Sharing our passion
For Preventing Diseases with Vaccination

SANOFI PASTEUR
Empowering Life
Life is a health journey which can be protected against life-threatening infectious diseases.

Smallpox used to kill millions of people worldwide.\(^1\)

Polio paralyzed and killed thousands of children over the course of decades.\(^2\)

Thanks to vaccination, smallpox is now a thing of the past and we are on the verge of eradicating polio. However, despite the availability of well tolerated and cost-effective vaccines, we continue to see outbreaks of severe infectious diseases in countries where we thought they were under control.

While vaccination saves up to 3 million lives every year, an additional 1.5 million deaths could be avoided with improved vaccination coverage.\(^3\)

At Sanofi Pasteur, the Vaccines Global Business Unit of Sanofi, we believe in a world where no one suffers or dies from a vaccine preventable disease. We are proud our vaccines can help protect us and our loved ones from a wide range of severe infectious diseases, at every stage of life.

Each year, we supply more than one billion doses to people around the world and seek, relentlessly, to extend the benefits of vaccination to new infectious diseases while improving existing vaccines to enhance health and wellbeing.
For over 100 years, Sanofi Pasteur has been committed to extending the life-saving power of vaccination as broadly as possible.

Our history is grounded in life science pioneers who discovered how infectious diseases work. They unlocked the public health potential of vaccination and developed efficient mass production methods to ensure the broadest access to vaccines.

We currently supply one billion doses to people around the world each year, and work hand-in-hand with our public health partners so our vaccines can help protect as many as half a billion lives annually.

Our portfolio of vaccines offers protection against a wide range of infectious diseases for people around the world.

Ranging from cholera, dengue fever and diphtheria, to Haemophilus influenzae type b, polio, pertussis, tetanus, Hepatitis A and B, meningococcal meningitis, influenza... to name a few.
Our team brings their passion to discover and develop vaccines to enhance protection for children, adolescents and adults alike.

Our researchers are seeking effective vaccines to extend the benefits of vaccination to a number of infectious diseases, such as respiratory syncytial virus infections which can cause severe lung infections among children, including bronchiolitis and pneumonia.

We are not standing still with our existing vaccines. Our latest generation of 6-in-1 pediatric vaccines helps improve childhood immunization and reduces the number of vaccination visits for infants while improving comfort for children and reducing anxiety for parents.

With the public health community we are actively involved in addressing funding, access and distribution challenges that inhibit vaccinations in countries with underdeveloped infrastructure. This is what drives us forward and gives us purpose.

Together with our public and private partners, we are all driven by a common goal:

**protect health and empower life**
The introduction of vaccination programs has led to dramatic decreases in disease, disability and death from many infectious diseases.

Vaccines save 5 lives every minute worldwide\(^5\).

**VALUE OF VACCINATION**

« Immunization has been a great public health success story. The lives of millions of children have been saved, millions have the chance of a longer healthier life, a greater chance to learn, to play, to read and write, to move around freely without suffering. »

NELSON MANDELA, WINNER OF THE NOBEL PEACE PRIZE 1993

**Vaccination Saves Lives**

With the exception of clean, safe drinking water, no human endeavor rivals immunization in combating infectious diseases and reducing mortality rates\(^6\).

At the dawn of the 20\(^{th}\) century, the major health threats were infectious and parasitic diseases that most often claimed the lives of infants and children\(^7\). Today, vaccination can prevent several infectious diseases, and there are new vaccines on the horizon with the potential to prevent even more. Mass immunization programs have proven successful in controlling or even eliminating disease.

Due to vaccination, we are on the verge of eradicating polio (with a 99% reduction already)\(^8\).
Vaccine-related disease reduction

History shows that a decrease in immunization coverage sets the stage for the reappearance of disease in previously protected populations. However, with stable and high vaccination coverage, disease declines and, for some diseases, may be eliminated.

For example, polio cases have decreased by over 99% since 1988, from an estimated 350,000 cases then, to 22 reported cases in 2017. As a result of the global effort to eradicate the disease, more than 16 million people have been saved from paralysis. According to WHO, as long as a single child remains infected, children in all countries are at risk of contracting polio. Failure to eradicate polio from these last remaining strongholds could result in as many as 200,000 new cases every year, within 10 years, all over the world.

