectives.

The question of public-private imbalance, however, needs to be analysed in the context of the current reality in many developing countries where deteriorating public health systems have forced people, including the lower income and needy sections of the population, to move to private health clinics and hospitals. The public sector is typically left with the most difficult cases in terms of health and incomes, while its capacity to attend to basic diseases and public health problems is limited by its inability to generate or attract resources. Thus, it is important to recognize that fundamental problems of inadequate resource allocation and the failure to accord due importance to the public health sector are the root cause of the public-private imbalance, and not liberalization of trade in health services *per se*.

2.2 IMPLICATIONS OF HEALTH INSURANCE LIBERALIZATION

Private health insurance can provide an alternative to out-of-pocket payments for health care services. This may help improve access to health services by alleviating short-term financial and liquidity constraints. Privatization of health insurance could result in a greater focus on the quality of services provided by health care establishments and service providers, thereby potentially encouraging investments by hospitals to upgrade the quality of their human and physical resources and indirectly helping to retain health care professionals in the country. Cross-border investment and ownership by private insurance companies can also help

in expanding the choice of providers and services both within the country and abroad. It is important to note, however, that insurance markets in general, as well as insurance for health care services, are subject to asymmetric information problems with resultant moral hazard and adverse selection effects. The potential for market failure in private health insurance markets therefore needs to be recognized.

Sbarbaro's background paper for WG4 highlights these concerns with respect to the privatization of health insurance services, particularly in developing countries where economic and social conditions and health characteristics may not be conducive to profit-oriented insurance programmes. For example, a private health insurance company is more likely to prefer healthy individuals with low health costs to those suffering from "pre-existing" disease conditions and major public health problems such as AIDS, malaria, and tuberculosis, so as to keep their premiums low and competitive. Moreover, since income tends to be negatively correlated with the incidence of disease and illnesses, private health insurance may not cater to the needs of those most affected, for example, by the 10 major diseases of the poor as identified by the World Health Organization (WHO). There are also limits to how far the fee-for-service type of private health insurance schemes can provide solutions for addressing the overall health needs of a large section of the population in developing countries, given their large number of sick, unemployed, and poor persons, and the limited scope for cross-subsidization between rich and poor patients. However, once again, these issues reflect problems that are inherent to health insurance markets, which may take on greater importance, and adapt more workable solutions, with the globalization of health insurance services.

It is clear that the overall effect of the liberalization of health insurance would depend on country-specific characteristics such as the extent to which there is a well-functioning public health system, the extent to which resources are allocated for public health needs, the prioritization of investments in the health sector, and other general economic and social factors.

2.3 IMPLICATIONS FOR AVAILABILITY AND ALLOCATION OF HUMAN RESOURCES

Since the health sector is highly human-capital intensive, the impact of the opening up of this sector on the quality and availability of human resources is a matter of concern. The possibility of "brain drain" usually dominates such concern. The concern is restricted not only to doctors and

nurses, but also to other professionals such as engineers and computer scientists. Nonetheless, because the health sector deals with human physical well-being, this concern is more pressing in the field of public health than in other fields. A large number of health care professionals emigrate from countries such as Egypt, India, Pakistan, and South Africa to the developed world, leaving their national health systems with considerable shortages of skill and providing little or no return for the large human capital investments made in these individuals by the system of public-sector education.

When cross-border movement of health care providers is of a permanent nature, it represents a drain of the best and the brightest from the country. A recent study by Bettcher, Yach, and Guindon (2000) and earlier studies dating back to the 1970s have argued that the direct and indirect costs of brain drain are likely to be only partially offset by macroeconomic benefits such as increased foreign remittances from health care professionals working abroad. It is important to note, however, that in a more wired and connected world and with growing potential for tapping overseas networks of expatriates, the resulting loss of human capital and associated positive externalities for the source country may be less. Moreover, it is important to recognize that the underlying reason for such outflows is not trade liberalization in health services but low wages, poor working conditions, inadequate standards, and insufficient investment in the health sector, which characterize most developing countries. In fact, in an increasingly integrated world, the positive contributions of such outflows are likely to be enhanced. Nonetheless, such skilled migration will place increasing pressure on the budgets of public health systems, which must increasingly compete not only with domestic but also foreign private systems.

Increased exports of health services could have a beneficial effect on the quality of a country's human resources in the health sector by helping its professionals to upgrade their skills and get increased exposure through cross-border delivery of their services, or enabling them to work with improved facilities and equipment in the case of commercial presence. The higher private returns to health care qualifications arising from opening up the health sector could also induce greater investment in the training of health care professionals and thus augment supply, similar to the case of IT professionals in recent years (see Chanda, 2002).

Thus, in terms of capacity building, improving technical expertise, enhancing access to the latest advances in medical science, and improving the dissemination of information and medical practices, expansion of

trade and investment opportunities in health can have a significant positive impact on human capital accumulation, and thus on standards and efficiency levels in this sector. The enhanced scope for such gains could also help in the retention of valuable skills and professionals in the country by reducing incentives for migration.

For importing countries, inflows of foreign health care providers can play a very important role in alleviating human resource constraints and addressing problems of technical expertise and capacity in the health sector. Zarilli and Kinnon (1998) provide examples of various developing countries, such as Mauritania and Mozambique, that have used short-term inflows of health care providers and collaborative arrangements with health care establishments in other countries to augment their supply of human resources in this sector.

2.4 REGULATORY ISSUES AND CONCERNS

There are numerous regulatory concerns associated with opening up the health sector. For instance, there are regulatory issues arising from the integration of information technology in health services. These include the recognition of professional credentials in the context of telehealth services, the treatment of malpractice insurance and cross-border payment arrangements for telemedicine services, and the protection of patient confidentiality and privacy in the course of health services rendered over the Internet, as discussed in Chanda's background paper for WG4. Mathur's WG4 background paper highlights the issues relating to data protection, privacy, remote liability, and intellectual property rights in the context of IT and health care.

Other important regulatory concerns relate to mutual recognition of medical training and qualifications across countries and establishing equivalence of standards across countries, such that public policy concerns are addressed while also facilitating trade in health services. Similarly, there are regulatory issues pertaining to the use of technical standards and technical barriers to trade on health products and interventions, which are not motivated by protectionism but by concerns for public health and safety.

2.5 OTHER APPREHENSIONS ABOUT GLOBALIZATION

Among the major direct risks of globalization is the spread of infectious diseases and food-borne health problems due to increased cross-border mobility of individuals and increased trade in food and agricultural products, respectively. Today, bacteria and viruses spread so quickly around the

world that boundaries between domestic and international health problems are blurred. The spread of diseases such as AIDS, tuberculosis, pneumonic plague, and influenza and, more generally, the spread of communicable diseases through human and other sources of transmission has no doubt been facilitated by various aspects of globalization, including increased travel across countries, falling transport costs and ease of travel, and trends such as sex tourism, migration, and expansion in commodity trade (see Diaz-Bonilla, Babinard, and Pinstrup-Andersen, 2001).

Globalization has enabled tobacco companies to realize greater market penetration through trade and investment and to target newly industrialized economies. The background note prepared by Bettcher et al. (2001) finds evidence of a significant and positive impact of tariff reduction on trade in tobacco products and more generally of increased openness to trade on cigarette and tobacco consumption, particularly in low-income countries. It suggests that trade liberalization in unmanufactured tobacco under the WTO Agreement on Agriculture or in the context of various regional trading agreements is likely only to fuel an increase in tobacco use with detrimental effects, such as increased incidence of lung cancer and tuberculosis and other public health problems that are well recognized. An added problem is the use of the Internet by tobacco retailers for online advertising and sales. The Internet provides the tobacco industry with a very useful and highly unregulated medium to introduce innovative marketing strategies. A significant rise in Internet-related advertising expenditures by the tobacco industry in recent years is indicated by a number of studies (see Bettcher et al., 2001).

Apart from the direct implications for public health, the spread of global bad practices such as tobacco use also have indirect negative effects, for example, costs to the economy's long-term growth potential by reducing the productivity of its stock of human capital and the health status of its population.

More generally, globalization, through greater integration of different economies, provides opportunities for mitigating the effects of domestic shocks. Greater integration, however, can also make countries more vulnerable to external shocks, given their domestic structural weaknesses. This increased vulnerability has adverse consequences for their economies and for resources available for investment in the health sector. Financial crises in developing countries such as Brazil, Indonesia, and Mexico not only disrupted their economies but also adversely affected public health budgets and private capacity to pay for health care as incomes were lowered (although these crises stemmed from domestic weaknesses in their

financial sectors and not external integration *per se*). The background paper by Diaz-Bonilla, Babinard, and Pinstруп-Andersen prepared for WG4 highlights the case of Indonesia, which has witnessed a significant deterioration in its nutritional and health indicators following the Asian crisis.

