

ACCESS TO HEALTHCARE

I. BACKGROUND

We operate in a world of constant change, where we seek solutions that meet patients' needs in an efficient and sustainable manner. Global trends including progress in treatments, increased vaccination coverage, and unhealthy lifestyles have led to a worldwide epidemiological shift from infectious to chronic non-communicable diseases (NCDs). Together with the growth and aging of their population, emerging countries like Brazil, China and India, and developing countries including many sub-Saharan African nations, are confronted with both old and new public health challenges. Most of them are still managing unfinished infectious disease agendas while also dealing with the rise of NCDs.

Life expectancy has improved since 2000 but remains strongly affected by income. In low-income countries, life expectancy is 18.1 years lower than in high-income countries. One child in every 14 born in a low-income country will die before their fifth birthday (<https://www.who.int/news-room/detail/04-04-2019-uneven-access-to-health-services-drives-life-expectancy-gaps-who>). In 2016, more than half of all deaths in low-income countries were caused by communicable diseases, maternal and newborn causes, and nutritional deficiencies. The same year, over three quarters of NCD deaths - 31.5 million -- occurred in low- and middle-income countries with about 46% of deaths occurring before the age of 70 in these countries.

(https://www.who.int/gho/ncd/mortality_morbidity/en/).

The complexity of this environment does not allow for one-sided practices but instead calls for systemic solutions. Overcoming the challenges limiting access to healthcare is critical in order to build sustainable health systems and gradually ensure equitable access for all while contributing to economic growth.

II. SANOFI'S POSITION

As a global healthcare company, Sanofi shares responsibility to improve access to quality healthcare with governments and other players, such as healthcare professionals, NGOs and the private sector. Access to healthcare involves a complex set of related issues. To address healthcare disparities globally, Sanofi supports the World Health Organization's (WHO) promotion of Universal Health Coverage in its three dimensions (broadening population covered, expanding services covered, and improving financial protection) and promote an integrated approach that spans the care continuum, from prevention to detection, early diagnosis, treatment and patient care.

- **Innovation** – While the discovery of new solutions plays an essential role in improving health, medicines and vaccines alone do not create public health impact. As a research-based pharmaceutical company, Sanofi is committed to the discovery, development, and provision of health solutions and will continue to work with key partners to leverage our expertise to ensure greater access for patients globally.
- **Availability** – Without strengthened regulatory bodies, secure supply chains and delivery services, access to quality products can be compromised. Sanofi is committed to sharing expertise with local stakeholders to ensure effective registration, production and supply of medicines and vaccines for patients globally, as well as fighting against falsified medicines.
- **Affordability** – Even when patients have access to adequate care, cost can be a key impediment to receiving health products. Sanofi is committed to developing innovative business models and to working with governments and other partners to address issues of affordability.
- **Quality Care and Patient Support** – Sanofi believes that enhanced patient pathways, alongside better and wider use of existing technologies and well-trained human resources, are critical to ensure the efficiency and sustainability of health systems. Sanofi is engaged to contribute to capacity building and patients' empowerment for better care management.

III. INNOVATION – DEVELOP NEW SOLUTIONS AND SERVICES FOR PATIENTS

Innovation is the essence of the research-based pharmaceutical industry. Developing a new medicine takes, on average, 10 to 13 years, with costs ranging from U.S. \$2.5-3.0 billion (including costs of failures) with about 12% of drugs entering clinical trials leading to an approved medicine. Over the last decades, Sanofi has demonstrated our sustained contribution to global health challenges by developing a large portfolio of solutions for a wide range of diseases that affect millions of people globally. At the end of February 2019, Sanofi's R&D pipeline contained 81 projects in clinical development, including 32 new molecular entities (NMEs) and vaccines and 35 projects in late stage development.

In July 2018, Sanofi also entered into an agreement with Evotec to combine resources and expertise to create a new open innovation R&D center, led by Evotec, to build critical mass and have greater impact in the fight against infectious diseases. Sanofi transferred its non-vaccine infectious diseases early stage R&D pipeline and research unit to Evotec and will provide €252 million in transfer costs, primarily consisting of payments to Evotec over a five-year period, including a one-time upfront payment of €60 million, and licenses to more than 10 R&D assets. The research of the open innovation center will initially focus on antimicrobial resistance, superbug infections, malaria, tuberculosis and the development of antiviral therapies with new mechanisms of action. Sanofi will continue internal R&D projects for HIV/AIDS and will be involved in other infectious diseases through its vaccine R&D and global health programs.

Our response to global public health needs and priorities is also shown by our strong engagement with public-private partnerships, such as our 10 year partnership with DNDi to develop fexinidazole as a new oral treatment for sleeping sickness. This partnership led to the development of fexinidazole, according to an alternative non-profit R&D model. Fexinidazole received a positive scientific opinion from the European Medicines Agency (EMA) in November 2018 and the national registration in the Democratic Republic of Congo in December 2018. This decision paves the way for the distribution of fexinidazole in endemic countries in 2019. Sanofi will donate fexinidazole to the WHO in the frame of the long term WHO-Sanofi partnership for neglected tropical diseases. In addition, Sanofi plays a role, thanks to its partnership with the non-profit organization Medicines for Malaria Venture (MMV), in the field of antimalarial drug research and development.

