

## 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, 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: 19.4 million children worldwide still have no access to a full cycle of basic vaccines. 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.

# TABLE OF CONTENTS

|  |          |
|--|----------|
| <b>1. BACKGROUND</b>   | <b>4</b> |
| 1.1. Vaccines bring long-term societal benefits  | 4        |
| 1.2. What vaccines have brought to society   | 4        |
| 1.3. Remaining challenges  | 4        |
| 1.4. Our commitment to sustainable access to vaccines  | 4        |
| <b>2. POLIO: PARTNER IN THE END-GAME ERADICATION STRATEGY</b>  | <b>5</b> |
| 2.1. Polio eradication is in sight   | 5        |
| 2.2. A long-term partner in the Global Polio Eradication Initiative  | 6        |
| 2.3. Sanofi Pasteur: Committed to making Injectable-Inactivated Polio Vaccine (IPV) accessible to every child in the world | 6        |
| <b>3. YELLOW FEVER: A LONGSTANDING COMMITMENT TO HELP PREVENT AND CONTAIN EPIDEMICS IN TROPICAL REGIONS</b>                | <b>6</b> |
| 3.1. A lasting threat to the poorest communities   | 6        |
| 3.2. Guaranteeing access to vaccines for large populations in response to outbreak situations                              | 7        |
| <b>4. DENGUE: THE FIRST VACCINE SOLUTION TO A DISEASE WITH GROWING GLOBAL INCIDENCE</b>                                    | <b>7</b> |
| 4.1. A growing concern to populations in endemic areas   | 7        |
| 4.2. Making an effective vaccine and diagnostic tool available   | 7        |
| <b>5. CHOLERA: BRINGING THE MOST SUITABLE VACCINE TO THE POOREST POPULATIONS</b>   | <b>8</b> |
| 5.1. A threat to public health in the poorest countries  | 8        |
| 5.2. At the forefront of the fight against cholera   | 8        |

**5.3. "Beyond the traditional cold chain" - Improving the use of vaccines in the field and reducing the overall cost of immunization.....9**

**6. INFLUENZA: REDUCING THE DISEASE ECONOMIC BURDEN AND PREPARING FOR A PANDEMIC.....9**

---

**6.1. A considerable economic burden .....10**

**6.2. Building local influenza vaccine production facilities to provide high quality vaccines continuously .....10**

**6.3. Partnering globally to strengthen disease understanding and public health action .....10**

## 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.<sup>1</sup> 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.

### 1.2. What vaccines have brought to society<sup>2</sup>

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 2018, poliomyelitis remains endemic only in parts of two countries with only 163 wild polio virus cases reported. Between 2000 and 2018, estimated measles-related deaths, mostly among children under the age of five, decreased by 73%.<sup>3</sup> 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.<sup>4</sup>

### 1.3. Remaining challenges

Despite these significant achievements, there is still a long way to go. In 2018, an estimated 19.4 million infants worldwide were not reached with routine immunization service.<sup>5</sup> 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.

### 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

---

<sup>1</sup> <https://www.sanofi.com/en/your-health/vaccines/value-of-vaccines>

<sup>2</sup> Investing in immunization through the GAVI Alliance evidence report.

<sup>3</sup> WHO Factsheet on Measles, last updated December 2019. <https://www.who.int/news-room/fact-sheets/detail/measles>

<sup>4</sup> <https://www.gavi.org/programmes-impact/our-impact/measuring-our-performance/2011-2015-indicators>

<sup>5</sup> WHO Factsheet on Immunization, last updated December 2019. <https://www.who.int/en/news-room/fact-sheets/detail/immunization-coverage>

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 2016 Access To Vaccines Index report <https://accesstomedicinefoundation.org/access-to-vaccines-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 2019, polio was endemic in only two countries (Afghanistan and Pakistan) with 163 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.<sup>6</sup>

Sanofi Pasteur has expanded its IPV production capacities in France and is in a position to supply the majority of doses for this unprecedented global rollout, including its ShanIPV vaccine, now produced by Shantha Biologics in India. Sanofi Pasteur supplied 80% of the IPV doses used by Unicef between 2014 and 2019 (223 million doses).<sup>7</sup>

## 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.<sup>8</sup> No specific antiviral treatment is available against yellow fever. The disease remains a major public health concern in both Africa and South

---

<sup>6</sup> GPEI webpage accessed March 2020: <http://polioeradication.org/news-post/to-succeed-by-2023-extraordinary-joint-statement-to-polio-eradicators/>

<sup>7</sup> Internal source

<sup>8</sup> WHO factsheet accessed March 2020: <http://www.who.int/mediacentre/factsheets/fs100/en/><sup>9</sup> WHO Factsheet on Dengue and Severe Dengue, accessed April, 2020: <https://www.who.int/news-room/fact-sheets/detail/dengue-and-severe-dengue>

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 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.<sup>9</sup> The 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 21 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.

---

<sup>9</sup> WHO Factsheet on Dengue and Severe Dengue, accessed April, 2020: <https://www.who.int/news-room/fact-sheets/detail/dengue-and-severe-dengue>

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 is collaborating 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 is to ensure higher sensitivity compared to currently available tests while maintaining high specificity. The collaboration is seeking to begin the registration of an optimized RDT from late 2020 onwards.