3. POLICY PRIORITIES

It is evident from the preceding discussion that policies, institutional frameworks, and regulations at the national and international levels are critical for harnessing the benefits arising from the opening up of the health sector. There are four broad areas where policy action is required:

1. investing in health with improved priorities,
2. building regulatory and institutional capacity,
3. rules on cross-border movement of health care providers, and
4. data collection and research on the health sector.

3.1 INVESTING IN HEALTH WITH IMPROVED PRIORITIES

A basic problem characterizing the health sector in almost all developing countries is inadequate allocation of resources as well as the inefficient and inappropriate use of the resources that are invested. WHO's *World health report* (2000) provides evidence of the inadequacy of expenditures in health care for countries such as India and Indonesia and highlights the problems of inequity, dualism, and internal brain drain that are likely to be aggravated when trade and investment liberalization occur in a resource-constrained and underinvested health sector, without adequate precautionary steps.⁵ Evidence from many developing countries further indicates that there is misuse and leakage of resources allocated to the health sector because of the lack of regulatory and institutional capacity in monitoring the use of these resources.

Given the hard budget constraints and the competing claims on resources faced by most developing country governments, it would be difficult to increase investment in the health sector unless resources are augmented. For this purpose, governments need to tap various possibilities for revenue generation. Wasserman and Cornejo (1994) highlight the experience of countries such as Chile and Cuba, which have focused on niche areas such as traditional medicines and alternative procedures of treatment, or combined the provision of health care with other services such as tourism and rehabilitation. The revenue generated by such strategies can be channelled back to the public health system for investment, provided of course that such linkage mechanisms are created. Wilder's background paper prepared for WG4 focused on the protection of traditional medicine as a mechanism for creating wealth—or transferring wealth—to the hold-

ers of knowledge concerning traditional medicine. In countries that do not have the scope for such revenue generation or where the resources generated by these means are likely to be grossly insufficient relative to the investment needs of the health sector, there is no avoiding the need to reallocate resources away from other sectors. Multilateral lending to the health sector would also have to play an important role in supplementing national resources in these countries.

Underinvestment in health is typically associated with poor prioritization of expenditures on the health sector. Thus, a large part of the expenditure is directed to salaries with very little for medicines and drugs. Also, most developing countries overinvest in the training of specialists and medical graduates and underinvest in the training of nurses, generalists, technicians, and primary health care practitioners.⁶

In most developing countries, an important priority would be to increase the number of hospitals, dispensaries, and beds, and to provide adequate funds for medicines. Linkages can be created between the public and private health care segments, such as by requiring free or subsidized beds for poor patients in private hospitals or by encouraging greater professional exchange, greater cooperation in the use of facilities, and collaboration in research and training between the two segments.⁷ Such linkages would help in reducing the imbalance between the public and private health care sectors in terms of the quality and availability of resources, and thereby also help in stemming the brain drain from the public sector to the private. An important development in this context is the growing number of public–private partnerships that are being formed at an international level for financing of research and development of drugs. Governments need to adopt measures to encourage such partnerships at the national level as well.

Greater synergy is required in policy making with other areas that have a bearing on the development of the health sector and on its prospects for trade and investment. For instance, to the extent that governments promote exports of health services in the form of consumption abroad, be it to earn foreign exchange or to upgrade infrastructure, their insurance sector policies and objectives will need to complement this export orientation by enabling portability of insurance.⁸ Similarly, investment in the health sector has to be supported by policies concerning medical and paramedical education and training, including the establishment of centres for education and training, the allotment of seats across specializations and professions within the sector, and the enforcement of uniform standards of training within the country. Likewise, a country's

telecommunication policy can have a major bearing on the tradability of health services via the Internet and outsourcing prospects in this sector. Synergy is required with policies in a variety of other areas, including immigration and labour market policies, policies governing professional associations, and standardization and certification procedures for practitioners and establishments, among others.

3.2 BUILDING REGULATORY AND INSTITUTIONAL CAPACITY

An important area for regulatory action is the enforcement of adequate standards of training and qualification and establishment of common certification requirements for professionals in the health sector. Many developing countries have very disparate standards across different regions and institutions within the country. Professional bodies need to play a more active role in weeding out institutions of low quality, monitoring training institutions, and introducing common exams and syllabi across institutions. Similarly, regulations are required to ensure minimum standards of treatment and quality in public and private health care establishments. There is need not only for strict registration and standardization requirements, but also for effective monitoring, perhaps with international assistance from agencies such as WHO.

On some regulatory issues, discussions are required at a multilateral level to establish appropriate regulatory frameworks. For instance, in the case of telehealth services, international regulations are required to deal with malpractice, payment arrangements, and patient privacy concerns. These issues need to be addressed in the GATS negotiations in health services and e-commerce. Likewise, international regulations are required to help establish an equivalence of standards across countries and mutual recognition of qualifications. Again, such issues need to be addressed in the GATS negotiations on professional services and cross-border mobility of labour (see Section 3.3). Developing countries need to participate more actively in the development of these international regulations and standards to ensure that they do not reflect the concerns of developed countries only.

Regulations pertaining to health warnings for tobacco products and consumer safety need to be strengthened. It is important to note, however, that taxes on tobacco products are a major source of revenue in many developing countries, and the measures to restrict consumption and sales of such products will have adverse implications for government revenue. There is also need to regulate smuggling of cigarettes and tobacco products. Given the increased use of the Internet in cigarette sales and market-

ing by tobacco companies, national regulatory controls on Internet access and content or government filters to control the use of cyberspace for advertising and sales of tobacco products may be warranted. In addition, international legal agreements on e-commerce in products that are “global public bads” may be important in controlling the dissemination of tobacco products.

Recent efforts at negotiating a Framework Convention on Tobacco Control (FCTC) and related protocols are an important regulatory step at the international level.⁹ This convention will consist of a variety of legal agreements aimed at eventually establishing a general system of governance for tobacco trade, use, and sales (see Bettcher et al., 2001). The FCTC and its protocols will be legally binding on those states that adopt and ratify these agreements once they enter into force. The convention is intended as a global regulatory complement to national and local actions to control tobacco use, and it is expected to facilitate international commitments on tobacco control and harmonization of national policies in this area. This international treaty will also include mechanisms designed to enhance the technical capacity of poor countries in developing tobacco control programmes and strengthening their implementation. Within this framework, however, the issues of illicit trade and Internet-based trade in tobacco products are likely to pose major challenges and will require a concerted regulatory effort at the international level.

The need for an effective regulatory framework for health insurance is well recognized. The World Health Organization will need to play an important supporting role in helping governments of developing countries introduce and enforce regulation on health insurance. As highlighted in Lipson’s background note for WG4, such support would include assistance in identifying and evaluating the infrastructure and financing of current health care systems; in assessing alternate private health insurance models and their impact on the health care system; in the licensing of private health insurance companies, including requirements for adequate financing/reinsurance; and in designing the structure of benefits, effective customer appeals processes, integration, and cooperation with government-supported public health and preventive services, and also in designing appropriate taxation policies. In this context, improved coordination between national health, trade, and insurance officials will be necessary.

3.3 RULES ON CROSS-BORDER MOVEMENT OF HEALTH CARE PROVIDERS

To address the problem of brain drain, countries have used negative incentives in the form of migration taxes, recovery of training costs, and delays in certification to control outflows in the health sector. Governments have also made use of positive incentives in the form of tax deductions, exemptions, and measures to improve working conditions so as to both retain and attract human capital in the health sector.¹⁰ Such unilateral policy responses at the national level are not enough, however, as is recognized in Bhagwati's brain drain tax proposal (see Bhagwati, 1997). There is need for coordinated effort between host and source countries to regulate cross-border flows of health service providers. There is also need for broad multilateral agreement on cross-border movement of labour under the WTO framework.

The GATS treats cross-border movement of service providers as one of four modes of trade in services on which countries can make commitments, both within a particular service sector and horizontally across different service sectors. The GATS framework and negotiations provide countries with an opportunity to facilitate and control the movement of service providers in keeping with their national interests and objectives.

Specific commitments made by countries in health services under the GATS, as well as GATS provisions pertaining to the movement of service providers, have to strike a balance between trade objectives, on the one hand, and public interest concerns, on the other. The commitments and provisions should encourage trade in health services through cross-border movement of health care providers while also establishing mechanisms to ensure that this movement is temporary.

