

Access to Healthcare and the Pharmaceutical Sector

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Health is higher on the international agenda than ever before, and improving the health of poor people is a central issue in development. Poor people suffer from far higher levels of ill health, mortality, and malnutrition than do those better off, and their inadequate health is one of the factors keeping them poor or for their being poor in the first place. Health is a crucially important economic asset, particularly for poor people. Their livelihoods depend on it. When poor people become ill or injured, their entire household can become trapped in a downward spiral of lost income and high healthcare costs—a vicious circle of poverty and ill health.

The current high-level focus on health by the international community recognizes the strong relationship between poverty and health. Three of the eight Millennium Development Goals (MDGs) call for specific health improvements by 2015: reducing child deaths, reducing maternal mortality, and slowing the spread of HIV/AIDS, malaria, and tuberculosis. Moreover, health is increasingly viewed as fundamental to the first Millennium Development Goal, eradicating poverty and extreme hunger. The health of the poor must thus be a matter of major concern for everyone committed to sustainable development, from policymakers to service providers.

The past 40 years have shown that innovation and technology are among the main forces driving improvements in the state of health in the developing world. Developing countries, according to the *Human Development Report 2010*, have increased life expectancy as much in half a century as the now-developed countries did in 300 years. Sick people in developing countries were able to benefit from innovations that were not available in the 17th, 18th, and 19th centuries. Innovations in medicine and other interventions promoting public health (such as sanitation, housing, education, and nutrition) became quickly available in many developing countries, benefitting hundreds of millions of people. Effective prevention—vaccines against tuberculosis (TB), diphtheria, neonatal tetanus, whooping cough, poliomyelitis, and measles—became available too. Poor countries benefited from the rapid spread of these improvements when the costs fell dramatically. The *Human Development Report 2010* cites a study showing that, since 1950, some 85% of mortality reductions in 68 countries can be attributed to innovations made globally.¹

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Desirable average improvements like these, however, have not occurred in all countries, and they have too often failed to reach people who needed them most.² The World Health Organization (WHO) estimates that about 30% of the global population—about 2 billion men, women, and children—have no reliable access to essential medicines. This figure rises to more than 50% in the poorest areas and the lowest strata of society in Africa and Asia.³ Places where human misery is greatest and life-threatening diseases are most pervasive often lack even rudimentary medical services, including effective and affordable medicines. This has fatal consequences for about 10 million people each year.⁴

Various representatives of nongovernmental organizations (NGO) as well as academics and officials in the U.N. system maintain that mainly the pharmaceutical industry is to blame for this human tragedy. In many campaigns and reports, their criticisms focus on patents or other mechanisms for the protection of intellectual property and the prices of drugs as the main—if not exclusive—obstacle to the access to medicines for the poor. They likewise criticize the research priorities of the pharmaceutical industry and companies' focus on profitable markets.

This paper intends to show that the overall problem of poor access to health services and medicines is much more complex than the sole reference to patents or prices would have us believe. The relative weighting of the significance of individual obstacles to access is subject to a great variety of opinions and influenced by diverging interests. It is therefore also to be expected that quite different conclusions and recommendations for action will be drawn from a largely undisputed factual situation.

The Social Determinants of Health

A publication that reflects a significant change within international public health policy and debate was the Final Report of the Commission on Social Determinants of Health.⁵ Whereas, previously, priorities were mainly set on specific health problems such as certain infectious diseases, nutrition-related health, maternal health, or access to healthcare services, the current focus addresses core societal factors that account for unequal chances for good health across populations. The World Health Organization (WHO) describes the social determinants of health as: "the conditions in which people are born, grow, live, work and age."⁶ It goes on to state that these conditions or circumstances are shaped by the distribution of money, power, and resources at global, national, and local levels. These are themselves influenced by policy choices. It makes clear the link between the social determinants of health and health inequalities, defined as the unfair and avoidable differences in health status seen within and between countries.⁷

The social determinants of health can loosely be defined as how the circumstances in which people live affect their mental and physical well-being and life expectancy and have been characterized as the causes of the causes⁸ of health (or ill health). As well as age, gender, and biological characteristics that are largely fixed, individuals are part of society, and, therefore, the debates around health policy and healthcare provision must reflect the influence of societal, economic, environmental, and cultural factors on a person's lifestyle, as well as their interactions with familial, social, and community networks. These interactions

and layers of influence affecting health are represented in the well-known diagram devised by Dahlgren and Whitehead in the early 1990s (Figure 1). A healthy life relies heavily on the physical and social infrastructure of communities: access to and uptake of healthcare and social support, the quality of services and amenities, and environmental factors such as pollution and access to green spaces.

