

# 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.

The complexity of this environment does not allow for monofunctional 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.

According to the World Health Survey, only 50.6% of respondents with a chronic condition in high-income countries reported having access to treatment, compared to 32% and 37.5%, respectively, in low and middle income countries (LMICs). Furthermore, LMICs, which are most heavily hit by infectious diseases, also account for almost 80% of NCD-related deaths worldwide. These inequities in access have become one of the greatest threats not only to global health, but also to human development.

## 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 is not just a matter of patients having access to affordable medicines and vaccines; it also 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 we promote an integrated approach that spans the care continuum, from prevention to detection, early diagnosis, treatment, and care and disease management.

- Innovation – While the discovery of new solutions plays an essential role in improving health, medicines and vaccines alone do not address the diverse issues that impact public health, especially in developing and emerging markets. 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 secure supply chains and delivery services, access to quality products can be compromised. Sanofi is committed to sharing our expertise with local stakeholders to ensure effective registration, production and supply of medicines and vaccines for patients globally.
- Affordability – Even when patients have access to adequate care, cost can be a key impediment to receiving health products. Sanofi is committed to working with governments and other partners to address issues of affordability. We support pricing models such as “no profit no loss” and tiered pricing, when economically viable, for populations living on limited incomes.

- 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 15 years, with costs ranging from U.S.\$1.24 billion to U.S.\$1.32 billion, with no guarantee of success. Over the last few 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 2017, Sanofi's R&D pipeline contained 44 projects (excluding Life Cycle Management) and vaccine candidates in clinical development. 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.

Due to highly disparate situations within countries, however, as well as market failures, there is a need for a case-by-case approach to intellectual property rights protection. In the event of an emergency, or a serious public health crisis, and providing the procedure is respected, 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). We are also aware that investment is insufficient in key therapeutic areas, and we understand the legitimate concerns of poorer countries that urgently need solutions. For this reason, we have taken our contribution one step further by developing specific initiatives.

In May 2011, Sanofi initiated a highly innovative and unprecedented undertaking by making available our library of proprietary data on neglected tropical diseases (NTDs) to the Drugs for Neglected Diseases initiative (DNDi).

At the same time, Sanofi has continued to invest in R&D programs on malaria, tuberculosis and NTDs to respond to potential future biological resistance.

Sanofi is also committed to fostering open innovation to harness knowledge and capabilities both within and beyond our organizational boundaries. In particular, Sanofi is engaged in the "WIPO Re:Search" project, a global innovation partnership with WIPO, other pharmaceutical companies, academic centers and product development partners for R&D in NTDs. By providing a searchable, public database of available intellectual property assets and resources, the "WIPO Re:Search" project offers a new and sustainable way to structure and manage R&D for NTDs.

Together with seven other pharmaceutical companies, eight research institutions and the Bill & Melinda Gates Foundation, Sanofi is a founding member of the TB Drug Accelerator (TBDA). This partnership targets the discovery of new tuberculosis drugs by collaborating on early stage research. The long-term goal of the TBDA is to create a TB drug regimen that cures patients in only one month.

### 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 antimalarial ASAQ Winthrop® is manufactured in a WHO-certified GMP factory in Casablanca, Morocco, a region severely affected by malaria.
- Sanofi Pasteur has initiated 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 collaboration with DNDi, Sanofi developed an innovative malaria field surveillance program for ASAQ Winthrop® to collect quality, safety and efficacy information in the field. This program is supported by Medicines for Malaria Venture. With more than 20,000 episodes of malaria treated, it is the most ambitious proactive pharmacovigilance program ever launched in Africa.

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 seek to facilitate international investigations and legal actions. Sanofi 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.

## 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:

- Generics – In 2013, Sanofi expanded our generics portfolio to Africa and the Middle East under the Zentiva brand umbrella. Through this acquisition as well as Medley (Brazil), Kendrick (Mexico), Genfar (Colombia), we demonstrate our commitment to increase the availability of quality, affordable medicines to patients.
- Patient assistance – Through the project Patient Connection™, launched in January 2012 in the U.S., Sanofi has embarked on a cutting-edge program including reimbursement support that provided assistance to more than 171,000 patients in 2016.
- Access schemes – In 2013, Sanofi launched StarBem in Brazil to support patients in the treatment of diabetes. Built on five pillars—information, education, support, access and solutions—this integrated service platform brings together all our company's initiatives for people with diabetes. It includes in particular the educational visit of an instructor, with the goal of explaining the basics of diabetes, the importance of self-monitoring and how to use insulin, the delivery of a kit with information materials, and the possibility of discounts in the treatment through a tiered-pricing program (insulin and medications for hypertension and cholesterol, glucose meters and strips). By late 2016, more than 55,000 patients had benefited from the tiered-pricing program.

## 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., in India for diabetes, as well as many initiatives in Mexico, Egypt, etc.); awareness-raising (e.g., the KiDS Project in four countries in partnership with IDF, etc.); and promoting healthy living.

Sanofi is furthermore 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 signed other partnerships, respectively in 2013 in Madagascar and in 2014 in Armenia with the Health Ministry to address mental health issues through awareness campaigns, patient education, training of professionals, and providing medical and IT equipment. While we will work to scale up these programs in those countries, other pilots will continue to be launched, for instance in Myanmar in 2017. These programs are part of our contribution to the Access Accelerated Initiative.

We are convinced that closing the treatment adherence gap is essential to improve quality of life for patients while supporting treatment compliance. We are committed to facilitating a move to patient-centered care through wide-scale initiatives, including fostering capacity building and providing locally-adapted and integrated tools to ensure patient empowerment:

- **Treatment** – We support compliance and the proper use of medicines by developing innovative devices, such as AllStar™, an easy-to-use insulin injection pen developed and produced in India since 2012. AllStar™, which is affordable and accessible to a large population of Indian patients, is the outcome of a multinational collaborative, cross-company project where technologies, resources and intellectual capital were shared to develop an injection pen that meets the needs of patients;
- **Care Coordination** – Sanofi has developed sustainable collaborations with healthcare professionals, such as the Care Companion for patients with breast, prostate and colorectal cancer in the Netherlands. This personalized on-line tool empowers patient/physician interactions by streamlining communication and information between hospital teams, physicians and patients; and
- **Capacity Building** – Since 2009, Sanofi has worked in close partnership with the Université numérique francophone mondiale (UNFM), the RAFT Network, and Senghor University (Egypt) to develop a unique educational program, “e-Diabeté,” which supports the training of health professionals in Africa in order to improve early diagnosis of diabetes and reduce risks of associated complications and premature death. More than 1,000 healthcare professionals in 13 French-speaking countries in Africa can now take part in monthly educational teleconferences to interact and exchange experiences with local and international diabetes experts.

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 22 pharmaceutical companies, the World Bank and UICC (Union for International Cancer Control).