One proposal that has been made in this context is that of creating a separate visa category, such as a GATS visa, which would be distinct from the usual immigration visa categories. This visa would be granted to service providers deputed abroad by their employers or those going abroad in an independent capacity, as is likely to be the case in the health sector, in accordance with the terms and conditions listed in the commitment schedule of the receiving country, for a particular sector and type of professional. This visa could be granted more easily without the usual problems of nontransparency and discretion that characterize immigration procedures, thus enabling countries to export human capital and earn foreign exchange in this sector. At the same time, there would be in-built mechanisms to prevent this visa from being used for permanent entry into the host country's labour market, as it would be distinct from other visas that

can translate into permanent residency and citizenship in the host country. The introduction of such a multilateral visa would require considerable cooperation and agreement among countries to review and change their immigration policies and procedures. Chanda's background paper prepared for WG4 discusses in detail the possible features of such a visa and the gains that it would make available.

The GATS framework also contains a number of provisions that, if strengthened, could play an important role in shaping cross-border flows of service providers and in mitigating some of the associated adverse effects of such flows in sectors such as health. For instance, GATS disciplines on domestic regulation require member country policies that have bearing on their liberalization commitments under GATS to be administered in a transparent and reasonable manner. However, labour market policies, such as economic needs tests and manpower planning requirements that are used by many governments to regulate the entry of foreign health care providers, are often highly nontransparent and without clear criteria on their use and administration. Thus, by establishing stricter norms on the use of regulations such as needs-based tests, GATS can facilitate the opening up of the health sector. Likewise, GATS can play a very important role by establishing international norms for the recognition of professional qualifications and standards. Recognition and certification requirements constitute a major impediment to trade in health services through movement of service providers, consumption abroad, and to some extent also telemedicine.

3.4 DATA COLLECTION AND RESEARCH ON THE HEALTH SECTOR

There is pressing need to improve data on the health sector, in particular on the nature and extent of trade and investment transactions in this sector. Much of current analysis on the effects of liberalization in the health sector is qualitative in nature, based mainly on experiences of particular countries, and that too frequently is anecdotal rather than based on hard data.

There is need for greater cooperation among professional associations; Ministries of Health and Ministries of Commerce; and multilateral agencies such as the United Nations (UN), WHO, WTO, the International Monetary Fund (IMF), and the World Bank to develop a comprehensive and systematic way of collecting data in the health sector, a way that also covers all four modes of supply. The first step would be to identify the sources and nature of the trade and investment data on the health sector, to identify the modes of supply that are most amenable to data collection

and improvement given the existing resource constraints, and to identify the remaining gaps in information.

There are very few in-depth case studies of the experience of individual countries following the opening up of their health sectors on cost and availability of health care.¹¹ More work is needed at the national and international levels to take stock of individual and cross-country experience to identify areas where there are clear prescriptions for policy and those where there is need for further research.

The background note for WG4 by Woodward et al. highlights the need for a full health impact assessment of international agreements and measures, whether direct or indirect, and the need to develop a conceptual framework within which the globalization of the health sector can be analysed, supported by empirical evidence.¹² Wilder's background paper prepared for WG4 draws attention to the special or differential needs of traditional—in particular indigenous—peoples with respect to basic health factors such as congenital conditions, dietary requirements and sensitivities, and resistance or susceptibility to particular contagious diseases. Mathur's background paper for WG4 points out the need for improved documentation and data on the use of IT in health care so as to permit a rigorous cost–benefit analysis in this area.

4. GLOBALIZATION AND ACCESS TO MEDICINES

4.1 DEFINITIONS AND CONCERNS ABOUT ACCESS

The term *access* has a supply as well as a demand dimension. It connotes first the supply of essential medicines, which has both a static context, referring to difficulties in distributing existing drugs, and a dynamic context, referring to how systemic features affect incentives to develop new drugs. The term *access* connotes also the demand for essential medicines, which depends on factors such as incomes, finance, and price. Demand patterns are also both static and dynamic. Overall, then, where consumption levels are insufficient to prevent or treat diseases adequately, as is common in the low-income developing countries, policies need to address both the willingness to supply drugs and the ability of patients and health systems to procure them. This prescription applies both to existing medicines and to vaccines and drugs to be developed in the future.

Access problems are often domestic in scope, but international trade and trade rules have potentially important effects as well. On the positive side, drug imports can provide a lower-cost source of supply, whether the drugs are from original manufacturers or foreign generics producers. In this regard, formal and informal import restraints, including tariffs, quotas, and monopoly distributorships, interfere with attaining adequate supplies of medicines at reasonable cost. Barriers to inward foreign direct investment (FDI) in the medicines sector can also restrain competition. Moreover, reducing trade impediments expands global markets, thus providing incentives for more development of new drugs. Imports and FDI can also provide additional technology transfer in health provision, particularly if they are accompanied by liberalization and improvement of health services.

Concern about trade stems from the potential exercise of market power that is supported by the protection of intellectual property through patents. The rules of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) at the WTO require all Member Countries to recognize product patents on new drugs by 1 January 2006, though under Article 66.1 this transitional period may be extended under application to the TRIPS Council. This means that Member Countries that

did not protect products with patents must do so. Further, countries that are not yet awarding patents must accept patent applications (pending their later examination with a priority claim) and award exclusive marketing rights during the transition period to drugs approved for sale. The issue of transition periods was discussed at the WTO Ministerial Meeting in Doha in November 2001. In the Declaration on the TRIPS Agreement and Public Health, WTO Ministers agreed that Least-Developed Countries (LDCs) would not be obliged to provide patent or trade secret protection with respect to pharmaceutical products until 1 January 2016. Even after that, such LDCs would still be able to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement.

Patents provide important incentives to develop and market new drugs, at least where demand is sufficient. However, because TRIPS will extend patent coverage to new markets and extend its length in many markets,¹³ the onset of generic competition for patentable new treatments will be delayed, tending to raise prices for such drugs. Similarly, patents raise the leverage of pharmaceutical firms in negotiating with public health agencies over procurement prices, raising concerns about public health budgets. Accordingly, the affordability of newly developed vaccines and drugs is an important issue towards which this Report is partly aimed.

Another potential impact of international trade is to tend to cause prices to converge across countries in areas where markets are linked by parallel trade (trade in patented or trademarked drugs without authorization of the manufacturer). To the extent this is true, it is costly for poor countries where prices might be expected to be lowest because of their demand characteristics. Also important is the regulatory practice of reference pricing, in which governments set prices with pharmaceutical suppliers on the basis of price indices computed from foreign rates. This policy encourages firms to set high prices in low-income economies.

4.2 FACTORS AFFECTING ACCESS TO MEDICINES

Several interrelated factors contribute to the shortfall of available medicines relative to the need in poor countries. Each factor requires attention by policy-makers, for failure of any of them endangers patients' access to the necessary medicines.

4.2.1 *Incomes and sustainable financing*

Poverty lies at the root of access problems. Impoverished families may forego medical treatment in favour of other needs. Extensive informal

employment limits the development of private insurance markets that can pool health risks across large patient volumes of employees, although typically in these economies only a small proportion of the labour force is employed for regular wages and salaries. The development of wider tax bases, effective insurance markets, and higher effective demand for health care associated with income growth is years (or generations) away in the low-income developing countries. Without question, these countries need to receive large and sustainable infusions of external funds in order to have any hope of addressing their chronic health problems.

Working Group 4 heard from numerous institutions and nongovernmental organizations (NGOs) about innovative and effective drug donation programmes aimed at specific diseases. As welcome as these programmes are, it is unlikely that drug donations can be sufficient on their own to address the problem, given its multiple dimensions.

4.2.2 *Adequate and reliable health care delivery systems*

In many poor nations, there is a chronic shortage of clinics, hospitals, medical personnel, and means for transporting patients to those facilities that do exist. In part, the inability to spend on health programmes is the result of chronically limited budgets, constrained by other fiscal needs. In part, it reflects the policy of placing relatively little emphasis on social programmes, including health. The resource constraint is compounded by the government's unwillingness and inability to levy user charges to cover even the operational costs of providing health care services through the public health system. Indigenous and other traditional communities may be isolated and excluded from existing health care delivery systems by factors such as geography, language, and historical patterns of mistrust and discrimination, as well as by differences in beliefs about disease and appropriate modes of healing.

The result is inadequate provision of all forms of health care, including very little funding for drug procurement. For example, few low-income economies come close to meeting the standard set out in the *World health report 2000*, which stipulates that governments should purchase "priority interventions", including essential drugs, for the entire population. The resource constraint results not only in weak delivery and care systems but also in inadequate staffing and expertise at health agencies, which in turn imply longer-than-necessary approval periods for drugs entering the market. At the same time, drug safety and quality may be compromised by inadequate testing and monitoring programmes. The health needs of the country, on the other hand, demand that effective

guidelines and mechanisms for allocating scarce health resources, including purchases and prescriptions of drugs, should be based on a rational determination of the country's needs, drug costs, and other factors.