Climate change is increasingly being recognized as a (social) determinant of health as well, and socially disadvantaged groups who lack adequate environmental protection, resources, and insurance are more prone to its effects on health.⁹ Although no area can escape the adverse impact of climate change, the Arctic, small islands, mega deltas in Asia and Africa, and the African region overall seem to be especially vulnerable because of their high exposure to the effects of climate change, their populations' limited capacity to adapt to the consequences, or both.¹⁰

The Vicious Circle of Poverty and Ill Health

Individual health is closely linked to, and dependent on, community health. When the infrastructure is ailing, individuals suffer. Issues of physical health are inexorably intertwined with economic welfare. When individuals suffer from extreme poverty and lack the income needed even to cover basic needs, a single episode of disease or a drought or a pest that destroys a harvest can be the difference between life and death. In households suffering from extreme poverty,

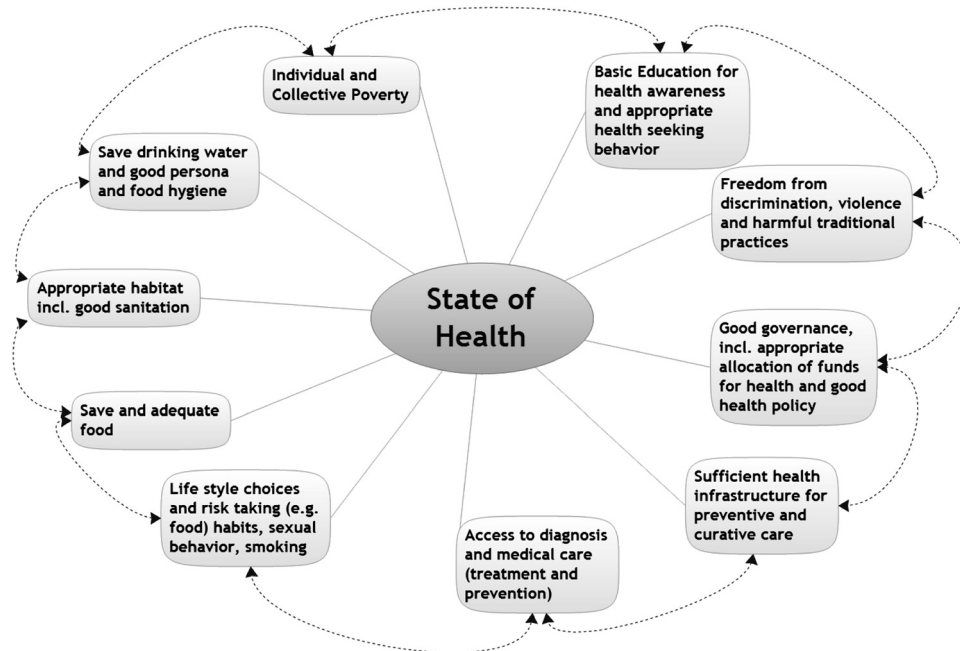


Figure 1. The determinants of health. Source: Dahlgren G, Whitehead M. *Policies and strategies to promote social equity in health*. Stockholm, Sweden: Stockholm Institute for Further Studies; 1991.

life expectancy is often around half that in the high-income world, 40 years instead of 80. It is common that of every 1,000 children born, more than hundred die before their fifth birthday, compared with less than 10 in the high-income world. An infant born in Sub-Saharan Africa today has only a 1 in 3 chance of surviving to age 65.

Take a typical village of subsistence farm households in a poor sub-Saharan African country for example. It lacks access to a paved road and public transport. There is no electricity, so people meet their energy needs by collecting wood from the scant scrublands. Inadequate sanitary facilities and human and animal excrements contaminate food and the local water reservoirs, turning them into a breeding ground for disease vectors. The children are sick from diarrhea, pneumonia, or malaria. Adults are dying of AIDS and TB. Farmers toil but do not produce enough food to feed even their families. The soils are depleted of nutrients, the rains fail, and there is no irrigation. In a village like this, women carry a multiple burden, caring for children, the elderly, and the sick, spending long hours to gather water and fuel wood, to process and produce food, and working on farms or in family enterprises for little or no income. Impoverished families here have more children than they desire because of poor access to education, contraception, decent employment opportunities, and sexual and reproductive health information and services. And because there is no emergency obstetric care, mothers die in childbirth at a hundred or more times the rate in rich countries.

Any health expenditure that threatens a household's financial capacity to maintain its subsistence needs can be catastrophic and does not necessarily equate to high healthcare costs. Even relatively small expenditures on health can be financially disastrous for poor households. This is because almost all their available resources are used for basic needs, and they are thus less able to cope with even very low health expenditures compared to richer households.¹¹ Certain household characteristics, such as households headed by a child or an elderly or disabled person, families with a low income and those who have a member with chronic disease are at risk for catastrophic expenditure. WHO estimates that families who spend 50% or more of their nonfood expenditure on healthcare are likely to be impoverished.¹² Households in developed countries are protected from catastrophic spending by adequate health insurance coverage or a tax-funded health system. In developing countries, however, high out-of-pocket payments, an absence of risk-pooling mechanisms in health financing systems, and high levels of poverty can result in personal catastrophies.

