

International Federation
of Pharmaceutical
Manufacturers & Associations

The Changing Landscape on Access to Medicines



This publication analyzes the recent changes in the landscape on access to medicines. Pharmaceuticals have allowed people to live longer and healthier lives, and more and more people throughout the world have access to them. This study focuses on access to medicines and healthcare questions in a holistic manner, involving multi-sector and often international partnerships, healthcare system strengthening, sound procurement and appropriate resource allocation.

There is no simple solution to advance today's achievements and to respond appropriately to the continuing health challenges we face. Strong political commitment is and will always be the lifeblood of public health, and health will always be the cornerstone of society's long-term socio-economic development.

With this publication, IFPMA aims to raise awareness amongst policymakers of the many tools they can use to improve global health and the lessons that can be drawn from the many experiences that are changing the way people access medicines and healthcare.

Key facts & figures

We live in a healthier world

- A child born in 1955 had an average life expectancy at birth of only 48 years, but by 2000 she or he could expect to live 66 years; globally, life expectancy is predicted to rise to 73 years by 2025¹.
- Whereas the global child mortality rate stood at 77 deaths per 1,000 live births in 2000, in 2009 this figure had already decreased to 62².
- In the first decade of the 21st century alone, an estimated 2.5 million deaths were prevented each year among children under the age of five through the use of measles, polio and diphtheria-tetanus-pertussis vaccines³.

Partnerships have changed the landscape on access to medicines

- With approved funding of over USD 22.6 billion, the Global Fund has helped support more than 1,000 programs in 150 countries since its inception in 2002, making it the main financier of programs to fight AIDS, tuberculosis and malaria⁴.
- Since its inception in 2004, US commitments to PEPFAR have amounted to over USD 39 billion. As of September 30, 2011, PEPFAR has directly supported life-saving antiretroviral treatment for more than 3.9 million men, women and children worldwide⁵.
- With the World Bank as its treasury manager, GAVI's International Finance Facility for Immunization has raised more than USD 3.6 billion up to 2012, helping to nearly double GAVI's funding for immunization programs⁶.

- The Global Drug Facility, run by the Stop TB Partnership, is expanding access to medicines for DOTS (Directly Observed Treatment Short course) scale-up; in just five years it has provided over 7 million TB treatments⁷.
- Due to the collective efforts of partners of the Global Alliance to Eliminate Lymphatic Filariasis, 466 million people have been treated for lymphatic filariasis worldwide⁸, and over 6.6 million children have been prevented from acquiring the disease⁹.
- Since its inception, the Mectizan Donation Program has donated nearly one billion treatments with Mectizan for river blindness¹⁰.
- The International Trachoma Initiative has reached millions of people in 18 countries through the donation of 280 million Zithromax treatments¹¹.
- After continued collective efforts to control sleeping sickness, the number of cases reported in 2009 dropped below 10,000 for the first time in 50 years; the trend was maintained in 2010 with only 7,139 new cases reported¹².
- Since 2009, more than 20 million children each year are being treated by Children Without Worms, thanks to donations by pharmaceutical companies¹³.

¹ World Health Organization, *Life in the 21st Century: A Vision for All*, World Health Report, 1998, http://www.who.int/whr/1998/en/whr98_en.pdf.

² Centers for Disease Control, *Ten Great Public Health Achievements - Worldwide, 2001-2010*, Morbidity and Mortality Weekly Report, June 24, 2011, <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6024a4.htm>.

³ Centers for Disease Control, *Ten Great Public Health Achievements - Worldwide, 2001-2010*.

⁴ The Global Fund to Fight AIDS, Tuberculosis and Malaria, *Who We Are*, 2012, <http://www.theglobalfund.org/en/about/whoweare/>.

⁵ US President's Emergency Plan for AIDS Relief, <http://www.pepfar.gov/results/index.htm>.

⁶ IFFIm, *About IFFIm - International Finance Facility for Immunization*, 2012, <http://www.iffim.org/about/>.

⁷ IFPMA, *Health Partnerships Directory*, April 15, 2012, <http://www.ifpma.org/resources/partnerships-directory.html>.

⁸ World Health Organization, *Weekly Epidemiological Record*, August 26, 2011.

⁹ Eric A Ottesen, Pamela J Hooper, Mark Bradley & Gautam Biswas, "The Global Programme to Eliminate Lymphatic Filariasis: Health Impact after 8 Years", *PLoS (Public Library of Science) Neglected Tropical Diseases* (2008).

¹⁰ IFPMA, *Ending Neglected Tropical Diseases*, 2012.

¹¹ IFPMA, *Health Partnerships Directory*.

¹² Serap Aksoy, "Sleeping Sickness Elimination in Sight: Time to Celebrate and Reflect, but Not Relax", *PLoS (Public Library of Science) Neglected Tropical Diseases* 5, no. 2 (February 22, 2011): e10008.

¹³ IFPMA, "Ending Neglected Tropical Diseases", 2012, p.7

Political commitment is the lifeblood of public health

- The World Health Organization, in a 2010 report on health systems financing, suggests total health expenditure should be at least 4-5% of GDP¹⁴.
- Between 2001 and 2009, essential medicines were available in only 42% of public sector and 64% of private sector facilities in developing countries¹⁵.
- The WHO estimates that 20-40% of health resources are wasted due to inefficient and inequitable use¹⁶.
- In some countries, tariffs can add an additional 10-15% to the cost of finished pharmaceuticals, while often generating less than 0.1% of GDP as revenue¹⁷.
- In some countries, wholesale markups can range anywhere from 2% to 380%, while retail markups can range from 10% to 552%¹⁸.
- For every USD 24 spent on new medicines for cardiovascular diseases in OECD countries, USD 89 were saved in hospitalization and other healthcare costs¹⁹.
- 95% of essential medicines, as defined by the WHO, are off patent, but still one third of the world's population does not have reliable access to them and, in parts of Africa and Asia, that is true for half the population²⁰.

The socio-economic determinants of health

- In the Philippines, a 10% increase in distance from healthcare facilities was associated with a 2% increase in mortality rates²¹.
- Worldwide, an estimated 115 million children under the age of five are underweight, and 179 million children are too short for their age group²².
- An estimated 1.1 billion people worldwide lack access to adequate water, and 2.6 billion lack adequate sanitation²³.
- In China alone, over 3,000 people die every day from tobacco-related diseases²⁴.

¹⁴World Health Organization, Health Systems Financing: The Path to Universal Coverage, World Health Report, 2010, <http://www.who.int/whr/2010/en/index.html>.

¹⁵United Nations, Millenium Development Goal 8. The Global Partnership for Development: Time to Deliver, MDG Gap Task Force Report, 2011, http://www.un.org/en/development/desa/policy/mdg_gap/mdg_gap2011/mdg8report2011_engw.pdf.

¹⁶World Health Organization, Health Systems Financing.

¹⁷Muge Olcay & Richard Laing, Pharmaceutical Tariffs: What Is Their Effect on Prices, Protection of Local Industry and Revenue Generation?, World Health Organization, 2005, <http://www.who.int/intellectualproperty/studies/tariffs/en/index.html>.

¹⁸A Cameron et al., "Medicine Prices, Availability, and Affordability in 36 Developing and Middle-income Countries: a Secondary Analysis", The Lancet 373, no. 9659 (January 17, 2009): 240-249.

¹⁹Frank R Lichtenberg, "Have Newer Cardiovascular Drugs Reduced Hospitalization? Evidence from Longitudinal Country-level Data on 20 OECD Countries, 1995-2003", Health Economics 18, no. 5 (May 1, 2009): 519-534.

²⁰World Health Organization and Health Action International (Global), Measuring Medicine Prices, Availability, Affordability, and Price Components (Geneva: 2008).

²¹A Brenneman & M Kerf, Infrastructure and Poverty Linkages (Washington DC: World Bank, 2002).

²²World Health Organization, World Health Statistics, 2011, http://www.who.int/gho/publications/world_health_statistics/en/index.html.

²³World Health Organization, "Progress on Drinking Water and Sanitation", March 2012, http://www.who.int/water_sanitation_health/publications/2012/jmp_report/en/index.html.

²⁴Bruce Heilbruth, "Double Burden", Development Asia, no. 11 (December 2011).

Today's health challenges

Non-communicable diseases

- Non-communicable diseases (NCDs), including cardiovascular conditions, cancer, and diabetes, account for around 60% of all deaths worldwide²⁵.
- 80% of those deaths occur in low- and middle-income countries²⁶.
- NCDs are predicted to cost the world economy an estimated USD 35 trillion by 2025²⁷. In the US, cancer alone is thought to have cost USD 18.2 billion due to lost productivity from illness, and USD 112 billion in mortality costs²⁸.
- In 2005, heart disease, stroke and diabetes caused an estimated loss of income of USD 18 billion in China, USD 9 billion in India, and USD 3 billion in Brazil²⁹.
- The research-based pharmaceutical industry has 1,500 new medicines in the pipeline to treat cancer, diabetes, heart disease, asthma, and mental and neurological disorders³⁰.

Infectious diseases

- It is estimated that 68% of deaths among children less than five years old can be attributed to infectious diseases like diarrhea, pneumonia, malaria and AIDS³¹.
- The number of new AIDS infections annually has decreased from 3.1 million in 2001 to 2.6 million in 2009, but there are still over 33.3 million persons living with HIV/AIDS worldwide³².
- SARS (Severe Acute Respiratory Syndrome) infected more than 8,000 people from 30 countries on six continents, killing more than 800 people in 2003, and costing Asian economies – which were at the heart of the epicenter – USD 11-18 billion³³.

Neglected tropical diseases

- More than one billion people suffer from one or more neglected tropical diseases (NTDs) and, as recently as 2006, an estimated 534,000 deaths annually were attributable to them³⁴.
- Research-based pharmaceutical companies have pledged to donate an average of more than 1.4 billion treatments for each of the ten years from 2011 to 2020 to eliminate or control nine NTDs (sleeping sickness, Chagas disease, lymphatic filariasis, soil-transmitted helminths, river blindness, onchocerciasis, schistosomiasis, leprosy, fasciolosis, and blinding trachoma) that represent more than 90% of the global NTD burden³⁵.
- The pharmaceutical industry was the second largest funder of R&D for neglected diseases in 2010, collectively investing more than USD 500 million³⁶.

The pharmaceutical industry's initiatives to expand access to medicines

- From 2000 to 2009, industry has donated to developing countries more than 2.4 billion treatments of medicines. In addition, the research-based pharmaceutical industry has pledged to donate 14 billion treatments for NTDs from 2011 to 2020³⁷.
- The research-based pharmaceutical industry is an active partner in over 200 global partnerships. Each initiative is unique, but often involves healthcare system capacity building, educational programs, and mechanisms to facilitate access to high-quality pharmaceuticals³⁸.

²⁵D E Bloom & E T Cafiero, *The Global Economic Burden of Non-communicable Diseases* (Geneva: World Economic Forum, 2011).

²⁶Bloom & Cafiero, *The Global Economic Burden of Non-communicable Diseases*.

²⁷Heilbruth, "Double Burden".

²⁸Dan Greenberg et al., "When Is Cancer Care Cost-Effective? A Systematic Overview of Cost-Utility Analyses in Oncology", *Journal of the National Cancer Institute* 102, no. 2 (January 20, 2010): 82–88.

²⁹World Health Organization, *Preventing Chronic Diseases: A Vital Investment*. (Geneva: WHO, 2005).

³⁰Mary Moran, Javier Guzman & Lisette Abela-Oversteegen, *Neglected Disease Research and Development: Is Innovation Under Threat? Policy Cures* December 2011, http://www.policycures.org/downloads/g-finder_2011.pdf?bcsi_scan_9688b637a46568db=0&bcsi_scan_filename=g-finder_2011.pdf.

³¹Centers for Disease Control, *Ten Great Public Health Achievements -- Worldwide, 2001--2010*.

³²<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6024a4.htm>.

³³Floyd Whaley, "Human vs. Bug", *Development Asia* no. 11 (July-December 2011): 21-24.

³⁴World Health Organization, *Neglected Tropical Diseases: Hidden Successes, Emerging Opportunities* (Geneva: WHO, 2006).

³⁵IFPMA, *Ending Neglected Tropical Diseases*.

³⁶Moran, Guzman & Abela-Oversteegen, *Neglected Disease Research and Development*.

³⁷IFPMA, *Research-Based Pharmaceutical Industry Pledges 14 Billion Treatments to Help End Nine Neglected Tropical Diseases*, News Release, January 30, 2012, http://www.ifpma.org/fileadmin/content/News/2012/IFPMA_Ending_neglected_tropical_diseases_January2012.pdf.

³⁸IFPMA, *Health Partnerships Directory*.

Executive Summary



Executive summary

The access to medicines landscape has changed considerably in the last decade. International partnerships have been providing countries suffering from insufficient capacity and resources with new means to support health programs that improve access to medicines for their populations. More and more governments are also allocating the necessary resources and political commitment to create performing healthcare systems—even in resource-limited contexts. The research-based pharmaceutical industry has actively collaborated in these achievements by bringing to market nearly all the medicines and vaccines in use today, and by supporting hundreds of national and international initiatives aimed at improving access to medicines, raising disease awareness, and fostering capacity building.

International partnerships to support effective healthcare systems

Over the past century, we have witnessed a marked enhancement in health outcomes across the globe. Improved living conditions, a better understanding of the causes of disease, and the ability to both prevent and treat a wide range of illnesses allow people to live longer, healthier lives. Much of these health gains can be attributed to improved control of infectious diseases. Thanks to an increased national and global focus on basic interventions including immunization, access to safe water, insecticide-treated bednets and antibiotics, many formerly common diseases are today virtually unknown.

Despite these global gains in healthcare and quality of life, substantial health disparities between populations still exist. This gap is particularly evident at the international level; individuals born in high-income countries have much higher average life expectancy rates than their counterparts in low-income countries. Evidence shows that countries with governments that make healthcare a key priority have significantly better health outcomes than others³⁹. The World Health Organization suggests that total health expenditure should be at least 4-5% of GDP⁴⁰, and that 20-40% of health resources are wasted due to their inefficient and inequitable use⁴¹.

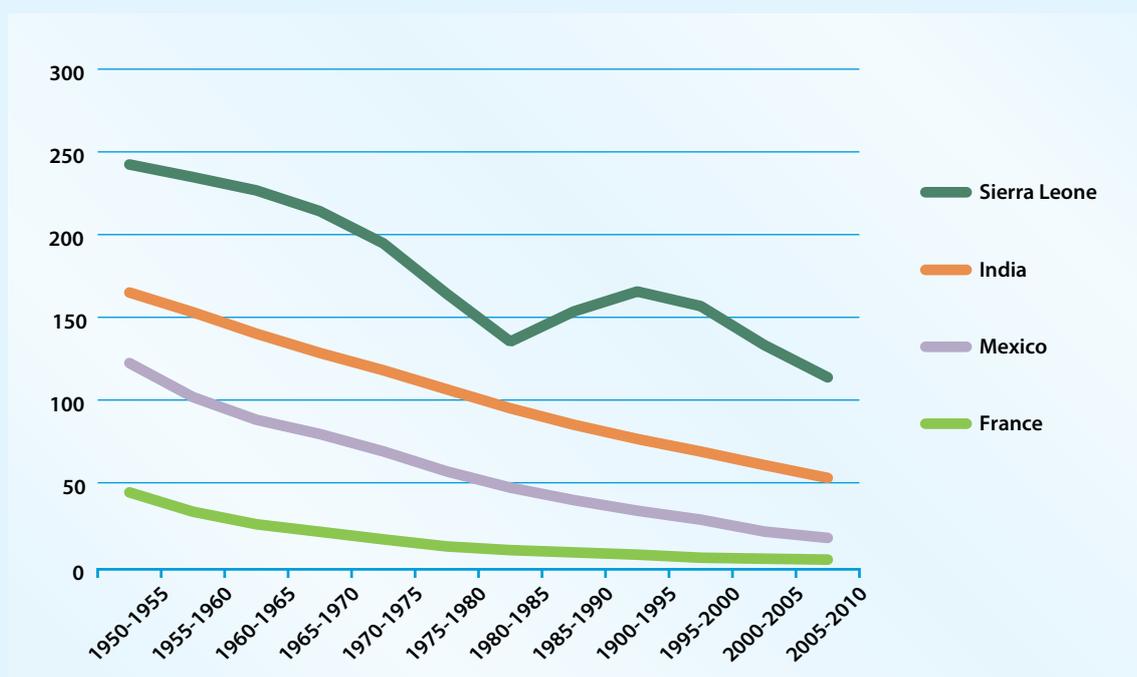
Where governments are unable to finance their basic national healthcare needs or lack the necessary expertise, they may engage in international partnerships. In the last decade, the international community has encouraged these initiatives to help countries overcome financing and capacity deficiencies that jeopardize wider access to needed medicines and vaccines. Today's global health access mechanisms take a more holistic approach to global health cooperation than their predecessors; they rely on a wide array of public and private sector partners to bring their own expertise to the table, focusing on longer-term sustainability of healthcare systems. To this end, the research-based pharmaceutical industry is an active partner in over 200 global partnerships.

However, global health partnerships cannot replace the pivotal role of governments in achieving health goals. Governments play a crucial role in allocating resources for building and maintaining a strong and efficient primary healthcare system, which reaches its population in a timely manner without undue financial hardship for patients. Consolidating a primary healthcare system is particularly challenging in countries characterized by low incomes, difficult geography and political instability. An efficient use of resources to increase the impact of healthcare expenditures will nevertheless result in positive health outcomes regardless of a country's income level.

³⁹Tim Wilsdon, Jim Attridge et al., *Evidence on Access to Essential Medicines for the Treatment of HIV/AIDS*, (Boston: Charles Rivers Associates, 2011).

⁴⁰World Health Organization, *Health Systems Financing: The Path to Universal Coverage*, World Health Report, 2010, <http://www.who.int/whr/2010/en/index.html>.

⁴¹World Health Organization, *Health Systems Financing*.



*Infant mortality in selected regions*⁴²

Ensuring sustainable access to medicines

Access to pharmaceuticals is one of the key pillars of any healthcare system. It helps to lower overall healthcare costs by reducing the need for hospitalization and expensive, invasive procedures⁴³. After improvements to basic sanitation, access to clean water and immunization, access to pharmaceuticals is one of the most cost-effective health-related measures⁴⁴.

While many essential medicines⁴⁵ often cost as little as USD 0.02-1.50, these prices can still be prohibitive for individuals earning less than USD 1 a day.⁴⁶ For this portion of the world's population – nearly one in seven individuals – out-of-pocket costs of medicines makes them the largest family expenditure item after food⁴⁷. Even though 95% of essential medicines are off patent, the World Health Organization found that between 2001 and 2009 they were only available in 42% of public sector and 64% of private sector facilities in developing countries⁴⁸. In many such cases, the cost of essential medicines can easily push patients below the poverty line⁴⁹.

⁴²United Nations, (New York: UN Department of Economic and Social Affairs, Population Division, 2011).

⁴³Michael C Sokol et al., "Impact of Medication Adherence on Hospitalization Risk and Healthcare Cost", *Medical Care* 43, no. 6 (June 1, 2005): 521–530.

⁴⁴S Simoens, "What Is the Value for Money of Medicines? A Registry Study", *Journal of Clinical Pharmacy and Therapeutics* (n.d.), <http://onlinelibrary.wiley.com/doi/10.1111/j.1365-2710.2011.01277.x/abstract>.

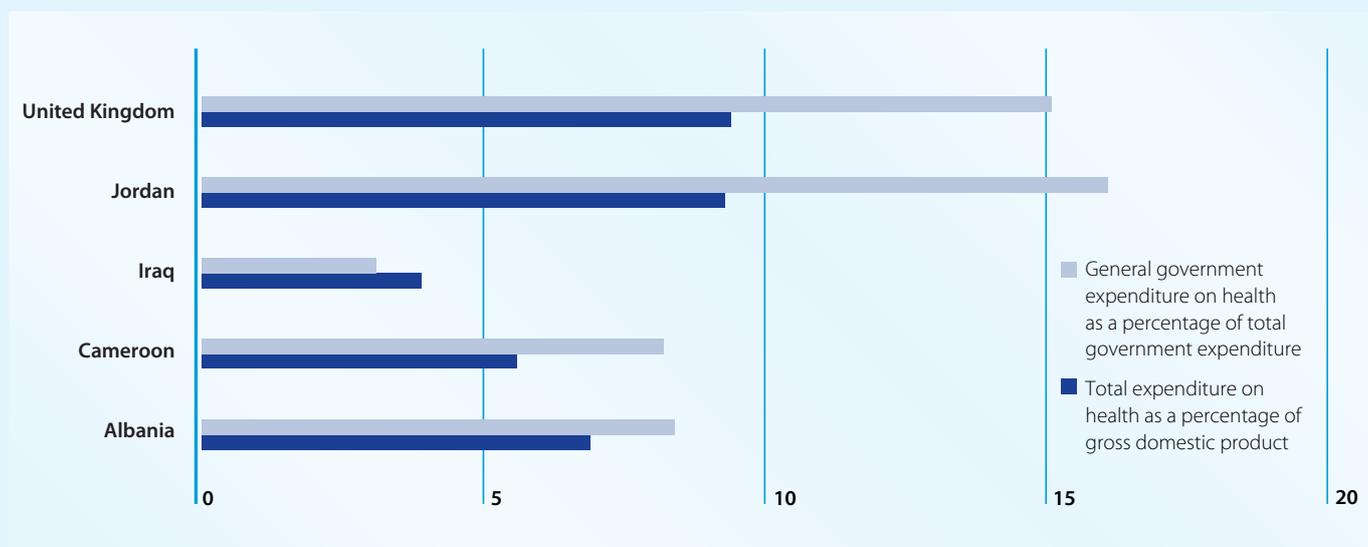
⁴⁵Essential medicines are those that satisfy the priority healthcare needs of the population. They are selected by the WHO with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness.