It should be noted that, despite these problems, there are important differences among poor nations in ensuring access to essential medicines. For example, WHO data show that approximately 20% of populations in Angola and Burundi have access to essential drugs, but Côte d'Ivoire and Gambia claim access figures over 80%. It is important to explore these differences through attempting in-depth case studies of these countries' health systems and policies.

4.2.3 *Affordable prices*

As discussed below, it is only weakly true that average wholesale drug prices tend to be lower in developing countries than in developed countries. Indeed, prices are often at least as high in developing economies, while incomes are much lower, thereby reducing patients' access to drugs through unaffordable prices. More studies of international price variations would provide valuable information, as at present our evidence is mixed and rudimentary. There is little systematic evidence on differences in retail prices. However, some studies indicate that such retail prices are often higher in low-income countries, while Scherer and Watal's background paper for WG4 found—at least in for the sample of HIV anti-retrovirals studied—that the “preponderant impression is one of much randomness among prices charged in low- and moderate-income nations relative to those quoted in the United States”.

There are several reasons why high drug prices may be sustained in developing countries. First, tariffs, taxes, and monopoly distribution channels may keep the costs of medicines and other treatments artificially high. In his WG4 background paper, Bale reports that average tariffs on active ingredients and medicaments in many poor countries ranged from 8.5 to 31% in the late 1990s, though numerous other nations had reduced their tariffs to 3% or lower. Second, governments may lack the capacity to negotiate significant price discounts with pharmaceutical firms, which is common in the regulatory structures of rich nations. Small countries in particular may not have sufficient potential demand, even if mediated through the public sector, to achieve favourable price discounts. Third, private insurance markets are thin or nonexistent, implying that insurance providers are not able to negotiate price discounts. (It should be noted that insurance firms may not achieve price cuts in some market circumstances. If they operate in a way that absolves patients from paying some price-

related co-payments, they could make demand less elastic and end up raising procurement prices.) Indeed, in many developing countries the majority of patients are not covered by either public or private health insurance, forcing them to absorb medical costs, including drug purchases, into their family budgets. In some cases, drug costs dominate household health care spending. For example, in Burkina Faso in 1995, 85% of household health spending went for drugs.

It is important to note that the delivery, funding, and pricing factors just discussed pertain to all drugs, whether they are on patent or off patent. The emphasis often placed in the public debate on the role of patents may be distracting from the larger issues of limited health delivery, inadequate funding, weak regulation, and insurance markets that would exist even in the absence of patents.

Nonetheless, patent protection can sustain elevated prices for a period of time by delaying and limiting the extent of generic competition (see Maskus, 2000a). This proposition does not apply to all patented drugs in all countries, for it is possible in many cases to develop drugs, albeit at potentially high cost, that offer similar therapeutic benefits without violating claims in the original patent. Therapeutic competition is an important moderating factor in drug prices. However, for those products without therapeutic substitutes and facing high demand, patents may support prices well in excess of marginal production and distribution costs. Another reason that some countries may not face substantial price hikes is that they can manufacture or import generic drugs because potential patent owners choose not to apply for patent protection in a given nation.¹⁴

In thinking about patents, some important institutional facts should be kept in mind. First, many developing countries had legislation providing product patents in pharmaceuticals in place before the TRIPS Agreement became effective for them. Thus, if firms were choosing not to patent drugs in certain low-income countries, the TRIPS Agreement should make little difference in that decision in the future. For other countries,¹⁵ the requirement to provide product patents under the TRIPS Agreement rules cannot cause products that already existed on their markets to be patented. At present, nearly all WTO members have implemented product patents for pharmaceuticals in any case.

Under these circumstances, as patents are applied for and granted in the future, it is likely that the onset of generic production will be slowed in places where it had been active. Note that generic competition will remain legally unrestricted in those countries where pharmaceutical firms

choose not to apply for patents. However, effectively such competition is nonexistent in most low-income countries as these countries do not have domestic capabilities for producing these drugs, though imports can serve this role. Moreover, pharmaceutical markets in countries that heretofore had seen sharp competition among numerous producers of drugs that were copies of drugs patented abroad are likely to become more concentrated and less competitive.¹⁶ One way of ensuring generic competition in low-income countries with no capacity to produce is to allow the few countries with such capabilities to supply these markets through exports under licensing arrangement. The key issue for health policy is to find mechanisms for ensuring that prices become and remain affordable in the environment of the TRIPS Agreement.

It is in the interest of poor countries for the emerging global patenting regime to be as competitive as possible. Although stronger patents may have some dynamic benefit in terms of R&D effort and product introduction, the earliest possible entry of generic competition for key drugs can help limit procurement costs and drug prices. Thus, the tendency in some developed countries to permit extension of effective patent terms could be harmful if adopted in poor nations; such an extension may be detrimental to generic production there in any case. Similarly, attempts to establish rules that effectively extend patent eligibility and the scope of protected claims in developing countries should be questioned.

4.2.4 *A failure of dynamic incentives*

Until quite recently, private pharmaceutical firms have devoted very little by way of R&D resources to the development of drugs for “neglected diseases” that disproportionately afflict poor countries. Firms will not rationally undertake expensive R&D programmes into treatments for these diseases if sufferers cannot pay for them. Patents can stimulate more drug development only to the extent that R&D costs may be recouped through charging a mark-up over marginal cost (and average cost, over the long run).¹⁷ These mark-ups may require prices sufficiently high that most patients in poor countries could not afford them. Put more simply, purchasing power, even aggregated across a number of poor nations, is not enough to make drug development to address these neglected diseases attractive.

More patent coverage in itself cannot address the problem of weak demand. A need clearly exists for subsidizing R&D for new drugs where effective demand is weak but medical needs are acute. Greatly expanded public procurement programmes funded by taxes and donations from the rich countries can be used to induce greater invention of drugs for targeted diseases and to distribute drugs cheaply. Put in other terms, policy needs to establish a separation between the dynamic problem of drug discovery and the static problem of distributing drugs widely and at low cost, while both efforts require internationally coordinated public and private funding.

5. EVIDENCE ON DIFFERENTIAL PRICING

A particular charge to WG4 was to consider means for increasing the affordability of drug prices in poor countries. An attractive option is to encourage differential pricing, under which drug manufacturers charge far lower prices in the poorest countries than elsewhere. Clearly, for this approach to be politically feasible, consumers in high-priced countries, especially the United States, must be persuaded that it would not raise prices there higher than they are under the existing system. Also, manufacturers have to be assured that the United States and other rich-country consumers would not be able to import the drugs from poor countries—that is, there would be no parallel imports.

Many economists point out that such pricing would emerge naturally if markets were segmented between poor and rich nations. On the presumption that consumers in poor countries are the most price-sensitive because of their low incomes and other factors, firms would offer the lowest prices there. As long as the price equals or exceeds marginal cost of production and delivery, firms would achieve some contribution to covering their R&D costs from even the poorest markets. The ability to separate markets is critical for this price differentiation, for if low-priced products could be shipped into high-priced markets, firms might choose not to supply poor countries at all. In economic terms, firms can increase net quasi-profits through market segmentation and price differentiation, supporting lowest prices in the poorest regions (Maskus, 2000b; Maskus and Ganslandt, 2002).

Some economic analysis has addressed the closely related concept of *Ramsey pricing*, in which prices of particular drugs should rise with average incomes, again presuming that demand becomes less sensitive to price as incomes go up. It is well documented that this strategy works in vaccines, in which large differences in per-unit prices exist between developed countries and poor countries (see the John F. Kennedy School of Government case study, *Vaccines for the developing world*, 1998).

The evidence of such pricing working, however, is far weaker in drugs. In their WG4 background paper, Scherer and Watal looked at the international distribution of wholesale prices (in dollars) of 15 widely marketed AIDS antiretroviral drugs over the period 1995 to 1999 (i.e. before the recent rounds of price-cutting) in a sample of 18 low-income or

intermediate-income countries or country groups. Prices were measured as a ratio of wholesale list prices in the United States. They found only a “faint indication” that price ratios were positively correlated with income levels. For example, despite the fact that all the included countries had a GNP per capita less than 33% of the US level, the average price ratio was 0.85. Thus, prices averaged 85% of US levels (and probably were at parity with discounted prices); in 98 of 465 cases, the prices in developing countries were higher than in the United States. The correlation coefficient between price ratios and purchasing-power-adjusted per-capita GNP was +0.21, which is significantly positive but far less than unity, which would be anticipated under full Ramsey pricing. Using regression analysis, they found that, controlling for other factors, although the price relatives were significantly and positively related to income, the magnitude of this effect was quite small. Further, although the average predicted price ratio fell from 1995 to 1999 (so that prices in the developing world were falling relative to those in the United States), evidence of Ramsey pricing diminished over the period. Overall, Scherer and Watal claimed that the price data mainly supported an impression of randomness in AIDS drug prices in low-income and moderate-income countries.