Human Resources—The Weakest Link in Healthcare Systems

Human resources—the different kinds of clinical and nonclinical staff who make each individual and public health intervention happen—are the most important health system inputs. The performance of healthcare systems depends ultimately on the knowledge, skills, and motivation of persons responsible for delivering services.

Much of the debate about scaling up efforts to achieve the Millennium Development Goals has focused on mobilizing sufficient financial resources. But human resources are likely to pose a more binding constraint. The countries with the most pressing health needs—many of them in sub-Saharan Africa—are

also those with the weakest human resource base. The need to respond to the HIV/AIDS pandemic only intensifies the competition for limited resources.

Good healthcare is the result of many complementary inputs that include drugs, infrastructure, and medical personnel, with skilled providers one of the most essential ingredients, evident in the strong correlation between health provider numbers and health service coverage. The Commission on HIV/AIDS and Governance in Africa found that a density of about 1.5 health workers per 1,000 people is on average associated with 80% coverage with measles immunization and 2.5 health workers per 1,000 people with 80% coverage of births with skilled attendants. Whereas Europe and North America have more than 10 health workers per 1,000 people, sub-Saharan Africa has on average about 1.¹³

Not enough workers are entering the public health sector, and too many are leaving. WHO estimates that some 100,000 health workers will need to be trained to reach the target of 3 million people on HIV/AIDS treatment. Another more recent analysis suggests that 20,000–120,000 medical staff will be needed to provide 3 million patients with antiretroviral therapy, depending on staffing ratios and what clinical officers do. The Joint Learning Initiative (2004) estimate of one million includes workers for all elements of a healthcare system, about three quarters of whom are auxiliaries and other health workers without formal qualifications as nurses, midwives, pharmacists, or physicians. Morale among health workers is very low because of poor pay, unattractive career paths (promotion and pay are rarely linked to performance), poor housing and working conditions (including on-the-job safety), and poor supervision. In many countries, formal limits on public spending combined with a low priority given to the health sector have exacerbated the problem. Careers in health are becoming less attractive, as secondary school leavers enter business and commerce for better earnings. In nearly all countries, health workers can obtain better opportunities and working conditions if they work for the private health sector.¹⁴

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Health in Fragile States

Fragile states are characterized by political instability, corruption, and poor governance; low acceptance of the rule of law; conflict; degraded infrastructure; poor access to basic services; migration of skilled workers; weak economic growth; and extreme poverty. The United Kingdom's Department for International Development (DFID) defines fragile states as countries that are unable or unwilling to provide the essential services required by its population.¹⁵ More recently, the potential spillover effects from fragile states have become a key area of concern in the global health security agenda. These include conflict, instability, organized crime, migration, human trafficking, and epidemic disease outbreaks. The World Bank estimates that although only 9% of the developing world's population live in fragile states, these states account for 25% of those living in extreme poverty. From 1990 to 2002, the gross domestic product per capita of fragile states was broadly flat, whereas that of other developing countries grew at 1.17% a year in real terms.¹⁶ Fragile states are home to 15% of the world's population,¹⁷ yet they account for one third of those living in absolute poverty, a third of maternal deaths, half of child deaths under age 5, and one third of people living with HIV.

Approximately 8.8 million children globally died in 2008 because of preventable causes such as birth complications, pneumonia, diarrhea, malaria, HIV, and

measles.¹⁸ Nearly 4 million of these child deaths occurred in fragile states.¹⁹ The 10 countries with the highest rates of child deaths have all emerged from conflict in the last decade. Many fragile states have been engaged in, or have been transitioning from, conflict or insecurity.

Conflict leads to an inability to effectively respond to the needs of the population. More than 2 million children have died over the past decade as a direct result of armed conflict.²⁰ More than half of these deaths occurred in three countries: Nigeria, Democratic Republic of the Congo, and Afghanistan. These three countries also account for 117,000 maternal deaths each year. Vaccine-preventable diseases account for about 25% of deaths among children under age 5, and nearly half of the children in fragile states are not fully vaccinated. The malaria mortality rate is 13 times higher in fragile states than in other developing countries.²¹ More than one third of all children who die before age 5 are malnourished. One in three people living in fragile states is malnourished.²² Despite progress in the health MDGs in some fragile states, the 2008 Global Monitoring Report stated that “on current trends, most countries are off track to meet most of the MDGs, with those in fragile situations falling behind most seriously.”²³

The World Bank’s Global Monitoring Report of 2007 still concluded that, “despite the enormous challenge of poverty in fragile states, progress against the MDGs is possible.”²⁴ Indeed, globally, fewer children are dying; since 1990 there has been a 27% reduction in child deaths. However, only five fragile states are on track to reach their MDG 4 target: Comoros, Laos, Indonesia, Haiti and Eritrea. These countries also have the lowest child mortality rates among the Organisation for Economic Co-operation and Development/Development Assistance Committee fragile states (the impact of the 2010 Haiti earthquake on child mortality rates is not yet known).

