

Pharmaceutical industry perspectives on solutions that work to create access to medicines

Contribution III from the:

- European Federation of Pharmaceutical Industries and Associations
- International Federation of Pharmaceutical Manufacturers and Associations
- Pharmaceutical Research & Manufacturers of America
- Japan Pharmaceutical Manufacturers Association

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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 helping to improve access to medicines by providing solutions that work. In keeping with the 2030 Agenda for Sustainable Development that business investments and innovations are “drivers of productivity, inclusive economic growth and job creation,” we provide examples that help to reduce fiscal barriers, promote local economic growth and drive collaborative research to increase access.

We conclude with several proposals for opportunities to elevate and scale up successes across R&D, sustainable financing and cross-sector collaboration to strengthen healthcare access. Each of the proposals is implementable, will improve policy coherence and advance human rights. Our proposals include:

- *Introducing and scaling up proven access models in new geographies and for new diseases;*
- *Establishing a community of practice joining all efforts to harness science, technology and business for enhanced innovation;*
- *Implementing an independent, transparent, and evidence-based monitoring and accountability framework to ensure that all sectors work collaboratively across the components of access to medicine.*

Two related Contributions focus on intellectual property protection and how it facilitates access to medicines, as well as systems barriers to access that impede scaling up effective solutions.

CONTRIBUTION

I. Strengthening Effective & Efficient Health Systems

Biopharmaceutical companies make substantial contributions to improve the effectiveness and efficiency of health systems and to improve access to quality healthcare and medicines through training healthcare workers (HCWs), advancing health information systems, disease awareness campaigns, technology transfer, improving point-of-care service delivery and investing in health infrastructure.

- a. **Sanofi's Mental Health Initiatives** take a system-wide approach to improve experiences of people affected by mental disorders in Benin, Madagascar, Mauritania, Morocco, Guatemala, Comoros, Armenia, India, and South Africa. Program includes: community-based disease awareness to combat stigma, training healthcare providers (HCP) in diagnosis and treatment of mental disorders, and differential pricing policies to make products accessible.¹ In Mauritania this contributed towards a 48% reduction in the schizophrenia treatment gap within 3.5 years (2009-2012).²
- b. **Merck KGaA, Darmstadt, Germany's Capacity Advancement Program (CAP)** helps improve the quality of diabetes treatment and raises awareness of this disease, especially in low- and middle-income countries. Merck KGaA established the CAP across Africa, India and Indonesia, in collaboration with Ministries of Health and academic institutions. Since 2012, Merck KGaA has conducted 250+ events, provided 25,000+ patients with free diabetes screening and medical check-ups and distributed 100,000+ diabetes patient leaflets.³
- c. **The Bristol-Myers Squibb Foundation's Secure the Future program** provides community-based care and support to people living with HIV/AIDS, and has committed USD180+ million to 250+ projects since 1999. Its Technical Assistance Program is a south-south skills transfer initiative in South Africa, Swaziland, Lesotho, Ethiopia, Kenya, Tanzania and Zimbabwe to strengthen community-based services and HCW training. As of 2015, Secure the Future has trained 185,000+ HCWs through 57 projects.⁴
- d. **GSK's 20% reinvestment program** puts profits back into participating countries' healthcare systems and human resources for health. This program is running in all LDC, totaling a contribution of USD30+ million.⁵ Training HCWs is the primary focus along with community education and public sector governance. GSK has trained 25,000 HCWs and reached 6.5 million people in 34 countries since 2011.⁶
 - e. **Neglected Tropical Disease (NTD) Drug Supply Chain Forum** brings together GSK, Johnson & Johnson, Pfizer, Merck KGaA (Darmstadt, Germany), Merck & Co. Inc. (Kenilworth, NJ, USA), Eisai, the WHO, Bill & Melinda Gates Foundation (BMFG), DHL and NGOs (Children Without Worms, the Mectizan[®] Donation Program, the International Trachoma Initiative and RTI International) to improve supply chain management for NTD medicines.⁷ A logistics "Control Tower" has been created, forecasting and planning tools are in development, and statistical modeling of supply chains is underway. These efforts have resulted in a 36% increase in donated treatments.⁸

