



# *Access to Healthcare*

**GRI Standards:**

N/A

## **EXECUTIVE SUMMARY**

Sanofi's strategy of improving access to healthcare for the underserved is as much about ending global epidemics of infectious diseases and avoiding their resurgence, as it is about meeting the growing needs of patients suffering from non-communicable diseases.

The complexity of the environment calls for systemic solutions. Sanofi strives to provide affordable access to its medicines and vaccines for patients and populations who need them around the world. It shares this responsibility with local healthcare systems and payers, and is committed to play its part.

To achieve such access goals, Sanofi employs an approach adapted to the specifics of both healthcare systems and patient needs through **commercial, social, and philanthropic** models.

Sanofi is committed to working with governments to develop national health systems that ensure populations' access to healthcare. Therefore, Sanofi leverages its expertise and promotes integrating innovation, availability, affordability, quality care and patient support. Sanofi also supports the World Health Organization's (WHO) promotion of universal health coverage to improve population coverage, service coverage and financial protection.

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## 1. 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.

Deaths from neonatal conditions are one of the categories for which the global decrease in deaths in absolute numbers over the past two decades has been the greatest: these conditions killed 2 million newborns and young children in 2019, 1.2 million fewer than in 2000.

Deaths from noncommunicable diseases are on the rise. Noncommunicable diseases accounted for 74% of deaths globally in 2019. The world's biggest killer is ischaemic heart disease, responsible for 16% of the world's total deaths. Since 2000, the largest increase in deaths has been for this disease, rising by more than 2 million to 8.9 million deaths in 2019.

There are large disparities based on the income level: People living in a low-income country are far more likely to die of a communicable disease than a noncommunicable disease. Despite the global decline, six of the top 10 causes of death in low-income countries are still communicable diseases. Lower-middle-income countries have the most disparate top 10 causes of death: five noncommunicable, four communicable, and one injury. Diabetes is a rising cause of death in this income group: it has moved from the 15th to 9th leading cause of death and the number of deaths from this disease has nearly doubled since 2000. *For more information, see: [The top 10 causes of death \(who.int\)](#).*

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

## 2. Sanofi's position on access to healthcare

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.

Sanofi believes that broadening access to medicines and vaccines requires adaptation to the specific context of health systems and patient needs; recognition of the value they provide to the whole of society today; and continued investment in the development of therapies that will improve the lives of patients tomorrow. Our approach will span the overall access solution spectrum across all of our Global Business Units and geographies, from standard commercial approaches, to social and to philanthropic ones.

Access to healthcare, treatments and vaccines requires continuous collaboration, commitment and a common agenda between health authorities and industry. Sanofi is asking for a joint effort between industry, authorities, and payers to reward the value of medicines while balancing affordability and support for innovation.

- **Innovation and Patent Management** – 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. Sanofi believes that patents do not pose a barrier to access and is committed to socially responsible patent management in developing countries. Sanofi partners with other stakeholders beyond where market forces work, including local investments, capability building,

technology transfer and voluntary licensing, to tackle immediate global health challenges, building sustainable healthcare systems and dynamizing local innovation ecosystems;

- **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; and
- **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.

### *3. Innovation and Patent Management – Develop new solutions for patients and manage patents responsibly*

#### **Innovation**

Innovation is the essence of the research-based pharmaceutical industry. Developing a new medicine takes, on average, ten 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 2021, the R&D pipeline contained 91 projects in clinical development, including 45 new molecular entities in clinical development (or that have been submitted to the regulatory authorities). 34 projects are in Phase III or have been submitted to the regulatory authorities for approval.

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 ten 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 to be involved in other infectious diseases through its vaccine R&D and global health programs.

Sanofi is engaged in supplying drugs and vaccines and contributing to the definition and implementation of public health policy beyond where market forces work through partnerships, such as our 10-year partnership with DNDi to develop fexinidazole as a new oral treatment for sleeping sickness. 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. Fexinidazole also received WHO prequalification in March 2019 and was submitted for registration to Ugandan health authorities in April 2019. It was included in the WHO Essential medicines list and WHO human African Trypanosomiasis treatment guidelines, as first line for first stage and non-severe second stage. On January 28, 2020, the first patient was treated with Fexinidazole in RDC, a key success for all partners involved. Sanofi will donate fexinidazole to the WHO in the frame of the long-term WHO-Sanofi partnership for neglected tropical diseases. In September 2020, Sanofi and DNDi announced that they are jointly developing acoziborole. The phase III clinical trials for this new chemical entity is being finalized and results should be published in 2022. If it proves a success, then acoziborole - in association with a rapid diagnostic test - could be administered immediately, at the same time as the test. This would be a game-changer in the bid to sustainably eliminate sleeping sickness. In December 2020, we renewed our long-standing partnership with the WHO to combat neglected tropical diseases, and to sustainably eliminate sleeping sickness by 2030. Under the new partnership agreement, we will contribute \$25 million (\$5 million a year) towards the prevention and treatment of 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. For instance, we are