The fragile states that have the highest child mortality rates have all undergone conflict or insecurity in recent years. Four countries have seen their child mortality rise since 1990: Kenya by 24%, Congo by 21%, Chad by 8%, and Central African Republic by 1%. The latter three countries have had ongoing conflict and low levels of political commitment and resources invested into health systems. The case of Kenya in particular demonstrates how fragile progress can be and how significant declines can be witnessed in a relatively short space of time.

Health System Strengthening

In recent years, there has been increasing interest in, and analysis of, the ways in which donors, governments, and other organizations can deliver aid more effectively to strengthen healthcare systems in fragile states. The challenge is in addressing essential and priority needs while also supporting approaches that will strengthen systems and enable longer term development. It is important that Ministries of Health, donors, the U.N., and implementing partners recognize the value and opportunities for health systems strengthening, even in the midst of chronic conflict or natural disaster. It is an essential component of early recovery activities.

Building resilient health systems is particularly important in countries prone to conflict, as gains in mortality reduction are fragile, as evidenced by Zimbabwe

and Kenya. Even when it is not possible to engage in health systems strengthening at a central level, it is possible to strengthen community healthcare services and district management teams with positive health outcomes, which can be built on when central health systems strengthening becomes possible.

Access to Healthcare Requires a Rational Division of Tasks

The factors impacting on health access for the poor described above are by far not complete, nor are they a full representation of the dimension and complexity of the subject. To elaborate on the diversity of specific circumstances in the various countries and regions of the world in the necessary detail and differentiation would fill volumes and still be insufficient to present the full picture of the human misery produced by poverty, conflict, and disease. The sections above may, however, be convincing enough to accept that the solutions to healthcare access problems are a shared responsibility and that there are specific areas of accountability for national governments, the international community, nongovernment organizations, and the private pharmaceutical sector.

In the spirit of the Universal Declaration of Human Rights and the various international conventions, health (or access to medical services) is a human right. This fact is of little tangible good for poor people's daily lives in developing countries unless we also address the duties of the different players involved.

National Governments and Their Institutions

U.N. institutions and WHO as well scientific institutes and political officials dealing with health issues all agree that local governments and the corresponding national institutions bear the main responsibility for ensuring that the health of people in their countries is as good as possible. They have the nondelegable duty to respect, protect, and fulfill the right to health progressively to the extent allowed by their scarce resources. It is obvious that difficult choices have to be made in the process.²⁵

A few years ago, WHO considered the health outcomes under the leadership of those bearing the primary duty as "unacceptably low across much of the developing world" and found a "failure of health systems" as the cause of the resulting human crisis.²⁶ In its new report on human development, the United Nations Development Programme (UNDP) analyzed the experiences from the past 20 years and arrived at the following conclusions, among others, with respect to health policy issues:²⁷

- National health policy (and thus the allocation and distribution of resources) plays an important part in determining the scope and depth of improvements in mortality rates and disease burdens.
- The efficient use of tried and tested methods in maternal and neonatal healthcare lowers neonatal and infant mortality rates.
- Many interventions to reduce mortality and improve health in developing countries are not costly. A lack of resources is therefore not always the main obstacle to providing essential healthcare services.
- Good governance, democracy, and transparent accountability correlate measurably with longer life expectancy and a lower probability of maternal

mortality. Contrary to naïve expectations, many countries rich in natural resources but poor in governance fare worse than average. This finding underscores the importance of good governance and the relativity of resource availability.

WHO defined “Six Building Blocks”²⁸ of sound health systems which, on close examination, are more common sense than anything else:

- *Health services* that deliver effective, safe, quality personal and nonpersonal health interventions to those who need them, when and where needed, with minimum waste of resources.
- A well-performing *health workforce* that works in ways that are responsive, fair, and efficient to achieve the best health outcomes possible, given available resources and circumstances, that is, there are sufficient numbers and mix of staff, fairly distributed, competent, responsive, and productive.
- A well-functioning *health information system* that ensures the production, analysis, dissemination, and use of reliable and timely information on health determinants, health system performance, and health status.
- *Equitable access to essential medical products, vaccines, and technologies* of assured quality, safety, efficacy, and cost-effectiveness and their scientifically sound and cost-effective use.
- A good *health financing system* that raises adequate funds for health in ways that ensure people can use needed services and are protected from financial catastrophe or impoverishment associated with user fees.
- *Leadership and governance* that involves ensuring strategic policy frameworks exist and are combined with effective oversight, coalition-building, appropriate regulations and incentives, attention to system design, and accountability.