- f. **Johnson & Johnson** and **ViiV Healthcare** have partnered with PEPFAR, BMGF and Girl Effect in the **DREAMS initiative**. DREAMS implements evidence-based approaches to address the structural drivers that increase girls' HIV risk, including poverty, gender inequality, sexual violence, and lack of education.
- g. **The London Declaration** unites healthcare companies, BMGF, World Bank, NGOs, and governments in a campaign to eliminate or control 10 NTDs by the year 2020. In the largest coordinated effort to date to combat NTDs, the coalition will sustain or expand existing medicine donation programs; share expertise and compounds to accelerate the development of new medicines; and strengthen distribution programs.⁹
- h. **The Pink Ribbon/Red Ribbon coalition** combines efforts by the Bristol-Myers Squibb Foundation, GlaxoSmithKline, MSD, and other private sector entities with George W. Bush Institute, Susan G. Komen, UNAIDS, USAID/PEPFAR and others to address cervical and breast cancers among women living with HIV in Africa.¹⁰
- i. The **Women's Cancer Initiative in the Americas** works to improve the quality and effectiveness of national breast and cervical cancer programs and the quality and completeness of national cancer registries. The PAHO Foundation, with support from IFPMA members, Bristol-Myers Squibb and Pfizer, coordinates the Women's Cancer Initiative in Latin America and the Caribbean, where breast and cervical cancer are leading causes of preventable and premature death among women.¹¹
- j. **Merck & Co., Inc.**, Kenilworth, NJ, USA's **MSD for Mothers** is a 10-year, USD500 million initiative to reduce maternal mortality. MSD works in collaboration with 75+ implementing partners in 30 countries. The initiative focuses on 1) access to affordable, quality care; 2) product innovation; and 3) advocacy and awareness. The MSD for Mothers' partnership with BMGF in Senegal has eliminated stock outs of contraceptives to <2% in public facilities throughout the country and contributed to an increase in the contraceptive prevalence rate of 8%.¹²
- k. Eli Lilly's **Non-Communicable Disease** and **Multidrug-resistant TB Partnerships** focus on evidence-based approaches to addressing healthcare system gaps for diagnosis, care, and management of MDR-TB. These programs represent a USD60 million commitment in 2012-2016 and have:
- Contributed to an increase in TB case detection in India where 3,000+ pharmacists have been engaged;¹³
 - Helped implement a protocol for rapid diagnosis of MDR-TB in Russia;¹⁴
 - Piloted health-systems interventions to improve NCD care at the primary care level in Mexico;¹⁵
 - Sponsored a controlled trial of lifestyle interventions to reduce the risk of diabetes in women previously diagnosed with gestational diabetes in Brazil¹⁶
- l. **Other examples include:**
- The African Comprehensive HIV/AIDS Partnerships between the Government of Botswana, BMGF, and Merck & Co., Inc., Kenilworth, NJ, USA's Merck Company Foundation¹⁷
 - Novo Nordisk's Changing Diabetes in Children¹⁸
 - The Novartis Malaria Initiative¹⁹
 - Japan Pharmaceutical Manufacturers Association members' Capacity Building Projects²⁰

II. Building Sustainable Economies & Affordable Access

The recently adopted SDGs build on robust literature linking health outcomes and poverty. Paragraph 67 in the 2030 Agenda for Sustainable Development recognizes the benefits of private business investments and innovations as “drivers of productivity, inclusive economic growth and job creation.”²¹ Companies have been developing methods that reduce fiscal barriers to medicines and promote local economic growth.

