

ACCESS TO VACCINES

GRI Standards :

416-1, 416-2 : Customer Health and Safety

EXECUTIVE SUMMARY

Vaccines have a great impact on public health. The World Health Organization considers immunization to be one of the most effective and cost-effective health interventions. It has eradicated smallpox, reduced the global incidence of polio by 99% to date,¹ and dramatically reduced morbidity, disability and mortality due to diphtheria, tetanus, pertussis, tuberculosis and measles.

Despite these important achievements, there is still a long way to go: 19.7 million children worldwide still have no access to a full cycle of basic vaccines.² Due to lower immunization coverage in some countries, we are witnessing a resurgence of diseases that had almost disappeared, such as measles or pertussis. This affects people around the world, including in high-income countries.

True to its vision of a world where no one suffers or dies from a vaccine-preventable disease, Sanofi Pasteur is committed to improve sustainable access to vaccines, with the help of key partnerships to provide effective and affordable vaccines and protection for all populations.

This document presents some of our key commitments and initiatives illustrating our longstanding dedication to global access to health through prevention and vaccination.

¹ WHO Factsheet on Poliomyelitis, last updated July 2019. <https://www.who.int/news-room/fact-sheets/detail/poliomyelitis>

² WHO Factsheet on Immunization, last updated July 2020. <https://www.who.int/en/news-room/fact-sheets/detail/immunization-coverage>

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1. BACKGROUND

1.1. Vaccines bring long-term societal benefits

Vaccines are powerful tools that help control diseases. Unlike many other health interventions, they help people stay healthy, and in doing so they help remove a major obstacle to human development.

Today, more than 26 common infectious diseases are vaccine-preventable.³ In addition to their impact on mortality, vaccines contribute significantly to the reduction of illness and long-term disability in children and adults. Vaccines generate savings by reducing visits to the doctor and hospitalization. Immunization brings broad, long-term economic and societal benefits, including increased educational attainment and productivity gains, as vaccination reduces the time needed for parents to take care of a sick child, and also has the potential to reduce absences from school, for instance during disease outbreaks. Expanding the use of immunization has also been identified as a solution to contain antimicrobial resistance, one of the 10 health threats that we are facing according to the WHO.⁴

1.2. What vaccines have brought to society⁵

The impact of vaccines on global public health has been impressive. Smallpox was declared eradicated by the World Health Organization (WHO) in 1979 after a global vaccination effort. In 1988, polio was endemic in 125 countries, paralyzing an estimated 350,000 children every year. In 2020, poliomyelitis remains endemic only in parts of two countries with only 140 wild polio virus cases reported.⁶ Between 2000 and 2018, estimated measles-related deaths, mostly among children under the age of five, decreased by 73%.⁷ Since the launch of the Global Alliance for Vaccines and Immunization (GAVI) in 2000, an increasing number of developing countries have introduced hepatitis B, Hib, pneumococcal and rotavirus vaccines into their routine vaccination programs, in line with WHO recommendations. Together, the original Expanded Program for Immunization (EPI) vaccines plus hepatitis B and Hib vaccines prevent more than 4 million deaths each year.⁸

1.3. Remaining challenges

Despite these significant achievements, there is still a long way to go. In 2019, an estimated 19.7 million infants worldwide were not reached with routine immunization service.⁹ At the same time, the benefit of vaccination is becoming less obvious to some populations. As a consequence of lower vaccination coverage, we are witnessing the resurgence of diseases that had almost disappeared, such as measles or pertussis. This affects populations across the world including in high-income countries.

3 <https://www.sanofi.com/en/your-health/vaccines/value-of-vaccines>

4 <https://www.who.int/news-room/spotlight/10-global-health-issues-to-track-in-2021>; https://www.who.int/immunization/leveraging_vaccines_VACAMAR/en/

5 Investing in immunization through the GAVI Alliance evidence report.

6 <https://polioeradication.org/where-we-work/>

7 WHO Factheet on Measles, last updated December 2019. <https://www.who.int/news-room/fact-sheets/detail/measles>

8 <https://www.gavi.org/programmes-impact/our-impact/measuring-our-performance/2011-2015-indicators>

9 WHO Factsheet on Immunization, last updated July 2020. <https://www.who.int/en/news-room/fact-sheets/detail/immunization-coverage>

1.4. Our commitment to sustainable access to vaccines

Access to vaccination is hampered by multiple barriers that may be structural (e.g. health systems, conflicts, affordability) or societal (behaviors, education, beliefs). This multifactorial challenge can only be addressed by committed partnerships between all those who have a stake in the sustained success of vaccination and prevention programs.