currently working to make a dispersible primaquine tablet available for children. Primaquine, which is widely used as a radical cure for *Plasmodium vivax* malaria, is also recommended as a transmission blocker in the elimination of *Plasmodium falciparum* malaria. For accurate dosing by body weight and ease of use, it is vital that appropriate dosages and formulations of this essential drug are made available.

One of Sanofi's Access to healthcare commitments is to develop a Global Access Plan for all new products/major innovations with the goal to make them available within two years post first launch wherever we can make an impact for patients and populations. This Global Access Plan is a systematic end to end approach that will apply to all of our innovative products in the pipeline. This aims to streamline our current approach and processes with an ambitious timeframe:

- we will focus on geographies where a significant unmet medical need remains and the healthcare ecosystem can support safe integration into clinical practices;
- we will strive to make all new products available as soon as possible, within two years of the first launch when external constraints allow;
- we aim to go beyond making products available by engaging in healthcare capability building when necessary to ensure patients have effective access; and
- we will investigate all possible ways to provide access, including non-commercial approaches.

The implementation of a Global Access Plan will require an end-to-end approach starting from phase IIb of R&D until commercial launch, with a dedicated governance in place.

## Patent Management

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.

Sanofi believes that patents are a fundamental incentive for driving innovation in the pharmaceutical sector. The development of new medicines and vaccines is a risky, costly, and lengthy process. Patents are an essential incentive for pharmaceutical companies to invest in research & development to address unmet medical needs. IP policies therefore need to be safeguarded. While patents by themselves should not be considered a barrier for access, Sanofi believes that being transparent and flexible with our patents can help address pressing health challenges in developing countries.

In order to enable access to our medicines and vaccines:

- Sanofi makes patent status of their Essential Medicines and Vaccines in developing countries publicly available (see Annex I);
- Sanofi does not file patent applications or enforce patent rights in all Least Developed Countries (LDCs) and Low-Income Countries (LICs);
- Sanofi does not file or enforce patents in several Lower-Middle-Income Countries (LMICs) and Upper-Middle-Income Countries (UMICs). See Annex II for the complete list of countries;
- Sanofi supports implementation of the 2001 WTO Doha Declaration on TRIPS and Public Health and the appropriate use of the flexibilities therein intended to protect public health;
- Sanofi supports the transition period that LDCs are exempted from obligations under the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement) regarding pharmaceutical patents until January 1, 2033. We support this exemption of LDCs and an extension of the exemption beyond 2033;
- Sanofi acknowledges the value of voluntary licensing agreements and patent pools for access to medicines in developing countries. We would consider joining patent pools and engaging in voluntary licensing if relevant to our portfolio, and aimed at accelerating access to medicines and vaccines in low- and middle- income countries;
- Sanofi respects compulsory licensing as a short-term and targeted measure where urgent access to patented medicines is critical to maintaining public health, and no appropriate alternative is available. We believe that compulsory licenses should only be used in extraordinary and very limited circumstances, such as meeting a health crisis or emergency; and
- Sanofi respects a formal exemption from patent infringement for activities which are undertaken as part of the regulatory review process: "[c]onducting the necessary studies and trials with a view to the application of paragraphs 1 to 4 [i.e. bioequivalents and biosimilars] and the consequential practical

requirements shall not be regarded as contrary to patent rights or to supplementary protection certificates for medicinal products.” (Bolar exemption, Directive 2004/27/EC. Article 10(6)).

**Annex I** - Patent Status of Sanofi’s Essential Medicines and Vaccines in Developing Countries

**Annex II** - Developing Countries in which Sanofi does not file or enforce patents\*

\* For products where Sanofi solely owns and controls the patent rights

## 4. 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 also participates in WHO Prequalification Programs, such as the tuberculosis and the sleeping sickness programs. 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 (Columbia) 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. *For more information, see our [Document Center: Fight Against Falsified Medicines and Illicit Trafficking Factsheet](#).*

## 5. 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 to patients in need. Broad access to medicines and vaccines requires wealthier countries to partner with the biopharmaceutical industry and make a commitment commensurate with their ability to pay in order to incentivize continued investment in innovation. Policies that reward the value of innovation ultimately improve the lives of patients around the world. This shared responsibility also enhances and accelerates patient access to our products for middle- and low-income countries or underserved populations, including

country-scaled access solutions based on new affordable models of access and programs that strengthen healthcare systems.