- a. **Novartis’s Arogya Parivar** is a social venture through which health educators are recruited and trained on disease prevention and healthcare seeking behaviors and local teams run health camps and mobile clinics in India. The venture turned profitable after 31 months, with a product portfolio including 100+ medicines in 2015. Ten million people have benefited from health education and 760,000 have received diagnosis and/or treatment.²²
- b. **AstraZeneca’s Healthy Heart Africa** is employing a sustainable chronic care model to tackle hypertension and cardiovascular disease in Kenya and Ethiopia. The business model is built on a secure, low-cost supply chain and reduction in prices for patients. Working with public sector and NGO partners, AstraZeneca is complementing the business model with education, awareness campaigns and screening as well as building healthcare worker capacity to diagnose and provide care.^{23,24}
- c. **Merck KGaA, Darmstadt, Germany’s Su-Swastha Project** is an access oriented business model in India which Merck supports with various NGOs and the Indian Health and Family Ministry. The project provides underserved rural populations with affordable health solutions and engages patients through community meetings and educational health programs. In 2015, it reached 15,000+ people through 717 community meetings and 43 health workshops.^{25,26}
- d. **Novo Nordisk’s Base of the Pyramid Project**, initiated in 2012, implements sustainable solutions that increase patient access to diabetes treatment and care in resource-limited settings. Novo Nordisk is training HCWs, setting up clinics and reducing prices to increase disease awareness, diagnoses, and access to affordable care and treatment.²⁷ In Kenya, the project achieved a price reduction for insulin of nearly 75%, set up 40+ diabetes patient support groups, and trained 600+ healthcare providers as of 2014.²⁸
- e. **MSD’s Project Penny**, known locally as Project Sambhav, aims to educate patients and their families about HCV and help manage the cost of treatment. MSD India, through a partnering financial institution, provides subsidies for financing treatment and also provides counseling to help educate about treatment, adherence and transmission prevention. The program, which has been expanded to 11 cities across four states in India, increased access to Pegintron for patients with limited or no insurance coverage in Punjab State from 2% to 45%.²⁹
- f. **Product donations** create access by eliminating fiscal costs associated with medicine acquisition. While often criticized for lacking sustainability, long-term commitments made by companies have reached millions of patients and demonstrate significant impact. Examples include:
 - Merck & Co., Inc., Kenilworth, NJ, USA’s Mectizan® Donation³⁰
 - Merck KGaA, Darmstadt, Germany, Praziquantel Donation Program³¹
 - Novartis Foundation’s Leprosy Program³²

- Janssen's Sirturo® Donation³³
- Pfizer Trachoma Initiative³⁴
- GSK Lymphatic Filariasis Program (including Eisai and MSD as partners)³⁵
- Sanofi partnership with the WHO for Human African Trypanosomiasis elimination³⁶

III. Driving Collaborative Research

SDG 3b outlines the need to “support the R&D of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries.”³⁷ Industry has consistently demonstrated its dedication to using its R&D capabilities to address public health needs and has facilitated participatory research that seeks to create solutions tailored to locally-identified needs.

- In 2016, the **Declaration on Combating Antimicrobial Resistance** was signed by pharmaceutical, biotechnology and diagnostics companies pledging to continue to invest in R&D to support collaboration between industry and public researchers to develop new antibiotics and diagnostics. Signatories committed to develop new valuation mechanisms with payors and policy-makers that better reflect levels of investment in product and technology development, and their benefits to society.³⁸ Thus far, 85 companies and nine industry associations in 18 countries have signed the declaration.³⁹
- The **Global Health Innovative Technology Fund (GHIT)** is the world's first product development fund with pioneering governance, management, and investment approaches, which facilitates international partnerships that bring Japanese innovation, investment, and leadership to the global fight against infectious diseases and poverty in the developing world. GHIT includes Astellas, Chugai, Daiichi Sankyo, Eisai, Shionogi, and Takeda. It has invested USD54 million; funded 53 partnerships; and supported 6 clinical trials in Uganda, Tanzania, Ivory Coast, Burkina Faso, Peru and Bolivia, with two additional trials set for 2017.⁴⁰
- The NTD Drug Discovery Booster** project aims to speed up the development of new treatments for Leishmaniasis and Chagas Disease, which 450 million people are at risk of contracting worldwide. The project brings together DNDi, Eisai, Shionogi, Takeda and AstraZeneca. DNDi can access millions of unique compounds to screen for potential treatments or cures for these diseases.⁴¹
- WIPO: Re:Search** is a global consortium of public and private sector organizations who share their IP, compounds, expertise, facilities and know-how with qualified researchers working on new solutions for NTDs, malaria and tuberculosis. WIPO Re:Search was established in 2011 by WIPO, BIO Ventures for Global Health, pharmaceutical companies and other private and public sector research organizations. It has 101 Members and has yielded 99 agreements.⁴²
- IFPMA members participate in **Product Development Partnerships (PDP)** including the **Medicines for Malaria Venture**⁴³, the **TB Alliance**⁴⁴ and the **Drugs for Neglected Diseases Initiative**.⁴⁵ These PDPs distribute the costs of development, make products more affordable and get new products to patients faster.
- Individual Company-led R&D Initiatives**
 - GSK Africa Open Lab for R&D⁴⁶
 - Pfizer's Infectious Disease Institute⁴⁷