True to our vision of a world where no one suffers or dies from a vaccine-preventable disease, Sanofi Pasteur is committed to working on multiple levels to optimize the impact of vaccination:

- Developing a broad portfolio of vaccines and solutions to address worldwide epidemiological challenges,
- Playing an active role in key public-private partnerships such as Gavi, the Vaccine Alliance,
- Providing effective and affordable vaccines and protection to all populations, and
- Contributing to local capacity building of healthcare systems to prevent infectious diseases.

This document presents some of our key commitments and initiatives illustrating our longstanding dedication to global access to health through prevention and vaccination.

More information on our commitment can be found in the 2021 Access To Medicine Index report <https://accesstomedicinefoundation.org/access-to-medicine-index/report-cards/sanofi#>

2. POLIO: PARTNER IN THE END-GAME ERADICATION STRATEGY



2.1. Polio eradication is in sight

Poliomyelitis is a contagious disease mainly attacking children under five. One in 200 infections leads to irreversible paralysis, usually in the legs. Among those paralyzed, 5% to 10% die when their breathing muscles become immobilized. Over the last 30 years, under the Global Polio Eradication Initiative (GPEI), 2.5 billion children have been immunized against polio resulting in a 99% reduction in the number of cases worldwide. At the end of 2020, polio was endemic in only two countries (Afghanistan and Pakistan) with 140 wild polio virus cases reported. As a result of the global effort to eradicate the disease, more than 18 million people have been saved from paralysis.

2.2. A long-term partner in the Global Polio Eradication Initiative

Since 1988, Sanofi Pasteur has been a key partner of the Global Polio Eradication Initiative and has supplied more than 14 billion doses of Oral Polio Vaccine (OPV) and 1.5 billion doses of Inactivated Polio Vaccine (IPV) in the world.

2.3. Sanofi Pasteur: Committed to making Injectable-Inactivated Polio Vaccine (IPV) accessible to every child in the world

In April 2013, the WHO's committee on policy on immunization (SAGE) recommended that all countries introduce at least one dose of IPV into their routine immunization programs to mitigate the risk of circulating vaccine-derived poliovirus. The introduction of IPV is a key component of the Polio End Game Strategy with 2023 as the target year for polio eradication.¹⁰ In October 2020, SAGE recommended a second IPV dose to be introduced in all countries that were currently administering one IPV dose in their routine immunization schedules.¹¹

Sanofi Pasteur has expanded its IPV production capacities in France and is in a position to greatly contribute to the demand of doses needed for this unprecedented global rollout, including its ShanIPV vaccine, now produced by Sanofi Healthcare India Private Limited in India. Sanofi Pasteur supplied 78% of the IPV doses used by Unicef between 2014 and 2020 (296 million doses).¹² Sanofi Pasteur is also developing a new hexavalent (6-in-1 combination) vaccine. By bringing injectable polio vaccination into combination with other childhood disease, it could help to increase the IPV vaccination coverage and thus contributing to the Global Polio Eradication Initiative. WHO Prequalification of this new 6-in-1 combination vaccine could be granted in 2022.

¹⁰ GPEI webpage accessed March 2020,: <http://polioeradication.org/news-post/to-succeed-by-2023-extraordinary-joint-statement-to-polio-eradicators/>

¹¹ Weekly Epidemiological Record. N°48, 2020, 95, 585-608.

¹² Internal source

3. YELLOW FEVER: A LONGSTANDING COMMITMENT TO HELP PREVENT AND CONTAIN EPIDEMICS IN TROPICAL REGIONS



3.1. A lasting threat to the poorest communities

Yellow fever is a viral hemorrhagic fever transmitted by infected mosquitoes, with no specific treatment. The WHO estimates that there are between 84,000 and 170,000 severe cases of yellow fever each year, resulting in 29,000 to 60,000 deaths.¹³ No specific antiviral treatment is available against yellow fever. The disease remains a major public health concern in both Africa and South America where vaccination is recommended in order to prevent and fight epidemics together with vector control programs. It is also recommended for travelers visiting endemic regions.

3.2. Guaranteeing access to vaccines for large populations in response to outbreak situations

The Sanofi Pasteur vaccine against yellow fever produced in France has been used since 1979. It is registered in more than 100 countries with more than half a billion doses distributed to residents and travelers to endemic areas. A single dose confers life-long protection against yellow fever. It is prequalified by the World Health Organization (WHO) for procurement by the United Nations.

In 2011, in response to a demand from Gavi, the Vaccine Alliance, Sanofi Pasteur launched a significant investment to double its production capacity of yellow fever vaccine. Regulatory clearance was obtained in early 2016, enabling the first doses from the new facility to be shipped to Africa to help fight a major yellow fever outbreak on the continent. In 2019, an all-time record of 29.4 million yellow fever vaccine doses were delivered to Unicef & PAHO. Sanofi Pasteur is currently the largest vaccine supplier to the yellow fever vaccine emergency stockpile reserved for outbreak response.