⁴⁶World Bank, "Poverty Analysis", *Poverty at a Glance* (2011).

⁴⁷A Cameron et al., "Medicine Prices, Availability, and Affordability in 36 Developing and Middle-income Countries: a Secondary Analysis", *The Lancet* 373, no. 9659 (January 17, 2009): 240–249.

⁴⁸United Nations, Millennium Development Goal 8. The Global Partnership for Development: Time to Deliver, MDG Gap Task Force Report, 2011, http://www.un.org/en/development/desa/policy/mdg_gap/mdg_gap2011/mdg8report2011_engw.pdf.

⁴⁹Laurens M Niens et al., "Quantifying the Impoverishing Effects of Purchasing Medicines: A Cross-Country Comparison of the Affordability of Medicines in the Developing World", *PLoS (Public Library of Science) Medicine* 7, no. 8 (2010).



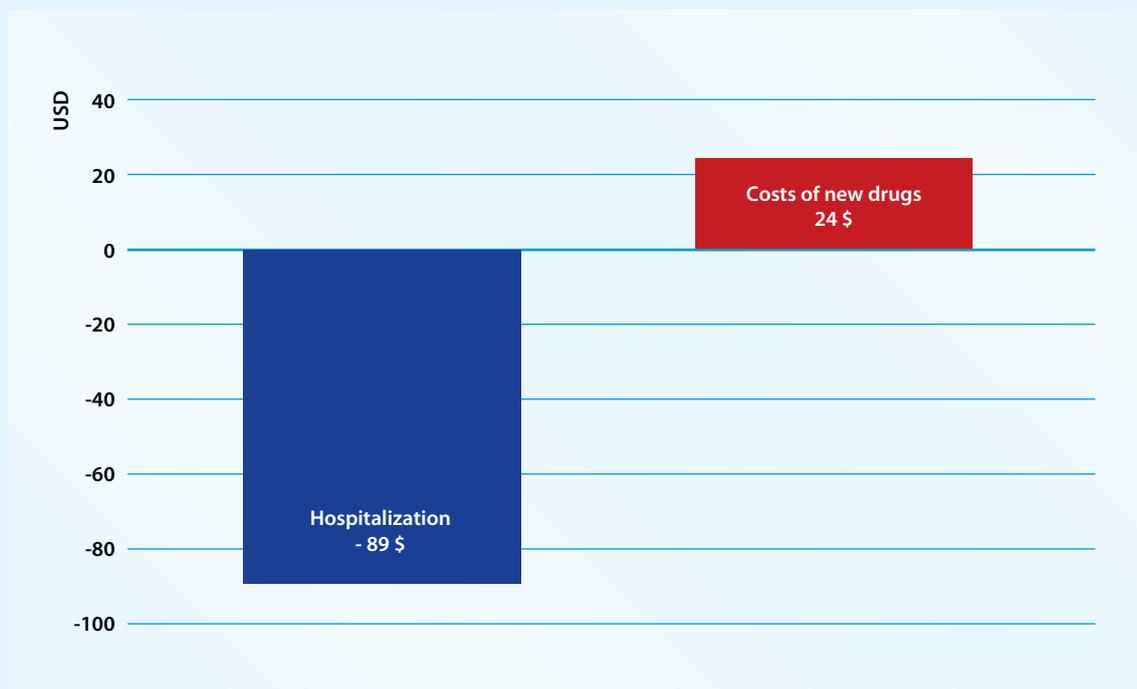
*Expenditure on health in selected countries*⁵⁰

In many countries, public and private insurance schemes or government-funded programs allow individuals and their families to access healthcare when they need it most. Both public and private health insurance systems work by pooling together the financial resources of a group of individuals over long periods of time. This helps ensure sustainability and affordability of healthcare coverage for all of the group members—making health insurance coverage a crucial factor that improves access to health⁵¹.

If procurement is done sustainably, countries can benefit from significant economies of scale and price reductions, whereas last-minute orders tend to increase costs. Despite recent improvements, many governments in lower-income countries tend to play a minor role in the purchase of pharmaceuticals. Inadequate public sector purchases of medicines make it harder for vulnerable citizens to access needed medicines and vaccines. When governments prioritize the purchase of medicines and vaccines as a public intervention that is worthwhile and cost effective, they are investing in the future of their country.

⁵⁰World Health Organization, <http://www.who.int/healthinfo/statistics/indhealthexpenditure/en/index.html>.

⁵¹World Health Organization, Health Systems Financing.



Cost of newer cardiovascular drugs compared to savings in hospitalization in 20 OECD countries (1995–2003)⁵²

The different dimensions of cost

The cost of medicines varies significantly across countries. Some of this price differential is due to production costs or preferential pricing offered to lower-income countries. Additionally, factors such as unnecessary mark-ups, taxes, tariffs and additional charges by middlemen can substantially raise the final price over the manufacturer's base price. Transportation, storage, staff salaries and stock losses all factor into the final cost of pharmaceutical products. In some countries, wholesale mark-ups can range anywhere from 2% to 380%, while retail mark-ups can range from 10% to 552%.⁵³ For populations living on the edge of poverty, these additional mark-ups can partially or even completely impede patient access to medicines and vaccines.

Innovative medicines can help control increasing costs within a healthcare system. For every USD 24 spent on new medicines for cardiovascular diseases in OECD countries, USD 89 were saved in hospitalization and other healthcare costs.⁵⁴ Before creation of antibiotics used to treat peptic ulcers, treatment for the disease consisted of major surgery and costly assistance with recovery, requiring as much as USD 17,000 and over 300 days of treatment. After the advent of antibiotics, the cost of treating ulcers plummeted to less than USD 1,000.⁵⁵

⁵²Source: Lichtenberg, Frank R. 2009. "Have newer cardiovascular drugs reduced hospitalization? Evidence from longitudinal country-level data on 20 OECD countries, 1995-2003," *Health Economics*, John Wiley & Sons, Ltd., vol. 18(5), pp. 519-534.

⁵³Cameron et al., "Medicine Prices, Availability, and Affordability".

⁵⁴Frank R Lichtenberg, "Have Newer Cardiovascular Drugs Reduced Hospitalization? Evidence from Longitudinal Country-level Data on 20 OECD Countries, 1995–2003", *Health Economics* 18, no. 5 (May 1, 2009): 519–534.

⁵⁵Centers for Disease Control, "Economics of Peptic Ulcer Disease and H. Pylori Infection", October 1998, <http://www.cdc.gov/ulcer/economic.htm>.

Local production and the role of intellectual property

Many countries do not have the local technical know-how or economic scale needed to be self-sufficient in the production of pharmaceuticals, making domestic production of pharmaceuticals an extremely challenging endeavor. In some developing countries with adequate technical expertise, reliable quality controls, appropriate legal and financial frameworks, and a viable market, local production of medicines is feasible and usually reflects the commercial business model of the pharmaceutical industry. When appropriate to specific conditions,⁵⁶ the R&D companies share technology and know-how with qualified partners around the world that can produce high-quality generic versions of innovative products. In other cases, a company might prefer to transfer technology to a subsidiary and produce locally some of its innovative products; positive externalities for local partner companies can enhance social and economic development.

In a number of African and Asian countries nearly half the population lacks access to medicines, even though most essential medicines can be produced by any generic manufacturer.⁵⁷ About 95% of essential medicines are off patent.⁵⁸ The dearth of medicines – innovators or generics – in a given country or region is mostly linked to the absence of a viable market that would offset the costs of entry. These costs are often exacerbated by inefficiencies in the regulatory system and the medicines distribution network. Experience has shown that low-income countries have managed to greatly expand access to medicines through strong political commitment, partnerships and good procurement, without resorting to policies that undermine their intellectual property systems.⁵⁹

In those cases where a product is still on patent, any manufacturer that wants to use the technology can approach the patent holder and negotiate a production license. The holder of the patent will examine the specifics of the case and, if the parties can agree, will license out the product through a voluntary license. One of the main advantages of this approach is that it often includes transfer of the know-how needed to ensure high-quality medicines are produced efficiently.

Voluntary licenses have been increasingly used to accelerate the entry of generics in lower-income country markets. They can increase the number of potential producers of a given medicine, while at the same time ensuring the high quality of medicines produced. However, they are not a panacea and are not necessarily appropriate to every country or situation. In some circumstances, companies might judge it more appropriate to facilitate access to their medicines through tiered pricing, procurement negotiations, donations or public-private partnerships.

⁵⁶IFPMA, *Technology Transfer: A Collaborative Approach to Improve Global Health. The Research-Based Pharmaceutical Industry Experience* (2011).

⁵⁷World Health Organization and Health Action International (Global), *Measuring Medicine Prices, Availability, Affordability, and Price Components* (Geneva: 2008).

⁵⁸Stanley Kowalski, *The Patent Status of Medicines on the WHO Model List for Essential Medicines*, presentation at Joint Technical Symposium by WHO, WIPO and WTO on Access to Medicines: Patent Information and Freedom to Operate, Geneva, February 17, 2011.

⁵⁹Tim Wilsdon, Jim Attridge et al., *Evidence on Access to Essential Medicines for the Treatment of HIV/AIDS*.

The research-based pharmaceutical industry contribution to improve access to medicines

Tiered pricing is one of the most effective and sustainable ways in which pharmaceutical companies have been helping to improve access to medicines. In essence, companies charge a higher price for the same product in higher-income countries than in lower-income countries. This cross-subsidy allows companies in many cases to sell medicines and vaccines at or below manufacturing cost. For example, low-income countries and those with the severest HIV/AIDS epidemics are offered branded antiretroviral drugs (ARVs) at significant discounts and in some cases even at not-for-profit prices.

The research-based pharmaceutical industry has also spearheaded a variety of donation programs. Some of these programs have existed for many years and involve significant financial commitments. Donations can be disease-specific to a global partnership, or can be broader in scope, with a wider range of medicines donated to charities and relief organizations. Furthermore, pharmaceutical company donations often play an important role in helping populations recover in the aftermath of national and regional catastrophes.

Since 2000, the scale of industry's donations has greatly increased. From 2000 to 2009, the research-based pharmaceutical industry has donated to developing countries more than 2.4 billion treatments⁶⁰. In addition, the industry has pledged to donate 14 billion treatments for neglected tropical diseases (NTDs) from 2011 to 2020.⁶¹ A sustainable healthcare system will not be built solely on donations, however. Companies may themselves face financial difficulties and might not be able to maintain a donation program indefinitely or scale it up to the extent needed to reach a broader population. It is only through the purchase of pharmaceuticals at a commercially viable price that a country can avoid medicine shortages and ensure reliability of supply.

⁶⁰IFPMA, *The Pharmaceutical Industry and Global Health: Facts and Figures*, 2011.

⁶¹IFPMA, *Research-Based Pharmaceutical Industry Pledges 14 Billion Treatments to Help End Nine Neglected Tropical Diseases*, News Release (Geneva, January 30, 2012), http://www.ifpma.org/fileadmin/content/News/2012/IFPMA_Ending_neglected_tropical_diseases_January2012.pdf.

Going forward

Sustainable access to quality pharmaceuticals goes beyond the pill. A number of variables reviewed in this publication—including the efficiency of the distribution system, infrastructure, effectiveness of healthcare systems, patient access to insurance, as well as government taxation and procurement policies—all play critical roles in determining the extent of patient access to medicines and vaccines in a safe and timely manner. An effective intellectual property system does not jeopardize access to medicines. On the contrary, it gives companies the confidence that their technology will not be unfairly used and thus facilitates the early introduction of new medicines in different markets and the development of new medicines. The biggest challenge in ensuring access to quality pharmaceuticals stems primarily from domestic deficiencies in the healthcare system that exacerbate existing disparities in the population. Low- and high-income countries alike have shown that political will to address healthcare challenges can lead to significant and tangible returns in health outcomes.

Chapter 1



The changing landscape on access to medicines and healthcare – the role of international players

The turn of the century marked a new maturity in global health cooperation. Since 2000, there has been an increasing realization that no one entity or body alone can solve global health problems and that a key way forward is through the intensification of partnerships. Many new international health partnerships of both public and private sector actors have emerged to tackle

access to medicines and other health issues in a more sustainable, effective and comprehensive way. These new partnerships include a variety of players that bring different expertise to the table. They are helping to change the landscape on access to medicines and are bringing concrete health improvements to the most vulnerable populations.

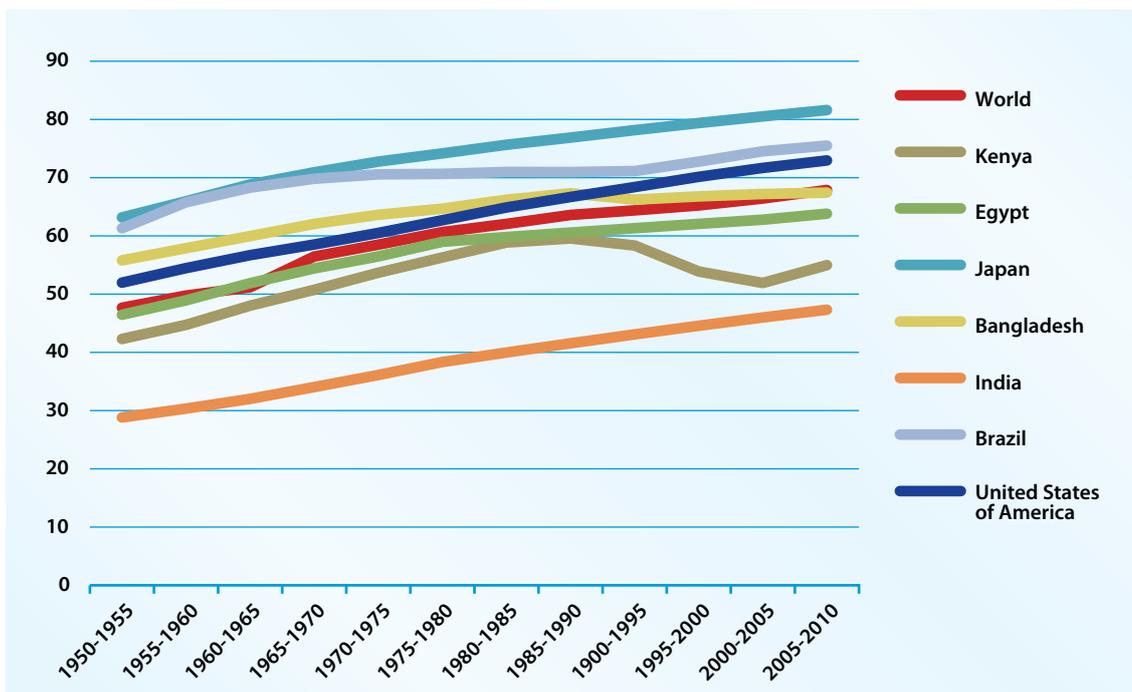


Figure 1: Life expectancy at birth in selected countries⁶²

⁶²United Nations, Department of Economic and Social Affairs, Population Division (2011).

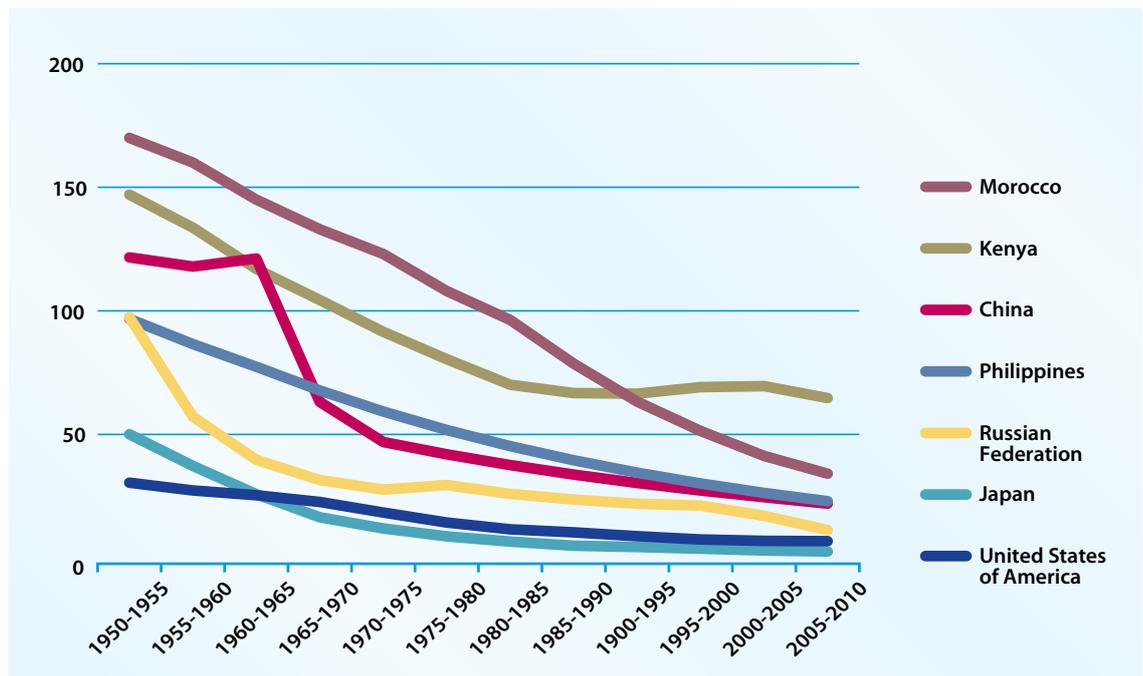


Figure 2: Infant mortality in selected countries⁶³

The global health achievements of the late 20th and early 21st centuries

Over the past century, we have witnessed a marked enhancement in health outcomes across the globe. Improved living conditions, a better understanding of the causes of disease, and the ability to both prevent and treat a wide range of illnesses are allowing people to live longer, healthier lives.

The power of human knowledge to prevent once-common diseases has translated into significant gains in quality of life and lifespan globally. A child born in 1955 had an average life expectancy at birth of only 48 years, but by 2000 she or he could expect to live 66 years; life expectancy is predicted to rise to 73 years globally by 2025.⁶⁴

The broad achievements in life expectancy have been complemented by lower infant mortality rates worldwide, with higher percentages of children living to see their fifth birthday than ever before. Whereas the global child mortality rate stood at 77 deaths per 1,000 live births in 2000, in 2009 this figure had already decreased to 62.⁶⁵

Much of these health gains can be attributed to improved control of infectious diseases. Thanks to increased national and international focus on basic interventions like immunization, nutrition, access to safe water, insecticide-treated bednets and antibiotics, many formerly common diseases are today virtually unknown to most medical practitioners.

⁶³United Nations, Department of Economic and Social Affairs, Population Division (2011).

⁶⁴World Health Organization, Life in the 21st Century: A Vision for All, World Health Report, 1998, http://www.who.int/whr/1998/en/whr98_en.pdf.

⁶⁵Centers for Disease Control, Ten Great Public Health Achievements - Worldwide, 2001-2010, Morbidity and Mortality Weekly Report, June 24, 2011, <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6024a4.htm>.

Moving towards elimination of diseases

Some of the most notable global health successes that date back to the past century have been partnerships for disease elimination. Elimination campaigns require extensive resources and cooperation with all sectors of public health, from the local to the international level, and can require many years before they achieve their results.

The most significant successes in this regard have been the eradication of smallpox and the near-eradication of polio, both vaccine-preventable diseases. Smallpox was the first disease ever to have been eradicated by human action. This viral infection blinded and killed untold millions over three millennia, but was eradicated in 1977 following an extensive global immunization campaign that lasted 12 years.⁶⁶ More recently, public health officials have made remarkable advances in their concerted effort to eradicate polio. The incidence of this disease, which mainly affects young children and can cause irreversible paralysis, has decreased sharply by over 99% through a global immunization campaign started in 1988.⁶⁷ Spearheaded by the World Health Organization, the campaign has helped eliminate polio from most regions, with 2010 seeing only 1,352 cases spread across a very limited number of countries.

Unlike polio and smallpox, which can be easily prevented with inexpensive vaccines, other diseases have been targeted for elimination by mass-treatment programs, which aim to break the diseases' contamination cycle. These complex partnerships usually require the administration of medicines to millions of patients in often remote areas, in addition

to the building of efficient surveillance systems. Some of these efforts date from the 1980s and have already achieved significant results. River blindness has been almost eradicated from the Americas,⁶⁸ while guinea worm disease transmission has been interrupted in all but four countries in Africa.⁶⁹

International partnerships to improve health outputs

Despite global improvements in health and quality of life, there remain substantial disparities in the quality of healthcare available to different groups, especially between rich and poor. This gap is particularly conspicuous at the international level, as individuals born in high-income countries have much higher average life expectancy rates than their counterparts in low-income countries. In the US, for example, average life expectancy rose from 70 years in 1970 to 78 years in 2010; in Japan, life expectancy is currently over 82 years. In comparison, most children born in low- and middle-income countries can only expect to live on average to the age of 65.⁷⁰

Part of this differential is due to the high infectious disease burden still experienced in many low- and middle-income countries. Lower-respiratory infections and diarrheal diseases combined are responsible for 18% of deaths in lower-income countries.⁷¹ In 2009, 68% of persons living with HIV (22.5 million) lived in sub-Saharan Africa.⁷² Similarly, child mortality is especially high in low- and middle-income countries, with 49% of childhood deaths occurring in sub-Saharan Africa, and another 33% in southern Asia.⁷³

⁶⁶World Health Organization, "Smallpox Fact Sheet", Media Centre, 2001, <http://www.who.int/mediacentre/factsheets/smallpox/en/>.