Additional health benefits of vaccination

**CANCER PREVENTION:** Vaccination can also contribute to the prevention of certain cancers linked to infections.

Chronic hepatitis B infection can lead to liver cancer, therefore vaccination against Hepatitis B prevents some liver cancers. This benefit has already been seen for hepatocellular carcinoma in some studies.

HPV vaccination combined with HPV based screening programs are estimated to reduce overall rates of cervical cancer in 2040 by up to 80%, as demonstrated in a recent study.

**REDUCING ANTIBiotic RESISTANCE:** Many infections are treated with antibiotics. However, we continue to see an increase in infections resistant to those antibiotics. Through vaccination, we can reduce the prevalence of infectious diseases and hinder the development of resistant strains.

The introduction of *Haemophilus influenzae* type b (Hib) conjugate vaccine has virtually eliminated Hib meningitis, bacteremia, pneumonia, and epiglottitis in regions where it has been widely deployed, including drug-resistant infection.

The pneumococcus is another example of a pathogen for which vaccination reduced drug-resistant disease, primarily through reducing the overall burden of disease but also by targeting the most resistant serotypes.

It has been estimated that the introduction of Hib conjugate and Pneumococcal Conjugate Vaccine (PCV-13) in 75 developing countries could reduce antibiotic use for these diseases by 47% and avert 11.4 million days of antibiotic use in children younger than five years old each year.

**SUPPORTING HEALTHY AGING:** While we are fortunate to be living longer in many countries, aging is associated with a higher prevalence of non-communicable diseases (such as diabetes, cardiovascular disease), that can be worsened by infectious disease. Vaccination against infectious diseases can provide valuable protection later in life.

In the elderly, influenza vaccination can decrease the rate of the illness and complications by up to 60%, and deaths by up to 80%.
Filling the gap

Since the introduction of vaccination, life expectancy has increased between 15-25 years. Further gains are expected and evidence suggests the control of disease with vaccination has largely contributed to this increased life expectancy\textsuperscript{20}. However, even with the undisputed success of immunization efforts, 1.5 million deaths still occur each year from vaccine-preventable diseases\textsuperscript{21}.

According to the WHO, vaccines will be the most important tool for reducing the high morbidity and mortality invariably associated with influenza pandemics\textsuperscript{22}.

In 2016, an estimated 19.5 million infants worldwide were not reached with routine immunization services such as diphtheria-tetanus-pertussis vaccine (DTP3)\textsuperscript{23}.

Dengue is a major public health concern with nearly half of the world’s population at risk. The WHO estimates up to 390 million infections per year of which 96 million manifest clinically\textsuperscript{24}.

Every year, around 3-5 million people contract influenza, leading to up to 650,000 deaths\textsuperscript{25}.

Health-economic benefits of vaccination

While vaccines can prevent death and suffering, they are also \textbf{one of the most cost-effective health-care investments available}\textsuperscript{26}. Vaccination has significantly reduced the burden of infectious diseases\textsuperscript{27}. As well as saving lives and reducing disability, vaccination can:

- Ease the pressure on healthcare systems due to fewer doctor visits and hospitalizations;
- Reduce time off work and lost productivity costs caused by illness\textsuperscript{28,29}.
VACCINATION CAN PROTECT YOU AND YOUR LOVED ONES AT EVERY STAGE OF LIFE AGAINST SEVERE INFECTIOUS DISEASES FOR WHICH NO ALTERNATIVE THERAPEUTIC SOLUTIONS MAY BE AVAILABLE.
We can be exposed to infectious diseases which put our health and the health of those around us at risk. **Vaccination is the most effective way to help protect you and your loved ones against potentially life-threatening vaccine preventable diseases**. 

Vaccination remains the only effective means of preventing Hib disease and is becoming increasingly important as Hib antibiotic resistance grows. Before a vaccine became available in 1992, some 20,000 U.S. children under age five got severe Hib infections every year, resulting in about 600 deaths.

**Vaccination can help you avoid contracting infectious diseases and prevent you from transmitting infectious diseases to others.**

Some people are not able to be protected by vaccination. This can be the case for children who are too young to be vaccinated, those with weakened immune systems not compatible with all vaccines and those who are too ill to receive vaccines (such as some cancer patients). **By getting vaccinated, we are able to provide “herd protection” to those not able to get vaccinated.**

“Herd immunity and / or protection” occurs when a high percentage of the population is protected against a virus or bacteria through vaccination, making it difficult for a disease to spread. In fact, as demonstrated recently in several countries around the world, when the vaccination coverage fell under a certain level, infectious disease outbreaks can occur.