4. DENGUE: THE FIRST VACCINE SOLUTION TO A DISEASE WITH GROWING GLOBAL INCIDENCE

4.1. A growing concern to populations in endemic areas

Dengue is the most rapidly expanding mosquito-borne viral disease in the world today. It is prevalent in tropical regions, with local variations in risk depending on rainfall, temperature, relative humidity

¹³ WHO factsheet accessed March 2020: <http://www.who.int/mediacentre/factsheets/fs100/en/>

and population density. The global incidence of dengue has increased significantly over recent years due to rapid urbanization and rising temperatures. Before 1970, only nine countries had experienced severe dengue epidemics, but today it is endemic in more than 100 countries. As a result, about half of the world's population is now at risk, and there are an estimated 100 to 400 million infections each year. ¹⁴The WHO has responded to this threat by declaring dengue to be one of the top ten threats to global health in 2019.

Because there are four types of the dengue virus (serotypes), it is possible to be infected with dengue up to four times. While the first infection with dengue is often asymptomatic or only produces mild, flu-like illness, secondary infections carry an increased risk of developing a potentially lethal complication, called severe dengue. Dengue affects most Asian and Latin American countries and has become a leading cause of hospitalization and death among children and adults in these regions.

4.2. Making an effective vaccine and diagnostic tool available

In 2015, after over 20 years of R&D, Sanofi Pasteur launched Dengvaxia® (CYD-TDV), the first vaccine approved for the prevention of dengue. Today, Dengvaxia® is licensed in more than 20 countries in addition to Europe. In most countries where the vaccine is approved, the indication is for individuals aged 9 to 45 years of age with prior dengue infection, living in a dengue-endemic area. Nearly 3 million vaccine doses have been distributed worldwide since launch.

Based on new results from a supplemental analysis of the long-term clinical data on the vaccine reported in November 2017, Sanofi Pasteur has recommended a label update for Dengvaxia® to target its use at people with prior dengue infection. The public health value of the vaccine for preventing subsequent, potentially more severe dengue has been endorsed by internationally recognized bodies including the WHO, who granted Dengvaxia® prequalification status on March 25, 2020.

In order to facilitate a 'screen and vaccinate' approach that will allow for the introduction of Dengvaxia® in targeted immunization programs, Sanofi Pasteur collaborated with a serotest manufacturer to co-develop an optimized point of care rapid diagnostic test (RDT) designed specifically to detect prior dengue infections. Our goal was to ensure higher sensitivity compared to currently available tests to detect acute dengue infections while maintaining high specificity. This RDT is CE-marked since September 2020 and is currently registered in more than 5 countries.

¹⁴ WHO Factsheet on Dengue and Severe Dengue, accessed April, 2020: <https://www.who.int/news-room/fact-sheets/detail/dengue-and-severe-dengue>

5. INFLUENZA: REDUCING THE DISEASE ECONOMIC BURDEN AND PREPARING FOR A PANDEMIC



5.1. A considerable economic burden

Influenza is a highly contagious disease, which one in ten individuals will come across annually, namely in North America and Europe. Influenza can be very serious, especially for high-risk groups, such as: pregnant women, children under the age of five, those living with chronic conditions like diabetes or cardiovascular disease, as well as older adults. Influenza can also lead to severe complications in people of any age, including healthy people. Every year, influenza claims between 290,000 and 650,000 lives, both in the Northern and Southern Hemispheres, and represents a huge burden and cost to society.¹⁵ The WHO recommends vaccination as the most effective way to prevent influenza.

5.2. Building local influenza vaccine production facilities to provide high quality vaccines continuously

As a global leader in influenza vaccination, Sanofi Pasteur distributed over 250 million doses of influenza vaccines in 2020; this production increase was in response to the double threat of concurrent influenza and SARS-CoV2 circulation. We are committed to increasing vaccination coverage while working continuously to broaden protection against influenza. To respond to the growing local demand for seasonal influenza vaccines, Sanofi Pasteur continues to invest in its production capacity in France and the US as well as in transfer of technology for local production in countries such as China, Mexico and Brazil. These facilities are designed to switch from seasonal influenza vaccine production to pandemic vaccine production in the event of a pandemic.