⁶⁷World Health Organization, "Poliomyelitis Fact Sheet", Media Centre, February 2012, <http://www.who.int/mediacentre/factsheets/fs114/en/index.html>.

⁶⁸The Carter Center, "Onchocerciasis Elimination Program of the Americas", The Carter Center River Blindness (Onchocerciasis) Program, 2012, http://www.cartercenter.org/health/river_blindness/oepa.html.

⁶⁹The Carter Center, "Carter Center Guinea Worm Eradication Program", Countdown to Zero: Carter Center Guinea Worm Eradication Program, 2012, http://www.cartercenter.org/health/guinea_worm/mini_site/index.html.

⁷⁰United Nations Population Division, Life Expectancy at Birth - Both Sexes, World Population Prospects, 2010, <http://esa.un.org/wpp/Excel-Data/mortality.htm>.

⁷¹Philip Stevens & Holly Linfield, *Death and Taxes: Government Mark-ups on the Price of Drugs*, (Washington: International Policy Network, 2009).

⁷²Joint United Nations Programme on HIV/AIDS (UNAIDS), *Report on the Global AIDS Epidemic, Global Report*, 2010, http://www.unaids.org/globalreport/global_report.htm.

⁷³Centers for Disease Control, *Ten Great Public Health Achievements - Worldwide, 2001-2010*.

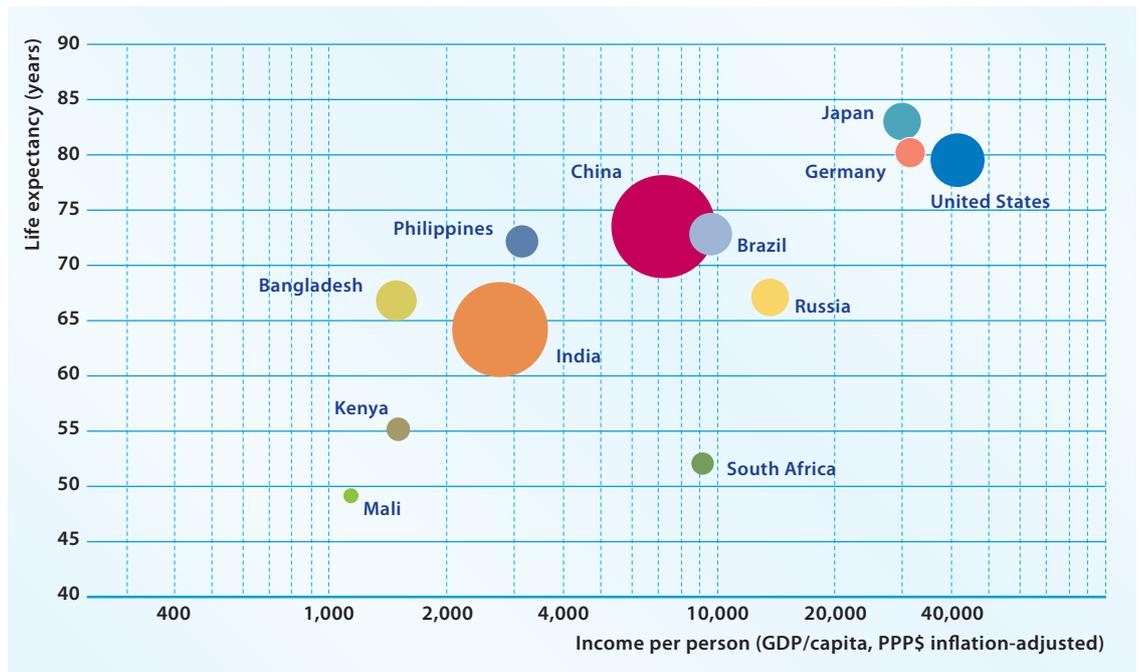


Figure 3: Correlation between income per capita and life expectancy (2011)⁷⁴

Countries whose governments prioritize healthcare have much better health outcomes than those that do not. The World Health Organization, in a 2010 report on health systems financing, suggests total health expenditure should be at least 4-5% of GDP.⁷⁵ Many developing countries do prioritize investing in health, but others are still a long way from reaching that goal. For example, the government of Laos spends less than 1% of its national budget on healthcare, and in the Philippines the comparable figure is 1.3%.⁷⁶

In addition to low investment in health, in many countries limited resources are badly spent. The World Health Organization estimates that 20-40% of health resources are wasted due to their inefficient and inequitable use.⁷⁷ Inadequate prioritization of investments, hospital inefficiency, waste and corruption account for a significant part of the disparities in health outcomes between countries with similar levels of health expenditure.

When governments lack the appropriate resources and/or expertise to build and maintain an efficient healthcare system, they may choose to engage with international partnerships. In this century, there has been a marked increase in these mechanisms, which aim to help countries overcome financing and capacity deficiencies that jeopardize wider access to needed medicines and vaccines. Today's global health partnerships take a more holistic and long-term approach to health challenges than their predecessors. Contrary to the piecemeal approach of the past, they can better leverage the expertise and resources of a multitude of public and private sector partners to help build sustainable healthcare systems.

The research-based pharmaceutical industry is an active partner in over 200 global partnerships. Each initiative is unique, but often involves healthcare system capacity building, educational programs and mechanisms to facilitate access to high-quality pharmaceuticals. These partnerships have been drastically redesigning the landscape on access to healthcare in their areas of activity.

⁷⁴Adapted from Gapminder "Global Trends: Wealth & Health of Nations" in 2010. Diameter of the circle reflects population size.

⁷⁵World Health Organization, Health Systems Financing: The Path to Universal Coverage, World Health Report, 2010, <http://www.who.int/whr/2010/en/index.html>.

⁷⁶Bruce Heilbruth, "Catastrophic Costs", Development Asia, no. 11 (December 2011).

⁷⁷World Health Organization, Health Systems Financing.

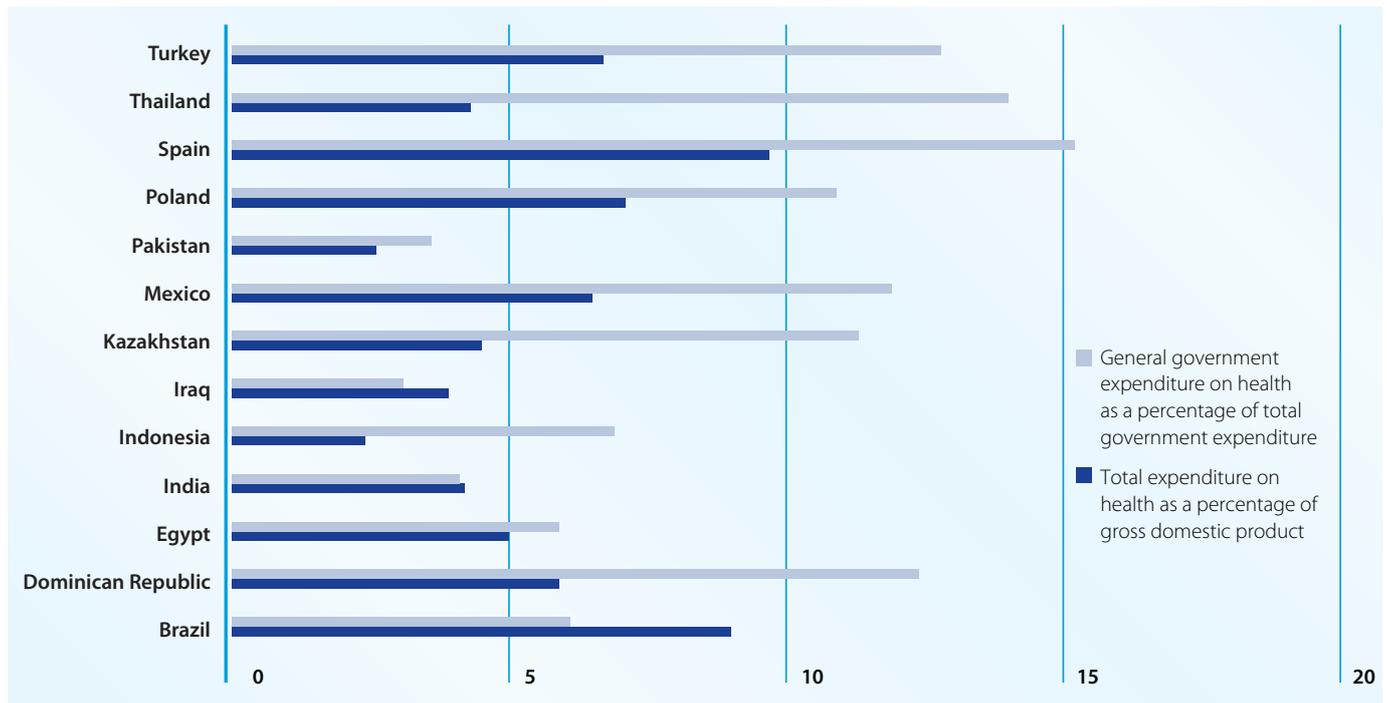


Figure 4: Expenditure on health in selected countries⁷⁸

The Global Fund to fight AIDS, Tuberculosis and Malaria

The Global Fund is a public-private partnership and financing institution that funds programs targeting HIV/AIDS, tuberculosis (TB) and malaria. With approved funding of over USD 22.6 billion, the Global Fund has helped support more than 1,000 programs in 150 countries since its inception in 2002, making it the main financier of programs to fight AIDS, TB and malaria.⁷⁹ It currently channels two thirds of the international financing provided to tackle malaria and TB, and a fifth of the finance for combating AIDS.

The Fund's model relies on performance-based funding and country ownership, which means that countries develop and implement their own programs in line with their national plans and priorities, with finance and technical assistance from the Fund. Around 39% of the Fund's resources are used for procurement of pharmaceuticals and other health products.⁸⁰ Recipient countries are responsible for procuring their own pharmaceuticals, while the Fund provides technical assistance and a Voluntary Pooled Procurement mechanism.

The research-based pharmaceutical industry contributes to the success of the Fund's programs through the different access initiatives it supports, which increase the impact of projects supported by the Fund. Most receiving countries are eligible for at-cost or highly discounted prices offered by the innovative companies. In addition, many companies have entered into voluntary licensing or non-assert agreements with generic producers, which have allowed the early production and trade of generic medicines in developing countries (see Chapter 3).⁸¹ Takeda Pharmaceutical is an active partner in the Global Fund through a pledge of USD 10 million over the 2010-2019 period,⁸² which is being used primarily to train healthcare workers and strengthen healthcare systems in Africa. Other companies are supporting different programs financed by the Global Fund.

⁷⁸World Health Organization, <http://www.who.int/healthinfo/statistics/indhealthexpenditure/en/index.html>.

⁷⁹The Global Fund, "Who We Are", 2012, <http://www.theglobalfund.org/en/about/whoweare/>.

⁸⁰The Global Fund, "Pharmaceutical Procurement and Supply Management", <http://www.theglobalfund.org/en/procurement/>.

⁸¹IFPMA, "Voluntary Licenses and Non-Assert Declarations: Actions by R&D Pharmaceutical Companies that Facilitate Access to Medicines"

⁸²IFPMA, Health Partnerships Directory, April 15, 2012, <http://www.ifpma.org/resources/partnerships-directory.html>.

President's Emergency Plan for AIDS Relief

The US President's Emergency Plan for AIDS Relief (PEPFAR) is a broad partnership that includes the US government, innovator and generic pharmaceutical companies, and multilateral organizations such as UNAIDS, the WHO and UNICEF. As of September 30, 2011, it has directly supported life-saving antiretroviral treatment for more than 3.9 million men, women and children worldwide. In addition, PEPFAR directly supported HIV testing and counseling for more than 9.8 million pregnant women in fiscal year 2011, as well as antiretroviral drug prophylaxis to prevent mother-to-child transmission for more than 660,000 of these women who tested positive for HIV, allowing approximately 200,000 infants to be born HIV-free.⁸³ Since its inception in 2004, US commitments to PEPFAR have amounted to over USD 39 billion.

Pharmaceutical companies, including Abbott, Bristol-Myers Squibb, Gilead, Merck & Co., and Viiv Healthcare actively support PEPFAR by working to find solutions to issues concerning pediatric HIV treatment, improved formulations and better access to antiretroviral treatment for people living with HIV/AIDS in resource-limited settings. Additionally, Viiv Healthcare and Abbott supply PEPFAR with pediatric HIV treatment formulations at access prices.

UNITAID

UNITAID is an international facility that aims to improve access to pharmaceuticals in low-income countries for HIV/AIDS, malaria and TB. It relies upon sustainable and predictable funding sources like the "air tax" on plane tickets and government contributions; its budget to date exceeds USD 1.3 billion. The organization uses its purchasing power to increase demand for health products needed to treat or prevent the three diseases, which in turn is aimed at generating economies of scale and price reductions.⁸⁴ The organization also supports the WHO Prequalification Program with over USD 40 million, helping to ensure the quality of the medicines being procured.

UNITAID relies on implementing partners to deliver the medicines it finances. It has traditionally worked with international health organizations such as the Clinton Health Action Initiative (CHAI), the Global Fund, the STOP TB Partnership and UNICEF. In 2010, UNITAID supported the delivery of over 700,000 ARV treatments in 52 countries, 250,000 TB treatments in 68 countries and 17.6 million malaria treatments in 32 countries.⁸⁵ UNITAID is also the main funder of the Medicines Patent Pool Initiative.

GAVI Alliance

Founded in 2000, the GAVI Alliance's mission is to reduce childhood morbidity and mortality from vaccine-preventable diseases by increasing immunization rates and improving vaccine access for children in developing countries. Crucell, GlaxoSmithKline, Merck & Co., Novartis, Pfizer and Sanofi Pasteur are founding partners of GAVI. The International Finance Facility for Immunization (IFFIm) is a financing mechanism set up in 2006 to boost the availability and predictability of funds for GAVI's immunization programs.

The IFFIm works by attracting legally-binding commitments of up to 20 years from donors, which it then sells on capital markets as "vaccine bonds". IFFIm benefits from USD 6.3 billion in donor contributions over 23 years from the governments of the United Kingdom, France, Italy, Norway, Australia, Spain, the Netherlands, Sweden and South Africa.⁸⁶ With the World Bank as its treasury manager, IFFIm has raised more than USD 3.6 billion up to 2012, helping to nearly double GAVI's funding for immunization programs.

⁸³US President's Emergency Plan for AIDS Relief, <http://www.pepfar.gov/results/index.htm>.

⁸⁴UNITAID, "Mission", 2012, <http://www.unitaid.eu/en/about/mission-mainmenu-89>.

⁸⁵UNITAID, "Key Performance Indicators 2010".

⁸⁶IFFIm, "ABOUT IFFIm - International Finance Facility for Immunisation", 2012, <http://www.iffim.org/about/>.

Stop TB Partnership

The Stop TB Partnership, founded in 2001, works to accelerate progress on access to TB diagnosis and treatment, spur research and development for new TB diagnostics, drugs and vaccines, as well as tackle drug-resistant and HIV-associated TB.⁸⁷ The Partnership operates in more than 100 countries and has more than 500 partners, including international, governmental, non-governmental and private sector organizations.

The Global Drug Facility, run by the Stop TB Partnership, is expanding access to medicines for DOTS scale-up; in just five years it has committed over 7 million TB treatments. Projects managing multidrug-resistant TB (MDR-TB) can apply through the Green Light Committee (GLC) for access to quality MDR-TB medicines at reduced prices - in some cases by as much as 99%. Lilly has a program to make two critical medicines for treatment of drug-resistant TB strains available in developing countries; it supplied 1.4 million vials of capreomycin at concessionary prices to the GLC in 2009. Novartis is donating 500,000 fixed-dose combinations to all adult patients in Tanzania through the Global Drug Facility during 2005-2012.⁸⁸ Bayer HealthCare has also committed to selling moxifloxacin at a reduced price under specifically defined conditions of treatment programs.

Affordable Medicines Facility for Malaria (AMFM)

The Affordable Medicines Facility for Malaria (AMFM) is a pilot initiative launched in 2010 to increase access to safe and effective artemisinin-based combination therapies (ACTs), by providing a global subsidy for their purchase. One of the AMFM's main goals is to curb the widespread use of oral artemisinin monotherapies, which are much cheaper than ACTs, but are likely to create resistance that threatens the entire class of artemisinin-based antimalarials. Even though ACT prices have dropped significantly in government-sponsored health facilities, many patients do not have access to these facilities and have to buy the medicines themselves.

The Global Fund hosts the AMFM and has negotiated with pharmaceutical manufacturers to reduce the price

of ACTs and to require that sales prices be the same for public and private sector first-line buyers. The Fund pays most of this reduced price directly to the manufacturer. First-line buyers are expected to pass on the highest proportion of this price benefit so all patients are able to buy ACTs across the public, private, not-for-profit and profit sectors at prices that are less than those of oral artemisinin monotherapies.⁸⁹ Novartis and Sanofi, which were already selling their antimalarials at discount prices for developing countries, are also supplying their medicines to the initiative.

The London Declaration on Neglected Tropical Diseases

Neglected tropical diseases (NTDs) affect nearly one billion people in lower-income countries. These diseases generally afflict the rural poor, often leaving them with life-long social stigmatization, disability and pain.⁹⁰ Nine NTDs (sleeping sickness, Chagas disease, lymphatic filariasis, soil-transmitted helminths, river blindness (onchocerciasis), schistosomiasis, leprosy, fasciolosis and blinding trachoma) represent more than 90% of the global NTD burden.⁹¹

In January 2012, 13 pharmaceutical companies, the governments of the US, the UK and the United Arab Emirates, the Bill and Melinda Gates Foundation, the World Bank and other global health organizations launched a new collaboration to accelerate progress toward eliminating or controlling ten NTDs by the end of the decade. The group announced that they would sustain or expand existing drug donation programs to meet demand through 2020; share expertise and compounds to accelerate R&D for new drugs; and provide more than USD 785 million to support R&D efforts and strengthen drug distribution and implementation programs.

Research-based pharmaceutical companies have pledged to donate an average of more than 14 billion treatments over the ten years from 2011 to 2020. This commitment builds on already existing initiatives on NTDs that have been drastically changing the lives of people affected by these diseases.⁹²

⁸⁷Stop TB Partnership, "About Us", 2012, <http://www.stoptb.org/about/>.

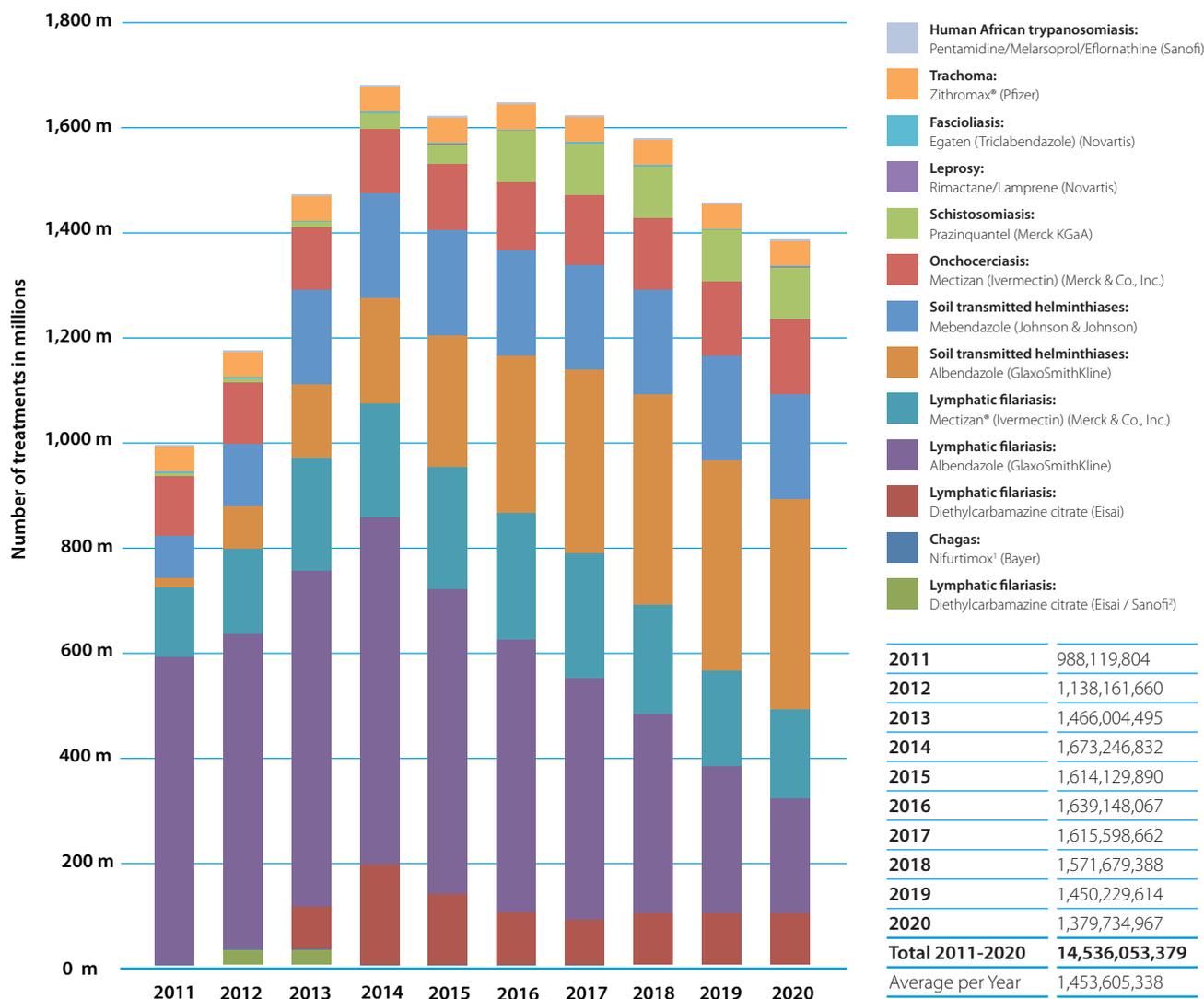
⁸⁸IFPMA, "Health Partnerships Directory".