Other evidence reported to WG4 indicated that, in a sample of both on-patent and off-patent drugs across many therapeutic classes, prices of brand-name drugs tended to be positively correlated with per-capita income (Maskus and Ganslandt, 2002). However, there were many cases in which prices in such countries as Brazil, Mexico, and South Korea were higher than those in Canada or several European nations. Average prices of these drugs were lowest by considerable margins in India, where patents on pharmaceutical products are not available. Note also that even where prices co-varied with incomes, the relative differences between rich countries and poor countries rarely reached such factors as 30 to 1 (i.e. the relative income differences). Clearly, income differences are not the sole determinant of price.

Four primary factors seem to explain the fact that prices in developing (developed) nations are often higher (lower) than might be anticipated based on differential pricing. First, many developing countries retain high tariffs and taxes on medicines, while local distribution systems may be monopolized and inefficient. Second, drug manufacturers may find it more profitable to sell low volumes of branded drugs at high prices to the relatively wealthy in developing countries, rather than selling at low prices in high volumes to the poorer segments. The former group is more likely to be covered by insurance and to have spending patterns (e.g. inelastic

demand) that support higher price mark-ups. The latter group may not be able to afford prices that cover even marginal costs and therefore may go unserved without public support. Third, because of price controls and monopsony purchasers in higher-income economies, prices may be effectively limited there. Fourth, despite the scope for segmenting markets through transport costs, restraints on parallel imports, and differences in packaging and trademarks, countries may be effectively integrated in other ways. Specifically, reference pricing systems and concerns that consumers in high-income economies would demand similar price advantages provide an incentive for firms to refuse significant price cuts in poor countries. These processes are likely to form a major impediment to differential pricing, which would otherwise be in the interests of pharmaceutical companies.

We conclude that the current system does not support the extensive differentiation that is necessary to achieve very low prices in the poorest nations. Structural policy reforms, such as tariff cuts and restraints on reference pricing, can achieve some of this differentiation. However, the pharmaceutical industry itself needs further incentives to accept significant price discounts in poor countries.

6. ACHIEVING AFFORDABLE PRICES

Members of WG4 are persuaded that differential pricing is an important element in resolving the problem of lack of access to pharmaceutical products in poor countries. The following discussion identifies ways that such differential pricing may be achieved. Throughout this discussion, as discussed at the outset of this Report, WG4 members are mindful of the conflict between dynamic efficiency arising from monopoly rights as an incentive to innovate and the need for equity arising from higher prices of medicines under a patent regime.

6.1 SUPPORTING MARKET-BASED PRICE DIFFERENTIATION

Some have argued that sufficient differential pricing would emerge spontaneously if policy measures supported effective market separation, at least across countries at tiered income levels. Indeed, some market-based price variations exist. For example, Novartis sells an anti-malarial drug (Coartem®) that is packaged and priced separately for high-income markets, low-income private-sector markets, and low-income public-sector markets.

The TRIPS Agreement permits countries to set their own policy regarding the exhaustion of intellectual property rights (IPRs) and, therefore, on the regulation of parallel imports. Indeed, in the Declaration on the TRIPS Agreement and Public Health, Ministers at the WTO Ministerial Meeting in Doha stated that the “effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge...”.

Nevertheless, it is evident that market segmentation to support differential pricing requires restraints on the “reverse flow” of products from low-priced countries to high-priced countries (and between markets within countries). Thus, those countries not in the target group would need to ban parallel imports in the designated drugs (both brand name and generics) from target countries. Preventing reverse flow might also require restraints on parallel exports from designated countries. Developed countries could refrain from including prices specific to poor countries in their reference pricing regulations. Such policies could be supplemented by labelling and packaging processes that identify covered medicines.

Although such an arrangement would probably sharpen differential pricing by pharmaceutical firms, the outcome might not be sufficient to solve the access problem in poor countries. Firms still might prefer to sell medicines to the wealthy segment of the population in poor countries at low volumes and high prices, barring some means of segmenting consumers internally within poor countries. Even if medicines were made available at low prices in poor countries, firms might choose not to supply them in sufficient quantities to meet patient needs, depending on the structure of costs. Such a scenario, of a small quantity of low-priced medicines made available to poor countries, would not reduce other impediments to low prices, including distribution monopolies and tariffs. It also would not provide much additional incentive to develop costly new drugs if the prices on offer could not provide some return on R&D costs. Finally, it could be difficult to convince consumers in developed countries to accept sharply higher prices if the price differentiation is seen as essentially a private-market outcome.

6.2 NEGOTIATIONS AND BULK PURCHASES

A second possibility would be to rely on bulk purchases and bilateral negotiations of price discounts in long-term agreements between companies and governments. In circumstances where governments have bargaining leverage stemming from large demand and threats of alternative sources of competition, negotiations can generate significant price reductions. For example, experience with both patented and nonpatented drugs, presented at the April WTO workshop in Norway, showed that reductions of 90% or more below developed-country prices could be procured. Moreover, this strategy has worked well in reducing the cost of procuring vaccines for many years. Working Group 4 supports appropriate use of this mechanism for reducing prices wherever feasible.

Some difficulties with this approach should be mentioned. First, because bilateral negotiations consume time and negotiating resources, coverage may be achieved across countries slowly and in piecemeal fashion. Further, the price outcomes may sometimes not be closely related to need. Small countries may find it especially problematic to assert leverage. Accordingly, coordinated regional price negotiations and bulk purchasing agreements may be more effective and sustainable. Yet even under regional arrangements, poor-country governments may be unable to attain prices they can afford, given the volume of patient needs. Thus, global purchases through some multilateral organization, financed in part by international assistance, may offer the best opportunity for price reductions. Note

that this approach is likely to be viewed as undesirable by pharmaceutical firms, which would lose bargaining power relative to a situation of bilateral negotiations. A concern, therefore, is that firms may opt not to participate. Finally, this approach would not add much to R&D incentives.

6.3 VOLUNTARY AND COMPULSORY LICENCES

As noted earlier, a significant determinant of price is the degree of generic competition. Such competition can emerge in three ways. First, patents may expire, may not be applied for, or may not be recognized in a particular country. The TRIPS Agreement requires the provision of product patents for 20 years, implying that the onset of generics through domestic production or imports will be delayed where patents are taken out. Second, patent owners may license production or distribution rights to rival firms voluntarily in order to earn a return on their inventions in locations where they take out a patent but do not wish to operate themselves. Incentives for voluntary licensing may include such elements as lower-cost production and linkages with local partners that have a complementary technological advantage. Third, governments may issue compulsory licences, thereby transferring production to local firms for reasons of public health need.

Note that voluntary and compulsory licensing are not necessarily independent processes. Firms may be more willing to negotiate a voluntary contract where there is an underlying threat of a compulsory licence. Under the TRIPS Agreement, compulsory licences must be nonexclusive (i.e. available to all potential producers, including the patent holder) and require adequate remuneration, based on the circumstances of each case and taking account of the economic value of the licence, through the negotiation and payment of royalties, standards that are ill-defined to date. The requirement for nonexclusivity raises a question about the negotiation process. If a compulsory licence were to be awarded on the basis of competitive bidding among potential licensees, royalty rates (and ensuing costs) might be driven to low levels but the licence might run afoul of the nonexclusivity clause. A more consistent approach would seem to be a negotiated royalty rate available to all producers that wish to enter under given market conditions.

Some argue for reliance on voluntary licences to address the access problem in poor countries. There are advantages to voluntary licensing. Pharmaceutical companies presumably would realize a larger return on R&D investments through the conclusion of mutually agreeable licensing terms. Because the licences are voluntary, firms also should be willing to

transfer full details of technology and know-how. Nevertheless, significant problems with voluntary licensing exist. First, under a voluntary licensing system, firms could rationally choose not to conclude an agreement for a variety of reasons, including inadequate royalties (reflecting a low willingness to pay from licensees or government subsidies) and concerns that local enterprises might not be sufficiently prepared to undertake production of safe and effective products. Second, patent-owning firms may prefer to work with only a single licensee. This approach provides an important incentive to the licensee to build and service the domestic market, but it also sacrifices potential competition. Third, there may not be viable domestic firms that are candidates for reaching and executing voluntary licensing contracts. Fourth, negotiations could proceed slowly and in a piecemeal fashion, making it difficult to meet the large volume of patient needs.