## 5. CHOLERA: BRINGING THE MOST SUITABLE VACCINE TO THE POOREST POPULATIONS

---



### 5.1. A threat to public health in the poorest countries

Cholera is a severe dehydrating diarrheal disease caused by the ingestion of food or water contaminated by the bacterium *Vibrio cholera*, leading to death if treatment is not given promptly. Every year, there are an estimated 1.3 to 4.0 million cholera cases and 21,000 to 143,000 deaths due to cholera.<sup>10</sup>

### 5.2. At the forefront of the fight against cholera

Since 2009, a bivalent oral vaccine against cholera used in large-scale vaccination campaigns to control epidemics has been made available by Sanofi Pasteur through Shantha Biologics, its Indian affiliate. Shanchol®, was developed through a partnership with the International Vaccine Institute (IVI) and was pre-qualified by the WHO in 2011. It is registered in countries in the most severely affected and at-risk endemic regions. Sanofi Pasteur is expected to contribute to the cholera vaccine stockpile that has been recently created under the management of the International Coordinating Group (ICG).

---

<sup>10</sup> WHO factsheet accessed March 2020: <http://www.who.int/mediacentre/factsheets/fs107/en/>

In March 2019, Shantha shipped 884,000 doses of Shanchol to Mozambique in response to the cholera outbreak caused by cyclone Idai.

### 5.3. "Beyond the traditional cold chain" - Improving the use of vaccines in the field and reducing the overall cost of immunization

Shanchol® is the first cholera vaccine granted Controlled Temperature Chain (CTC) indication by the WHO. CTC is a "last mile" flexible approach allowing vaccines to be kept at temperatures outside of the traditional cold chain of +2°C to +8°C for a limited period of time under monitored and controlled conditions, as appropriate to the stability of the antigen. The objective is to reduce logistics constraints and costs during the final steps of immunization campaigns in areas where cold chain infrastructures may be a challenge, while guaranteeing that the vaccines remain safe and efficacious.

Shanchol® vaccine can be kept for up to 14 days at up to 40°C immediately prior to administration. The WHO approval was granted in February 2018 after a review of specific stability data generated by Sanofi Pasteur.

This new flexibility not only improves vaccine delivery and increases campaign efficiency by reaching more people in remote areas during mass vaccination campaigns, in particular in response to outbreaks in refugee camps and natural disasters; but it also brings environmental, medical and economic benefits for the populations and the country healthcare systems<sup>11</sup>:

- reduced wastage as ice packs or cool water packs in vaccine carriers are no longer needed,
- reduced risk of vaccine freezing, leading to improved vaccine safety and potency,
- reduced costs (fewer freezers) and better staff productivity (fewer journeys and less staff time are needed to manage and maintain cold chain requirements).

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

---



---

<sup>11</sup> WHO, Supply Chain webpage accessed on April 16, 2019: [http://www.who.int/immunization/programmes\\_systems/supply\\_chain/ctc/en/](http://www.who.int/immunization/programmes_systems/supply_chain/ctc/en/)

### 6.1. 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 keep you in bed for a week, and can be very serious, especially for high-risk groups, such as: pregnant women, children under the age of five, those living with underlying chronic conditions like diabetes, and the elderly. 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.<sup>12</sup> The WHO recommends vaccination as the most effective way to prevent influenza.

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

As a global leader in influenza vaccination, Sanofi Pasteur distributed over 200 million doses of influenza vaccines in 2019 and is 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 middle income countries such as China, Mexico and Brazil. These facilities are designed to easily switch from seasonal influenza vaccine production to pandemic vaccine production in the event of a pandemic.

### 6.3. Partnering globally to strengthen disease understanding and public health action

The need for strengthening influenza disease surveillance and disease burden estimate has been highlighted recently in a WHO report<sup>13</sup>: “Influenza is a global public health threat, with seasonal and pandemic influenza resulting in substantial impact on health, the economy and society. Many low- and middle-income countries (LMICs), especially those in the tropics, are grappling with understanding the impact of influenza and to determine whether such interventions are cost-effective vis-à-vis interventions for other diseases. Furthermore, LMICs are likely to have the highest burden of influenza in children, but these are also the countries with the least data available.”

In 2011, Sanofi Pasteur initiated The Global Influenza Hospital Surveillance Network (GIHSN)<sup>14</sup> for Influenza disease surveillance and disease burden estimate strengthening in LMICs, with the objective to strengthen capacities of laboratory and monitoring surveillance of influenza viruses at local level. The GIHSN is a network of country sites affiliated with national health authorities and laboratories coordinating 60 hospitals and using a standardized surveillance protocol. Influenza virus circulation, lab-confirmed severe influenza burden and vaccine protective effect are yearly assessed. The network now includes 18 countries across the world including eight LMICs: Mexico, Peru, Ivory Coast, South Africa, Kenya, Tunisia, China and India.

The GIHSN is supported by the Foundation for Influenza Epidemiology, created in 2015 by Sanofi Pasteur and in the next season, will benefit from the support of the Influenza Vaccine Supply group (IFPMA). Through formal and regular dialog with the WHO Global Influenza Program, a partnership with GISAID and the constitution of an Independent Scientific committee, the Foundation aims to

---

<sup>12</sup> WHO, influenza factsheet accessed March, 2020: <http://www.who.int/mediacentre/factsheets/fs211/en/>

<sup>13</sup> WHO-sponsored Special Issue in Influenza (2018): [https://www.who.int/influenza/surveillance\\_monitoring/bod/BOD\\_IORV\\_collection/en/](https://www.who.int/influenza/surveillance_monitoring/bod/BOD_IORV_collection/en/)

<sup>14</sup> [www.gihsn.org](http://www.gihsn.org)

strengthen surveillance capacities and the understanding of the strain evolution of strains for vaccine strain selection in alignment with the international public health agenda.

During the 2018-2019 season, more efforts have been dedicated to develop capacities for Whole Genome Sequencing (WGS) of strains through a better coordination of GIHSN laboratory capacities and a collaboration with GISAID<sup>15</sup>. Several WGS sequencing reports from the sites were shared with WHO ahead of the Vaccine composition in February and genetic sequences uploaded into the GISAID platform.

---

<sup>15</sup> <https://www.gisaid.org/>