To fulfill their duty, governments of poor countries are expected to be deliberate, concrete, and focused on meeting their health-related obligations. As with the other social and economic responsibilities, governments with limited resources should obey the principle of *progressive realization* and move incrementally, but expeditiously, toward the set goals. Reforms of current (public) health systems are, in most countries, unavoidable. To have a substantial impact on neonatal, child, and maternal mortality as well as on the heavy burden of disease, public health services must be carefully designed around the needs of the poor or they run the risk of failing to benefit those who need improvements most.

Why do not all governments deliver low-cost interventions to improve health? The *Human Development Report 2010* sees politics “to be part of the answer.” Concretely: “There is growing evidence that health services are better provided when governments are democratic”; the transition to democracy can reduce infant mortality by as much as 5 per 1,000 and lowers the probability of women dying in childbirth.²⁹ Evidence suggests that accountability is the key.

National spending on health from domestic sources is an important indicator of a government’s commitment to the health of its people and is essential for the sustainability of health programs. Countries that treat health aid as a substitute for, rather than as a supplement to, government health spending weaken their health systems. But even with the strongest political will, the best needs-oriented

allocation of resources, and the most modern management methods, a minimum of financial means has to be allocated for health purposes. Otherwise, ambitious goals cannot be attained and millions of lives are wasted—which means the international community has to step in as yet another responsible party.

The International Community

In June 1945, with the horrors of war and the misery resulting from it still freshly in people's minds, the international community pledged in Articles 55 and 56 of the Charter of the United Nations to take "joint and separate action" to achieve "higher standards of living, full employment, and conditions of economic and social progress and development" and to arrive at "solutions of international economic, social, health, and related problems."³⁰ The ideas articulated in this document serve until today as the moral framework for international development assistance and were reaffirmed as a "collective responsibility" in many subsequent U.N. conventions as well as in the Millennium Declaration signed by 147 Heads of State in 2000.

The object is not "only" to transfer financial and technical resources, but also to see to the total set of relationships between industrialized and developing countries. This includes issues of trade, agricultural subsidies, climate protection, and other matters that result for many developing countries in hundreds of billions a year of lost income—income that could otherwise be used for investments in the health sector.³¹ Agricultural subsidies in the OECD countries alone, for example, are estimated to cost US\$1 billion a day. The export of surpluses that is made possible by these politically motivated subsidies is valuable as emergency aid in cases of famines, but under normal circumstances it costs agriculture in many developing countries more in terms of lost income per year than is ever "reimbursed" in the form of development assistance.

WHO, UNICEF, and such institutions as the Global Fund to Fight AIDS, Tuberculosis and Malaria require a minimum of financial and human resources from the international community to carry out their mandates in a professional manner. Direct budget support to health institutions (governmental ministries, authorities, etc.) in poor countries is of vital significance, too. In most cases, greater and faster progress could be made in all aspects of poverty alleviation if the international community would live up to its promises and make the appropriate financial resources available.³² Historic successes in fighting certain diseases, such as eradicating smallpox, containing poliomyelitis, and making progress in family planning to prevent unwanted pregnancies, would not have come about without the assistance of the international community. Fortunately, the resources for development cooperation have been increasing over the past two years after a long decline. They still lag behind pledges made at international conferences, however.

International resources need to be provided not only for the use of already existing knowledge and available technologies but also for drug research and development to treat what are known as "neglected diseases." Examples of these include leishmaniasis, filariasis, Chagas disease, dengue fever, and schistosomiasis, all of which cause substantial disease burdens and preventable deaths. Comparable observations can be cited about tuberculosis. WHO estimates that one third of the people in the world are infected with TB. Each year 10 million people get infected, and nearly 2 million people die as a consequence.³³

Medicines for diseases largely besetting patients living in poverty rarely have a prospect of being profitable, and pharmaceutical companies therefore usually neglect them when it comes to allocating scarce R&D resources.³⁴ To compensate for this, innovative financing and cost-sharing models are needed. They could involve national institutions (public research institutions, for instance, in countries such as China and India), multilaterally financed international institutions (the World Bank, for example), and private foundations (such as the Bill and Melinda Gates Foundation) as well as pharmaceutical companies having active substances in their patent library. Companies could also make available patented chemical compounds for the exclusive use in treating poverty-related and tropical diseases. New alliances are necessary for achieving progress with neglected diseases.