## Global access and Pricing Principles

Our goal is to give broad access to Sanofi's products and solutions to patients and people in need. We seek to do this:

- **focusing on best-in-class** products for unmet needs;
- **continuing to invest in research and development** of new and innovative medicines and vaccines; and
- ensuring that the responsibility to bring these innovations to patients is **shared between Sanofi and local healthcare systems**.

Our innovation brings value to our patients, our society, and our healthcare systems. Given the growing concerns over rising healthcare costs, we have developed an approach to pricing that reflects our commitment to broadly expanding patient access to medicines and vaccines while maintaining sustainable investment in Research & Development. The *Pricing & Affordability Principles* we put forth are founded on two pillars:

- **clear rationale for pricing and access** at the time of launch of a new medicine or vaccine; and
- **inclusion of affordability criteria** into pricing considerations for new launches.

*For more information, see our [Document Center](#): Global Access and Pricing Principles.*

- **Sanofi pricing principles in the USA:** in May 2017, Sanofi committed to further addressing concerns over rising health care costs with the introduction of our Pricing Principles, which remain the most comprehensive assessment of corporate pricing decisions in the industry. Our approach to the prices of our medicines reflects a continued effort to support patient access while minimizing our contribution to health care spending growth. In March 2022, Sanofi published [a report on 2021 key pricing decisions in the US](#).
- **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 540 million treatments have been distributed, mainly in Sub-Saharan Africa.
- **US Patient assistance:** in order to address the needs of patients with diabetes in the U.S., Sanofi was the first company to introduce a program in which uninsured patients could access insulin for a single, low monthly cost. With our Insulins Valyou Savings Program, introduced in 2018 and expanded in April 2019, all uninsured patients, regardless of income level, can access one or multiple Sanofi insulins for a fixed monthly price. Additionally, our copay assistance programs for commercially insured patients, regardless of income level, limits out-of-pocket expenses for a majority of participating patients. Through the project Sanofi Patient Connection™, launched in January 2012 in the U.S., we provide free medications to eligible patients with a demonstrated financial need. In 2021, a total of 99,337 patients received free products through patient assistance programs.
- **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/>). Sanofi has played a pivotal role in the polio eradication campaign from the outset and

has supplied vast numbers of doses of oral polio vaccine (OPV) – over 14 billion in total – to support the GPEI. In 2021, Sanofi supplied 50.5 million IPV doses to UNICEF for GAVI-eligible countries. Sanofi Pasteur also supplied 31 million doses to Brazil, India, Indonesia and the Philippines for their national polio vaccination campaigns. 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.

## 6. 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 awareness initiatives, such as the KiDS Program for diabetes, initiated by the International Diabetes Federation (IDF), the International Society for Pediatric and Adolescent Diabetes (ISPAD) and Sanofi in 2013. KiDS is a schools-based educational program designed to bring diabetes education to schools to fight diabetes-related stigma and promote healthy lifestyles to tackle the preventable risk factors for type 2 diabetes. From its inception in 2013 through the end of 2021, the program has reached more than 340,000 children and nearly 19,800 teachers, in over 2,100 schools across ten countries.

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 comprehensive healthcare 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. For example, the program in Mali that began in 2018 has already enabled over 3,692 new patients to be diagnosed and treated by trained general practitioners and is still under way with the aim of training a further fifty or so general practitioners via an e-learning platform. An initiative launched in Senegal in partnership with the Ministry of Health (*Ministère de la Santé et de l'Action Sociale*) combines the use of the eLearning platform with a series of six interactive webinars facilitated by local psychiatrists. The objective is to train 300 primary HCPs (mainly General Practitioners – GPs – and nurses). As of February 28, 2022, 299 HCPs had registered and 64% had at least completed one module, with 20% who had completed all 12 modules and had each attended the series of six webinars. And in South Africa, after an initial phase that delivered training to 1,120 front-line healthcare staff, a second round of training was organized in 2021. The three-day workshops had to be done virtually due to the COVID-19 pandemic and 613 HCPs were trained (123% to target). 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. The number of connections to the 'e-Diabete' training courses online is increasing steadily, from 31,150 in 2015 to 48,250 in 2018, 57,630 in 2019, 78,200 in 2020 and 80,045 in 2021.