Through these partnerships Sanofi is engaged in supplying drugs and vaccines and contributing to the definition and implementation of public health policy. Our interactions with health authorities, regulatory agencies, medical experts and patients are also used to define our priorities and response to global public health needs.

Through the Sanofi Pasteur Awards, created in 2012, Sanofi and the Institut Pasteur are also engaged to promote and support scientific excellence and innovation in global health in the areas of immunology, microbiology & Infection.

Intellectual property rights established by the World Trade Organization have performed a critical role in stimulating R&D. By sharing risks and rewards, this system has created the appropriate environment for delivering the greatest returns for society not just for today, but also for tomorrow.

However, due to highly disparate situations within countries, as well as market failures, there is a need for a case-by-case approach to intellectual property rights protection. Sanofi considers that intellectual property rights should not be an obstacle to access to medicines or vaccines. Sanofi supports extending the deadline (buffer) for least-developed countries to comply with the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement).

Sanofi also promotes innovative open-innovation approaches where market forces do not work. As such, Sanofi has been recognized for two consecutive years by the U.S. Commerce Department's United States Patent and Trademark Office (USPTO) as a recipient of its prestigious Patents for Humanity program, recognizing the use of our intellectual property portfolio to tackle global humanitarian challenges, in our case for our commitment to antimalarial drug development.

IV. AVAILABILITY – SEEK REGISTRATION AND ENSURE QUALITY PRODUCTION AND DISTRIBUTION CAPACITY

Sanofi considers that seeking registration everywhere for our medicines and vaccines is critical to expand access for all. Sanofi supports the WHO Prequalification Program's work. With a local presence in more than 100 countries, Sanofi is also committed to sharing our expertise with developing countries to ensure local manufacturing, effective delivery and secured supply chains in local environments.

Sanofi is committed to supporting local production capacity, where it is justified and sustainable to more efficiently serve the needs of patients, in particular through the training and employment of local staff in line with International Good Manufacturing Practices (GMP) :

- Sanofi has established more than 30 factories in emerging countries. For example, the transfer of primaquine from Valeant (Canada) to Cali (Colombia) made it feasible to manufacture primaquine in Colombia and closer to endemic countries which need the drug for malaria cases.
- Sanofi Pasteur has implemented major local manufacturing projects and built facilities in Thailand, Argentina, Brazil, Mexico, China and India that respect GMP processes and bio-security laws.

Sanofi believes that no compromise can be made regarding the quality of medicines and vaccines and is committed to providing patients with the right product at the right time in the right place. We strive to ensure the delivery of safe, high-quality medicines and vaccines by developing best practice policy tools.

In order to preserve the integrity of our supply chain, Sanofi works closely with local authorities and global security organizations to improve awareness about counterfeit medicines and vaccines and the serious threat they pose to patients' health. We also seek to facilitate international investigations and legal actions. Sanofi has also developed innovative technologies to protect our products (i.e. packaging security, safety labeling, data matrix, etc.) and we are pursuing the fight against counterfeit drugs through our central anti-counterfeit laboratory in Tours (France), where a team of experts uses state-of-the-art technologies to analyze Sanofi products suspected of being counterfeit. (see more details in our factsheet 'fighting falsified medical products (https://www.sanofi.com/-/media/Project/One-Sanofi-Web/Websites/Global/Sanofi-COM/Home/common/docs/download-center/Fighting_Falsified_Medical_Products_2018.pdf)'.

V. AFFORDABILITY – ENSURE THE PROVISION OF AFFORDABLE TREATMENT

Sanofi recognizes that unequal living conditions, together with inappropriate policies, can constitute a major barrier for people to enjoy the best possible health. Sanofi is committed to working with governments to strengthen national health systems and ensure populations' access to healthcare and affordable medicines:

- **Medicines for infectious diseases** - Artesunate Amodiaquine Winthrop® (ASAQ) is an anti-malarial medicine developed by Sanofi and DNDi. This drug is manufactured in Morocco and is registered in most sub-Saharan African countries. Being pre-qualified by the WHO for 10 years, ASAQ Winthrop® is accessible to major international programs, such as the Global Fund, UNICEF and the President's Malaria Initiative. To ensure its accessibility, ASAQ Winthrop® is sold according to adapted policies consistent with applicable laws to public organizations (such as governments, NGOs and international funders). The price, which was set by Sanofi and DNDi when ASAQ Winthrop® was first launched at less than one dollar to treat an adult and 50 cents to treat a child, has become the standard reference price for new anti-malarial drugs. To date, more than 450 million treatments have been distributed, mainly in Sub-Saharan Africa.
- **Patient assistance** – Through the project Sanofi Patient Connection™, launched in January 2012 in the U.S., Sanofi has embarked on a cutting-edge program, including reimbursement support that has provided assistance, including medication at no cost, to more than 171,000 patients in 2016, and an average of 185,000 patients each year.
- **Access to affordable high quality vaccines** – Sanofi Pasteur is committed to making Injectable-Inactivated Polio Vaccine (IPV) accessible to every child in the world as part of the Global Polio Eradication Initiative (GPEI) which aims at eradicating poliomyelitis by 2023 (<http://polioeradication.org/news-post/to-succeed-by-2023-extraordinary-joint-statement-to-polio-eradicators/>). Since 1988, Sanofi Pasteur has produced more than 1.5 billion doses of IPV for the world and has been a major supplier of UNICEF for low income countries. Over the 2016-2018 period, Sanofi Pasteur supplied more than 80% of the IPV vaccines used in some of the 73 world's poorest countries supported by GAVI (Global Alliance for Vaccines & Immunization). During that period, an estimated 40 million children (nearly 1 in 2) born in those countries received a dose of IPV produced by Sanofi Pasteur. Through UNICEF, Sanofi Pasteur offers the lowest price for low income countries and tiered pricing for middle income countries, guaranteeing a sustainable supply of high quality vaccines.
- **Access schemes** – In the US, Sanofi launched **Valyou**, a new insulin savings program which aims to lower out-of-pocket costs for people living with diabetes. This includes all uninsured patients who don't qualify for traditional patient assistance programs.

VI. QUALITY CARE AND PATIENT SUPPORT – RAISE AWARENESS AND PROMOTE THE PROPER USE OF MEDICINES AND VACCINES

Sanofi has long understood that the most effective way to eliminate the human and financial burden of disease is through prevention and early detection, enabling patients to manage their conditions earlier, thereby avoiding complications and related costs. Sanofi is contributing to the promotion of disease prevention in multiple ways. Our programs include: screening initiatives (e.g. ., Brazil for cardiovascular diseases, ,etc.); awareness-raising (e.g. the KiDS Project in eight countries in partnership with the International Diabetes Federation (IDF), etc.); and promoting healthy living.

Furthermore, Sanofi is committed to using our specialized knowledge and ongoing collaborations to support healthcare systems with appropriate evidence-based solutions, tailored to countries' needs and resources, in particular through the development of integrated care programs.

For instance, in the field of mental health, following successful pilot projects launched in 2008 in Mauritania and Morocco, Sanofi has initiated partnerships with local Ministries of Health and/or NGOs in Armenia, Benin, Bolivia, Cameroon, Cambodia, Comoros, Guatemala, Laos, Madagascar, Mali, Myanmar and South Africa. These initiatives aim to address the huge treatment gap for mental disorders and epilepsy, and the stigma surrounding these diseases. They are based on training health workers, raising public awareness and educating patients and their families. Projects recently launched in Myanmar and South Africa are also leveraging digital technology. These programs are part of our contribution to the Access Accelerated Initiative.

Sanofi is also involved in supporting training programs for healthcare professionals. For example, since 2009, Sanofi has worked in close partnership with the Université Numérique Francophone Mondiale (UNFM), the Réseau en Afrique Francophone pour la Télémédecine RAFT Network, and Senghor University (Egypt) to develop a unique educational program, "e-Diabete" which supports the training of health professionals in Africa via low-speed internet in order to improve early diagnosis of diabetes and reduce risks of associated complications and premature death. During 2018, 32,500 health professionals attended at least one e-diabete course in 15 countries during monthly educational teleconferences that allow them to interact and exchange experiences with local and international diabetes experts.

To help in raising awareness, Sanofi has developed innovative tools, such as the MOSKI KIT which offers children the opportunity to learn essential information about malaria, its dangers and its prevention, in a fun and interesting way. Presented in a school carrying case, the MOSKI KIT contains several complementary tools to teach key messages and remember key points. The MOSKI KIT has already been used successfully in Benin, Burkina Faso, Cameroon, Côte d'Ivoire, the Democratic Republic of the Congo, Gabon, Ghana, Guinea, Kenya, Mozambique, Niger, Nigeria, Senegal, Tanzania, Togo and Uganda. In March 2016, the MOSKI KIT was awarded the Most Valuable Patient Initiative or Service Award at the eyeforpharma Barcelona Awards.

Access to healthcare is a founding principle of Sanofi's strategy. Yet ensuring equitable access for all is a complex challenge. While the Millennium Development Goals have provided an unprecedented opportunity to boost efforts towards global development, their achievement was not sufficient to guarantee access for all by 2015. There is a need for cross-sector approaches acknowledging the shared responsibility of all sectors in supporting both the individual and the healthcare systems. Sanofi is committed to playing our part to contribute to scaling up efficient health systems everywhere in the world, especially in the context of the Sustainable Development Goals. This commitment was strengthened through our contribution to the Access Accelerated Initiative that was launched in January 2017 at the World Economic Forum in Davos. This initiative aims to overcome the full spectrum of barriers to non-communicable disease prevention and care in low-income and lower-middle income countries through a collaborative approach between 25 pharmaceutical companies and strategic partners, such as the World Bank, the Union for International Cancer Control, PATH, the NCD Alliance and the World Heart Federation.