

Pharmaceutical industry perspectives on access to medicines – overcoming barriers to access

Contribution II from the

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ABSTRACT

Achieving Sustainable Development Goal (SDG) 3.8 on universal health coverage is a challenging but urgent task, requiring coherent, aligned global policies that enable coordinated action by governments, multilateral organizations, civil society and the private sector. The 2030 Agenda for Sustainable Development recognizes the importance of “the role of the diverse private sector, ranging from microenterprise to cooperatives to multinational corporations” to achieve the SDGs, and calls for a “revitalized global partnership” that includes the private sector.

The biopharmaceutical industry is at the center of global efforts to create access to medicines through its engagement in developing effective public policies, strengthening health systems, overcoming economic and poverty barriers, and driving biopharmaceutical innovation.

This Contribution highlights ways in which pharmaceutical companies are improving access to medicines, focusing on efforts to overcome systemic access barriers.

We conclude with proposals for initiatives that are being implemented successfully and could be scaled to achieve greater impact on public health outcomes. Each of the proposals is implementable, will improve policy coherence and advance human rights. Our proposals include:

- *Creating public-private alliances to provide healthcare access while strengthening local economic capacity through social business models;*
- *Collaborating for leaner, more effective distribution systems; and*
- *Scaling up successful strategies to grow local infrastructure and train healthcare workers.*

Two related Contributions focus on IP protection and how it facilitates access to medicines, and how to build on existing solutions to improve access to medicines and other health technologies.

CONTRIBUTION

Sustainable Development Goal (SDG) 3.8 calls upon the world to “achieve universal health coverage, and provide access to safe and effective medicines and vaccines for all.”¹ Every

year, the pharmaceutical industry develops new solutions that transform health outcomes; for many, however, even basic healthcare services are beyond their reach. Weak systems and incoherent national policies exacerbate inequalities, making poverty both a primary determinant and ongoing consequence of poor access to healthcare.

New mechanisms to improve access to medicines will not achieve our shared goals unless they are pragmatic and engage a coalition of actors in both the public and private sector. The viability of the pharmaceutical industry and the societal benefits it provides depends on the existence of functional pathways that bring our medicines to the people who need them. We are deeply engaged in strengthening health access as a central part of our global operations. Together with government, nonprofits, and multilateral organizations, industry is addressing healthcare access as a multidimensional issue that requires comprehensive approaches.

I. Cost Barriers to Healthcare Access

Poverty represents the greatest barrier to health access worldwide. Currently, many costs of healthcare fall heavily on users, leading to inequalities of access. Nearly three-fourths of the world's poor live in middle-income countries (MIC);² building health systems and policies that align with health access goals in these countries is an urgent priority. Many discussions focus exclusively on the issue of the cost of patented pharmaceuticals, a concern that the industry is addressing (see Contributions #1 and #3 for further discussion). However, it is important to recognize that patented medicines typically make up a small proportion of healthcare spend and that medicines are only one component of healthcare costs. Healthcare systems must be designed that take a bottom-up approach to create equity for marginalized groups.

- a. Sufficient financing of health systems is a fundamental building block of sustainable systems to enable improved access to medicines, and stronger investment is needed in many countries.** In 2001, heads of state of African Union (AU) countries affirmed the Abuja Declaration, pledging to improve social and economic conditions in the world's poorest countries by 2015. As a key component, AU countries committed themselves to allocating at least 15% of their annual budgets to improve the health sector, and called for a development assistance funding goal of 0.7% of GNI from donor countries. However, as of 2015, only six AU countries had achieved this budgetary goal, and only five donor countries have consistently reached development assistance goals.^{3,4} Moreover, for the last decade, India's investment in health as a percentage of its GDP has averaged around 4%, despite its large domestic generic drug industry.⁵ India's current level of spending is one of the lowest figures in the world, ranking it below Haiti and Ethiopia.⁶ There are also low levels of spending on health in ASEAN, with most countries in the region allocating less than 5% of GDP as expenditure on health in 2012, with the exceptions of Cambodia (5.4%) and Vietnam (6.6%).⁷
- b. Many countries have not implemented effective risk-pooling mechanisms to shield patients from the direct costs of healthcare.** Insurance systems pool together the financial resources of a group of individuals over long periods of time, ensuring sustainability and affordability of healthcare coverage for all group members by spreading risk. However, a recent study of 50 low- and middle-income countries