⁸⁹The Global Fund, "Affordable Medicines Facility – Malaria", <http://www.theglobalfund.org/en/amfm/>.

⁹⁰World Health Organization, *Neglected Tropical Diseases: Hidden Successes, Emerging Opportunities* (Geneva:WHO, 2006).

⁹¹World Health Organization, "First WHO report on neglected tropical diseases", 2010.

⁹²IFPMA, "Ending Neglected Tropical Diseases", 2012.



¹ Nifurtimox, generally used as 2nd-line drug.
² The Bill and Melinda Gates foundation is also contributing.

Figure 5: Donation commitments of pharmaceutical companies for NTDs⁹³

Global Alliance to Eliminate Lymphatic Filariasis (GAELF)

The Global Alliance to Eliminate Lymphatic Filariasis (GAELF) was created in 1998 to eliminate one of the world’s leading causes of disability and disfigurement as a public health problem by the year 2020. An estimated 120 million people in at least 80 countries suffer from the disease, and one billion (20% of the world’s population) are at risk of infection.⁹⁴

Since its inception, the Alliance has evolved into a global partnership between international organizations in the public and private sectors, academia and non-governmental organizations (NGOs), working in partnership with ministries of health in tropical countries where lymphatic filariasis is endemic. As a result of partners’ collective efforts, 466 million people have been treated worldwide,⁹⁵ and over 6.6 million children have been prevented from acquiring the disease.⁹⁶

⁹³FPMA, “Ending Neglected Tropical Diseases”.
⁹⁴World Health Organization, Working to Overcome the Global Impact of Neglected Tropical Diseases, WHO Report on Neglected Tropical Diseases (Geneva: WHO, 2010).
⁹⁵World Health Organization, Weekly Epidemiological Record, August 16, 2011.
⁹⁶Eric A Ottesen, Pamela J Hooper, Mark Bradley, Gautam Biswas, “The Global Programme to Eliminate Lymphatic Filariasis: Health Impact after 8 Years”, PLoS (Public Library of Science) Neglected Tropical Diseases. (2008).

The WHO recommends that lymphatic filariasis be prevented with a combination of Albendazole (donated by GlaxoSmithKline) with either DEC (supplied by Sanofi and Eisai) or Mectizan (donated by Merck & Co.). To break the cycle of transmission, drug administration for people living in endemic areas is recommended once a year for at least five years. As of 2009, Merck had donated over 414 million treatments of Mectizan and GlaxoSmithKline had donated over 1.4 billion treatments of Albendazole to endemic countries. Eisai will begin manufacturing and supplying 2.2 billion tablets of DEC to the WHO from late 2013. In addition to medicines donations, pharmaceutical partners are providing financial grants to support research programs, coalition building, workshops and communications.

Merck Mectizan Donation Program (MDP)

Commonly known as river blindness, onchocerciasis is an infectious disease caused by a parasite transmitted through the bite of infected blackflies. The larval worms move through the body and when they die cause a variety of conditions, including skin rashes, lesions, intense itching, skin de-pigmentation and blindness. Onchocerciasis is the world's second leading infectious cause of blindness.

The Merck Mectizan Donation Program (MDP) was launched in 1987, when Merck & Co. announced that it would donate Mectizan (ivermectin) for the treatment of river blindness to all who needed it for as long as necessary. A multi-sectoral partnership was established with governments in countries where river blindness is endemic, their ministries of health and other national

and international stakeholders, including the WHO, to ensure appropriate infrastructure, distribution and support. The Mectizan Donation Program is the longest-running, disease-specific drug donation program and public-private partnership of its kind. Since the inception of the program, Merck has donated nearly one billion treatments with Mectizan for river blindness. The program currently provides 100 million treatments annually through river blindness programs in Africa, Latin America and Yemen.⁹⁷

International Trachoma Initiative

Trachoma is an infectious eye disease, caused by the bacterium *Chlamydia trachomatis*, which spreads by contact with an infected person's hand or clothing.⁹⁸ The disease used to be found around the world, but these days it typically affects only the poorest of the poor in lower-income countries.

Pfizer and the Edna McConnell Clark Foundation founded the International Trachoma Initiative (ITI) in 1998 in response to the World Health Organization's call to eliminate blinding trachoma by 2020.⁹⁹ Collaborating with a range of partners in various sectors such as water, sanitation and education, the ITI helps control trachoma through the WHO-recommended SAFE strategy of Surgery, Antibiotics, Facial Cleanliness and Environmental Improvement. To date, ITI has reached millions of people in 18 countries through Pfizer's donation of 280 million Zithromax® treatments, assistance to countries and partners to develop supply-chain capacity where needed, and extensive collection of data and management of knowledge on trachoma.¹⁰⁰

⁹⁷IFPMA, "Ending Neglected Tropical Diseases".

⁹⁸International Trachoma Initiative, "The World's Leading Cause of Preventable Blindness", 2012, <http://www.trachoma.org/world%E2%80%99s-leading-cause-preventable-blindness>.

⁹⁹International Trachoma Initiative, "Fighting Blinding Trachoma", 2012, <http://www.trachoma.org/iti-fighting-blinding-trachoma>.

¹⁰⁰IFPMA, "Health Partnerships Directory"

Sleeping sickness elimination

Sleeping sickness is a major health threat to rural populations in African countries where the tsetse fly is endemic. Diagnosis and treatment of the disease are complex and require specifically skilled staff. Sleeping sickness cases often go undiagnosed until it is too late to act because sufferers live far from healthcare facilities.¹⁰¹

In 2001, Sanofi committed USD 25 million over the years 2001-2006 to help the WHO implement a strategy of adequate medicine supplies, disease surveillance and management, and R&D for new treatments.¹⁰² The company has also pledged to supply unlimited amounts of eflornithine, melarsoprol and pentamidine to the WHO until 2020. Bayer HealthCare joined the effort in 2002, providing an initial supply of 50,000 ampoules of Germanin® (suramin), a commitment which was renewed for the period 2008-2013. In September 2009, Bayer committed to support the WHO in the implementation of Nifurtimox-Eflornithine Combination Therapy (NECT), with an annual donation of 400,000 tablets of Lampit® (nifurtimox). After continued control efforts, the number of cases of sleeping sickness reported in 2009 dropped below 10,000 for first time in 50 years; the trend was maintained in 2010 with only 7,139 new cases reported.¹⁰³

Children Without Worms

Soil-transmitted helminthiasis (STH), an infection of intestinal worms, affects an estimated 400 million children worldwide. STH causes malnutrition, increases susceptibility to other serious infections, and stunts growth during a critical development period. Diagnostic tools and treatments exist, but fewer than 20% of at-risk children were reached with de-worming treatment in 2005.¹⁰⁴

In 2007, Johnson & Johnson partnered with the Task Force for Child Survival and Development to develop and launch Children Without Worms.¹⁰⁵ In addition to promoting hygiene education and increased access to water and sanitation facilities, the partnership also distributes the de-worming medications Albendazole, donated by GlaxoSmithKline, and Mebendazole, donated by Johnson & Johnson. Since 2009, more than 20 million children a year are being treated thanks to these donations, and this number is expected to expand over the next five years through the pledged annual donations of 200 million tablets of Mebendazole and 400 million doses of Albendazole (also used to treat lymphatic filariasis).¹⁰⁶

¹⁰¹World Health Organization, "Human African Trypanosomiasis (Sleeping Sickness) Fact Sheet", Media Centre, 2012, <http://www.who.int/mediacentre/factsheets/fs259/en/>.

¹⁰²IFPMA, "Health Partnerships Directory".

¹⁰³Serap Aksoy, "Sleeping Sickness Elimination in Sight: Time to Celebrate and Reflect, but Not Relax", PLoS (Public Library of Science) Neglected Tropical Diseases 5, no. 2 (February 22, 2011): e1008.

¹⁰⁴Children Without Worms, "The World's Children Free of Intestinal Worms", 2011, <http://www.childrenwithoutworms.org/>.

¹⁰⁵IFPMA, "Health Partnerships Directory".

¹⁰⁶IFPMA, "Ending Neglected Tropical Diseases", p.7.

Conclusions

Global health cooperation has been an important tool to help countries improve access to medicines. Through multilateral financing mechanisms and public-private partnerships, substantial progress has been made in improving health outcomes. There has been an intensification of the scale and quality of the numerous commitments and initiatives established this century. It will be necessary to sustain and continue to build upon these successes over the next decade.

At the same time, these successes may mask underlying weaknesses of healthcare systems. Chapter 2 will examine the building blocks required to lay the foundations for health systems capable of addressing emerging global health needs in a sustainable way.

Chapter 2



Building sustainable health systems to address today’s challenges

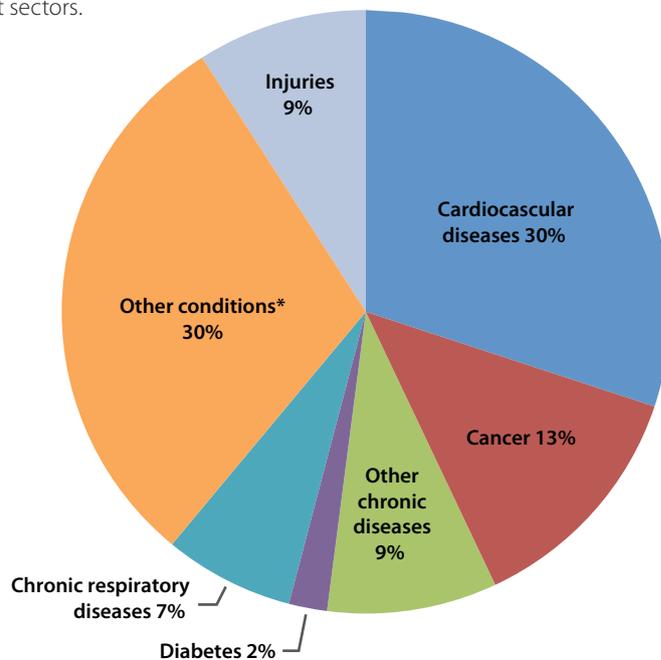
While international health partnerships have been drastically changing the access to medicines and healthcare landscape for millions of people, sustainable health outcomes will only be maintained if countries build strong healthcare systems for themselves. Health is fundamental to a country’s long-term socio-economic development and policymakers should prioritize it. Political commitment and adequate allocation of resources are and will remain fundamental in tackling the health challenges of today and tomorrow.

Today’s global health challenges

International cooperation has led to substantial improvements in longevity and quality of life worldwide. Still, more progress is needed to address today’s health challenges. Monitoring and effectively tackling non-communicable diseases and new infectious diseases will require performing healthcare systems. This will take strong political will, inclusive health policies, and broad cooperation amongst different sectors.

Non-communicable and chronic diseases

Non-communicable and chronic diseases are fast becoming a major health issue in most countries around the globe. These diseases – including cardiovascular and respiratory conditions, cancer and diabetes – now account for around 60% of all deaths worldwide.¹⁰⁷ This epidemiological shift is attributed partly to lifestyle and other environmental factors. Alcohol abuse, physical inactivity, poor diet, stress and tobacco use are estimated to be responsible for about half of all non-communicable diseases (NCDs).¹⁰⁸ Non-modifiable factors – such as genetics, sex and age – are thought to play an equally important role in determining who is at risk.



* Other conditions comprises communicable diseases, maternal and perinatal conditions and nutritional deficiencies.

Figure 6: The global distribution of cause of death¹⁰⁹

¹⁰⁷D E Bloom & E T Cafiero, The Global Economic Burden of Non-communicable Diseases (Geneva: World Economic Forum, 2011).

¹⁰⁸World Health Organization, Preventing Chronic Diseases: A Vital Investment, WHO Global Health Report, 2005, http://www.who.int/chp/chronic_disease_report/en/.

¹⁰⁹World Health Organization.

Regardless of their root causes, NCDs are characterized by their long duration and slow progression. Mental and neurological disorders, cancer, rheumatoid arthritis, diabetes and other non-communicable diseases impose substantial clinical and economic burdens on their sufferers. The chronic nature of these illnesses means that patients have to deal with them day in, day out for long periods of time. As well as creating an economic burden in the form of increased consumption of health services, patients generally face reduced income and lower work productivity over time.¹¹⁰ The economic repercussions of non-communicable diseases extend beyond the home; by one count, they are predicted to cost the world economy an estimated USD 35 trillion by 2025.¹¹¹ In the US, cancer alone may have cost USD 18.2 billion due to lost productivity from illness, and USD 112 billion due to mortality costs.¹¹²

Many people wrongly associate health problems like diabetes or obesity solely with wealthy countries. However, they are just as prevalent in low- and middle-income countries. The infectious disease burden generally decreases as income rises, but the same

is not true for non-communicable diseases. Many developing countries face a double disease burden, fighting infectious and non-communicable diseases simultaneously. While 60% of all deaths worldwide are attributable to NCDs, 80% of those deaths are in low- and middle-income countries.¹¹³ These deaths are often due to natural causes linked to ageing.

In developing countries, NCDs are closely linked with poverty, creating an additional burden in the form of slower economic growth. In 2005, heart disease, stroke and diabetes caused income losses of USD 18 billion in China, USD 9 billion in India, and USD 3 billion in Brazil.¹¹⁴ The World Bank estimates that in India alone, eliminating non-communicable diseases would increase GDP by 4-10%.¹¹⁵ Mental and neurological disorders are also expected to contribute to this growing disease burden. In the US, nearly 5.4 million individuals live with Alzheimer's disease, which is estimated to create a burden of USD 200 billion in 2012 alone.¹¹⁶ By 2050, Alzheimer's disease is expected to afflict up to 16 million Americans, costing an estimated USD 1.1 trillion.

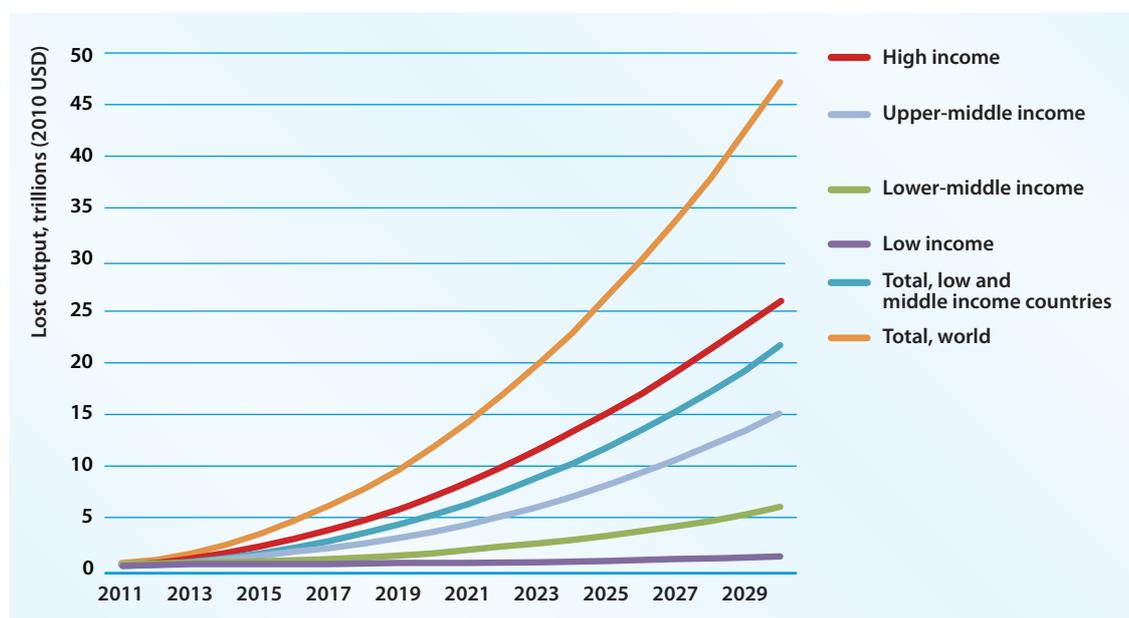


Figure 7: The global economic burden of non-communicable diseases¹¹⁷

¹¹⁰World Economic Forum, Harvard School of Public Health & World Health Organization, From Burden to "Best Buys": Reducing the Economic Impact of Non-Communicable Diseases in Low- and Middle-Income Countries (2011).

¹¹¹Bruce Heilbruth, "Double Burden", *Development Asia*, no. 11 (December 2011).

¹¹²Dan Greenberg et al., "When Is Cancer Care Cost-Effective? A Systematic Overview of Cost-Utility Analyses in Oncology", *Journal of the National Cancer Institute* 102, no. 2 (January 20, 2010): 82–88.

¹¹³Bloom & Cafiero, *The Global Economic Burden of Non-communicable Diseases*.

¹¹⁴World Health Organization, *Preventing Chronic Diseases*.

¹¹⁵World Health Organization, *Global Status Report on NCDs, 2010*, http://www.who.int/chp/ncd_global_status_report/en/index.html.

¹¹⁶Alzheimer's Association, "Alzheimer's Disease Facts and Figures", 2012, http://www.alz.org/alzheimers_disease_facts_and_figures.asp.

¹¹⁷Bloom & Cafiero, *The Global Economic Burden of Non-communicable Diseases*.

Recognizing the growing health and economic burden of NCDs, the research-based pharmaceutical industry has 1,500 new medicines in the pipeline to treat cancer, diabetes, heart disease, asthma, and mental and neurological disorders.¹¹⁸ However, the best approach for most NCDs is prevention.

It is estimated that half the deaths caused by NCDs are preventable through increased health literacy, awareness and simple behavioral changes.¹¹⁹ As the increased

prevalence of NCDs poses a mounting challenge to healthcare systems worldwide and to public and private finances, prevention represents a cost-effective solution for alleviating their economic burden. Reducing mortality and morbidity through increased investment in prevention programs will contribute to higher economic growth and allow limited resources to be focused efficiently on patients most in need.

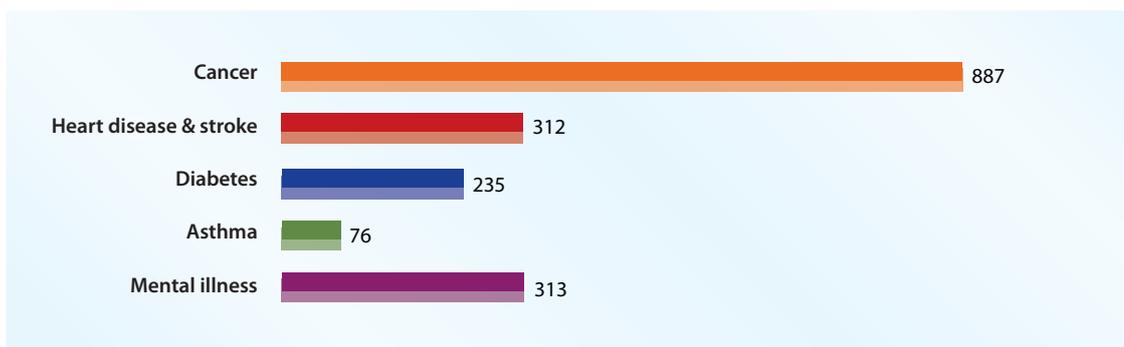


Figure 8: Current medicines in development¹²⁰

Sanofi: Impact epilepsy program for developing countries¹²¹

Sanofi is committed to treating epilepsy worldwide. In addition to using a tiered pricing policy to increase access to its two treatments, Gardenal and Depakine/valproate Winthrop, the company has also partnered with a number of organizations in Africa and Asia to provide training and capacity building. Initiatives include:

- In Mali, with the Santé Sud and the Association des Médecins de Campagne, creation of a Réseau Action Recherche contre l'Epilepsie, helping to diagnose and treat more than 2,500 patients;
- In Kenya, with the Kenya Association for the Welfare of People with Epilepsy, training for 295 healthcare professionals and treatment of 11,000 patients;
- In Cambodia, creation of the first association in the country to combat epilepsy.

¹¹⁸Mary Moran, Javier Guzman & Lisette Abela-Oversteegen, Neglected Disease Research and Development: Is Innovation Under Threat? (Policy Cures, December 2011), http://www.policycures.org/downloads/g-finder_2011.pdf?bcsi_scan_9688b637a46568db=0&bcsi_scan_filename=g-finder_2011.pdf.

¹¹⁹World Health Organization, Preventing Chronic Diseases.

¹²⁰PhRMA: "Medicines in Development for Selected Chronic Diseases", 2010.

¹²¹IFPMA, Health Partnerships Directory, April 15, 2012, <http://www.ifpma.org/resources/partnerships-directory.html>.