Given these problems, some observers argue for recourse to compulsory licences (CL) for ensuring widespread production and distribution of essential medicines in target countries. A central concern is the relation of CL to the TRIPS Agreement, which provides a degree of flexibility to governments in compelling licences.¹⁸ The right to issue CL may be invoked without prior negotiation with the right holder in declared states of public emergency.¹⁹ Governments may make use of patented inventions when they intend a noncommercial public use. In the former case, the CL must cease when the emergency conditions supporting it disappear and are unlikely to recur. Given the desperate state of public health in the poorest countries, these provisions seem to provide sufficient justification for resort to CL where patents exist and the market is not otherwise being served adequately. Governments may also issue CL as a means of disciplining anticompetitive behaviour and reducing prices, or where rights holders are not working their patents in sufficient quantities to meet market needs. In the latter cases, there must have been unsuccessful efforts by local firms to conclude voluntary licences within a reasonable time period, production under compulsory licences must be predominantly for the supply of the domestic market, adequate compensation must be paid to the patent holder, and patentees must be awarded the rights to independent review.

These restraints raise several problems for some developing countries in employing CL. First (and assuming that a patent has been applied for and granted in the country), if there are no domestic production facilities or enterprises that may produce a new drug, there cannot have been prior negotiations for voluntary licences, unless a generic producer in another

country undertakes them for the purpose of exporting to the market in question. However, no such negotiations would be required if the CL were invoked on the basis of a national emergency. Second, small countries without production capabilities must import generically produced goods if they wish to have access to generic competition. However, such imports would require a compulsory import licence (unless the pharmaceutical firm that developed the drug chose not to patent it locally), the legality of which under the TRIPS Agreement is subject to debate.²⁰ Even if such import licences were issued, generic imports could come only from another country where the product is not under patent or that had issued its own CL for the drug, which might not happen if disease patterns and needs are different elsewhere. Moreover, given that such a country can issue a CL authorizing production only that is “predominantly for the home market”, there might be difficulties in meeting export demands in poor nations. In sum, the TRIPS Agreement raises barriers to the use of CL by poor countries without competitive pharmaceutical producers.

A third problem is the determination of royalty rates under compulsory licensing. Article 31(h) of the TRIPS Agreement calls for “adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization”. As discussed by Scherer and Watal in their background paper for WG4, experience on setting royalty rates in cases where licences are awarded without the permission of the right holder run from the relatively high end of the range—in drug patent licensing decisions in the United Kingdom—to the comparatively low end of the range—in the United States in key antitrust case orders. They concluded that “choices made in industrialized nations provide ample precedent for royalty-setting on the modest side of the range of possibilities”. Again, the struggle at the macroeconomic level would be to find reasonable royalties that permit substantial price differentiation (maximize static efficiency) and still provide incentives for new R&D (maximize dynamic efficiency).

Despite the potential for CL to accelerate generic competition rapidly in poor countries, some difficulties must be recognized. First, compulsory licensees must be capable of reverse engineering or importing the product without the assistance of the patent holder, which cannot be forced to provide its production know-how. Second, firms hoping to receive production rights under CL are likely to be attracted only to drugs with large volumes and profitable drug markets, meaning that essential medicines with small volumes or poor patients will not attract many applicants. Third, in small markets, anticipated production volume may be so small as to deter application for CL. Fourth, firms (and govern-

ments) may not be able to pay even modest royalties and still provide generic drugs at low prices. Fifth, if pharmaceutical firms anticipate that new drugs will be routinely subjected to CL at low rates of compensation, they would choose not to undertake R&D programmes into treatments of greatest interest to poor countries. Further, they could choose not to supply those markets and not to take out patents there, especially if local competitive threats are weak.

6.4 DRUG DONATIONS AND TAX INCENTIVES

Many pharmaceutical firms and vaccine producers provide important assistance through effective drug donation programmes, while multilateral organizations and NGOs also make treatments for specific neglected diseases available for free or at nominal cost. In addition, the United States and other developed economies provide some tax relief to firms that donate medicines. It is conceivable that tax breaks could be made sufficiently generous to make large-scale donations economic, thereby transferring much of the cost of providing drugs to rich-country taxpayers. Thus, drug donations can play an important role in improving access.

However, donation programmes alone are likely to be insufficient. Funding for private charities and NGOs cannot reasonably be expected to meet the immense needs of patients in the poor countries, nor could such funding be considered sustainable. It is doubtful that significant expansion of tax advantages for this purpose would find political approval in some countries and, in any case, indirect funding through the tax code is an inefficient form of procuring assistance. Note also that increasing global donations through this route could require international cooperation in tax treatment among donor countries. Finally, reliance on donation and tax cuts would do relatively little to expand R&D incentives.

7. IMPROVING INCENTIVES FOR NEW DRUG DEVELOPMENT

Efforts to raise patient access to essential medicines through reducing prices are essential and need to be made as quickly as possible (Ganslandt, Maskus, and Wong, 2001). By themselves, however, such efforts would not result in much additional spur to R&D into new medicines. Such incentives could emerge in products of interest to nations of all income levels, to the extent that larger volumes sold in poor countries at prices just above marginal cost complement returns to R&D earned in the richer nations. However, price cuts would do little to enhance development of drugs and vaccines of particular interest to poor countries. Again, the market incentives for developing treatments for “neglected diseases”, such as tuberculosis, malaria, and tropical diseases, are far less than those for “global essential drugs”, where markets in developed countries also exist.²¹

It is conceivable that stronger patent rights in poor countries could generate an attractive market for pharmaceutical firms, including local firms that may choose to emphasize such markets. In aggregate, poor-country markets are large in terms of population and needs. However, it is unlikely that this hands-off approach could work for an extended time. First, purchasing power in the low-income developing countries will be severely limited for many years, and patent rights likely will be poorly enforced, implying low returns in those markets. Second, weak distribution and health-delivery systems will reduce enthusiasm of drug firms to devote resources to new medicines for poor countries. Third, even if developing and selling drugs for high-volume diseases were economic, patents would do little to stimulate R&D for diseases with smaller case loads and localized conditions.

7.1 PUBLIC R&D AND PUBLIC-PRIVATE PARTNERSHIPS

It is possible to rely on publicly funded or publicly performed R&D. Cases exist in which public R&D programmes succeeded in meeting needs or achieving basic breakthroughs. For example, research in agriculture supported through public funding, both national and international, has given benefits to many developing countries through bringing the “green revolution”. The Human Genome Project is another example of successful

results arising out of public funding. This model could be explored for R&D in targeted diseases.

Under the existing system, many governments, especially those in the rich countries, provide extensive funding to universities and laboratories for medical research, with the ultimate goal of developing new treatments after the results of basic research have been transferred to pharmaceutical firms. But such funding overwhelmingly is provided for research that could develop drugs of interest to patients in the rich countries themselves. It cannot be relied upon to fund work on the diseases of poverty.

It is worth noting also that, although public research laboratories have experienced some success in undertaking or funding basic medical research, governments have had a poor track record in commercializing the resulting products. For their part, governments in poor countries are unlikely to be able to fund such research for some time, though some middle-income economies and large poor countries have some basic support programmes in place. Also, a considerable public-goods problem exists in that, if one poor country were to undertake the costs of developing new medicines with wide applicability, other countries would be likely to free-ride on the outcome of the research. Thus, for reasons akin to those underlying the unwillingness of private enterprises to perform such activity, public R&D programmes in individual countries would not generate sufficient research activity. It is unreasonable, in any event, to expect the poorest countries to allocate scarce fiscal and technical resources to medical research.

These observations support WG4's view that greater funding for R&D needs to come from donors, including rich-country governments, multilateral organizations, foundations, and NGOs. By aiming it at developing treatments for targeted diseases, such financing would resolve the free-riding problem—the essential justification for the establishment of the Global Health Research Fund.²² Further, the funds should support public research on the pattern of the Consultative Group on International Agricultural Research (CGIAR) and collaboration between the public and private sectors.

A number of innovative research programmes have been undertaken by private firms or collaborations and funded by governments, NGOs, and multilateral organizations. Examples include the Medicines for Malaria Venture and work done by Merck and Company in the Mectizan® Donation Program to combat river blindness. A particularly effective programme is the International AIDS Vaccine Initiative (IAVI), which attempts to solve both the R&D and access problems. It provides

for public–private agreements in which private firms that develop certified HIV vaccines retain full IPRs in the industrial countries and IAVI gains distribution rights for HIV vaccines in developing countries where company partners are unable or unwilling to produce and distribute the vaccines at affordable prices. Under this system, a variety of private and public R&D partnerships are working to develop AIDS vaccines.