(LMICs) revealed that 88% required direct payment at government healthcare facilities.⁸ Out-of-pocket spending represents 90% of private health spending in low-income countries (LICs), as compared with only 15% in high-income countries.⁹ As a result of having to pay out-of-pocket for healthcare, 150 million people each year in LMICs suffer financial hardship.¹⁰

- c. **Out-of-pocket health spending is a prohibitive barrier to access for even essential, generic medicines.** Many of the biggest killers of children in LICs are easily preventable or treatable with cheap, off-patent medicines. However, affordability remains a major issue: a recent study showed that up to 86% of the population in LMICs would fall into poverty if forced to pay out-of-pocket for just one of four common generic medicines.¹¹ According to the WHO, it is difficult to achieve universal health coverage if out-of-pocket expenditure as a percentage of total health spending is equal to or greater than 30%.¹²
- d. **Transaction costs associated with healthcare can be significant and prevent access.** There are many transaction costs associated with healthcare, including the costs of transport, foregone earnings and care for dependents. One study of patients obtaining free breast cancer care in Haiti found that out-of-pocket non-medical costs forced 52% of participants into debt and 20% to sell possessions.¹³ Even with free treatment, out-of-pocket expenses accounted for more than 91% of annual earnings.¹⁴
- e. **Mark-ups along the distribution chain increase the price of medicines in all countries.** The problem is most acute in LMICs. In Kenya, for example, mark-ups along the chain can add 300% to the manufacturer-selling price of a medicine, and 200% in Brazil.¹⁵ The WHO has created a technical guide to international pharmaceutical pricing policies that collates data from other studies relating to mark-ups and reports average public sector retail mark ups of 40-123% globally.¹⁶ Taxes also contribute to the price of medicines, and a number of countries maintain tariffs of over 8% on medicines, including India (10%), Brazil (9.8%) and Thailand (9.3%).¹⁷ This is clearly an instance of policy incoherence; collecting taxes has a direct impact on limiting availability and affordability of medicines.

II. Supply Chain Barriers to Healthcare Access

National procurement and supply systems for medicines are often inefficient; as a result, resources are wasted, the introduction of new medicines is delayed and stock-outs occur.

- a. **Lengthy registration processes for pharmaceuticals can delay access to important new innovations for years.**¹⁸ Highlighted by the WHO, regulatory barriers that delay access include: complicated guidelines and assessment procedures; long timeframes for registration; administrative backlogs; and missed opportunities to coordinate with foreign regulatory authorities and/or the WHO's Prequalification program.¹⁹ In India and Brazil, registration of an original product takes 15 months and 13 months, respectively.²⁰ Five-year delays in South Africa are not uncommon.²¹

- b. Inefficient procurement and distribution systems result in frequent stock-outs of pharmaceuticals and medical devices throughout the health system.** Many countries fail to plan adequately for drug procurement to distribute medical supplies in a timely manner, resulting in stock-outs – even if the supplier has provided the requested quantities. A 2009 survey of 36 countries found that 15 common generic medicines listed on the WHO Essential Medicines List are frequently unavailable in either the public or private sectors, with regional availability ranging from 29% in Africa to 54% in the Americas.²²
- c. Poor storage facilities and conditions can cause significant wastage of pharmaceutical supplies, driving up healthcare costs significantly.** USD550.000 worth of antiretrovirals and USD10 million antimalarial doses recently expired in Uganda’s National Medical Stores (NMS).²³ In India, a study followed a series of vaccine vials through the distribution process, finding that 76% failed a quality test, because the vaccines they contained were frozen during the study period.²⁴ In another assessment, storage of vaccines outside the recommended temperature range was observed in 8 to 26% of facilities in Ghana, Kenya, and Uganda.²⁵
- d. Complex customs clearance processes can create importation bottlenecks, slowing the availability of medicines and medical supplies.** Customs clearance procedures, regulated by recipient country governments, are often complex and changeable. Breakdowns in customs procedures may cause delivery delays, product shortages, and stock-outs.²⁶