Infectious diseases

While NCDs are a growing burden for countries' healthcare capacities and national economies, the risk of infectious diseases is still very real, particularly in low-income countries. Some of these diseases can result in death and disability, particularly among children, those who have a debilitated health status, and the elderly. For example, it is estimated that 68% of deaths among children less than five years old can be attributed to infectious diseases-related such as diarrhea, pneumonia, malaria and AIDS.¹²²

Among the array of infectious diseases that afflict humans, much attention worldwide over the past twenty years has focused on HIV/AIDS. This disease, which emerged in the early 1980s, continues to be a major global health challenge, despite successes in averting new infections and increased access to medical treatment. Although the number of new infections annually has decreased from 3.1 million in 2001 to 2.6

million in 2009, there are still over 33.3 million persons living with HIV/AIDS around the globe.¹²³

As HIV/AIDS showed the world, the risk of emerging infectious diseases is a continuing threat. In 1918, for example, Spanish influenza infected around one third of the world's population, killing an estimated 50 million people in less than two years. More recently, SARS (Severe Acute Respiratory Syndrome) infected more than 8,000 people from 30 countries on six continents, killing more than 800 people in 2003, and costing Asian economies – which were at the heart of the epicenter – USD11-18 billion.¹²⁴

Developing innovative treatments and prevention tools for infectious diseases is an important part of the research-based pharmaceutical industry's work portfolio; this includes research on 97 new medicines and vaccines for HIV/AIDS, 34 for malaria, and 25 for tuberculosis.¹²⁵

Bristol-Myers Squibb's SECURE THE FUTURE®

Since 1999, Bristol-Myers Squibb and the Bristol-Myers Squibb Foundation have committed more than USD 160 million to develop, replicate and scale up innovative and sustainable solutions for communities affected by HIV/AIDS in Africa, with special emphasis on community treatment support programs, care for children and building infrastructure.

To date, SECURE THE FUTURE® has supported more than 240 projects focused on community-based care and outreach, and medical care and research. For example, in the area of pediatrics, SECURE THE FUTURE® in partnership with Baylor College of Medicine and national governments developed a five-country initiative which now has over 110,000 children in its care and has been responsible for the training of over 52,000 healthcare workers. SECURE THE FUTURE® has also expanded its reach from five to 21 countries and evolved from a broad-based grant-making initiative to a technical assistance and skills transfer program. The SECURE THE FUTURE Technical Assistance Program capitalizes on SECURE THE FUTURE's funding, program management experience, and expertise and track record as a committed private-public partnership program. The aim is to replicate SECURE THE FUTURE's lessons, experiences and successful models to address the strategic challenge of operational multi-sectoral collaborations in HIV by harnessing community resources and capacity.

In 2011, the Bristol-Myers Squibb Foundation entered into a collaboration with the World Health Organization's Stop TB Department to strengthen community-based prevention, care and control of tuberculosis (TB), including co-infection with HIV, in South Africa, Tanzania, Kenya, Ethiopia and the Democratic Republic of Congo. The initiative will leverage technical assistance through community care experts from the SECURE THE FUTURE® program.

¹²²Centers for Disease Control, Ten Great Public Health Achievements - Worldwide, 2001-2010, Morbidity and Mortality Weekly Report, June 24, 2011,

¹²³<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6024a4.htm>.

¹²⁴Floyd Whaley, "Human vs. Bug", Development Asia. no. 21 (July-December 2011): 21-24.

¹²⁵IFPMA, "Overview of Research-Based Pharmaceutical Industry Contributions to the Health-Related UN MDGs", September 2010, http://www.ifpma.org/fileadmin/content/News/2010/EditorNote_UN_MDGs_Summit_16Sep2010.pdf.

Neglected Tropical Diseases (NTDs)

Neglected tropical diseases (NTDs) are a major public health problem in some countries. Many of these diseases, which are endemic to rural areas of sub-Saharan Africa and poor urban settings in low-income countries in Asia and Latin America, lead to long-term disability, reduced employment opportunities, disfigurement, and impaired childhood growth. More than one billion people suffer from one or more of these diseases and, as recently as 2006, an estimated 534,000 deaths annually were attributable to them.¹²⁶

Complementing its participation in large-scale drug distribution and prevention initiatives (discussed in Chapter 1), the pharmaceutical industry is leveraging its research know-how to help develop better treatments for NTDs. Since 2000, a number of companies have created research centers of excellence specifically dedicated to developing new treatment therapies, and there are currently 93 independent research and product development projects for tropical diseases. In fact, the research-based pharmaceutical industry was the second largest funder of R&D for neglected diseases in 2010, collectively investing more than USD 500 million.¹²⁷

This new research landscape for neglected diseases has been catalyzed by the product development partnership (PDP) model, in which stakeholders from the private, non-profit and public sectors work together to develop new pharmaceuticals. Indeed, the majority of industry R&D projects for diseases of the developing world now involve collaboration with PDPs.¹²⁸ Companies provide the R&D, technology, manufacturing

and distribution expertise, with funding and logistical contributions from partners, such as governments or philanthropic organizations. Academic institutions are also involved in providing research capabilities and disease area knowledge. In order to be successful, a collaborative platform like a PDP needs to overcome barriers that restrict socially valuable partnerships, encourage intellectual property owners to contribute to the scheme, and be flexible enough to adapt to a variety of different circumstances in order to facilitate timely innovation.¹²⁹

An important example of the role played by PDPs in enhancing long-term access to medicines for NTDs is ASAQ, a fixed-dose combination of artesunate and amodiaquine. This is the first antimalarial treatment to be developed by a public-private partnership, in this case between Sanofi and the Drugs for Neglected Diseases initiative (DNDi). To improve treatment compliance by patients and diminish risks of resistance, the use of a drug should be as simple as possible. ASAQ's new formulation allows neonates and children up to the age of 13 years to be treated using just one tablet a day for three days. For teenagers aged 14 years and above and for adults, the dosage regimen is also simplified. The tablets can be dissolved or crushed and given in liquid or semi-liquid food, making them much easier to administer to children. To improve accessibility for as many patients as possible, Sanofi took the decision not to patent this innovation, and to provide the medicine at affordable prices - less than USD 1 for an adult treatment and less than USD 0.50 for a child treatment. Since 2008, ASAQ has been included on the WHO's list of pre-qualified medicines.¹³⁰

¹²⁶World Health Organization, *Neglected Tropical Diseases: Hidden Successes, Emerging Opportunities* (Geneva: WHO, 2006).

¹²⁷Moran, Guzman & Abela-Oversteegen, *Neglected Disease Research and Development: Is Innovation Under Threat?*

¹²⁸Moran, Guzman & Abela-Oversteegen, *Neglected Disease Research and Development: Is Innovation Under Threat?*

¹²⁹IFPMA, "Principles to Facilitate Pharmaceutical Industry Collaboration in 'Neglected' Disease Areas", 2011, http://www.ifpma.org/fileadmin/content/Innovation/Research%20and%20Dev/Collaborative_Innovation_Models/IFPMA_Principles_Ind_Collaboration_Sept201.pdf.

¹³⁰Sanofi, "Focus on Malaria Treatment", http://en.sanofi.com/our_company/highlights/malaria/treatments/treatments.aspx.

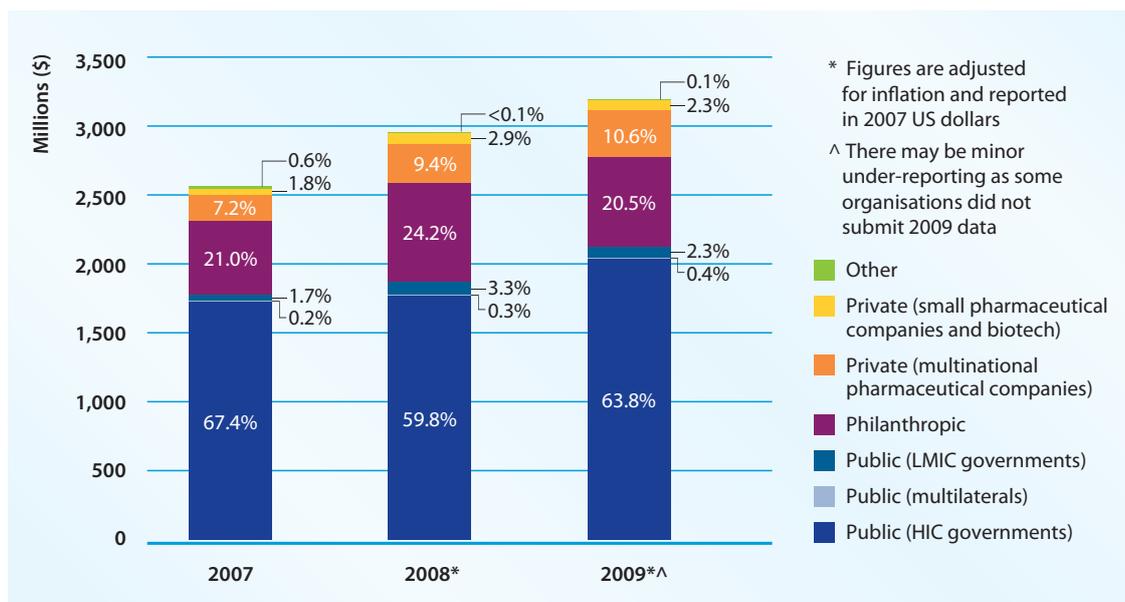


Figure 9: Total funding for neglected diseases by funder type (2007-2009)¹³¹

WIPO Re:Search – a consortium of public and private sector organizations

Recognizing the need for more progress in neglected disease research, WIPO Re:Search was formed in 2011 through the efforts of several of the world's leading pharmaceutical companies, the World Intellectual Property Organization (WIPO) and BIO Ventures for Global Health (BVGH). WIPO Re:Search provides access to intellectual property for pharmaceutical compounds, technologies, and – most importantly – know-how and data available for research and development for neglected tropical diseases, tuberculosis and malaria. By providing a searchable public database of available intellectual property assets and resources, WIPO Re:Search facilitates new partnerships to support organizations that conduct research on treatments for neglected tropical diseases, ultimately improving the lives of those most in need.

WIPO RE:Search has three major components:

- A database, hosted by WIPO, providing details of intellectual property available for licensing from a provider, as well as services and other technology or materials not necessarily protected by intellectual property rights that can be accessed by users.
- A Partnership Hub, managed by BVGH, where members and other interested parties can learn about the consortium, available licensing and research collaboration opportunities, networking possibilities and funding options.
- A range of specific supporting activities, led by WIPO in cooperation with BVGH, to facilitate negotiations of licensing agreements and to address technical matters such as identifying research needs and opportunities, among others, with technical advice from the World Health Organization (WHO).

For products resulting from licenses through the consortium, all providers of intellectual property agree to:

- Provide licenses for these products on a royalty-free basis for use and sale in all least-developed countries (LDCs).
- Consider in good faith the issue of access to these products for all developing countries, including those that do not qualify as LDCs.

More information at: <http://www.wipo.int/research>

¹³¹Moran, Guzman & Abela-Oversteegen, Neglected Disease Research and Development: Is Innovation Under Threat?

Eliminating or controlling NTDs is achievable. The WHO has set a 2020 target to end nine NTDs that represent 90% of the global NTD burden. Reaching this target relies on a multi-stakeholder approach that integrates elements such as environmental improvements, capacity building, effective health policies, better screening, availability of quality, safe and effective medicines, and, in some cases, further research and development. In addition to boosting its NTD research program, the research-based pharmaceutical industry has committed to donate 14 billion treatments from 2011 to 2020.¹³²

Building sustainable primary healthcare systems

One robust indicator of positive health outcomes is government commitment to and investment in building and maintaining a strong and efficient primary healthcare system that reaches its population in a timely manner without undue financial hardship for patients. In many cases, a lack of investment in basic health infrastructure – including appropriate distribution of healthcare facilities and medical staff in each region – combines with factors like inefficient transportation networks, making it difficult for poor individuals to have access to healthcare facilities.

Consolidating a primary healthcare system is particularly challenging in countries characterized by low income, difficult geography and political instability. However, an efficient use of health resources will result in better health outcomes regardless of a country’s socio-economic situation. For instance, after Bangladesh started a health program focused on its most vulnerable populations - the poor, women and children - life expectancy rose above and the proportion of underweight children fell below levels in neighboring India, despite Bangladesh’s more modest per capita income.¹³³

In addition to improving the geographic distribution of medical facilities, making it easier for all populations to get the care they need, many governments in low- and middle-income countries face the challenge of hiring enough doctors and nurses, who often prefer to migrate to countries with higher salaries and more modern equipment. Locations with higher doctor and nurse ratios are not only better able to deal with emergencies as they arise, but a higher ratio also means that healthcare practitioners have time to speak with patients about preventive care, including proper medication adherence, which improves patient healthcare outcomes over the long run.

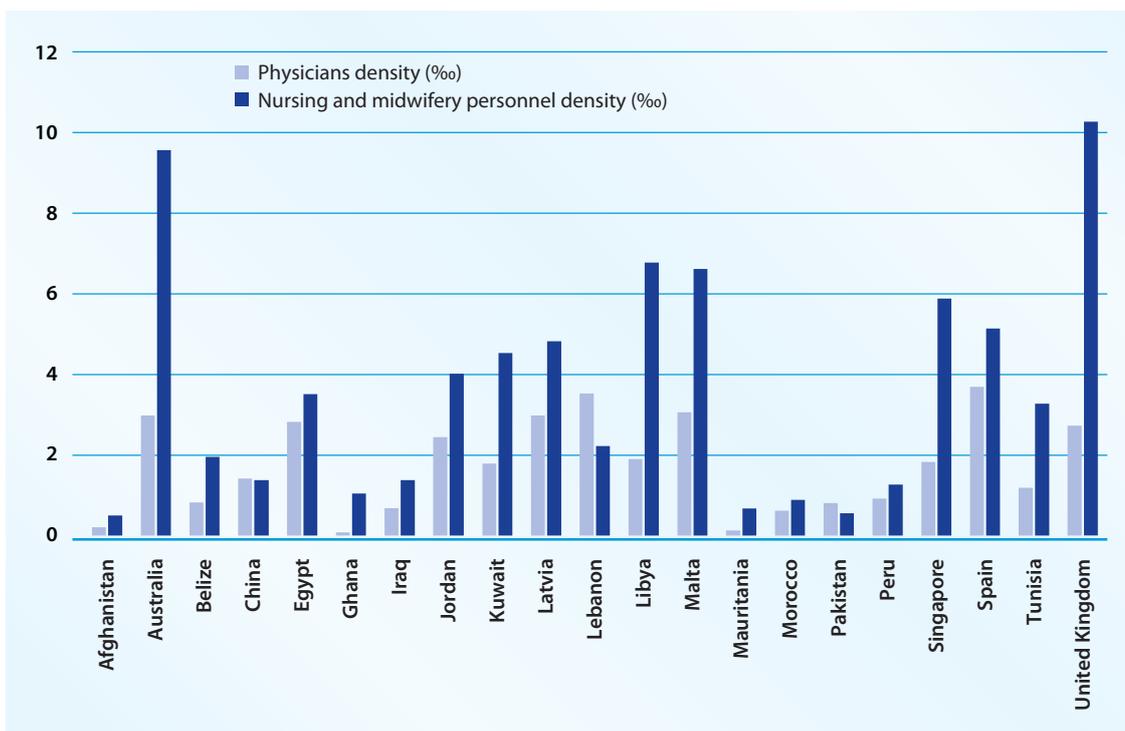


Figure 10: Healthcare professionals - density per 1,000 population (2009)

¹³²London Declaration on NTDs, http://www.unitingtocombatntds.org/downloads/press/ntd_event_london_declaration_on_ntds.pdf.

¹³³Bruce Heilbruth, "Bangladesh Flags a Way Forward", Development Asia, no. 11 (December 2011).

Recent studies have shown that patients may avoid seeking medical treatment because the cost of transportation and lost income can be more prohibitive than the actual cost of healthcare, particularly in the case of chronic diseases.¹³⁴ One study in the Philippines, for example, showed that a 10% increase in distance from

healthcare facilities was associated with a 2% increase in mortality rates. Another study, in Lusaka, Zambia, found that 50% of patients attended hospitals if they were within 5km of their homes, but that only 2% of patients did so if they were between 30km and 44km from their homes.¹³⁵

Daiichi mobile health care clinics

Daiichi Sankyo Company and Ranbaxy Laboratories have started a synergistic initiative to sponsor mobile healthcare field clinics in India, Cameroon and Tanzania as part of their global social contribution activities. The initiative has been implemented in India through the Ranbaxy Community Health Care Society, a non-profit organization established by Ranbaxy, and in Cameroon and Tanzania through an international NGO, Plan Japan, utilizing Ranbaxy's accumulated know-how and experience in providing mobile healthcare services.

A mobile clinic van has medical equipment and supplies for basic medical care, immunizations, maternal and child health services, health education, and so on. Making the most of its mobility, the van can provide greater access to medical and primary healthcare and save many lives in areas that are far from regular healthcare facilities.

The African Comprehensive HIV/AIDS Partnerships (ACHAP)

The African Comprehensive HIV/AIDS Partnerships is a public-private partnership between Merck & Co., Botswana, and the Bill and Melinda Gates Foundation that targets HIV/AIDS and TB co-infection.

- ACHAP partners provide treatment, care and support for people living with HIV/AIDS. In addition to the donation of medicines, partners have constructed 35 infectious disease care clinics, trained about 7,000 health workers and lay personnel, and provided equipment to support laboratory diagnostic and monitoring services.
- Botswana has one of the highest rates of adult prevalence of HIV/AIDS in the world. Prior to the partnership, only 5% of HIV/AIDS patients received care, and 20% of children were transmitted the virus from their mother. After 12 years, 90% of patients receive care, and the rate of mother-to-child transmission is down to less than 4%.¹³⁶

¹³⁴World Health Organization, Health Systems Financing: The Path to Universal Coverage, World Health Report, 2010, <http://www.who.int/whr/2010/en/index.html>.

¹³⁵A Brennenman & M Kerf, Infrastructure and Poverty Linkages (Washington DC: World Bank, 2002).

¹³⁶The African Comprehensive HIV/AIDS Partnerships, "ACHAP Overview", 2012, http://www.achap.org/achap_content.php?cid=128; Merck & Co., "Working in Partnership Against HIV/AIDS", Community: Fighting HIV/AIDS, 2012, <http://www.merck.com/about/featured-stories/achap.html>.

The economic benefits of medicines and vaccines

Access to pharmaceuticals is one of the pillars of a strong healthcare system. Access can be defined as the timely availability—subject to economic and physical conditions—of quality, safe and effective medicines or vaccines to those who need them. Appropriate

access helps lower overall healthcare costs by reducing the need for hospitalization and expensive, invasive procedures.¹³⁷ After improvements to basic sanitation and access to clean water, access to pharmaceuticals is one of the most cost-effective health-related measures.¹³⁸

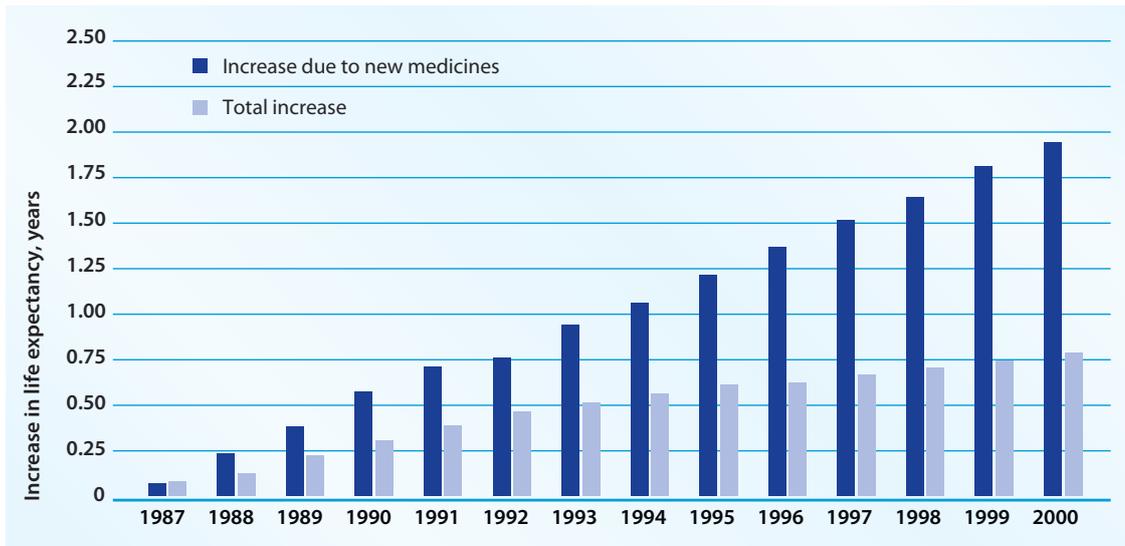


Figure 11: Increase in life expectancy due to new medicines¹³⁹

Innovative medicines can help control increasing costs within a healthcare system. For every 24 dollars spent on new medicines for cardiovascular diseases in OECD countries, 89 dollars were saved in hospitalization and other healthcare costs.¹⁴⁰ Prior to the creation of antibiotics used to treat peptic ulcers, treatment for the disease consisted of major surgery and costly assistance with recovery, requiring as much as USD 17,000 and over 300 days of treatment. After the advent of antibiotics, the cost of treating ulcers plummeted to less than USD 1,000.¹⁴¹

Medicines are particularly effective when patients adhere to the pharmaceutical regimen prescribed by their doctors. Two recent studies, which looked at the cost of pharmaceuticals for chronic diseases, found that not only did non-adherent patients have higher hospitalization and mortality rates than their adherent counterparts, but adherent patients also incurred lower overall medical costs, even after taking into account the cost of a full course of medication.¹⁴²

¹³⁷Michael C Sokol et al., "Impact of Medication Adherence on Hospitalization Risk and Healthcare Cost", *Medical Care* 43, no. 6 (June 1, 2005): 521–530.