While some diseases are rare in certain parts of the world, due to routine vaccination or environmental factors, in others they continue to be endemic. As more people travel globally, often to areas where fewer people may be vaccinated, it becomes even more important to ensure we are vaccinated to prevent illness in ourselves and families, and transmission to those back home.
By vaccinating yourself during pregnancy against diseases such as influenza and pertussis*, you protect yourself and pass immunity directly to your baby.

When your baby is born, his or her immune system is fighting off millions of germs (bacteria and viruses). Newborns may be protected against some infections because they have received antibodies from their mother and some of the antibodies created through vaccination are passed on to the baby before birth. But that protection begins to fade in the first months of life, leaving your baby vulnerable to infectious diseases.

Before pregnancy

By getting vaccinated against measles, mumps and rubella**, you may reduce the chance of the baby contracting the disease. It is all the more important as diseases such as rubella can cause very severe damage to your developing baby with severe lifelong consequences (deafness, heart defects, intellectual disability). As this immunity only lasts for up to a year, it is important to speak to your doctor to ensure your baby’s vaccines are up to date with local guidelines.

* Vaccination against pertussis during pregnancy is not recommended in all countries. Please refer to your doctor for more information.
* *MMR vaccines are contraindicated for pregnant women and pregnancy should be avoided until one month after receiving the vaccine.
During pregnancy

By getting vaccinated against pertussis, your body will create protective antibodies to provide early, short-term protection against pertussis for your baby.*41

A influenza vaccination during pregnancy can reduce the risk of your newborn contracting influenza and prevent influenza complications for yourself42.

Vaccinating your children protects them against life-threatening diseases, many often with no therapeutic alternatives43.

Protecting your child from disease is linked to improved cognitive abilities, better educational performance and higher earnings for them later in life44.

As your child starts day care or school, booster vaccinations help protect them from disease and can also stop the spread of infection to younger as well as older siblings and friends.

We produce a range of high-quality pediatric vaccines for the global market.

Our most advanced pediatric combination vaccine can provide protection for your little ones against six infectious diseases at the earliest stages of life.

Our vaccines (single and multi-dose) help protect infants from vaccine-preventable diseases, such as diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis and invasive infections caused by Haemophilus influenzae type b, reducing the number of injections your baby needs and offering protection against major childhood diseases.

* Vaccination against pertussis during pregnancy is not recommended in all countries. Please refer to your doctor for more information.

ADOLESCENTS

In the close quarters of school campuses, our teenagers are at greater risk for certain infectious diseases.

Vaccination is the most effective way to prevent rare but unpredictable fast-evolving and very severe meningococcal disease.

• Did you know that meningococcal diseases can permanently damage the health of 10 to 20% of people infected and can cause death, even with appropriate care, in up to 10% of patients?45

• Vaccination from these preventable diseases may help your teens stay healthy, avoiding time off school for them and time off work for you.

As immunity against diphtheria, tetanus, and pertussis fade over time, it is important to ensure they are up to date with booster vaccinations.

For over 40 years we have worked to reduce the incidence and impact of meningococcal disease, working hand in hand with the public health community and patient associations, and will continue to do so to reduce suffering from this potentially fatal disease.
It is important to know that later in life your loved ones can help safeguard their health through vaccination.

As we age, there is a higher prevalence of noncommunicable diseases, such as diabetes and cardiovascular disease, which can be worsened by infectious diseases. Vaccination against diseases such as influenza, pneumococcal disease and shingles can help protect your loved ones later in life.

- People aged over 65 years are at a higher risk of severe influenza complications, with the majority of deaths from influenza occurring in this age group.\(^4\)

- Grandparents are increasingly involved in childcare, putting them at risk of disease if they or their grandchildren are not vaccinated.\(^4\)

We continue to work to improve our influenza vaccines, specifically for those over the age of 50 through new vaccine technologies and initiatives to enhance their protective power.