Nongovernmental Organizations (NGOs)

Many NGOs have played a significant and positive role and rendered great service to international development work through their commitment to health issues. Their efforts to sensitize society to the misery in developing countries have raised our level of awareness and thus the provision of resources for assistance. The work done by relief agencies on site usually benefits the poorest of the poor and supplements, or indeed in many situations substitutes, the inadequate efforts of government institutions. Oxfam, Médecins sans Frontières, ^{AU4} WWF, and a number of similar organizations have set standards for good assistance practices and deserve great respect for this.

In a situation where most of the OECD countries will have to consolidate their budgets and reduce their debt burden, funds earmarked for development cooperation will not be spared from cuts. Some programs supported so far by official development assistance (ODA) will be taken over by NGOs; their significance in the fight against poverty, disease, and lack of perspectives is likely to increase. As one of the consequences, they are likely to gain importance, also as members in public-private-civil society partnerships.

The scarcer ODA resources become the more important will be the effectiveness and efficiency of development programs.³⁵ Also, NGOs will have to become more selective, and they will also have to make better use of available knowledge and resources. But even the best organized and most professional NGOs cannot solve the poor world's health problems alone. They can increase the impact of their work by cooperating with suitable partners. The criteria for cooperation should be strictly objective: what matters is the problem-solving contribution that specific actors bring to the table, not their "provenience." Because the significance of nonfinancial obstacles is often underestimated when discussing deficits in the healthcare sector of low-income countries, it will be important to consider the private sector as not only a financial contributor, because it has much more to offer. Money is important, but what makes sustainable success possible is making *the right mix* of skills and resources available.

The experience of the Novartis Foundation for Sustainable Development over the past 30 years shows that many management tools and methods common in the corporate environment can be applied to achieve social ends on a large scale. Entrepreneurial skills can also help nonprofits operate for-profit ventures to

generate revenues. Although this is an important trend, business know-how can inspire farther reaching transformative forces to improve people's lives: what business entrepreneurs are to the economy, social entrepreneurs can be to social change. Innovative out-of-the-box thinking from private sector actors might lead to new approaches at affordable costs by combining available individual solution components (community-based health workers providing primary care at the village level) and adding cutting edge technology (mobile telephony to use urban call centers and mobile health clinics).³⁶ By the way, governments could benefit in the same way from good corporate sector practices.

The atmosphere between most NGOs and the private sector has improved markedly in recent years, and their interactions today are much more comfortable and professional than 20 years ago. As a consequence, there has been a rise in the number of successful partnerships for solving a wide variety of development problems. The fact that a mix of different actors can contribute their specific know-how and resources to joint projects results, in most cases, in better and faster outcomes. Some civil society organizations and corporate managements may still be waging the ideological battles of the Cold War, but, fortunately, they are declining in number and in influence.

The Pharmaceutical Industry

Given the complexity of the problems at stake and the diversity of responsibilities assigned to various stakeholders, what exactly is the responsibility of pharmaceutical companies? What are "good" companies expected to do—and if it is something that goes beyond their direct business case, why? In line with a conventional definition of corporate responsibility, the main responsibility of the pharmaceutical industry lies first and foremost in the research and development of medicines and their production and sale at market prices. This statement is compatible with efforts to facilitate the access of poor patients to essential medicines. There are problems the market can solve and those it cannot. Generally, markets are not good at ensuring the provision of public goods, such as health, education, or security.³⁷ However, consistent use should be made of markets where they are able to help in solving problems in a sustainable way. In cases where poor patients' access problems can be solved through innovative business models, such as C.K. Prahalad's bottom-of-the-pyramid approach,³⁸ preference should be given to those models over transfer efforts by governments, NGOs, or the private sector.

The health benefits achieved by successful corporate research and development, cost-effective production, and effective distribution are statistically well documented³⁹ reductions in mortality rates for certain diseases, prevention and cure of diseases, improvements in the quality of life of chronically ill patients, and a shortening of hospitalization time and disability. Also, a company that is successful in its core competence creates many further positive effects for society, be it productive jobs, purchases from suppliers, payment of taxes and insurance premiums, or social security contributions.