¹³⁸S Simoens, "What Is the Value for Money of Medicines? A Registry Study", *Journal of Clinical Pharmacy and Therapeutics* (n.d.), <http://onlinelibrary.wiley.com/doi/10.1111/j.1365-2710.2011.01277.x/abstract>.

¹³⁹Frank R Lichtenberg, "The Impact of New Drug Launches on Longevity: Evidence for Longitudinal, Disease-Level Data from 52 Countries, 1982–2001", *International Journal of Healthcare Finance and Economics* 5 (2005):47-73.

¹⁴⁰Frank R Lichtenberg, "Have Newer Cardiovascular Drugs Reduced Hospitalization? Evidence from Longitudinal Country-level Data on 20 OECD Countries, 1995–2003", *Health Economics* 18, no. 5 (May 1, 2009): 519–534.

¹⁴¹Centers for Disease Control, "Economics of Peptic Ulcer Disease and H. Pylori Infection", October 1998, <http://www.cdc.gov/ulcer/economic.htm>.

¹⁴²Sokol et al., "Impact of Medication Adherence on Hospitalization Risk and Healthcare Cost".

Vaccines are another class of pharmaceuticals to which access is essential and cost-effective. Vaccines teach the body to recognize and fight off viruses of relatively common infectious diseases, like measles, influenza or rabies. Immunized individuals have a much lower risk of contracting diseases that they have been vaccinated against. In communities where most people have been vaccinated, there is an additional benefit due to the so-called “herd effect”, whereby individuals that have not yet been vaccinated are indirectly protected by the vaccination status of others.

Thanks to globally rising vaccination coverage rates, most children will never contract dangerous diseases like measles or mumps. In addition to its undeniable public health benefits, vaccination can avoid expensive treatments, which needlessly burden the healthcare system. In the first decade of the 21st century alone, an estimated 2.5 million deaths were prevented each year among children under the age of five through the

use of measles, polio and diphtheria-tetanus-pertussis vaccines.¹⁴³ Newer vaccines, such as Haemophilus influenzae type B (Hib) vaccine, already have a global coverage rate of about 38%, which is helping to prevent an estimated 130,000 pneumonia and meningitis deaths annually among children under the age of five.¹⁴⁴

	Actual hospitalizations avoided	Annual premature deaths avoided
Actual prevention: Based on current treatment rates	833,000	86,000
Potential additional prevention: If untreated patients received recommended medicines	420,000	89,000

Figure 12: Annual hospitalizations and deaths avoided through use of antihypersensitive medications¹⁴⁵

¹⁴³⁻⁴Centers for Disease Control, Ten Great Public Health Achievements - Worldwide, 2001-2010.

¹⁴⁵D M Cutler et al., “The Value of Hypertensive Drugs : A Perspective on Medical Innovation” Health Affairs (2007).

The role of regulatory systems

A well-functioning medicine regulatory authority is essential for any effective healthcare system. Regulatory authorities are needed to assess the quality, safety and efficacy of domestic and imported pharmaceuticals alike. They are in charge of the registration or marketing approval process, which allows approved pharmaceuticals to be sold legally in their markets.

A well-resourced and efficient regulatory system is necessary to ensure access to safe pharmaceuticals. An important part of the world's population, however, lives in countries with inadequate regulatory systems due to resource and technical constraints.¹⁴⁶

These barriers often lead to slower or inadequate patient access to quality pharmaceuticals, which can be exacerbated when countries do not work together to standardize and simplify the pharmaceutical registration process. In most cases, if a company wishes to sell its product in multiple markets, it needs to fill out separate forms, conduct different regulatory tests for each country, meet local packaging requirements, and organize separate inspections of manufacturing sites.

A number of countries have worked together to harmonize their regulatory requirements for product registration, using a common submission format and common technical standards, and conducting pilot joint assessments and inspections. This harmonization reduces duplication of testing and reporting during the research and development phase and streamlines the regulatory assessment, facilitating the best utilization of resources by both companies and regulators. The end result is that medicines of assured quality reach the market faster. Given the savings in time and resources, experts believe that all countries should move towards increased regulatory collaboration and harmonization in the near future, particularly as the rising sophistication of pharmaceutical products and more complex supply chains are increasing the amount of information and oversight to be assessed before market approval.¹⁴⁷

Weak regulatory capacity can be deadly for patients, helping to spread substandard pharmaceutical products, particularly in lower-income countries.

Increased capacity to regulate the products in their markets allows countries to identify substandard medicines, which can include inadequate amount of ingredients, contamination, poor-quality ingredients, poor stability and inadequate packaging.

Of particular concern to regulatory authorities and patients alike is the malicious breaching of the pharmaceutical supply chain. In no matter which country, criminal groups and other individuals have been known to deliberately and fraudulently mislabel medicines and vaccines, and attempt to pass them off to unsuspecting suppliers and consumers as the real product. While there are higher rates of circulation of these products in lower-income countries, the reality is that these criminals have managed to sell their wares to consumers around the world.

Counterfeiters can irreversibly compromise patients' health and lives by substituting the active pharmaceutical ingredient with inert material or lethal ingredients.¹⁴⁸ Counterfeit vaccines, for example, might be filled with tap water, exposing patients to new pathogens. Using printing technology, counterfeit drug producers are able to copy product boxes and blister packs, making it difficult to detect counterfeits with the naked eye. In recent years, some criminals have been able to mimic anti-counterfeiting measures on packaging, like barcodes and holograms, making it even harder to identify counterfeits. The product can look identical to the original, and it is only with testing that counterfeits can be identified.¹⁴⁹

¹⁴⁶World Health Organization, African Medicines Regulatory Harmonization Initiative (AMRHI): A WHO Concept Paper (Geneva: WHO).

¹⁴⁷Lembit Rãgo, How Are We Responding? WHO Viewpoint, presented at the Meeting on Improving Medicines through Supporting African Plans to Harmonize Medicines Registration in Africa, London, November 19, 2009.

¹⁴⁸C S Gautam, A Utreja & G L Singal, "Spurious and Counterfeit Drugs: a Growing Industry in the Developing World", *Postgraduate Medical Journal* 85, no. 1003 (May 2009): 251–256.

¹⁴⁹Paul N Newton et al., "Counterfeit Anti-infective Drugs", *The Lancet Infectious Diseases* 6, no. 9 (September 2006): 602–613.

There is a lack of data on the overall scope and scale of the problem because of the clandestine nature of the crime. However, information collected by the Pharmaceutical Security Institute (PSI) confirms the increasing trend towards counterfeiting of medicines. During 2010, 2,054 counterfeit medicine incidents were recorded by PSI, of which at least half involved more than 1,000 dosage units.¹⁵⁰

The research-based pharmaceutical industry is committed to safeguarding patients from the harmful effects of counterfeit medicines. It works closely with the authorities to detect and test suspect products, pursues legal actions as appropriate, and is working with key health partners on education campaigns about the risks posed by counterfeits.¹⁵¹

Combating counterfeits in Cambodia

The Japanese Pharmaceuticals Manufacturers Association (JPMA) has established a partnership with the Cambodian Ministry of Health and Kanazawa University.

- Quality control surveys conducted from 2006 to 2010 in Cambodia detected sales of counterfeit and substandard drugs on the pharmaceutical market. Many of these products were being marketed without registration, and were labeled with incorrect registration numbers.
- The partners are working together to build regulatory capacity of the Cambodian National Health Product Quality Control Centre (NHQC) through technology transfer, donation of analytical instruments, and on-site guidance by experts in pharmaceutical science and technology quality control.
- Since starting the program in 2006, the number of unregistered drugs and illegal pharmacies has decreased, saving health and lives from unscrupulous middlemen.

Socio-economic determinants of health

A modern conception of the healthcare system recognizes that medical care cannot be isolated from important environmental and socio-economic factors, like improved sanitation, food security or education levels. Access to quality healthcare interacts with these socio-economic variables to further influence health outcomes.

Health literacy

Health illiteracy is a significant problem around the world, and is often found in individuals from resource-limited backgrounds. In essence, health literacy is the “capacity of an individual to obtain, interpret, and understand basic health information and services” that will help them better interact with medical staff, understand prescriptions, and make lifestyle choices

that lead to better health and wellbeing.¹⁵² One recent study from University College London found that when elderly patients did not understand basic health-related information given to them, they were more than twice as likely to die within five years as those with no literacy problems.¹⁵³

A better perception of health and increased understanding of risk factors can be a starting point to drive the behavioral changes required to reduce incidence of non-communicable diseases (NCDs) and other unhealthy behaviors that expose patients to illness of all types. A study conducted in the Russian Federation found that individuals’ inadequate perceptions of health jeopardize their willingness to address risk factors.¹⁵⁴ Regular visits to a physician remain the most influential means of raising awareness of the risk factors that threaten a person’s health.

¹⁵⁰Pharmaceutical Security Institute, “Incident Trends”, <http://www.psi-inc.org/incidentTrends.cfm>.

¹⁵¹IFPMA, “The IFPMA Ten Principles on Counterfeit Medicines”, 2010, http://www.ifpma.org/fileadmin/content/Global%20Health/Counterfeits/IFPMA_Ten_Principles_Counterfeit_Medicines_12_May_2010.pdf.

¹⁵²Deborah Chinn, “Critical Health Literacy: A Review and Critical Analysis”, *Social Science & Medicine* 73, no. 1 (2011): 60–67.

¹⁵³S Bostock & A Steptoe, “Association Between Low Functional Health Literacy and Mortality in Older Adults: Longitudinal Cohort Study”, *British Medical Journal* 344 (March 15, 2012): e1602–e1602.

¹⁵⁴Association of International Pharmaceutical Manufacturers (Russia) and IFPMA, “Population Attitude to Personal Health: Perception of Health, Understanding of Risk Factors, Morbidity and Mortality”, 2011.

The Lundbeck Institute

The Lundbeck Institute aims to improve, through education and information, the treatment of people suffering from brain disorders. Over 80 international specialists collaborate with the Institute, which held eight seminars in 2010 attended by a total of 184 doctors from 23 countries. The Institute is responsible for the DepNet website, where patients, relatives and healthcare professionals can share experiences about depression and receive product-independent advice from doctors affiliated with the service. DepNet has been launched in 18 countries.¹⁵⁵

Self and social stigma about diseases

In many communities, certain diseases – including mental and neurological disorders, and some infectious diseases, like HIV/AIDS - carry negative social connotations. While all of us are at risk for diseases because of factors beyond our control, the social stigma that can accompany illnesses in different times and places can make it harder for individuals in those communities to seek medical help.

Each community has its own prejudices, which influence which diseases are considered shameful. In some developing countries, for example, neglected tropical diseases like leprosy, lymphatic filariasis and leishmaniasis are feared and are a source of strong social stigma.¹⁵⁶

To avoid harassment, many individuals with these diseases simply stay at home and do not interact with others. In addition to hastening the advance of their disease, doing so can lead to a loss of income from not working and put them at greater risk of depression due to social isolation. In other cases, individuals with some infectious diseases may hide their condition from others, while still going about their daily life without taking precautions to prevent the spread of the disease, thereby inadvertently putting others at risk. Education, care and community support programs are needed to help counter the ignorance and stigma surrounding such diseases.

¹⁵⁵Lundbeck Institute, Communication on Progress Report, 2010, p.10.

¹⁵⁶World Health Organization, Neglected Tropical Diseases: Hidden Successes, Emerging Opportunities.

Positive action on HIV/AIDS¹⁵⁷

Positive Action on HIV/AIDS is ViiV Healthcare's HIV/AIDS Education, Care and Community Support Program. Set up in 1992, it works with community organizations to build capacity to counter stigma surrounding HIV and AIDS through outreach, education and advocacy.

Active with 17 programs in 46 countries across Africa, Asia, Latin America and Eastern Europe, the initiative funds a range of programs that raise awareness about the treatment and prevention of HIV/AIDS and provides support to patients, particularly those identified as vulnerable communities. They include men who have sex with men, intravenous drug users, sex workers, migrants, young people, orphans and vulnerable children, and marginalized poor rural women.

Nutrition

Just as important to ensuring good health is access to nutritious food. Malnutrition and under-nutrition put individuals at higher risk of catching diseases. Even when medicine is available, it often works less well in conditions of malnutrition. Studies have shown that under-nutrition contributes to at least one third of all childhood deaths, usually in interaction with infectious causes.¹⁵⁸ Chronic malnutrition is still an issue in many countries. Worldwide, an estimated 115 million children under the age of five are underweight, and 179 million children are too short for their age group.¹⁵⁹

At the same time, the world is facing a childhood obesity epidemic, even among poor populations. In many countries, including the US, lower-income families tend to concentrate their food purchases on meals with poor nutritional value because they are less expensive. A healthy diet is not necessarily cheap and, combined with exorbitant transportation costs for individuals who live in "food deserts", steady access to healthy food options can be out of reach for many people.¹⁶⁰

¹⁵⁷IFPMA, Health Partnerships Directory.

¹⁵⁸Centers for Disease Control, Ten Great Public Health Achievements - Worldwide, 2001-2010.

¹⁵⁹World Health Organization, World Health Statistics, 2011, http://www.who.int/gho/publications/world_health_statistics/en/index.html.

¹⁶⁰Harvey Morris, "The Endangered Mediterranean Diet", IHT Rendezvous, March 6, 2012, <http://rendezvous.blogs.nytimes.com/2012/03/10/the-endangered-mediterranean-diet/>.

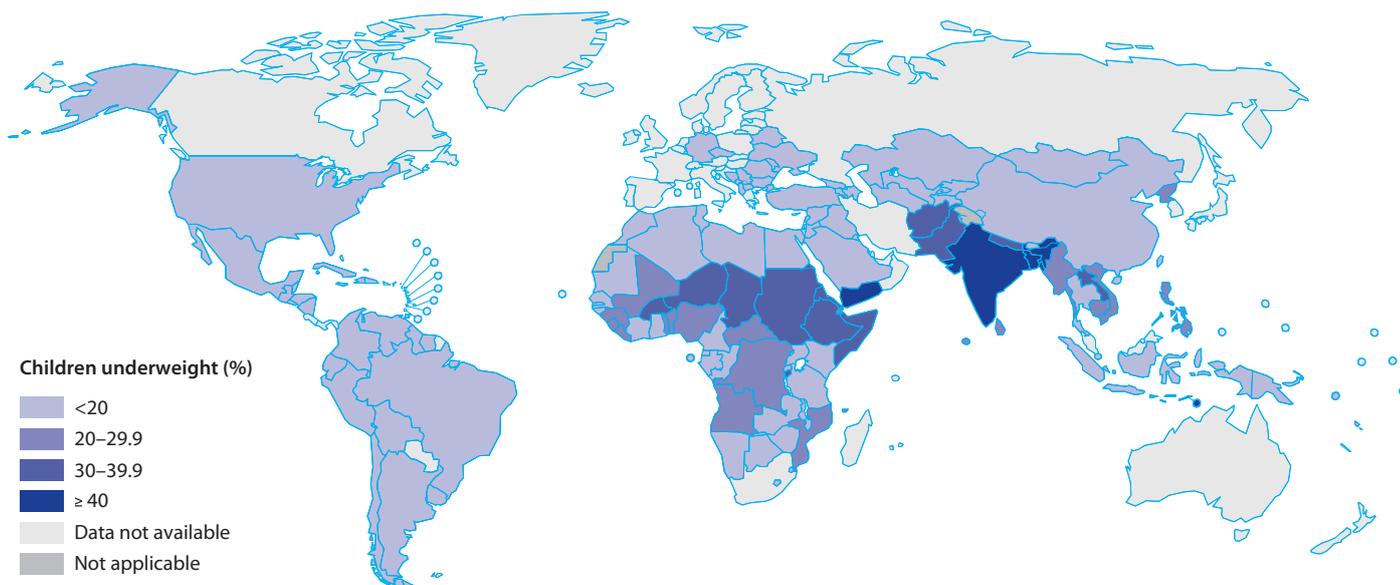


Figure 13: Children aged under 5 years underweight (%)¹⁶¹

Abbott and Abbott Fund program to fight pediatric malnutrition in Vietnam

Abbott and Abbott Fund are partnering with AmeriCares and Giao Diem to address pediatric malnutrition in Vietnam, and have invested USD 880,000 to date on this initiative. During the 2010-2011 school year, the partnership supported classrooms across four rural provinces. The majority of participating children live in the Hue and Quang Tri provinces in Vietnam's Central Highland region, where malnutrition rates are among the highest in the country. Mountainous terrain and limited arable land make these provinces extremely vulnerable to the impact of natural disasters, which have a detrimental effect on livelihoods, health status, food security and infrastructure.

On a daily basis, children are provided with soy milk, freshly made and fortified with peanuts and soybean oil. Donations of Abbott's nutritional products are made each year during the flood/hurricane season. Students enrolled in the program also undergo three health screenings by health professionals. The program provides on-site training seminars for both parents and teachers, teaching them about proper nutrition needs and care as well as how to use local materials and resources, like soybeans, to provide for children. The program also supports the refurbishment and improvement of school kitchens.

¹⁶¹World Health Organization, World Health Statistics, 2011.

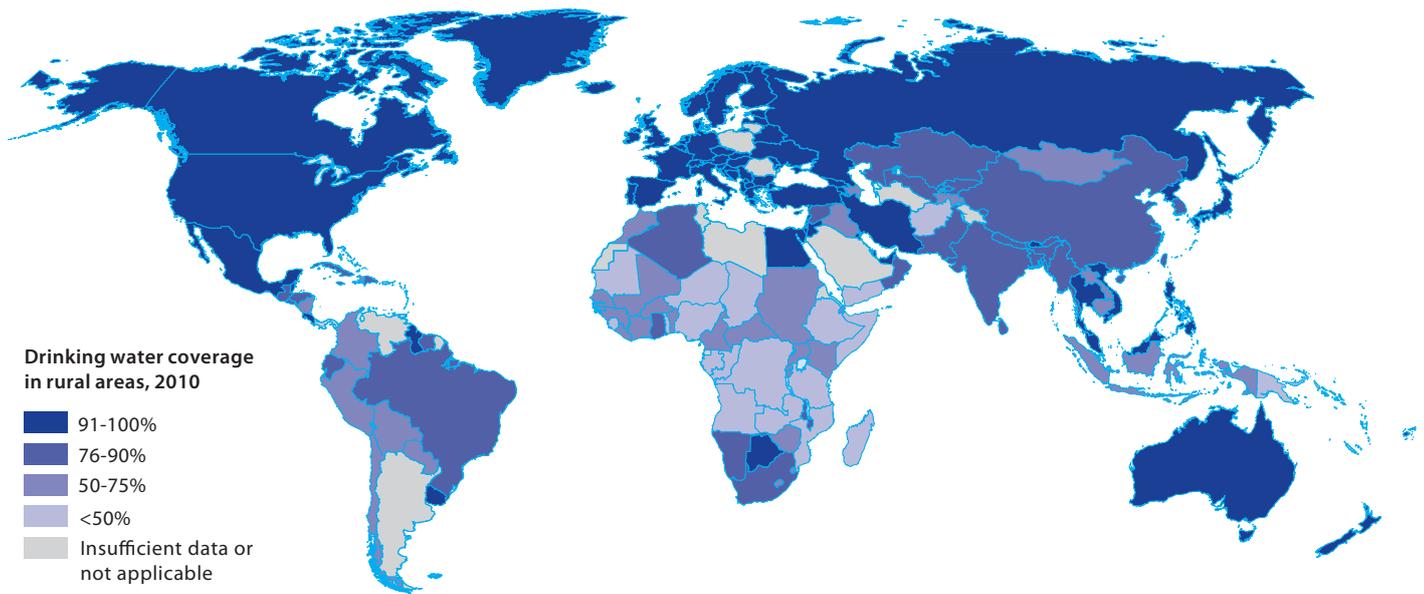


Figure 14: Drinking water coverage in rural areas (2010)¹⁶²

Sanitation and clean water supplies

Access to sanitation services and clean water supplies is one of the best benchmarks for good health. Exposure to unclean water and unhygienic sanitation causes a wide variety of diseases, including cholera, typhoid, parasitic worms, and intestinal diseases that cause diarrhea.¹⁶³ In fact, water-related diseases cause over 2.5 billion cases of diarrhea annually; they are the second leading cause of childhood mortality worldwide, killing 1.5 million children under the age of five, more than deaths due to AIDS, malaria and measles combined.¹⁶⁴

An estimated 1.1 billion people worldwide lack access to adequate water, and 2.6 billion lack adequate sanitation.¹⁶⁵

Lack of access occurs in both rural and urban areas, but is primarily concentrated among poor populations in both locations. In cities, the water and sanitation systems often do not reach the slums and temporary settlements where the poor live, while many rural areas lack clean water and sanitation altogether.¹⁶⁶

Despite the challenges posed by poor sanitation, there is significant historical and scientific evidence to show that diseases like cholera and typhoid can be easily eliminated with clean water technologies, filtration and chlorination. In fact, by one estimate, these innovations were responsible for nearly half the total mortality reduction in major cities between 1900 and 1936.¹⁶⁷

¹⁶²World Health Organization, "Progress on Drinking Water and Sanitation".

¹⁶³Philip Stevens & Holly Linfield, *Death and Taxes: Government Mark-ups on the Price of Drugs*, (Washington: International Policy Network, 2009).

¹⁶⁴Centers for Disease Control, *Ten Great Public Health Achievements - Worldwide, 2001-2010*.

¹⁶⁵World Health Organization, "Progress on Drinking Water and Sanitation", March 2012, http://www.who.int/water_sanitation_health/publications/2012/jmp_report/en/index.html.

¹⁶⁶Brenneman & Kerf, *Infrastructure and Poverty Linkages*.