Despite the considerable benefits of such programmes, they are unlikely to meet fully the enormous present and future needs of poor countries. Research into neglected diseases remains chronically underfunded. For its part, IAVI is progressing largely because a need for AIDS vaccines exists in both rich and poor countries, making partnerships economic and serving as a model for further work in such shared diseases. However, this programme does not address the provision of treatments for existing sufferers, where the potential cost is greatest.

7.2 PAYING FOR PRODUCTION AND DISTRIBUTION RIGHTS

As discussed earlier, the essential dynamic problem is that purchasing power in poor countries simply is insufficient to provide an expected return on R&D costs into neglected diseases. Public research efforts have failed to fill this gap, partly due to inefficiencies and partly due to limited financing. Means must be found to promote private-sector R&D, or private–public collaboration, while permitting widespread distribution of new drugs at very low cost.

8. RECOMMENDATIONS

Working Group 4 supports proposals to increase funding through such mechanisms as a Global Health Research Fund. Because it is a major theme throughout the Report, we only repeat here that major increases in funding for health programmes are required. These funds need to be allocated to improving health care delivery and financing systems, increasing medical staffing, and procuring essential medicines. They also need to be established on a sustainable financial basis. Beyond this, WG4 has identified a number of elements that could usefully be included in solutions to the problems that have been identified in this Report, and recognizes that a multifaceted approach is necessary. The elements and the implications of each are as follows:

For Donors

1. *Establish an adequate and sustainable financing mechanism.*

Donations from private foundations and NGOs are welcome but not likely to be sufficient for the needs. Thus, large increases in funding from the foreign assistance budgets of developed and higher-income developing countries are required. Such funding needs to become established items in government budgets and allocated annually over several years.

For Developing Countries

2. *Improve health delivery systems.* It is imperative that developing countries give the highest priority to building strong health delivery institutions capable of effectively using pharmaceuticals and other medical products. Drug approval processes could be streamlined, subject to mandates of safety. Health care financing systems need also to be established or improved, with a view towards spreading health risks more widely across patients in a way that is not regressive.
3. *Reduce impediments to low prices.* Developing countries should reduce barriers to imports of medical products, including tariffs and quotas, and avoid use of anti-dumping duties (except in demonstrable cases of predation). They should consider whether taxes on drug consumption are costly in terms of net health status of the economy. Monopolistic distribution systems should be made more competitive

- by ensuring that there is free entry by competing distributors into that service.
4. *Support price differentiation.* Poor countries should assist in preventing the export of targeted drugs in ways that could upset price differentiation. They could remain open to parallel imports and also permit drug exports to other designated poor nations.
 5. *Focus on access to high-impact drugs.* Careful drug selection is vital to better access. Factors taken into account would include the burden of the disease, cost-effectiveness and safety of the treatment, appropriateness of medical infrastructure, and other related factors.
 6. *Emphasize generic products.* Countries should promote greater use of and reliance upon non-patent protected generic pharmaceuticals.
 7. *Adopt TRIPS-compliant legislation that supports generic competition.* Developing countries should ensure that generics become available as quickly and as broadly as possible upon expiration of basic patents protecting basic products. They can, for example (following the pattern of the US Bolar amendment),²³ permit generic manufacturers to undertake certain preparatory activities during the patent term so as to be ready to market the product upon patent expiration. Poor countries should retain in their laws the possibility of compulsory licensing.
 8. *Increase incentives for firms to sell to the poor.* Reforms could promote price differentiation on internal markets through the inclusion of poor patients in public insurance, bulk purchasing programmes, and price negotiations.
 9. *Ensure quality.* Health authorities should ensure that products that are imported or produced domestically meet assured quality standards.
 10. *Engage in competitive bulk procurement.* Where national bulk purchasing is feasible to achieve low prices, it should be done according to internationally recognized good pharmaceutical tendering practices. Where national purchase volumes or management capabilities fail to yield low prices, use could be made of existing low-cost international purchase channels such as those created by the United Nations Children's Fund (UNICEF) and the Pan American Health Organization (PAHO). We recommend that the purchasing practices of groups such as these be studied with a view to wide adoption of the best practices.
 11. *Support other effective drug supply channels.* Governments should facilitate the operations of appropriate service delivery NGOs,

employers, and civil society organizations in financing and supplying health care, including medicines.

For Developed Countries

12. *Accept and support differential pricing.* Differential pricing, with a distinction at least among low-income and other markets, should be recognized as meeting the global public interest. This goal would be supported by the following actions:
 - *De-link reference pricing systems.* Reference pricing systems or other price controls should permit clear price differentiation between high-income and low-income markets.
 - *Restrain parallel imports.* Developed countries should permit firms to use their intellectual property rights to exclude parallel imports of drugs from low-income economies in order to protect price differentiation. They should avoid restricting exports to poor countries.
 - *Engage in awareness campaigns.* Consumers in developed countries must understand that a system of differential pricing would not imply higher prices for medicines in their economies. Moral suasion could be applied to reduce political pressures to import products from low-priced countries. Consumer resentment in the highest-price countries, such as the United States, could be assuaged if other developed countries were to relax their price controls in order to absorb a larger share of funding R&D costs.
13. *Promote drug donations.* Tax incentives for drug donations could be further explored and, if necessary, harmonized among developed countries. Such programmes are most appropriate in times of emergencies and for dealing with specific disease outbreaks and achieving disease eradication.
14. *Support developing-country policies that improve access to essential drugs.* Recognizing the need for flexibility facing the poorest countries, developed countries should continue to exercise restraint when asserting WTO rights against the former group. Enhanced provision of technical and financial assistance in the health care area would also be beneficial. Countries should recognize that collaborative agreements among pharmaceutical firms, governments, and donor organizations, for the purposes of establishing differential pricing, may require exemptions from antitrust actions.

For the International System

15. *Establish Guidelines on Access to Patented Health Products for Poorer Countries.* One possible mechanism would be to establish guidelines to further the objective of providing access to patented key medicines for poorer countries at the lowest achievable price, while maintaining the patent incentive for R&D. These Guidelines would address issues related to pricing and licensing of production of key medicines in poorer countries.

The Guidelines would enable differential pricing to become more sustainable and more predictable for developing countries. It would allow patent holders to make key medicines available to poorer countries at the best possible price, either through their own production, in return for reasonable royalties, or in return for good will gained by offering patent waivers. Generic producers would benefit to the extent that they are able to obtain licences or patent waivers for products that they can produce at the most competitive price.

General principle

Under the guidelines, patent holders would agree to license their technologies to high-quality generic producers and/or commit individually and voluntarily to offer key medicines for poor countries at the lowest achievable price. If the price offered by the patent holder is still felt by recognized international or national health programmes to be excessive, according to transparent criteria reached in consultation with all major interested parties, then the health programmes would have the option of conducting a competitive tender among qualified suppliers as certified by international or national health programmes. In the event the patent holder's bid was not the winning bid, the patent holder would at its discretion either (1) license their product to the winning producers or (2) agree not to sue the producer for patent infringement. Reasonable royalties would be paid to patent holders in order to sustain incentives for new drug development.

Specific conditions

- The Guidelines would apply to the supply of *key medicines* for major public health problems, as identified by international agencies and/or national governments.
- The licence or patent waiver would be subject to specific *geographic limitations* and *time limitations*, depending on the scope and nature of the programme.

- All potential manufacturers would have to meet *international quality standards* (i.e. WHO standards) for good manufacturing practices (GMP). Because many of the programme countries lack production facilities, licensed production by generic producers in third countries, strictly for export to designated markets, would be allowed. To accomplish this would require a WTO consensus that such licensing is permissible²⁴ and, probably, would also require amendment of national intellectual property laws in the producing/exporting country.
- International agencies or governments who are procuring key medicines under this scheme would have the option of requiring, as a contractual condition, that producers offer the *same low price to nongovernmental organizations and other not-for-profit health services* in the target countries.
- *Monitoring programmes*, production reporting, and marking systems for identifying programme drugs would be needed in order to discourage diversion to third countries, including markets in which production takes place.
- Developed country governments would agree that, under the Guidelines, *prices offered would not be considered in any reference pricing system* or other form of price comparisons in developed countries.
- Governments and companies would work together *to strictly prevent diversion of drugs* to markets outside designated areas. Repeated and systematic diversion would result in the disqualification of a country from the licensing regime.
- Developing countries benefiting from the Guidelines would *retain all rights and flexibility provided for within the TRIPS Agreement*.
- Patent holders would receive *reasonable royalty payments*. These royalties would be paid for by a combination of international donors, developing country governments, or local health care institutions. Royalty payments would be determined by a rotating commission of experts that would include industry representation.
- *Guidelines for setting royalty rates* for future medicines should be set, inter alia, in order to encourage market-based development of new innovations for conditions in developing countries. These Guidelines should also account for the proportion of R&D costs supported by public funds.
- This same approach can be used for producers of *key diagnostics* such as HIV test kits.