To help in raising awareness, Sanofi has developed innovative tools, such as the MOSKI KIT<sup>®</sup> 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<sup>®</sup> contains several complementary tools to teach key messages and remember key points. The MOSKI KIT<sup>®</sup> 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<sup>®</sup> 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. 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.

## 7. The new Sanofi Global Health unit – Provide access to essential medicines and to programs in the world’s poorest countries

To organize and expand on its existing efforts, Sanofi launched Sanofi Global Health in April 2021, a non-profit business unit with a remit to increase access to medicines considered essential by the World Health Organization (WHO) for patients in some of the least developed regions of the world, by donation or selling of its medicines at affordable prices while also funding local support programs. Sanofi Global Health will be self-financed to ensure it remains sustainable over time, charging just enough to cover operating expenses and local implementation projects.

Sanofi Global Health is equipped at the start with a portfolio of 30 products manufactured by Sanofi covering both neglected tropical diseases and non-communicable diseases. Since 2007 Sanofi has been working with intergovernmental agencies (IGAs) and non-governmental organizations (NGOs) in providing medicines at affordable prices or through donation programs to treat malaria, tuberculosis, leishmaniasis and sleeping sickness. Sanofi Global Health unit will continue to work with IGAs and NGOs in the distribution of those medicines across all low and middle-income countries where access is still needed. More importantly, SGHU will address the growth of unmet needs for patients living with non-communicable diseases across the 40 countries.

Sanofi Global Health unit (SGHu) has a two-pronged approach, combining both its medicines and its expertise to achieve sustainable access to medicines for the most vulnerable:

- provision of medicines: initially, Sanofi Global Health unit (SGHu) will operate in 40 countries among those with the lowest Gross Domestic Product (GDP) per capita<sup>(1)</sup>, and will supply 30 of our most essential medicines, including treatments for cardiovascular diseases, diabetes and cancer; and
- screening, disease management and training programs: as the provision of medicines is not enough in itself to meet unmet needs, SGHu will also work with local health authorities and care providers to train healthcare professionals and raise disease awareness, and help set up sustainable healthcare systems for diseases that require chronic treatment and complex care.

### Annex I Sanofi Products<sup>(1)</sup> as of 2021 listed on the WHO Essential Medicine List (EML, 2019)

MEDICINES					
Product	Active Ingredient(s)	Patent Rights			
			ASAQ Winthrop®	Artesunate/ amodiaquine	No
			AZITRHOMYCIN	Azithromycin dihydrate	No
			BETANOL®	Atenolol	No
AGEN®	Amlodipine	No	BETAXOLOL	Betaxolol hydrochloride <sup>(2)</sup>	No
APPROVEL®	Irbesartan <sup>(2)</sup>	No	BLEOMYCINE	Bleomycin	No
ARSOBAL®	Melarsoprol	No	CALCORT	Deflazacort	No

<sup>1</sup> According to the World Bank Data: <https://data.worldbank.org/indicator/NY.GDP.PCAP.CD>