¹⁶⁷David M Cutler & Grant Miller, *The Role of Public Health Improvements in Health Advances: The 20th Century United States*, National Bureau of Economic Research Working Paper Series No. 10511 (2004), <http://www.nber.org/papers/w10511>.

Tobacco use

Tobacco is one of the world's biggest public health threats, with staggering annual figures of tobacco-related deaths and disease. Among adults, tobacco use accounts for one in ten adult deaths, or nearly 6 million people each year, dying primarily from serious cardiovascular and respiratory diseases, including coronary heart disease and lung cancer. In China alone, over 3,000 people die every day from tobacco-

related diseases.¹⁶⁸ Individuals exposed to second-hand smoke are also at risk, with more than 600,000 premature deaths each year; children account for 28% of deaths attributable to second-hand smoke.¹⁶⁹ There is increasing concern over the concentrated geographic spread of tobacco use, as over 80% of the world's 1.2 billion smokers reside in low-income countries.¹⁷⁰ For example, whereas only one in five Australians smokes, in Indonesia, the prevalence among adults is over 45%.¹⁷¹

AstraZeneca Young Health Program

Adolescent health is a significantly underserved aspect of the healthcare agenda. Globally, the biggest health issues for this age group are related to sexual and reproductive health. Early pregnancy and sexually transmitted diseases, including HIV, have a considerable impact on their health as well as negatively impacting individual life chances. Other health issues can be dependent on geography and include substance abuse such as tobacco and alcohol, mental health problems, including suicide, violence, accidents and injuries, and suboptimal diets ranging from general malnutrition in poorer communities to obesity in high-income countries.

AstraZeneca's Young Health Program provides a global framework with the flexibility to enable its local business units to identify urgent young health needs in their local communities and address these with appropriate and sustainable local programs. Young Health Program initiatives are currently running across four continents and the Program target is to reach up to 15 countries by the end of 2012. The areas of focus for local programs vary from country to country. For example, AstraZeneca in India is focusing on hygiene, infection and reproductive health; in Brazil and Zambia, it is educating young people on sexual and reproductive health; and in the UK it is helping young homeless people improve their mental and physical health.¹⁷²

Conclusions

Each country faces different challenges in addressing the prevention and treatment of non-communicable and infectious diseases. Despite facing different disease burdens, all countries can improve health outcomes by strengthening national healthcare systems. Focused investment in key areas can save countless lives. These range from a quality primary healthcare system that addresses the needs of the most vulnerable and prioritizes preventive measures, to a competent regulatory system that can monitor the safety and integrity of the pharmaceutical supply.

¹⁶⁸Heilbruth, "Double Burden".

¹⁶⁹World Health Organization, "Tobacco", July 2011, <http://www.who.int/mediacentre/factsheets/fs339/en/index.html>.

¹⁷⁰World Health Organization, "Tobacco".

¹⁷¹Heilbruth, "Double Burden."

¹⁷²AstraZeneca, <http://www.astrazeneca.com/Responsibility/Community-investment/AstraZeneca-Young-Health-Programme>.

Chapter 3



Re-thinking the debate on access to medicines, affordability and intellectual property

Insufficient access to medicines can be a major problem and a serious impediment to quality of life. Although 95% of essential medicines, as defined by the WHO, are off patent, still one third of the world's population does not have reliable access to them. Governments willing to build cost-efficient, effective and inclusive healthcare systems have many policy tools outside the intellectual property system that have proven to be effective in improving access to pharmaceuticals and making them affordable. Medicine costs should also be seen from a holistic perspective as they are normally offset by savings in hospitalization and other more sophisticated medical procedures. It is also important to take into account wider social and economic benefits when patients recover and resume their normal life in a significantly shorter time. The research-based pharmaceutical industry has increasingly engaged with governments and other players to find sustainable approaches to balance the need both to ensure patient access to medicine and to sustain incentives for pharmaceutical innovation.

National and international disparities in access to medicines

Patients with little or no savings may risk serious financial hardship when they are ill. This is particularly true for those patients that have to pay out-of-pocket for medicines and healthcare services, which is the case for up to 90% of patients in developing countries.¹⁷³

While the price of many essential drugs (95% of which are off patent) often cost as little as USD 0.02-1.50, these amounts can be unaffordable for individuals earning less

than USD 1 a day.¹⁷⁴ The World Bank estimates that nearly 883 million people still live on less than USD 1.25 per day. In many such cases, the cost of essential medicines can easily push patients below the poverty line.¹⁷⁵ Worse still, many families not only incur heavy costs to purchase medicines, but also lose a source of income when breadwinners fall ill.

Access to medicines in lower-income countries is also often jeopardized by the limited availability of medicines. Even when enough financial resources are available, it can be hard to acquire essential medicines in certain countries. The World Health Organization found that, between 2001 and 2009, essential medicines were available in only 42% of public sector and 64% of private sector facilities in developing countries.¹⁷⁶ Because most patients in these countries often needed to purchase their medicine from private sector distributors, they generally ended up paying about 6% more than the international reference price.¹⁷⁷

Ensuring medicines are available and affordable

For a variety of reasons, many individuals simply do not have access to safe, quality pharmaceuticals. This is an especially serious problem in many lower-income countries. As with the broader issue of access to health, access to pharmaceuticals is generally only an issue when governments have not invested sufficiently in healthcare or otherwise inefficiently spend their resources. Numerous lower-income countries have shown that with efficient distribution and good procurement practices, they are able to provide wider access to pharmaceuticals.

¹⁷³World Health Organization, "Medicine Pricing and Financing", 2012, <http://www.who.int/medicines/areas/access/en/index.html>.

¹⁷⁴World Bank, "Poverty Analysis", Poverty at a Glance, 2011.

¹⁷⁵Laurens M Niens et al., "Quantifying the Impoverishing Effects of Purchasing Medicines: A Cross-Country Comparison of the Affordability of Medicines in the Developing World", PLoS (Public Library of Science) Medicine 7, no. 8 (2010).

¹⁷⁶United Nations, Millenium Development Goal 8. The Global Partnership for Development: Time to Deliver, MDG Gap Task Force Report, 2011, http://www.un.org/en/development/desa/policy/mdg_gap/mdg_gap2011/mdg8report2011_engw.pdf.

¹⁷⁷World Health Organization, Health Systems Financing : The Path to Universal Coverage, World Health Report, 2010, <http://www.who.int/whr/2010/en/index.html>.

Procurement policies

In most healthcare systems, a mix of public and private sector funding sources is used to purchase medicines and vaccines. If procurement is done in a predictable way, it can benefit from significant economies of scale and price reductions, while last-minute orders tend to be considerably more expensive and can often result in a medicines shortage. Good procurement practices also assure medicine quality and reliability of supply.

In most countries, governments make purchases to ensure that their citizens have access to the medicines and vaccines they need. A growing number of developing countries are making substantial efforts to expand access to medicines and reach out to their most vulnerable populations; they have often achieved impressive public health results. Nevertheless, overall, governments in lower-income countries tend to play a smaller role in the purchase of pharmaceuticals. Insufficient procurement makes it harder for vulnerable citizens to access needed medicines, as many rely on government-sponsored programs for healthcare.

Lack of political will is one of the greatest obstacles to funding healthcare.¹⁷⁸ When governments prioritize the purchase of medicines and vaccines as a worthwhile and cost-effective public good, they give weight to the idea that investing in health is investing in the future of one's country. Procurement of medicines can also more than pay for itself by reducing expensive hospitalization, surgery and other healthcare costs.¹⁷⁹

Taxes and tariffs on pharmaceuticals

The cost of medicine varies significantly across countries. While some of this price differential is due to production costs or preferential pricing offered to lower-income countries, unnecessary mark-ups, including taxes, tariffs, and additional charges by intermediaries, can substantially raise the final price over the manufacturer's base price. For populations living at the edge of poverty, these additional mark-ups can be a major contributing factor hindering patient access to medicines and vaccines.

A significant source of price mark-ups comes from customs duties applied to the value of imported pharmaceutical products (as either final products or active pharmaceutical ingredients). As with other types of mark-ups, tariffs increase the final cost to the consumer. In some countries, tariff rates can add an additional 10-15% to the cost of finished pharmaceuticals.¹⁸⁰ When added to active ingredients, the rate is even higher, due to the compounding effect on price as the product moves through the supply chain.

Because of their life-saving nature, numerous countries exempt medicines, vaccines and active pharmaceutical ingredients from tariffs.¹⁸¹ A recent survey found that tariffs are lowest among the richest and poorest countries, while the highest tariff rates on pharmaceuticals are found in countries with intermediate income levels (see Table 1).¹⁸² Some middle-income countries have especially high tariffs on antibiotics, used to treat lower-respiratory infections and diarrheal diseases, which still affect important parts of their population.¹⁸³

Tariffs are unnecessary mark-ups on the price of pharmaceuticals and, in most cases, fail to generate significant revenue for governments. In 2005, when the first systematic survey on pharmaceutical tariffs was completed, researchers found that in 92% of countries for which data were available, the tariffs generated less than 0.1% of Gross Domestic Product (GDP).¹⁸⁴

Removing these tariffs is an easy way to reduce the final price of pharmaceutical products. Many policymakers have realized this and tariff rates on finished products and active ingredients have gradually begun to decline in most regions. However, while average tariff rates have fallen, as of 2009, 69 countries still imposed tariffs on active ingredients, and 40 countries still imposed tariffs of up to 15% on imported vaccines.¹⁸⁵

¹⁷⁸Tim Wilsdon, Jim Attridge et al., "Evidence on Access to Essential Medicines for the Treatment of HIV/AIDS" (Boston: Charles Rivers Associates, 2011).

¹⁷⁹Frank R Lichtenberg, "Have Newer Cardiovascular Drugs Reduced Hospitalization? Evidence from Longitudinal Country-level Data on 20 OECD Countries, 1995–2003", *Health Economics* 18, no. 5 (May 1, 2009): 519–534.

¹⁸⁰Muge Olcay & Richard Laing, *Pharmaceutical Tariffs: What Is Their Effect on Prices, Protection of Local Industry and Revenue Generation?* (Geneva: World Health Organization, 2005), <http://www.who.int/intellectualproperty/studies/tariffs/en/index.html>.

¹⁸¹Olcay & Laing, *Pharmaceutical Tariffs*.

¹⁸²Philip Stevens & Holly Linfield, *Death and Taxes: Government Mark-ups on the Price of Drugs* (Washington: International Policy Network, 2009).

¹⁸³Stevens & Linfield, *Death and Taxes*.

¹⁸⁴Olcay & Laing, *Pharmaceutical Tariffs*.

¹⁸⁵Stevens & Linfield, *Death and Taxes*.

Country	VAT %	Other taxes
Central African Republic	19	
Benin	18	
Burkina Faso	18	
Cote d'Ivoire	18	
Senegal	18	
Tanzania	18	
Brazil	17.5	5% sales tax on domestic medicines; 15% corporation tax
China	17	
Bangladesh	15	
Pakistan	15	16% sales tax on raw material and packaging
Zimbabwe	15	
Botswana	10	
Philippines	12	
Algeria	7	Customs fees of 2% and 0.4%
Djibouti	0	7% consumption tax
Tunisia	6	3% customs inspection tax
India	4	
Ghana	0	1% port inspection charge, 0.5% ECOWAS levy, 0.5% export and development and investment levy
Angola	0	10% consumption tax

Table 1: Selection of domestic taxes on medicines from different countries¹⁸⁶

Another source of mark-ups on pharmaceutical products comes from taxes, including sales tax and value-added taxes (VAT). The complexity of tax laws and difficulty in conducting comparative studies mean that international data are scarce, but some authors have been able to illustrate the impact of these surcharges on the final price of pharmaceutical products. In China, for example, in addition to a 4% tariff rate, the government levies a value-added tax of 17% and a sales tax of 5%.¹⁸⁷

Tariffs and taxes are particularly problematic because of their compounding effect on the final cost of

pharmaceuticals. While these percentages of taxes and tariffs – typically ranging from 5-20% - might not seem significant mark-ups by themselves, they can significantly distort the original price by serving as a new base price that distributors and retailers use to add their own mark-ups. For example, a 10% tariff may add 20% to the price of a medicine, once additional mark-ups are taken into account.¹⁸⁸ This compounding effect is particularly strong when taxes or tariffs are applied early in the supply chain.

Supply chain integrity and efficiency

Transportation, storage, staff salaries and stock losses all factor into the final cost of pharmaceutical products. In some countries, wholesale markups can range anywhere from 2% to 380%, while retail markups can range from 10% to 552%.¹⁸⁹

Importation of pharmaceutical products can also involve additional costs related to port charges, pre-shipment inspection and strict supply routes. For instance, in China, for products that are being imported for the first time, there are only three designated ports to which products must be sent before being allowed into the country.¹⁹⁰ These and other restrictions are beyond the control of the manufacturer, and often increase the cost of imported pharmaceuticals.

The sources of additional mark-ups vary from country to country, but, essentially, the more complex the distribution system and supply routes to the final destination, the more opportunities middlemen have to add their own mark-ups. Given the cumulative nature of these mark-ups, the consumer inevitably ends up paying far more than the manufacturer's price. While wealthier individuals might be able to afford these inflated prices, it is inevitably the poorest who are hit hardest by this financial burden.

¹⁸⁶Stevens & Linfield, Death and Taxes.

¹⁸⁷Stevens & Linfield, Death and Taxes.

¹⁸⁸Carmen Perez-Casas, Emilia Herranz & Nathan Ford, "Pricing of Drugs and Donations - Options for Sustainable Equity Pricing", *Tropical Medicine & International Health* 6, no. 11 (November 1, 2001): 960–964.

¹⁸⁹A Cameron et al., "Medicine Prices, Availability, and Affordability in 36 Developing and Middle-income Countries: a Secondary Analysis", *The Lancet* 373, no. 9659 (January 17, 2009): 240–249.

¹⁹⁰Stevens & Linfield, Death and Taxes.

	Sri Lanka	Kenya	Tanzania	South Africa	Brazil	Armenia	Kosovo	Nepal	Mauritius	Average
Import tariff	0%	0%	10%		11.7%	0%	1%	4%	5%	
Port charges	4%	8%	1%				4%			
Clearance and freight		1%	2%					1.5%	5%	
Pre-shipment inspection		2.75%	1.2%							
Pharmacy board fee			2%							
Importers' margins	25%						15%	10%		
VAT				14%	18%	20%	0%			
Central govt. tax										
State govt. tax					6%					
Wholesaler	8.5%	15%	0%	21.2%	7%	25%	15%	10%	14%	
Retail	16.3%	20%	50%	50%	22%	25%	25%	16%	27%	
Total markup	63.9%	54.2%	74.3%	74%	82.3%	87.5%	73.6%	48%	59.6%	68.6%

Table 2: Examples of “hidden” costs of pharmaceutical procurement¹⁹¹

At the same time, complex supply chains can also facilitate entry of counterfeit pharmaceuticals into the distribution system. One study of the intra-European Union pharmaceutical market showed examples of medicines originally destined for one country being repackaged and re-exported to other higher-income countries. The authors found that the pharmaceuticals passed through as many as 20-30 pairs of hands before finally reaching the patient, creating many opportunities for opportunistic middlemen to slip in counterfeits.¹⁹² When products change hands so many times, it complicates efforts to trace product origins, which is essential to ensure patient safety. Complex supply chains increase financial burdens and health risks, as every time a product changes hands increases the risk for human error or criminal opportunism.

Healthcare financing

Some diseases can be expensive to treat. Seeking medical attention is proportionately more expensive for poor individuals who must spend more of their income to travel to healthcare facilities, pay medical

costs up-front, and often forego their daily income.

This is especially true for patients with chronic diseases, as their expenses are spread out over a longer period of time. For example, one study in Jamaica found that 59% of those affected with chronic diseases faced financial difficulties, and in many cases avoided medical treatment as a result.¹⁹³

In many countries, public and private insurance schemes or government-funded programs permit individuals and their families to access healthcare when they need it most. Both public and private health insurance systems work by pooling together the financial resources of a group of individuals over long periods of time. This process helps ensure sustainability and affordability of healthcare coverage for all of the group members, as it spreads the risk of falling ill. However, one recent WHO study found that only one in five individuals worldwide has access to social security protection to help cover lost wages in the event of illness and that, overall, less than half the world's population has any formal social protection.¹⁹⁴

¹⁹¹L. Levison & R. Laing, “The Hidden Costs of Essential Medicines” *Essential Drugs Monitor*, no. 033 (2003).

¹⁹²Panos Kanavos et al., *The Economic Impact of Pharmaceutical Parallel Trade in European Union Member States: A Stakeholder Analysis* (London School of Economics and Political Science, January 2004).

¹⁹³Aldrie Henry-Lee & Andrea Yearwood, *Protecting the Poor and the Medically Indigent Under Health Insurance: a Case Study of Jamaica* (Bethesda, MD: The Partnerships for Health Reform, 1999).

¹⁹⁴World Health Organization, *Health Systems Financing: The Path to Universal Coverage*, *World Health Report*, 2010, <http://www.who.int/whr/2010/en/index.html>.

Each day without insurance is a gamble. In the event of a major injury or illness, financial ruin is a very real possibility. In some countries, up to 11% of the population suffers severe financial hardship due to medical expenses, with about 150 million people worldwide suffering financial catastrophe annually.¹⁹⁵

It is easier and safer for patients to access both generic and innovator pharmaceuticals and other healthcare interventions when they do not have to pay for those expenses out-of-pocket.

Many countries recognize the financial and health risks that uninsured citizens face, and are therefore moving to encourage health insurance uptake. In one of the most sweeping examples, China launched the New Rural Cooperative Medical Scheme in 2003, an insurance plan that covers 95% of the population. With premiums at less than CNY 50, or USD 7 per year, beneficiaries pay for treatment up front but are reimbursed for about 70% of their medical care.¹⁹⁶

Improving access to primary healthcare services in rural areas: The Initiative Accès in Mali

The Initiative Accès aims to improve access to primary healthcare specifically for children and women in the region of Ségou, Mali. Supported by the Novartis Foundation for Sustainable Development as well as the regional authorities, the initiative is based on a framework that states that access can only be improved in an appropriate and sustainable way if the local healthcare system and its services are aligned with the needs, expectations and available resources of clients.

To improve the availability and quality of healthcare services, the Initiative strengthens the infrastructure, management and human resources in health centers. Moreover, healthcare staff are trained in specific clinical and public health areas. To ensure that the services are transparent and adequate for clients, opening hours and rates for all treatments are posted on a blackboard in each health center. In the frame of an outreach strategy, health personnel offer vaccinations and prenatal services directly in the villages. In addition, the Initiative Accès trains village health workers to offer basic promotional services, for example, against child malnutrition in communities.

Strengthening health insurance schemes

To make healthcare more affordable and ensure that people seek immediate care in case of illness, the Initiative Accès strengthens existing health insurance schemes, provides grants to women's savings groups, and supports farmers in setting up viable income generation activities.

The biggest rural health insurance scheme in the area, the Mutuelle de Santé of Cinzana, has almost doubled its number of beneficiaries from 1,151 to 2,212 people between 2004 and 2010. A professional insurance administrator has been employed and the benefit package improved: now 75% of primary healthcare costs and 100% of costs related to birth delivery are covered. A recently conducted research study on the Cinzana scheme revealed that total average healthcare costs during the six-month observation period were lower for insured households than for the uninsured (USD 18 compared with USD 23). Moreover, increasing healthcare costs were associated with a decreased likelihood of being insured. Households who sold assets to finance healthcare costs were also more likely to be uninsured. These results confirm that insurance coverage does protect people financially.

¹⁹⁵World Health Organization, Health Systems Financing.

¹⁹⁶Bruce Heilbruth, "Catastrophic Costs", Development Asia, no. 11 (December 2011).

Local production and the role of intellectual property

Many countries do not have the local technical know-how or economic scale needed to be self-sufficient in the production of pharmaceuticals. Strict quality controls and well-qualified staff are necessary to ensure the safety and integrity of products. Maintaining high quality standards can be particularly challenging for some products, particularly vaccines and biopharmaceuticals, which sometimes require stable temperatures and absolutely sterile conditions to be safe and effective. Taking into account the growing complexity of pharmaceutical products, the investments to ensure quality and safety will only grow over time.

Many countries also lack a large domestic population that could justify these investments in terms of economies of scale. Weak domestic demand for pharmaceuticals – often due to a mix of poverty and small patient populations – means that, in many cases, production would have to be heavily subsidized or run at a financial loss. Poor economies of scale, combined with high market entry costs and other issues, like political stability, geographical location, sporadic energy availability, a weak transportation sector and poor governance, mean that very few manufacturers – generics or innovators – may be willing to take the risk to produce locally.

Nonetheless, in some developing countries with sufficient technical expertise, reliable quality controls and a viable market, local or regional production of medicines is feasible and usually reflects the commercial business model of the pharmaceutical industry. When appropriate to specific conditions,¹⁹⁷ the R&D companies share technology and know-how with qualified partners around the world that can produce high-quality generic versions of innovative products. In other cases, a company might prefer to transfer technology to a subsidiary or a local partner and produce locally some of its innovative products. These transfers of technology are much more likely to happen in a country with an efficient intellectual property system.

Despite the proven track record of technical cooperation and licensing to improve the supply of medicines, claims have often been made that patents are a serious barrier to the production and availability of pharmaceuticals in low-income countries by preventing local production or the import of generics. In many parts of the African and Asian continents nearly half the population lacks access to medicines, even though most essential medicines can be produced by any generic manufacturer. Approximately 95% of essential medicines are off patent.¹⁹⁸ The dearth of medicines – innovators or generics – in a given country or region is mostly linked to the absence of a viable market that would offset the costs of entry. These costs are often exacerbated by inefficiencies in the regulatory system and the medicines distribution network. Experience has shown that low-income countries have managed to greatly expand access to medicines through strong political commitment, partnerships and good procurement, without resorting to policies that undermine their intellectual property systems.