A number of companies have, for many years, gone far beyond what is legally required and what is possible through satisfying demand in different market segments.⁴⁰ The following additional responsibilities are part of the portfolio of good practices today:⁴¹

- *Differential pricing*, that is, reduced tenders for selected drugs against poverty-related and tropical diseases for use in least developed countries, particularly for single-source pharmaceuticals (those with patent protection or marketing exclusivity).⁴²
- *Donations* for disease eradication programs or emergencies, adhering to WHO Guidelines for Drug Donations.⁴³
- *Research and development investments* for diseases affecting predominantly poor people in the developing world (so-called neglected diseases) where the means of treatment are not available today (such as for dengue fever), where a risk of resistances to available therapies are growing (TB, but also malaria), or where available medicines have serious side effects or entail complicated and arduous treatments that make it difficult for patients to adhere to the therapy.⁴⁴
- *Support for broader health and development goals* in developing countries.⁴⁵
- *Work with stakeholders* in host countries to ensure access-to-medicines initiatives are integrated into national systems and priorities and to avoid “vertical” and “parallel” systems.
- *Exploring opportunities for production in developing countries*, including through wholly owned subsidiaries and the use of voluntary licenses, where these measures would increase sustainable access to essential medicines.

High prices for medicines indisputably pose an obstacle to poor patients all over the world. Markets fail because the existing supply is not met with sufficient demand due to customers’ lack of purchasing power. Patent-protected medicines from companies in OECD countries are generally too costly for patients living in poverty. One reason is that research-based pharmaceutical companies usually add the total research and development costs to the prices of marketed medicine. Another reason is that drug prices always contain a risk premium.

Life-saving drugs marketed as generics after their patent protection expires are often substantially cheaper. These reductions discharge the original manufacturer from the obligation of further responsibilities. Where patent protection is still in place and prices remain high, enlightened pharmaceutical companies use preferential prices or patient support programs to give patients with little purchasing power access possibilities they would not otherwise have through conventional means. Many companies (but by far not all of them) have access-to-medicines programs. Concerns about preferential prices arise not so much from an unwillingness to dispense with part of the proceeds to benefit poor patients but rather from the worry that medicines dispensed at extremely low prices will not only benefit poor patients. Instead, they could take a circuitous route and end up in the regular sales channels in industrialized countries. There they can be sold at great profit by well-organized groups at customary market prices. This concern could be mitigated if companies cooperated more effectively with the national authorities in recipient countries.

Another obstacle to a greater willingness by companies to use preferential prices is the authorities’ widespread practice of applying “reference prices” to set prices on drug markets. In other words, authorities use the lowest price that a company has demonstrated a willingness to dispense a medicine for in a given

country or region as the benchmark for all other markets. There has to be a shared understanding that special circumstances (such as facilitating poor patients' access to life-saving medicines) also require special approaches (such as preferential prices) and that companies performing solidarity services such as these should not be punished in other markets for doing so. Without this understanding, the willingness to offer preferential prices depends largely on the social awareness and the normative orientation of the top management of a pharmaceutical company. Such companies are therefore in a minority today.

Even drug donations are far from a guarantee that needy patients will actually receive them. The effective distribution of medicines dispensed for free largely depends on the quality of work done by the health authorities and their personnel in peripheral rural areas. They are the weakest link in a long chain of responsibility. In places where insufficiently or inadequately trained or unmotivated staff is in charge of distribution, or where corruption and mismanagement are widespread, problems often begin at the very moment the medicines arrive in the country. They get "lost," stored in the wrong place, or sold to third parties or re-exported for the personal enrichment of corrupt individuals. When the medicines arrive in poor rural areas, some of them are administered for the wrong purposes or in incorrect dosages, with negative consequences for patients.

Sustainable Solutions Require Constructive Cooperation of all relevant stakeholders

Each of the players mentioned above bears part of the responsibility, and each is unable to come even close to solving health access problems as a single actor. The only way to bring about lasting improvements in poor patients' access to essential medicines is to ensure each duty bearer lives up to his or her specific responsibility. Ideally, "project teams" for ensuring access to essential medicines should be formed from country to country or to fight specific diseases. As there is no "one size fits all" approach to facilitate access to medicines between countries and sometimes even within countries, the first tasks of the project team would consist of the following:

- Assessing the characteristics of the intended target population or subpopulation (morbitiy and mortality patterns, social determinants of health, etc.)
- Assessing the local health infrastructure (doctors, nurses, health workers, health centers, etc.) using the WHO recommended minimum standards as benchmark
- Identifying relevant stakeholders and engaging their financial, technical, political, and human resources
- Developing and planning customized healthcare interventions, including seizing opportunities to achieve short-term successes (quick wins) that help mobilize and motivate the intended population and partners
- Setting joint priorities, defining clear objectives and success indicators, and agreeing on principles and rules of cooperation
- Assessing and bringing together additional resources needed to address barriers, constraints, and obstacles identified (including, for example, removing price barriers to access to medicine).

In our experience, success in multistakeholder projects was especially impressive:

- In projects where partners were able to overcome stereotypical classifications based on the origin of the player involved and instead measured the value of each other's work according to whether the resources, techniques, experiences, and methods contributed did help solving the problem: the "enhanced" mix of resources was usually more efficient than what individual players could have contributed alone, no matter how well meaning they might have been
- In projects in which all individual project partners had an interest in and measured their own success in terms of the overall success of the joint project and not merely in terms of their specific contribution and its visibility
- In cases where all participants felt accountable for actual outcomes to the population they wanted to serve through the joint value creation efforts.