**ADULTS**

In daily life we may not always notice the benefits of vaccination. Vaccinations help protect us from some serious diseases that could result in poor health, missed work, medical bills, and not being able to care for our family.\(^4\)

It’s important to keep vaccination up to date to help maintain immunity and prevent transmission to friends and family members, especially infants.\(^4\) Talk to your doctor to find out more about your local vaccination guidelines.

Our pertussis vaccines have been developed to provide protection throughout different stages of life. Although adults suffer relatively mild complications from the disease, it can be very serious for infants who are too young to be protected through vaccination.
How does your immune system work?

The Immune response is a natural mechanism activated by the human body when it detects the presence of an infectious agent. Among our immune system’s most important features is its ability to distinguish cells and molecules that belong to the body from those that don’t. Its role is to stop a pathogenic agent (a virus, bacteria, or parasite, etc.) from spreading inside our bodies.

Once an infectious agent is recognized, the immune system responds to the invasion by producing antibodies and competent cells in adequate quantities, targeting specifically the infection or the disease.50
During the first encounter with the infectious agent (the pathogen), the defense mechanism is not yet up and running, and the disease has time to develop. By the second encounter, however, the pathogen will immediately be recognized and eliminated before it has time to cause disease. This applies to measles or polio, as the body produces an immune response. Influenza is different, however, as it is a constantly mutating virus that avoids detection by our bodies’ surveillance system.

There are two lines of defense:

- **The nonspecific or innate response**, which consists of all the barriers and non-specific tools that prevent harmful substances from getting inside our bodies – such as our skin. It also includes non-specific cells (like macrophages) or molecules designed to eliminate pathogens or reduce their spread.

- **The specific response**, which is also present from birth is infinitely more complex, timely and involves recognizing, destroying, and memorizing intruders, and neutralizing them if they reappear. The purpose of vaccination is to create this memory.

### What is an infectious disease?

Infectious diseases are caused by microorganisms, such as bacteria, viruses, parasites, or microscopic fungi. They are a major cause of death, particularly in children below five.

### How does vaccination stimulate the body’s natural defenses?

Vaccination works using the body’s immune response. The vaccine creates a non-pathogenic alert, which triggers an immune response. When the body comes into contact with the infectious agent, it has been trained to defend itself on its own.

Vaccines undergo various processes in order to destroy their ability to cause disease while preserving their ability to stimulate an immune response. They are produced from bacteria or viruses, their components, or the substances that they secrete. Vaccines achieve immune protection without a person contracting the disease and suffering potential consequences. For certain illnesses, several doses of a vaccine are required in order to achieve immunity and protection. Vaccination is typically recommended by the health authority of each country.

### The main vaccine types

- **Live Attenuated Vaccines**
  A vaccine prepared from living micro-organisms (viruses, bacteria) that have been weakened under laboratory conditions. LAV vaccines will replicate in a vaccinated individual and cause an immune response.

- **Inactivated Vaccines**
  Made from microorganisms (viruses, bacteria, other) that have been killed through physical or chemical processes. These killed organisms cannot cause infection.

- **Recombinant Vaccines**
  Produced by genetic engineering. Animal cells or yeasts are used for the synthesis of vaccine antigens.
What is herd immunity?

- Collective immunity or herd immunity is achieved when a high percentage of a population has been vaccinated. In this case, the infectious agents are no longer transmitted to the rest of the population. Thus, vaccinated individuals indirectly provide protection for vulnerable people who cannot get vaccinated.

- Vaccination is also an act of collective protection for certain infections, since it prevents the illness from spreading.

- The vaccine coverage needed for herd immunity varies depending on the pathogen. For polio, for example, the rate of coverage needed is 80-86%.

Immunization and Eradication

Mass vaccination can stop the circulation of a virus to the point of totally eliminating it. In 1967, the World Health Organization set up a plan to fight against smallpox, and it was declared eradicated in 1980. On the same model, the World Initiative to Eradicate Polio and Global Polio Eradication Initiative was launched in 1988, and polio may well become the second human disease to have disappeared, thanks to vaccination.
SANOFI PASTEUR PRODUCES A PORTFOLIO OF HIGH-QUALITY VACCINES THAT MATCHES ITS AREAS OF EXPERTISE.
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BACTERIAL DISEASES

CHOLERA

Cholera is a strictly human disease caused by a bacterium, vibrio cholerae, that is transmitted from person to person through fecal contaminated food and water and can kill within hours if left untreated. It mainly affects developing countries in Asia, South America, and Africa. In 2016, a total of 132,121 cholera cases and 2,420 deaths were reported to WHO by 38 countries. While hygiene and sanitation are the cornerstones in the fight against this disease, oral vaccines can be used to control outbreaks and for prevention in high-risk areas.