5.3. Partnering globally to strengthen disease understanding and public health action

A key area of work through partnerships is the improved understanding of the burden of disease. In 2014, Sanofi Pasteur initiated the **Global Influenza Hospital Surveillance Network (GIHSN)**¹⁶, a platform to generate epidemiological evidence on influenza severity and to support vaccine strain selection through timely sharing of clinical and laboratory data. GIHSN was set up to inform policy decisions and serve as a network for improved respiratory viruses surveillance capacity building and

¹⁵ WHO, influenza factsheet accessed March, 2020: <http://www.who.int/mediacentre/factsheets/fs211/en/>

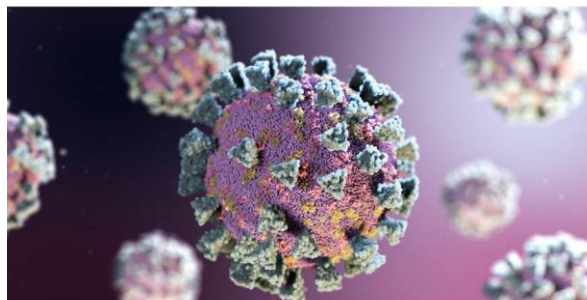
¹⁶ www.gihsn.org

response, notably in low to middle income countries (LMICs). This is a network of 100+ hospitals in 20+ countries performing active respiratory surveillance following the same modality. Current network countries include Canada, Mexico, Peru, Brazil, Ukraine, Romania, France, Spain, Morocco, Ivory Coast, South Africa, Lebanon, Kenya, Turkey, India, Nepal, China and Russia. The network expanded its scope 2 years ago to conduct virus genome sequencing analysis linked with clinical data to assess the severity of circulation strains. Several sites are now also testing for a full range of respiratory viruses including SARS-Cov2. The activity and the output of the network is regularly discussed with health authorities including WHO and US CDC. New funders have recently joined the network (Illumina, Seqirus, IFMPA).

Sanofi Pasteur also works closely with health care professionals' associations to improve understanding of the disease and support their ability to communicate on the benefits of immunization particularly to people at risk. With the World Heart Foundation in Latin America (Mexico, Peru, Brazil) our program is raising awareness amongst Cardiologists (Inter-American Society of Cardiologists, IASC); with the International Pharmacists association (FIP), we are promoting ease of access to understanding the benefits of vaccination including for Health Care Workers – and making vaccination easier to access; and alongside Non Communicable Disease Alliance (NCDA) this year we will raise awareness for chronic disease sufferers particularly in LMICs.

Lastly, older people around the world are at a higher risk of the severe effect of influenza: we support projects to promote equitable access to their immunization, effective communication on disease prevention with older people and advocacy for the value of older people in our societies, and hence the need to protect them from vaccine preventable diseases like influenza.

6. COVID-19: PLAYING OUR ROLE IN THE RESPONSE TO THE PANDEMIC



6.1. Pandemic preparedness

Sanofi Pasteur is a long-term partner in epidemic and pandemic preparedness through initiatives like stockpiling for UNICEF, and arrangements to rapidly switch to influenza pandemic strain manufacture with supply to LMICs. Our current rapidly evolving environment underlines the importance of Sanofi Pasteur's array of manufacture platforms, of innovative R&D investments and a flexible, broad industrial footprint, as well as openness in thinking differently about how best to solve a global problem, in the short term first and then sustainably.

6.2. Putting our scientific expertise in the development of two vaccine candidates

Sanofi Pasteur R&D and Clinical teams have joined forces with partners to develop two vaccine candidates to help prevent and control COVID-19. One vaccine candidate in collaboration with the US BARDA will utilize our recombinant protein manufacturing platform together with GSK's

pandemic adjuvant platform. The other vaccine candidate in partnership with Translate Bio uses novel messenger RNA technology.

6.3. Expanding large-scale manufacturing capabilities for pandemic response

We are increasing our manufacturing capabilities to be able to deliver large quantities of approved vaccines.

Our recombinant vaccine candidate is based on existing manufacturing technology, and we will ultimately have the capacity to manufacture large quantities when approved.

On the mRNA vaccine candidate side, Translate Bio has established relatively large-scale manufacturing for this more novel technology.

In 2021, Sanofi will also provide temporary support to manufacture other companies' COVID-19 vaccines, in order to help address global needs in a pandemic context.

6.4. Partnering to ensure global access

Sanofi Pasteur is committed to working with governments and NGOs to ensure our COVID-19 vaccine(s), once approved, will be available worldwide. Financial support systems such as Advance Purchase Agreements are phased over time and activated by milestone results achieved along the way. As part of the agreements, governments secure quantities of vaccines for their populations.

In addition, a key piece of our policy has been to support the international public health community through the global pooled procurement mechanism called the COVAX Facility (part of the Act-Accelerator) co-led by the World Health Organization, GAVI and CEPI. The Facility brings vaccine access to any and all participating countries in an efficient and optimally equitable way, regardless of development status. We are participating in this Facility and will continue discussions with Gavi and partners over time as the pandemic and vaccine project development evolve.