III. Infrastructure Barriers to Healthcare Access

In many countries, existing physical healthcare infrastructure is insufficient to reach much of the population. 70% of the world’s poor live in rural areas,²⁷ and when healthcare is far away or transportation systems are inadequate, lack of access results in negative health outcomes.^{28,29,30} A new International Labor Organization report shows that 56% of people living in rural areas worldwide do not have access to healthcare services – more than double the figure in urban areas (22%).^{31,32} This barrier is particularly acute for diseases requiring specialized care such as cancer. For example, Ethiopia, a country of some 90 million people, is served by a single radiation treatment center located in the capital of Addis Ababa.³³

- a. There is currently a global shortage of 7.2 million healthcare workers, a figure that may rise to 12.9 million by 2035.** More than 80 countries currently fail to meet the basic threshold of 23 skilled health professionals per 10,000 people.³⁴ This shortage poses particular barriers to access to specialist care for non-communicable diseases: one study showed how shortages of specialists in Vietnam and the Philippines limit access to diabetes drugs.³⁵ Shortages of clinical staff mean that patients may be unable to see a doctor when they enter the health system. One survey of patients in Colombia and Brazil found that up to 60% of people were not seen by doctors when they attended a public facility.³⁶

PROPOSALS

Creating and ensuring strong health systems is essential to improving access to medicines. The following proposals highlight initiatives that are being implemented successfully and could be scaled to achieve greater impact on health outcomes. Each of the proposals is implementable, will improve policy coherence, and advance human rights.

- 1. Create public-private alliances to provide healthcare access while strengthening local economic capacity through social business models.** Social business models are sustainable mechanisms for addressing health issues in resource-limited settings. These models rely on differentially priced products and services aligned with the purchasing power of the community. They empower local ownership so that communities can develop and utilize the services they want and need while building the local economy. Social businesses recognize the need for sustainability and cost-recovery of social initiatives.

By tailoring their offerings to local economic and social situations, private companies have improved health for new populations, expanded their market shares and entered new markets. For example, programs such as Novartis Access, Arogya Parivar and AstraZeneca's Healthy Heart Africa project, as well as other efforts to improve supply chains demonstrate how locally-tailored business models can increase access to treatment and care. Arogya Parivar, for example, has brought health education to more than 10 million people across 10 Indian states.³⁷ While small-scale implementation is underway, considerations moving forward should include global promotion as well as country-level prioritization of such businesses.

- 2. Collaborate for leaner, more effective distribution systems.** Regulatory barriers should not prevent vital new medicines from reaching patients in need or jeopardize treatments through stock-outs. Lean, regulated, and locally-sourced supply chains are an effective way of increasing efficiencies while transparent practices can reduce irregular or excessive markups, fees, and corruption, creating more equitable access.

Achieving a lean distribution system requires expert coordination across sectors especially private manufacturers and distributors, government procurement agencies, and NGO or multilateral product procurers. Currently, there are collaborations between governments, multilateral organizations and the private sector to harmonize regulations and strengthen supply chains. For example, in Kenya, Novo Nordisk's Base of the Pyramid project is working with distributors to limit price markups for medicines and services and has achieved a price reduction for insulin of nearly 75%.³⁸ Additional, more expansive efforts should be a priority for the global health community and look to replicate the successes of such projects.

- 3. Scale up successful strategies to build local infrastructure and train healthcare workers.** SDG 3 explicitly states the need to "substantially increase health financing and the recruitment, development, training and retention of the health workforce in developing countries, especially in least developed countries and small-island developing states."³⁹ With a growing library of successful interventions to strengthen human resources for health, global health investors and implementers should focus on taking these to scale, coordinating and aligning efforts and policies to ensure successful collaboration.

For example, the Frontline Health Workers Coalition⁴⁰ and One Million Health Workers⁴¹ (which are supported by the pharmaceutical industry) have shown that outreach and capacity building of field workers can help improve access to care in isolated areas. Moreover, GSK's 20% reinvestment program is investing in human resources for health in least developed countries, with a total contribution of more than USD30 million to date.⁴² This initiative has trained 25,000 healthcare workers and reached 6.5 million people in 34 countries since 2011.⁴³ The Bristol-Myers Squibb Foundation's Delivering Hope™ initiative has been helping communities and healthcare workers in China and India to build the capacity of healthcare providers to address HBV and HCV, and promote disease prevention in at-risk populations.⁴⁴ Delivering Hope™ has reached nearly 90,000 patients, diagnosed over 1,600 patients and trained over 91,000 healthcare workers.⁴⁵

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