Sanofi Pasteur has provided millions of doses around the globe to fight cholera and protect lives. Our commitment to public health and our spirit of innovation are demonstrated in a recent update to our cholera vaccine, which can now be kept outside of the traditional cold chain up to 14 days at ambient temperatures up to 40°C. This improvement to our product helps ensure access for those who live in remote areas in Asia and Africa, where the vaccine is mostly used.

SYMPTOMS AND TREATMENT

Following an incubation period ranging from hours to four days, some patients experience acute watery diarrhea associated with vomiting causing severe dehydration, which can lead to death within a few hours.

Treatment relies on a re-hydration based on the patient’s condition.
DIPHTHERIA

Before the introduction of routine diphtheria vaccination, the disease ranked among the leading causes of infant mortality. Diphtheria is a bacterial infection caused by Corynebacterium diphtheriae.

For over 40 years, Sanofi Pasteur has provided a diphtheria vaccine for people around the globe. In the 1980s, when the vaccine was not readily available, it was estimated that approximately 1 million cases including 50,000 - 60,000 deaths occurred in low and middle income countries each year. Up to half of the people who got the disease did not survive. Diphtheria affects people of all ages, but most often it strikes unimmunized children. When diphtheria was added with pertussis in a vaccine combination, it became the foundation of any childhood vaccination program.

SYMPTOMS AND TREATMENT

Typical diphtheria presents as sore throat, followed by a thick coating on the back of the throat which can lead to difficulty breathing, heart failure, paralysis, and even death.

Treatment relies mainly on the administration of diphtheria antitoxin. Antibiotics are also used to contain bacterial growth, but they have no effect on toxin-induced symptoms.
HAEMOPHILUS INFLUENZAE TYPE B (HIB) INFECTIONS

Haemophilus influenzae type b (Hib) disease is most common in babies and children younger than 5 years old⁶⁰.

Before a vaccine was introduced, WHO estimated that about two billion people worldwide were infected with the disease. **Hib infections accounted for three million cases of severe illness, and 400,000 deaths annually, with a peak of incidence among infants of age 4 to 18 months**⁶¹. Since 1987, Sanofi Pasteur began offering a vaccine to protect against this potentially deadly disease.

**SYMPTOMS AND TREATMENT**

If the bacterium enters the bloodstream and spreads, it can result in different clinical forms of Hib disease: meningitis, pneumonia, epiglottitis, arthritis, cellulitis, osteomyelitis. Hib meningitis is often fatal (in 5 to 40% of cases depending on the country) and may lead to neurological sequelae such as deafness, motor deficit, or mental retardation⁶².

The disease is treated with antibiotics.
BACTERIAL DISEASES

MENINGOCOCCAL INFECTIONS

Meningococcal diseases are rare but can cause lifelong impact, and death in 10-15% of cases.

As a partner on the health journey, we envision a world where no one suffers or dies from a vaccine preventable disease. **Vaccination is the most effective way to prevent unpredictable and fast evolving meningococcal diseases.** For over 40 years we have passionately worked to reduce the incidence and impact of meningococcal diseases, working hand in hand with the public health community and patient associations. We will pursue our efforts to remove suffering from these potentially fatal diseases.

**SYMPTOMS AND TREATMENT**

Meningococcal meningitis usually occurs during infancy, adolescence and young adulthood and is characterized by an infectious syndrome (fever, severe headaches, vomiting) with meningismus (stiffness of the neck, lethargy, consciousness disorder, and even coma).

Appropriate antibiotic treatment must be started as soon as possible.
PERTUSSIS

Pertussis is a slowly progressing disease (several weeks) that is particularly severe among young infants, which is easily transmitted by close contact, mainly through coughing. It is an infection of the respiratory tract caused by the bacterium *Bordetella pertussis* that lives in the mouth, nose, and throat. Pertussis is highly contagious and it is one of the diseases which does not provide life-long immunity. Please refer to your local health authorities for recommendations on booster shots.