- Novartis Institute for Tropical Diseases⁴⁸
- Sanofi Anti-Infective Therapeutic Strategic Unit⁴⁹
- Merck KGaA, Darmstadt, Germany's Global Health R&D Translational Innovation Platform⁵⁰
- Merck & Co., Inc., Kenilworth, NJ, USA's Global Health Innovation Fund⁵¹

PROPOSALS

The Agenda for the Sustainable Development Goals 2030 calls for a “revitalized global partnership,” including the private sector, particularly to address access to medicines.⁵² The recommendations below represent opportunities to scale proven successes across R&D, sustainable financing, and cross-sector collaboration to strengthen healthcare access. Each of the proposals is implementable, will improve policy coherence, and advance human rights.

- 1. Introduce and scale proven access models into new geographic areas and diseases to reach more communities around the world.** These models should be sustainable and transfer ownership to communities at the local level. Programs such as Novartis Access, Novartis Arogya Parivar, AstraZeneca Health Heart Africa, Lilly MDR-TB and NCDs Partnerships, among others demonstrate how locally-tailored programs can increase access to treatment and care. While small scale implementation is underway, considerations should include global adoption and promotion as well as country-level prioritization of such initiatives.
- 2. Establish a community of practice joining all global health R&D and efforts to harness science, technology and business for enhanced innovation towards achieving the SDGs.** By encouraging innovation and sharing promising R&D approaches, this collaborative learning network will allow industry, academia, government and other actors to leverage resources, expertise and technology to expedite health innovation. Such an initiative complements existing IP policies and facilitates the pooling of resources and expertise between established research firms, academia, the public sector and industry towards the goal of promoting drug discovery and development to find treatments for unsolved public health issues.

Collaborative R&D can take place through investments in countries where the disease burden lies, building capacity of local human resources and laboratory infrastructure. Ideally, this initiative would be modeled after existing successful collaboration frameworks such as the Joint Learning Network established for Universal Health Coverage.⁵³ The recently established Technology Facilitation Mechanism also provides potential platform to encourage a collaborative approach to business, technology and innovation within the SDG agenda. Other successful collaborations include Declaration on Combating Antimicrobial Resistance; Global Health Initiative Technology Fund; NTD Drug Discovery Booster; WIPO: Re:Search; GSK Africa Open Lab for R&D; Pfizer Infectious Disease Institute.

- 3. Implement a transparent, robust and evidence-based monitoring and accountability framework to ensure that all sectors work collaboratively across the many components of access to medicine.** A monitoring and accountability framework could

build on the recently established Technology Facilitation Mechanism and associated multi-stakeholder fora to facilitate greater shared accountability. In fulfillment of paragraphs 72-90 of The 2030 Agenda for Sustainable Development,⁵⁴ this initiative should be inclusive, transparent and rigorously evidence-based, including a multi-sector expert panel to review activities and inform decision-making on access to medicines initiatives. Its composition should be a balanced mix of relevant stakeholders, guided by independent thought leaders. Reports would be used by relevant international bodies (i.e., WHO, WIPO, WTO, UNDP, UNICEF, UNFPA, UNAIDS). The Independent Expert Review Group of the UN *Every Woman, Every Child* initiative is well-known and seen widely as a successful model.

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