In this context, it is useful to refer to the stakeholder approach developed by business ethicist Josef Wieland. He argues that cooperation in partnerships (such as in particularly difficult public-private-civil society partnerships) is not about the (ethical) legitimacy of the action of individual players but rather about the legitimacy of the action of *all parties* with respect to the outcomes of their cooperation for solving problems a single player cannot solve alone.⁴⁶ Based on this concept, the different parties bearing responsibility for poor patients' access to medical care (and hence also access to essential medicines) can be viewed as "access stakeholders." The problem to whose solution all stakeholders make a commitment is improving access to medical care for needy parts of the population. If we use Wieland's definition of stakeholder, the different parties responsible for improved access to essential medicines are resource owners. They must become part of a "solution team" that cooperates constructively and is motivated to generate a "cooperation-induced return on investment"⁴⁷; in this case, the fact that poor patients have better access to medical care and essential medicines is a result of the solution team's work.

If the team's success is viewed as resulting from the cooperation between team members, all members of the problem-solving team will satisfy their own (sub) interests through the success of the overall effort. The team leadership's most important task is to manage the relationships between the various team members in such a way that

- a critical mass of shared convictions shapes the cooperation
- the maximum possible synergy occurs with the minimum possible points of friction
- all members of the problem-solving team receive a fair share of credit (or benefits, as the case may be) for the jointly achieved successes.

Different players obviously have different needs, interests, and potential for working together. By no means are all players who could potentially contribute necessarily actually suitable as members of a solution team. With all due respect for political pluralism, stakeholders and agitation groups bound to narrow ideologies and fundamentalist arguments are not suited to be members of

a solution team. Bias and prejudice tend to render cooperation on complex issues impossible and block the way to small, incremental successes that are otherwise possible through pragmatic and goal-oriented cooperation. Only actors with a certain compatibility ought to be considered as members in a solution team. At a minimum they ought to have a constructive attitude and motivation for the joint work to succeed. And they need to have tangible, intangible, economic, or moral resources at their disposal and be prepared to make them available to the solution team in order to contribute to the joint endeavors.

Outlook

The sustainable improvement of access to essential medicines by poor people is perhaps the most complex challenge for all players engaged in the health sector. Progress is only possible if all players pool their expertise and resources and jointly apply them to bring about improvement. It is encouraging to see that the Internet sites of nearly all NGOs and international organizations engaged in development and health policy feature almost identical statements about the obligation to promote the achievement of the health-related Millennium Development Goals. At the Global Compact Private Sector Forum in connection with the U.N. General Assembly on the Millennium Development Goals in September 2010, the tenor of companies from industrialized and developing countries came through loud and clear: many companies want to get involved and be “part of the solution.” There is a pronounced will to help achieve the goals and to reduce maternal and child mortality rates and fight HIV/AIDS, malaria, TB, and other diseases common to poor people. Likewise, there is a willingness to enter into partnerships with other competent players.

For enlightened managers in the pharmaceutical industry, corporate responsibility means more than competing with integrity and striving for high profits. Enlightened managers want to achieve more than the next quarterly results and engage in contributing to broader social goals. They view society as the totality of all actual and potential customers. Their view of the world and their personal normative attitudes actively shape corporate strategy. Improving poor patients’ access to essential medicines is one of the cornerstones of enlightened strategies. The litmus test of good conduct on the part of national authorities, multilateral institutions, and NGOs is whether they are willing to cooperate constructively with actors from the private sector who wish to contribute reliably to lasting solutions in the healthcare sector.

The roundtable talks that the Bill and Melinda Gates Foundation and the chief executive officers of the world’s leading pharmaceutical companies have been conducting since early 2009 are an additional reason for optimism that new coalitions are possible and access to life-saving, essential medicines for poor patients in developing countries can be improved. The envisaged activities cover promotion of R&D on medicines to fight poverty-related and tropical diseases as well as field projects to improve access to medicines in sub-Saharan Africa, Asia, and Latin America. These projects examine various courses of action to determine their relative effectiveness in improving access to essential medicines. Partners for the field projects beginning in 2011 will be the governmental agencies, NGOs, and internationally operating pharmaceutical companies.

We should not expect miracles, however, nor do we have to. Modest aspirations appear appropriate, given the complexity and dimension of the problems discussed. As Amartya Sen advised in the preface of *The Idea of Justice*, the goal is not to create a perfect world. Instead we should apply all our strength and resources today to eliminating the most glaring injustices and most obvious social wrongs. And this at least should be feasible, shouldn't it?

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