When a product is still patented, any manufacturer that wants to use the technology is free to approach the patent holder and negotiate a production license. The holder of the patent will examine the specifics of the case and, if judged appropriate, will license out the product through a voluntary license. The main advantage of this approach is that it will often include transfer of the know-how needed to ensure the high quality of the medicines produced. A non-assert declaration works in a similar way. It is a covenant where the rights holder commits not to enforce certain patents in a defined group of countries, allowing a generic version of the patented product to be produced in a resource-limited setting.

Voluntary licenses and non-assert declarations have been increasingly used to accelerate the entry of generics in the markets of lower-income countries.¹⁹⁹ Both tools are designed to increase the number of potential producers of a given medicine or vaccines, while at the same time ensuring the high quality of medicines produced. An efficient intellectual property

¹⁹⁷IFPMA, *Technology Transfer: A Collaborative Approach to Improve Global Health. The Research-Based Pharmaceutical Industry Experience*, 2011, <http://www.ifpma.org>.

¹⁹⁸Stanley Kowalski, *The Patent Status of Medicines on the WHO Model List for Essential Medicines*, presentation at Joint Technical Symposium by WHO, WIPO and WTO on Access to Medicines: Patent Information and Freedom to Operate, Geneva, February 17, 2011.

¹⁹⁹IFPMA, "Voluntary Licenses and Non-Assert Declarations: Actions by R&D Pharmaceutical Companies that Facilitate Access to Medicines", 2010, http://www.ifpma.org/fileadmin/content/Innovation/IP%20and%20Access/20100728_Statement_VoluntaryLicensing_NonAssert_28July10.pdf.

system facilitates the use of these access mechanisms, as companies will have fewer concerns that their technology will be used in an unfair way, or that the resulting products will not meet the necessary quality standards. However, voluntary licenses and non-assert declarations are not a panacea for all

problems concerning access to medicines, and are not necessarily appropriate to every country and situation. In some circumstances, companies might judge it more appropriate to facilitate access to their medicines through tiered pricing, procurement negotiations, donations or public-private partnerships.

Extended access to nevirapine through non-assert declaration

Products containing the active ingredient nevirapine, which was researched and developed by Boehringer Ingelheim, are widely available in the developing world from a number of generic manufacturers. Over the last four years, the company has granted non-assert declarations to generic manufacturers pre-qualified by the World Health Organization (WHO) to manufacture products containing nevirapine. The policy applies to all low-income countries, all LDCs and all African countries (78 countries in total). This has led to an increase in patients being treated with medicines containing nevirapine. The non-assert policy stipulates that patents will not be enforced, that no royalties have to be paid and, most importantly, that high product quality will be ensured.

Innovation to ensure long-term access to medicines

Innovation is vital in addressing the global health needs of today and tomorrow. Without constant research into and development of new medicines, many of today's health improvements may be jeopardized in the long run by the growth in drug resistance and changes in disease profiles. Intellectual property rights in both developed and developing countries, supported by sound government regulatory processes and healthcare financing, are key enabling factors for the pharmaceutical industry's research and development efforts - its primary contribution to public health. Without these enabling conditions, industry could not provide innovative medicines or be able to support partnership initiatives in developing countries.

Effective intellectual property systems - including protection of patents, trademarks and proprietary data - are critical for stimulating R&D. They provide some assurance that, if a new medicine is successfully approved, the innovator has a chance to generate revenues sufficient to justify the investments in R&D and so ensure sustainable innovation into the future. The vast majority of medicines available today would not exist without the incentive provided by intellectual property rights. A significant number of developed and emerging developing countries have improved their level of protection for intellectual property rights in the past two decades, a positive trend for innovation and patient access to new medicines.

The pharmaceutical industry's initiatives to improve access to medicines

The R&D pharmaceutical industry has developed many initiatives to increase access to pharmaceuticals around the world. They can take the form of donations, preferential pricing, or technology and capacity-building programs.

Tiered pricing

Tiered pricing is one of the most effective and sustainable ways in which pharmaceutical companies help to improve access to medicines. In essence, they charge a higher price for the same product in higher-income countries than in lower-income countries. This cross-subsidy in many cases allows companies to sell medicines and vaccines at or below manufacturing cost. For example, low-income countries and those with the severest HIV/AIDS epidemics are offered branded antiretroviral (ARV) drugs at significant discounts or not-for-profit prices by most ARV-producing research-based companies. Abbott, for example, sells its heat-stable lopinavir/ritonavir tablet for USD 375 per year in Africa and least-developed countries, which is less expensive than the generic products in those markets.²⁰⁰ Similarly, since 2001 ViiV Healthcare has offered not-for-profit financing for all of its ARVs in sub-Saharan Africa and least-developed countries.

²⁰⁰Médecins Sans Frontières, Untangling the Web of Antiretroviral Price Reductions, <http://utw.msaccess.org/drugs/lopinavir-ritonavir>. Kanavos et al.,

Though successful in increasing sustainable access to needed pharmaceuticals, this mechanism can be put at risk by the proliferation of parallel trade, whereby middlemen purchase medicines at low prices in one country and resell them at higher prices in another. Care needs to be taken to ensure that parallel trade does not decrease the supply of medicines within the country

of export. Not only can re-exported medicines be put in incorrect packaging, but many of the safety leaflets are “printed in the wrong language, with the wrong trademark, carrying inaccurate, missing, or confusing information about side effects, expiry date, manufacture address, dosage, or batch number”.²⁰¹

AmpliCare

Diagnosis and monitoring are as essential to effective HIV/AIDS treatment as medicines. The earlier a diagnosis is made, the better the results of treatment. Doctors also need to monitor the progression of the disease so they can prescribe the most effective treatment and make adjustments if the patient’s viral load increases.

Through the AmpliCare initiative, Roche Diagnostics’ HIV viral load test, which measures the amount of the virus in the blood stream, is being made available in the countries most affected by HIV/AIDS, along with education programs to support the use of tests and treatment. AmpliCare began in 2002 and supplies HIV viral load tests at the lowest possible price in sub-Saharan Africa, South America and the least-developed countries defined by the United Nations. In addition, in 2010, Roche launched a simple and rapid test to detect mycobacterium tuberculosis. AmpliCare has also helped local authorities to build hospitals, equip laboratories and train laboratory workers.²⁰²

Donations

The pharmaceutical industry has spearheaded a variety of donation programs. Some of these programs have existed for many years and involve significant financial commitments.

Donations are often disease-specific. For example, Novartis has established the Glivec® International Patient Assistance Program (GIPAP), which provides Glivec at no cost to patients with certain forms of chronic myeloid leukemia and gastrointestinal stromal tumors, who would not otherwise have access to treatment. For more than a decade, Boehringer Ingelheim has donated its antiretroviral Viramune® in a program that has contributed to preserving the health of more than 2 million babies born to HIV-positive mothers throughout the developing world.²⁰³ Bayer HealthCare has been collaborating with the WHO since 2004 to fight Chagas Disease and has committed to donate up to 5 million tablets of nifurtimox in the period between 2012-2017.

Other initiatives are broader in scope, with a wider range of medicines donated to charities and relief organizations. Under these programs, donations are made at the request of charitable organizations. For example, through the Merck Outreach Program (MMOP), Merck & Co. donates critical pharmaceuticals, vaccines and consumer health products to a limited number of qualified, US-based NGOs for use in their ongoing humanitarian programs in the developing world, and in support of major disaster relief efforts within the United States and abroad. In 2011, Merck donated medicines and vaccines worth USD 66 million in market value through the MMOP.

Furthermore, pharmaceutical company donations often play an important role to help populations recover in the aftermath of national and regional catastrophes. For example, within 24 hours of the South Asian tsunami, Pfizer contributed USD 10 million of financial aid to local and international relief organizations participating

²⁰¹The Economic Impact of Pharmaceutical Parallel Trade.

²⁰²Roche, “AmpliCare”, http://www.roche.com/corporate_responsibility/patients/access_to_healthcare/developing_countries/amplicare.htm.

²⁰³Boehringer Ingelheim, “Combating HIV/AIDS”, http://corporateresponsibility.boehringer-ingenelheim.com/corporate_citizenship/combating_hiv_aids.html.

in the disaster relief work. In addition, healthcare products worth more than USD 45 million were donated, including antibiotics, anti-fungals and anti-inflammatories.²⁰⁴

Overall, the scale of industry's donations has greatly increased since 2000, as Figure 15 demonstrates. From 2000 to 2009, the research-based pharmaceutical industry donated more than 2.4 billion medicine treatments to developing countries. In addition, the industry has pledged to donate 14 billion treatments for neglected tropical diseases (NTDs) from 2011 to 2020.²⁰⁵

Donations comprise a traditional component of companies' corporate social responsibility initiatives. A sustainable healthcare system will not be built, however, solely on donations. Companies may face financial difficulties themselves and might not be able to maintain a donation program indefinitely or scale it up to the extent needed to reach a broader population. It is only through the ownership of their access programs, and purchase of pharmaceuticals at commercially viable prices, that a country can avoid medicine shortages and ensure reliability of supply.

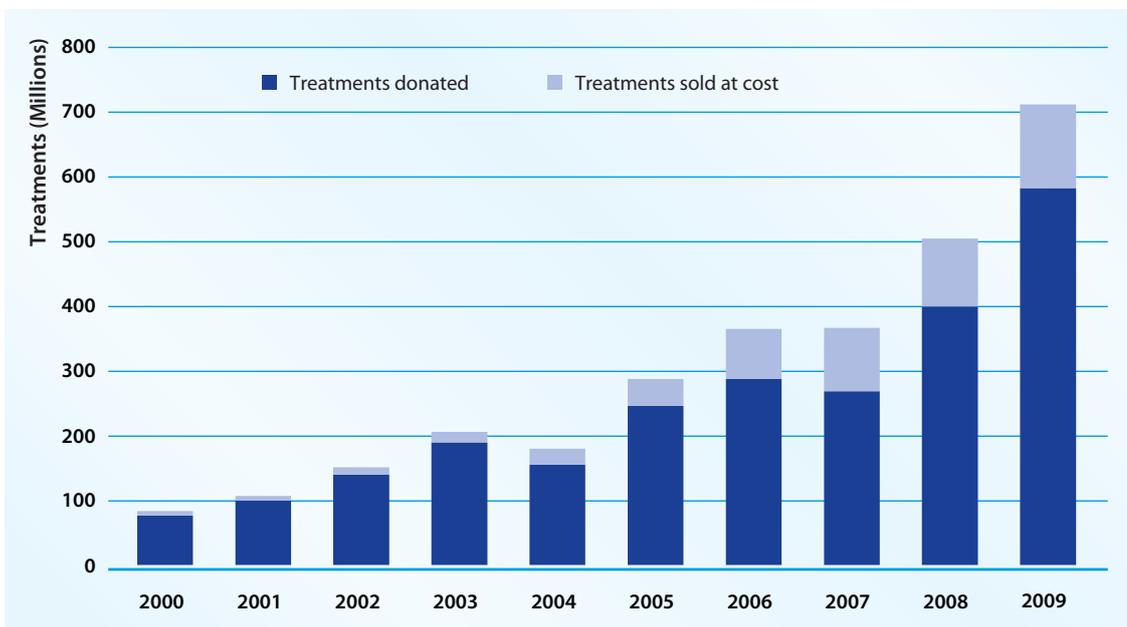


Figure 15: Treatments donated and sold at cost in developing countries²⁰⁶

Merck KGaA Praziquantel Donation Program (MPDP)²⁰⁷

Under the current Merck Praziquantel Donation Program (MPDP), about 19 million children infected with schistosomiasis have been treated in 15 African countries since 2008. Merck KGaA plans to increase its annual donation of tablets from 20 million to 250 million tablets, sufficient to treat about 100 million children per year, which will contribute to the elimination of the disease by 2020. Praziquantel is known to be the most effective therapy currently available for schistosomiasis infections, which are caused by parasitic worms. In addition, Merck KGaA will financially support a WHO-led school awareness program in Africa, the objective of which is to educate children about the consequences of schistosomiasis and ways to prevent the disease.

²⁰⁴IFPMA, Partnerships to Build Healthier Societies in the Developing World (Geneva: 2006).

²⁰⁵IFPMA, Research-Based Pharmaceutical Industry Pledges 14 Billion Treatments to Help End Nine Neglected Tropical Diseases, News Release (Geneva, Switzerland, January 30, 2012), http://www.ifpma.org/fileadmin/content/News/2012/IFPMA_Ending_neglected_tropical_diseases_January2012.pdf.

²⁰⁶IFPMA "Health Partnerships Survey".

²⁰⁷IFPMA, "Ending Neglected Tropical Diseases", 2012.

Technology transfer, infrastructure and capacity building

Transfer of technology, which enables local production and capacity building, is an integral part of the pharmaceutical industry's business model. As such, it has taken place consistently throughout the years and has been more marked when enabling conditions are in place, like political stability, effective intellectual property systems, availability of skilled workers and the existence of a viable and accessible market. By its very nature, even in cases where a direct transfer of manufacturing technology is not involved, trade in pharmaceuticals in and of itself disseminates knowledge worldwide about new medical procedures and facilitates the creation of a services network that will enhance the performance of the health workforce.

In specific situations, companies may choose to foster generic production of innovative medicines by issuing voluntary licenses or by committing not to enforce some patent rights. In many cases, these decisions are not commercially driven and are part of the company's wider policy to facilitate access to medicines. Merck & Co., GlaxoSmithKline, Gilead and Pfizer have all entered into voluntary licensing agreements with various generic companies, in countries as diverse as India, Kenya, South Africa and Thailand, to produce generic versions of antiretrovirals. Other companies, including Roche, Boehringer Ingelheim, and Bristol-Myers Squibb, have offered non-assert declarations on antiretrovirals in Sub-Saharan Africa.

Even when medicines are freely available, there is no guarantee that they will reach patients or that they will be used according to the recommended medical prescription. As discussed in Chapter 2, safe and sustainable access to medicines requires an efficient healthcare system, with quality control measures

and well-trained medical staff who can monitor the authenticity and integrity of pharmaceuticals and advise patients on drug indications. To improve the safe uptake of its products, the pharmaceutical industry has engaged in projects to transfer knowledge and technology, to help countries use the medicines that are available in the most efficient and safest manner.

The number of these access and capacity-building programs has increased steadily over the last few years and now totals more than 50 for HIV/AIDS, 10 for tuberculosis and 7 for malaria.²⁰⁸ To illustrate, Sanofi has supported the French Agence de Médecine Préventive (AMP) since 2001 to train doctors in epidemiology, applied computing, vaccinology and health management in eight African countries, while the Merck Vaccine Network-Africa (MVN-A) training centers in Kenya, Mali, Uganda and Zambia work to provide health professionals with hands-on training in vaccine management and immunization services.

Importantly, many of these technology transfer and capacity-building initiatives comprehensively address weaknesses in the healthcare system that would otherwise hinder the absorption of technology transfer. For example, the Eli Lilly and Company Multidrug-Resistant Tuberculosis (MDR-TB) Partnership, set up in 2003, works with the WHO to provide access to medicines, transfer manufacturing technology to the developing world, train healthcare workers, raise awareness and promote research and prevention. To date, the Partnership has transferred the technology, expertise, formulas and trademarks to manufacture Lilly's two antibiotics for MDR-TB, capreomycin (Capastat®) and cycloserine (Seromycin®), to manufacturers in South Africa, China, India and Russia — some of the world's highest-burden countries.²⁰⁹

²⁰⁸IFPMA, Health Partnerships Directory, April 15, 2012, <http://www.ifpma.org/resources/partnerships-directory.html>.

²⁰⁹IFPMA, Technology Transfer: A Collaborative Approach to Improve Global Health.

Technology transferor	Beneficiary	Receiving country	Year started
Biken	PT. Bio Farma (Persero)	Indonesia	2007
Bristol-Myers Squibb	Emcure; Aspen Pharmacare	India; South Africa	2006
Research Institute	Government Pharmaceutical Organization	Thailand	2010
Daiichi Sankyo	Daiichi Sankyo Pharmaceutical (Shanghai) Co., Ltd.; Inter Thai; Olic (Thailand) Ltd.	China; Thailand	2004; 2005
Eisai	9 manufacturers	China; India; Indonesia; Jordan; Thailand	2004-2010
Gilead	14 generic companies	India; South Africa	2006
GlaxoSmithKline	Oswaldo Cruz Foundation (Fiocruz)	Brazil	1985; 2010; 2007
Johnson & Johnson (Tibotec)	Hetero Drugs Limited; Matrix Laboratories Limited (a Mylan company); Aspen Pharmacare	India; South Africa	2011
Eli Lilly	Hisun Pharmaceuticals; Shasun Chemicals and Drugs; SIA International; Aspen Pharmacare	China; India; Russian Federation; South Africa	2003
Merck & Co., Inc. (Nobilon)	Government Pharmaceutical Organization in Thailand; Serum Institute of India; Zhejiang Tiayuan Biopharmaceuticals in China	China; India; Thailand; WHO	2009
Merck KGaA (MerckSerono)	MerckSerono Mexico	Mexico	2007
Novartis	Advanced Bio Extracts (ABE)	Kenya; Uganda; Tanzania	2005
Bristol-Myers Squibb; Gilead; Johnson & Johnson; Merck & Co., Inc.; ViiV Healthcare	International Partnership for Microbicides (IPM)	Global	2008
Roche	State Pharmaceutical Laboratory of Pernambuco (LAFEPE)	Brazil	2003
Sanofi-aventis	Sanofi-Aventis Morocco	Morocco	2006
Takeda	Tianjin Takeda Pharmaceuticals Co., Ltd.; P.T. Takeda Indonesia	China; Indonesia	1999; 2002; 2003; 2004
ViiV Healthcare	8 licensing agreements	India; Kenya; South Africa	2001

Table 3: Selected examples of technology transfer²¹⁰

²¹⁰ For a more complete list of technology transfer initiatives, see IFPMA, Technology Transfer: A Collaborative Approach to Improve Global Health. The Research-Based Pharmaceutical Industry Experience, 2011, <http://www.ifpma.org>.

Janssen Generic ARV licensing

Janssen R&D Ireland (formerly Tibotec Pharmaceuticals), an affiliate of Johnson & Johnson, has granted multiple non-exclusive licenses to Hetero Drugs, Emcure Pharmaceuticals, Strides ArcoLab and Matrix Laboratories in India, and Aspen Pharmacare in South Africa, to manufacture, market and distribute generic versions of its non-nucleoside reverse transcriptase inhibitor rilpivirine hydrochloride (TMC 278), subject to its approval for use with other antiretroviral agents in the treatment of treatment-naïve HIV-1 infected adults. The Indian companies will have rights to market the product in 112 countries in sub-Saharan Africa, the Asia-Pacific region, Latin America and the Caribbean, Eastern Europe and Central Asia. Aspen will have rights to market the product in sub-Saharan Africa, including South Africa.

The generic manufacturers will be able to use TMC 278 as a single-agent medicine and to include it in fixed-dose combination (FDC) products. Janssen R&D Ireland will provide the generic manufacturers with the technical information and knowledge to allow them to manufacture the single-agent product. The generic manufacturers will pay royalties ranging from 2% to 5% and will be responsible for timely regulatory filing for generic TMC 278 and for seeking pre-qualification from the World Health Organization (WHO) and the US Food and Drug Administration's Abbreviated New Drug Application for generic drug approvals.²¹¹

Conclusions

Sustainable access to quality pharmaceuticals is a multi-faceted issue. A number of variables – including the efficiency of the distribution system, infrastructure, effectiveness of healthcare systems, patient access to insurance, as well as government taxation and procurement policies – all play a major role in determining the extent of patient access to medicines and vaccines in a safe and timely manner. An effective intellectual property system does not jeopardize access to medicines. On the contrary, it gives companies the confidence that their technology will not be unfairly used and thus facilitates the early introduction of new medicines in different markets. It also provides the needed incentives for the development of new medicines to treat unmet needs. More often than not, the biggest challenge in ensuring access to quality pharmaceuticals stems from domestic deficiencies in the healthcare system that exacerbate existing disparities in the population. Low- and high-income countries alike have shown that political will to address the domestic sources of poor quality and inequity of care can lead to significant returns on health outcomes. Global health partnerships that help address both the short- and long-term healthcare system challenges have shown the tremendous synergies possible through cooperation when the political will is there.

²¹¹ IFPMA, Health Partnerships Directory.

Abbreviations

AIDS	Acquired immune deficiency syndrome
ARV	Antiretroviral
DOTS	Directly observed treatment short course (for tuberculosis)
GAVI	Global Alliance for Vaccines and Immunization, now the GAVI Alliance
GDP	Gross domestic product
Global Fund	Global Fund to Fight AIDS, Tuberculosis and Malaria
HIV	Human immunodeficiency virus
IFPMA	International Federation of Pharmaceutical Manufacturers and Associations
LDC	Least-developed country
MDR-TB	Multidrug-resistant tuberculosis
NCDs	Non-communicable diseases
NGO	Non-governmental organization
NTDs	Neglected tropical diseases
OECD	Organization for Economic Cooperation and Development
PEPFAR	US President's Emergency Plan for AIDS Relief
R&D	Research and development
TB	Tuberculosis
UNAIDS	Joint United Nations Program on HIV/AIDS
UNICEF	United Nations Children's Fund
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

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