Since the 1950s, the incidence of pertussis has decreased by more than 90% in countries that have introduced vaccination. According to the WHO, in 2016 there were 139,535 reported cases globally. Unfortunately, the disease still raises concern due to the increase in the proportion of cases occurring in infants too young to be vaccinated and in adolescents and adults in whom the protection provided by the disease or vaccination during their childhood is waning. The latter group may serve as a reservoir for the transmission to young infants. Sanofi Pasteur provides vaccines to more than 70 million children a year in more than 120 countries around the globe.

SYMPTOMS AND TREATMENT

Typical pertussis is characterized by a persistent cough (over three weeks) in most cases in the absence of fever.

The disease may be particularly severe and even fatal in infants.

There are several antibiotics (medications that can help treat diseases caused by bacteria) available to treat pertussis.
TETANUS

Tetanus is a non-communicable disease occurring all over the world, but is more prevalent in low and middle-income countries, where the maternal and neonatal form of the disease is still frequent and devastating. This often-fatal infectious disease is caused by the toxigenic strains of the Tetanus bacillus, when grown in the absence of oxygen, penetrate the body through lesions or as a result of medical acts performed under insufficient aseptic precautions.

For nearly 100 years, Sanofi Pasteur and its preceding companies have provided a vaccine for this disease. The WHO estimates that in 2015, approximately 34,000 newborns died from neonatal tetanus67. In the absence of treatment, the outcome is almost always fatal, particularly in the very young or the elderly, and even after appropriate treatment, tetanus-related mortality remains high. In 2016, about 86 percent of infants worldwide (116.5 million infants) received three doses of diphtheria-tetanus-pertussis (DTP3) vaccine, from manufactures around the world, helping protect them against infectious diseases that can cause serious illness and disability68.

SYMPTOMS AND TREATMENT

Tetanus most often presents with contractions of the jaw muscle, followed by spasms of the back muscles and sudden convulsions.

Treatment involves medicine called human tetanus immune globulin (TIG), wound care, antibiotics and vaccination69.
Typhoid fever is a bacterial infection that has become rare in industrialized countries, but is still common in countries with poor hygiene where it is responsible for up to 20 million cases and up to 161,000 deaths every year. Typhoid fever is contracted by drinking or eating the Salmonella typhi bacterium in contaminated food or water.

Sanofi Pasteur is working each day to reduce the burden of this disease around the globe. Prevention relies on good hygiene and vaccination as the emergence of drug-resistant strains makes treatment more complex. Sanofi Pasteur distributes typhoid-containing vaccines to more than 100 countries worldwide (including single antigen and combination).

**SYMPTOMS AND TREATMENT**

Typical signs include diffuse abdominal pain, possibly high fever, anorexia, diarrhea, daytime drowsiness and nighttime insomnia. Possible complications include gastrointestinal hemorrhage and perforation, heart failure, and encephalitis.

Effective antibiotics are available, and the prognosis in patients under treatment is usually favorable.
VIRAL DISEASES

DENGUE FEVER

Dengue is a mosquito-borne disease that affects about 390 million people a year. The incidence has increased 30-fold over the last 50 years, with 3.9 billion people at risk in over 128 countries. Sanofi Pasteur has been relentlessly seeking to develop a vaccine against dengue for over 20 years. In 2015, we introduced the first dengue vaccine which is registered in several of the most endemic countries in the world. Implementation of public dengue vaccination should be consistent in each country where it is approved as part of integrated dengue prevention efforts that include vector control, disease management and surveillance.

SYMPTOMS AND TREATMENT

Dengue clinical symptoms include high fever, severe headache, with or without rash, and possible bleeding complications. The fever can progress to dengue hemorrhagic fever, which can lead to dengue shock syndrome and in rare cases death. There is no specific medication for treatment of a dengue infection.
HEPATITIS A

Hepatitis A is caused by a virus resulting from an acute inflammation of the liver and is the most common form of all viral hepatitis as a result of a lack of safe water, and poor sanitation and hygiene. It is encountered frequently in urban areas but the incidence rates differ according to geographical regions and socio-economic levels. The hepatitis A virus (HAV) is transmitted through ingestion of contaminated food and water or through direct contact with an infectious person.