			VACCINES		
			Product	Vaccine Type	Patent Rights
CAPTEA	Captopril/Hydrochlorothiazide	No			
CEFTRIAZONE	Ceftriaxone	No			
CERUBIDINE®	Daunorubicin	No			
CETAPIN®	Metformin hydrochloride	No			
CIDOMYCIN®	Gentamicin	No			
CLAFORAN®	Cefotaxime sodium	No			
COLISTIN	Colistimethate	No			
CORGARD	Nadolol	No			
DEPAKINE®	Valproate sodium	No			
EFAVIRENZ	Efavirenz	No			
ELOXATIN®	Oxaliplatin	No			
ENOXAPARIN	Enoxaparin	No			
ERYTHROMYCIN	Erythromycin	No			
ETHATYL	Ethionamide	No			
EURELIX	Piretanide	No			
FEXINIDAZOLE Winthrop	Fexinidazole	No <sup>(3)</sup>			
FLAGYL®	Metronidazole benzoate	No			
FLUDARA®	Fludarabine phosphate	No			
FRISIUM®	Clobazam	No			
GARDENAL®	Phenobarbital	No			
GLUCANTIME®	Meglumine antimoniate	No			
INSUMAN®	Insulin human	No			
ISONIAZID	Isoniazid	No			
KURACEF®	Cefixime	No			
LARGACTIL®	Chlorpromazine	No			
MALOCIDE®	Pyrimethamine	No			
NIVAQUINE®	Chloroquine sulfate	No			
NOZINAN®	Levomepromazine <sup>(2)</sup>	No			
ORNIDYL	eflornithine	No			
PENTACARINAT®	Pentamidine	No			
PLAVIX®	Clopidogrel	No			
PRIFTIN®	Rifapentine	No			
PRIMAQUINE	Primaquine diphosphate	No			
PYRAZINAMIDE	Pyrazinamide	No			
QUINIMAX®	Quinine	No			
RIFADIN®	Rifampicin	No			
RIFAFOUR®	Rifampicin/ isoniazid/ pyrazinamide/ ethambutol	No			
RIFATER®	Rifampicin/ isoniazid/ pyrazinamide	No			
RIFINAH®	rifampicin/ isoniazid	No			
RISORDAN®	Isosorbide dinitrate	No			
SALBUTAL®	Salbutamol	No			
SECTRAL®	Acebutolol <sup>(2)</sup>	No			
STEMETIL®	Prochlorperazine mesilate <sup>(2)</sup>	No			
SURMONTIL®	Trimipramine	No			
TAVANIC®	Levofloxacin	No			
TAXOTERE®	Docetaxel	No			
TENOFOVIR	Tenofovir disoproxil	No			
TERCIAN	Cyamemazine	No			
TERIVALIDIN	Terizidone	No			
TRITACE®	Ramipril/Hydrochlorothiazide	No			
TRIAPIN®	Ramipril/Felodipine	No			
VERAPAMIL	Verapamil	No			
			ACTHIB®	<i>Haemophilus influenzae</i> polysaccharide type b conjugated to tetanus protein (PRP-T)	No
			ADACEL®	Diphtheria, Tetanus, Pertussis (acellular, component) Vaccine (adsorbed, reduced antigen(s) content)	No
			DENGVAXIA®	Dengue live attenuated tetravalent chimeric vaccine	No <sup>(4)</sup>
			HEXAXIM®	Diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inactivated) and <i>Haemophilus influenzae</i> type b conjugate vaccine (adsorbed)	No <sup>(5)</sup>
			MENACTRA®	Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine	No <sup>(5)</sup>
			PENTAXIM®	Diphtheria, tetanus, pertussis (acellular, component), poliomyelitis (inactivated) vaccine and <i>Haemophilus</i> type b conjugate vaccine, adsorbed	No
			SHAN5®	Diphtheria, Tetanus, Pertussis (Whole Cell), Hepatitis B (rDNA) and <i>Haemophilus influenzae</i> Type B Conjugate Vaccine (Adsorbed), which may be further abbreviated as DTWp-HepB-Hib Vaccine	No
			SHANCHOL®	Killed bivalent (o1 and o139) whole cell oral cholera vaccine	No
			STAMARIL	Yellow Fever Vaccine	No
			TETAVAX®	Purified tetanus toxoid (PTT)	No
			TETRAXIM®	Booster vaccine	No
			TYPHIM VI®	Typhoid polysaccharide vaccine	No
			VAXIGRIPTETRA®	Quadrivalent influenza vaccine (split virion, inactivated)	No
			VAXIGRIP®	Influenza vaccine (split virion, inactivated)	No
			VERORAB®	Rabies vaccine, inactivated	No

(1) Sanofi products encompass the products marketed and/or distributed in 2021 by Sanofi and its affiliates. Trademarks followed with ® mean that the trademark is registered in one or some of the countries listed in Annex II. Depending on the countries, (i) some products are associated with other trademarks, not listed in Annex I and (ii) some trademarks are used under licensing by Sanofi. FLUDARA® is a registered trademark of Alcaflou. TAVANIC® is a registered trademark of Daiichi Sankyo limited. CETAPIN® and CIDOMYCIN® are registered in countries other than those listed in Annex II.

(2) Products followed with <sup>(2)</sup> are considered clinically equivalent medicines to a representative example within a pharmacological class listed on the 2019 WHO EML, as indicated by the square box symbol. All other products are listed on the 2019 WHO EML as core essential medicines.

(3) For countries via ARIPO, actions have been taken in June 2020 to effectively abandon patents directed to Fexinidazole. Therefore, the “no patent” statement applies to the product FEXINIDAZOLE Winthrop for countries listed in Annex II.

(4) For Lao, action has been taken in July 2021 to effectively abandon the patent covering DENG VAXIA®. Therefore, the ‘no patent’ statement applies to the product DENG VAXIA® for countries listed in Annex II, except for Lao for which it will apply soon.

