

# ACCESS TO VACCINES

## 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.

## 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 three countries with only 33 wild polio virus cases reported. Between 1990 and 2008, estimated measles-related mortality among children under five decreased by 86%. 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 2.5 million deaths each year.<sup>3</sup>

## Remaining challenges

Despite these significant achievements, there is still a long way to go. 19.5 million children worldwide still miss out on a full course of basic vaccines.<sup>4</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.

## 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.

<sup>1</sup> <https://www.sanofipasteur.com/en/immunization-essentials/the-value-of-vaccines/>

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

<sup>3</sup> *The New England Journal of Medicine*, 369, November 22, 2013, from [nejm.org](http://nejm.org)

<sup>4</sup> <https://www.sanofipasteur.com/en/immunization-essentials/the-value-of-vaccines/>

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>

## I. POLIO: PARTNER IN THE END-GAME ERADICATION STRATEGY



### 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 2018, polio was endemic in only three countries (Afghanistan, Nigeria and Pakistan) with 33 wild polio virus cases reported.

### 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 13 billion doses of Oral Polio Vaccine (OPV) and 1.5 billion doses of Inactivated Polio Vaccine (IPV) in the world.

### 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<sup>5</sup> as the target year for polio eradication.

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. Over 2016-18 period, Sanofi Pasteur supplied more than 80% of the IPV vaccines used in the 73 world's poorest countries supported by GAVI (Global Alliance for Vaccines & Immunization) Over the period, an estimated 40 million children born in those countries (one in two) received a dose of IPV produced by Sanofi Pasteur.<sup>6</sup>

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<sup>5</sup> GPEI webpage accessed on April 16, 2019: <http://polioeradication.org/news-post/to-succeed-by-2023-extraordinary-joint-statement-to-polio-eradicators/>

<sup>6</sup> Internal source

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



### 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 200,000 cases of yellow fever each year, resulting in 30,000 deaths.<sup>7</sup> 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.

### 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 2018, an all-time record of 27.5 million yellow fever vaccine doses were delivered to Africa. Sanofi Pasteur is currently the largest vaccine supplier to the yellow fever vaccine emergency stockpile reserved for outbreak response.

## III. HIV: A LONG-TERM COMMITMENT TO THE DISCOVERY OF A VACCINE SOLUTION

### Despite progress in access to treatment, HIV remains a worldwide public health burden

Human immunodeficiency virus (HIV) is a blood-borne virus typically transmitted via sexual intercourse and shared intravenous needles. Since the beginning of the epidemic, almost 70 million people have been infected with the HIV virus and about 35 million people have died of AIDS.<sup>8</sup> Sub-Saharan Africa remains the most severely affected area, with nearly one out of 20 adults living with HIV and accounting for 69% of the people living with HIV worldwide.

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<sup>7</sup> WHO factsheet accessed on April 16, 2019: <http://www.who.int/mediacentre/factsheets/fs100/en/><sup>8</sup> WHO, Global Health Observatory (GHO) accessed on April 16, 2019: <http://www.who.int/gho/hiv/en/>

<sup>8</sup> WHO, Global Health Observatory (GHO) accessed on April 16, 2019: <http://www.who.int/gho/hiv/en/>

## The first results of a vaccine efficacy study performed in Thailand in 2009

Results from a Phase III vaccine efficacy study called RV-144, which was conducted in Thailand, were published in the fall of 2009. Although efficacy results were modest, this study provided the first evidence that a safe and preventive HIV vaccine was possible for humans. Post-hoc analyses of this study provided a correlation of risk that could be used to substantiate and expand upon such results.

## P5 coalition, partnering toward a common goal

In 2011, Sanofi Pasteur entered into the P5 (Pox-Protein Public-Private Partnership) with GSK, the Bill & Melinda Gates Foundation, the U.S. NIH, the HIV Vaccine Trials Network (HVTN), and the U.S. Military HIV Research Program.<sup>9</sup> This collaboration is expected to accelerate progress towards an effective and lasting HIV vaccine solution by bringing together key stakeholders including industrial partners, funders, research organizations, governments and experts in the field of HIV vaccine development.

## Sanofi Pasteur collaborates in a Phase I/II clinical trial in South Africa for a vaccine against HIV

South Africa is particularly poised as a key driver of HIV vaccine innovation, since it has the highest incidence of the disease and is well-equipped with world-renowned researchers and infrastructure to conduct HIV studies. The in-country partners along with HVTN sites provide primary and follow-up care to communities involved in clinical trials. They educate the local communities and raise awareness about HIV and vaccine trials.

The preliminary results of a study performed in healthy volunteers show that all fully vaccinated candidates developed a strong humoral and cellular immune response. These results published on June 10 in the *Lancet HIV*, support the continuation of a large scale Phase 2b/3 study performed in South Africa (HVTN 702). The results of this study are expected in 2021.

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



### A global threat 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 1.4 to 4.3 million cholera cases and 28,000 to 142,000 deaths due to cholera.<sup>10</sup>

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<sup>9</sup> Vaccine Enterprise P5 webpage accessed on April 16, 2019: <http://vaccineenterprise.org/content/P5Partnership>

<sup>10</sup> WHO factsheet accessed on April 16, 2019: <http://www.who.int/mediacentre/factsheets/fs107/en/>

## 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).

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

## "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).

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



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<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/)

## 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.

## 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 2018 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.

## 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 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.

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<sup>12</sup> WHO, influenza factsheet accessed on April 16, 2019: <http://www.who.int/mediacentre/factsheets/fs211/en/>

<sup>13</sup> WHO-sponsored Special Issue in Influenza accessed: [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)

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