As this Report has made clear, two sets of issues have assumed great importance in recent years in both global and national level discussions on health: the first set arising from the increased liberalization of trade in health-related services, and the second from the role of intellectual property protection in encouraging R&D crucial to the development of new medicines while at the same time ensuring the affordability of medicines. The TRIPS Agreement of the WTO, with all the apprehensions that it has raised among the developing countries, and the AIDS pandemic in several countries have imparted an unprecedented urgency to action on this front.

The recommendations contained in this Report assume special significance in the light of the goals set out by the Commission on Macroeconomics and Health. We believe that the recommendations contained in this Report are feasible. Some of the proposals outlined, such as programmes for donation of medicines, have been tried before; others are being discussed, and yet others need to be put on the agenda for discussion and action.

NOTES

1. The OECD countries account for 90% of world health care expenditures. There is significant variation in per capita health expenditures, from some LDCs spending US\$ 5 per year all the way to developed countries such as the United States spending US\$ 3500 per year. The sector's share in GDP also varies significantly across countries, from as low as 2 or 3% to over 10% in some developed countries.
2. The phrase *consumption abroad* is borrowed from the GATS terminology of modes of supply in services. It refers to situations where the consumer/importer of a service consumes the service in the country exporting the service.
3. See Chanda (2001) and the discussion on how to address movement of natural persons under the GATS framework for health services, later in this Report.
4. See WHO (1999), Widiatmoko and Ganni (1999), and Chanda (2001) for examples of countries that have opened up to FDI in health services and for a discussion on regional health care networks.
5. See the *World development report* (World Bank, 1993) and the *World health report* (WHO, 2000) for a discussion on investment needs in the health sector.
6. This mirrors the general tendency to overinvest in higher education relative to primary education within the education sector.
7. Such policies have, however, been criticized by some economists as being inefficient and distorting incentives. Their effectiveness really depends on the ability to enforce and monitor such regulations.

8. It is important to note that there are regulatory and administrative capacity limitations in most developing countries that would make implementation of such policies difficult. These constraints are outlined later in this Report.
9. In order to strengthen and coordinate global responses to the tobacco epidemic, in May 1999, the World Health Assembly adopted a resolution to enable multi-lateral negotiations on a WHO Framework Convention on Tobacco Control (FCTC) and related protocols. The first draft of the FCTC was released in January 2001. The FCTC is still in the process of negotiation.
10. Other measures include tapping networks of professionals residing abroad through the establishment of brain gain networks or return of talent programmes, and entering into short-term bilaterally negotiated assignments for health care providers and between health care establishments across countries. See Chanda (2001) for a discussion on policies used to address brain drain.
11. There are some case studies on Canada, Thailand, and some other countries. See Zarilli and Kinnon (1998).
12. See Woodward et al. (2001) for a summary of the priorities for research in the area of globalization and health.
13. As Scherer and Watal (2001) report, fewer than 20 of the current WTO developing-country and least-developed country members excluded pharmaceutical products *per se* from the grant of patents.
14. For example, the situation on the ground varies from country to country—even in the area of drugs for the treatment of HIV/AIDS. See <http://www.unaids.org/publications/documents/health/access/patsit.doc>. Attaran and Gillespie-White (2001) provide expanded data—albeit for a more limited cohort of countries (Africa).
15. As of 1992, 48 countries excluded pharmaceutical products from patentability, including Argentina, Brazil, Finland, Pakistan, Spain, Thailand, and Turkey (WIPO, 1992), while by January 1995, as reported by Scherer and Watal (2001), that number dropped to less than 20 (including Angola, Argentina, Bangladesh, Brazil, Cuba, Egypt, Guatemala, India, Kuwait, Madagascar, Morocco, Pakistan, Paraguay, Qatar, Tunisia, Turkey, United Arab Emirates, and Uruguay).
16. However, it should be noted that patent protection in the United States co-exists with a thriving generic drug industry.
17. More accurately, because R&D costs for a given product on the market are sunk costs, current profits enable companies to generate capital to reinvest in R&D to bring new products to market.
18. The Declaration on the TRIPS Agreement and Public Health made by WTO Ministers at the November 2001 Doha Ministerial Meeting stated that “each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted”.

19. In this connection, the Declaration on the TRIPS Agreement and Public Health made by WTO Ministers at the November 2001 Doha Ministerial Meeting stated that “Each [WTO] Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency”.
20. Note that the European Union submitted a document to the TRIPS Council arguing that the TRIPS Agreement could be interpreted as permitting such import licences (see EU, 2001). Legal argumentation for this interpretation is provided in Abbott (2001). WTO Ministers, in the Declaration on the TRIPS Agreement and Public Health made at the WTO Ministerial Meeting at Doha, November 2001, stated that they recognized “that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement [and instructed] the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002”.
21. Some public–private partnerships, such as the Medicines for Malaria Venture and the Concept Foundation, strive to achieve incentives for both R&D and distribution.
22. The entry for GHRF in the glossary of the CMH Report says that it is “A new fund for health research advocated by the Commission on Macroeconomics and Health. It is one of the major channels recommended by the Commission to increase health-related research and development, with disbursements of around \$1.5 billion per year. This fund would support basic and applied biomedical and health sciences research on the health problems affecting the world’s poor and on the health systems and policies and needed to address them. A key goal of the GHRF would be to build long-term research capacity in developing countries themselves, by providing vital funding for research groups in low-income countries” (WHO, 2001: 191–192).
23. US law, recognized and accepted by the World Trade Organization, that allows manufacturers of generic drugs to prepare in advance to enter a market after a patent expires. The Bolar Amendment is seen as a minor check on the power of patent holders. Specifically, the Bolar Amendment states: “It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products”.

24. European Union (EU). Paper submitted by the EU to the TRIPS Council, for the special discussion on intellectual property and access to medicines, 20 June 2001.

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ANNEX I LIST OF ACRONYMS

CGIAR	Consultative Group on International Agricultural Research
CL	Compulsory licences
FCTC	Framework Convention on Tobacco Control
FDI	Foreign direct investment
GATT	General Agreement on Tariffs and Trade
GATS	General Agreement on Trade in Services
GMP	Good manufacturing practices
IAVI	International AIDS Vaccine Initiative
IMF	International Monetary Fund
IPR	Intellectual property rights
IT	Information technology
OECD	Organisation for Economic Co-operation and Development
LDCs	Least-Developed Countries
NGOs	Nongovernmental organizations
PAHO	Pan American Health Organization
TRIPS	Trade-Related Aspects of Intellectual Property Rights
UN	United Nations
UNICEF	United Nations Children's Fund
WHO	World Health Organization
WTO	World Trade Organization

ANNEX 2 BACKGROUND PAPERS PREPARED FOR WORKING GROUP 4

- Paper 1:** Post-TRIPS Options for Access to Patented Medicines in Developing Countries (**Scherer FM, Watal J**)
- Paper 2:** Differentiated Pricing of Patented Products (**Barton J**)
- Paper 3:** Consumption and Trade in Off-Patented Medicines (**Bale, Jr. HE**)
- Paper 4:** Protection of Traditional Medicine (**Wilder R**)
- Paper 5:** Trade in Health Services (**Chanda R**)
- Paper 6:** Trade Liberalization in Health Insurance: Opportunities and Challenges in Middle and Low Income Countries (**Sbarbaro J**)
- Paper 7:** Globalization and Health: A Survey of Opportunities and Risks for the Poor in Developing Countries (**Diaz-Bonilla E, Babinard J, Pinstrup-Andersen P**)
- Paper 8:** The Role of Information Technology in Designs of Healthcare Trade (**Mathur A**)

ANNEX 3 BACKGROUND NOTES FROM WHO PREPARED FOR WORKING GROUP 4

Background Note 1: GATS and Trade in Health Insurance Services
(Lipson DJ)

Background Note 2: Confronting the Tobacco Epidemic in an Era of
Trade Liberalization (Bettcher D, Subramanian C, Guindon E,
Perucic A-M, Soll L, Grabman G, Joossens L, Taylor A)

Background Note 3: Trade Barriers and Prices of Essential Health-Sector
Inputs (Woodward D)

Background Note 4: Globalization and Health: A Framework for
Analysis and Action (Woodward D, Drager N, Beaglehole R,
Lipson DJ)

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