(5) For Syria, Tajikistan and countries via **ARIPO** or via **OAPI**, actions have been taken in November 2019 to effectively abandon patents or patent applications directed to HEXAXIM® or MENACTRA®. Therefore the ‘no patent’ statement” applies to the products HEXAXIM® and MENACTRA® for countries listed in Annex II.

For all other products listed with no patent in the present Annex I, this statement applies for countries listed in Annex II and for all other countries worldwide.

## **KEYS**

**ARIPO.** ‘African Regional Intellectual Property Organization’ Countries:

Botswana; Gambia; Ghana; Kenya; Lesotho; Liberia; Malawi; Mozambique; Namibia; Rwanda; Sierra Leone; Sudan; Swaziland; Tanzania; Uganda; Zambia and Zimbabwe.

**OAPI.** ‘Organisation Africaine de la Propriété Intellectuelle’ Countries:

Benin; Burkina Faso; Cameroon; Central African Rep.; Chad; Comoros; Congo, Rep.; Côte d’Ivoire; Equatorial Guinea; Gabon; Guinea; Guinea-Bissau; Mali; Mauritania; Niger; Senegal and Togo.

**Annex II**  
**Developing Countries in Which Sanofi Does not File or Enforce Patent**

Country	UN Classification (Feb. 2021)	World Bank Classification (June 2021)
Micronesia, Fed. Sts.	NO	LMIC
Cambodia	LDC	LMIC
Kiribati	LDC	LMIC
Korea, Dem. Rep	NO	LIC
Lao PDR	LDC	LMIC
Myanmar	LDC	LMIC
Mongolia	NO	LMIC
Papua New Guinea	NO	LMIC
Solomon Islands	LDC	LMIC
Timor-Leste	LDC	LMIC
Tonga	NO	UMIC
Tuvalu	LDC	UMIC
Vanuatu	NO	LMIC
Samoa	NO	LMIC
Tajikistan	NO	LMIC
Belize	NO	LMIC
Guyana	NO	UMIC
Haiti	LDC	LMIC
Suriname	NO	UMIC
Djibouti	LDC	LMIC
Iraq	NO	UMIC
Palestine, State of (West Bank and Gaza)	NO	LMIC
Syrian Arab Rep.	NO	LIC
Yemen, Rep.	LDC	LIC
Afghanistan	LDC	LIC
Bangladesh	LDC	LMIC
Bhutan	LDC	LMIC
Maldives	NO	UMIC
Nepal	LDC	LMIC
Angola	LDC	LMIC
Burkina Faso	LDC	LIC
Burundi	LDC	LIC
Benin	LDC	LMIC
Botswana	NO	UMIC
Congo, Dem. Rep.	LDC	LIC
Central African Rep.	LDC	LIC

Country	UN Classification (Feb. 2021)	World Bank Classification (June 2021)
Congo, Rep.	NO	LMIC
Côte d'Ivoire	NO	LMIC
Cameroon	NO	LMIC
Cape Verde	NO	LMIC
Eritrea	LDC	LIC
Ethiopia	LDC	LIC
Gabon	NO	UMIC
Ghana	NO	LMIC
Gambia, The	LDC	LIC
Guinea	LDC	LIC
Equatorial Guinea	NO	UMIC
Guinea-Bissau	LDC	LIC
Comoros	LDC	LMIC
Liberia	LDC	LIC
Lesotho	LDC	LMIC
Madagascar	LDC	LIC
Mali	LDC	LIC
Mauritania	LDC	LMIC
Malawi	LDC	LIC
Mozambique	LDC	LIC
Namibia	NO	UMIC
Niger	LDC	LIC
Rwanda	LDC	LIC
Sudan	LDC	LIC
Sierra Leone	LDC	LIC
Senegal	LDC	LMIC
Somalia	LDC	LIC
South Sudan	LDC	LIC
São Tomé and Príncipe	LDC	LMIC
Swaziland	NO	LMIC
Chad	LDC	LIC
Togo	LDC	LIC
Tanzania	LDC	LMIC
Uganda	LDC	LIC
Zambia	LDC	LMIC
Zimbabwe	NO	LMIC

**LDC:** Least Developed Country, UN Human Development Index, February 2021.

**LIC:** Low-income country, World Bank income classifications, June 2021.

**LMIC:** Lower middle-income country, World Bank income classifications, June 2021.

**UMIC:** Upper middle-income country, World Bank income classifications, June 2021.