Approximately 1.4 million cases are reported each year73. Despite progress in sanitation and hygiene, hepatitis A occurs sporadically and in epidemics worldwide, with a tendency for cyclic recurrences. The disease can lead to significant economic and social consequences in communities. The impact on food establishments identified with the virus, and local productivity in general, can be substantial. Epidemics related to contaminated food or water can erupt explosively, such as the epidemic in Shanghai in 1988 that affected about 300,000 people74.

SYMPTOMS AND TREATMENT

Hepatitis A is often asymptomatic in young children, and more severe in adults. The onset of the disease is marked by a sensation of generalized malaise including, fever, headache, muscle soreness, fatigue, and gastrointestinal disorders; often accompanied by jaundice, particularly in adults75.

There are vaccines available for Hepatitis A.
HEPATITIS B

Hepatitis B is caused by a virus (HBV) which results in an inflammation of the liver. An estimated 257 million people are living with a hepatitis B virus infection (defined as hepatitis B surface antigen positive). HBV is transmitted primarily through blood, and to a lesser extent by other body fluids.

In 2015, hepatitis B resulted in 887,000 deaths, mostly from complications (including cirrhosis and hepatocellular carcinoma). The vaccine can help prevent infection and the development of chronic disease and liver cancer due to hepatitis B. Sanofi Pasteur has been providing vaccines to protect against Hepatitis B for more than thirty years. Today, the most common administration route is with other childhood vaccines in a pentavalent or hexavalent combination. Sanofi Pasteur distributes vaccines to help protect against hepatitis B in more than 120 countries.

SYMPTOMS AND TREATMENT

Acute hepatitis B is usually associated with a loss of appetite, weakness, nausea, abdominal pain, jaundice, skin rash, and joint pain; risk of transition to a chronic state is frequent among immune-depressed individuals and newborns.

Following HBV infection, 5% of patients will develop chronic hepatitis (i.e., persistence of HBV in the body) with the potential risk to develop cirrhosis and liver cancer. Vaccines for Hepatitis B are available.
INFLUENZA

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. The WHO recommends vaccination as the most effective way to prevent influenza.

As a global leader in influenza vaccination, Sanofi Pasteur distributed over 200 million doses of influenza vaccines in 2017 and is committed to increasing vaccination coverage while working continuously to broaden protection against influenza.

SYMPTOMS AND TREATMENT

Seasonal influenza is characterized by a sudden onset of fever, cough, headache, muscle and joint pain, severe malaise (feeling unwell), sore throat and a runny nose.

High-risk patients for developing severe or complicated illness, (see above) should be treated with antivirals in addition to symptomatic treatment as soon as possible.
Japanese encephalitis, a mosquito-borne flavivirus, is the main cause of viral encephalitis in Asia. With approximately 67,000 cases and up to 20,000 deaths reported each year, Japanese encephalitis is the most frequent and most severe viral encephalitis, and the leading cause of viral neurological infection among children in Asia.

As there is no cure for the disease, treatment focuses on relieving severe clinical signs and supporting the patient to overcome the infection. Sanofi Pasteur partners with global organizations and governments in affected countries to ensure maximum protection for those at risk.

Sanofi Pasteur manufactures and distributes a vaccine for Japanese encephalitis mostly in Asia, in endemic countries.

**SYMPTOMS AND TREATMENT**

The disease is characterized by abrupt onset of high fever accompanied by headaches, behavioral changes, as well as speech and motor disorders (paralyses). Evolution of the disease is marked by the gradual onset of consciousness disorders that can evolve into coma. The mortality rate is high and sequelae are common, especially among children (up to 50%).

There is no specific treatment for the disease.
VIRAL DISEASES

POLIOMYELITIS

Over the centuries, Polio has wiped out millions of lives. In 1988, close to 1,000 cases of paralytic polio were recorded every day in 125 endemic countries. It was at that point that the World Health Organization took action and launched the Global Polio Eradication Initiative.

As a health journey partner, Sanofi Pasteur has been involved in this fight from the very beginning. We have provided more than 6 billion doses of oral polio vaccine and more than one billion doses of IPV and IPV-containing combination vaccines which made the final stage of the Eradication Initiative program possible. Today, the number of cases has decreased by more than 99% globally. We could be soon living in a polio-free world.

SYMPTOMS AND TREATMENT

In most cases, the infected patient will remain asymptomatic or present only a influenza-like syndrome similar to that observed with other benign viral infections.

In less than 1% of cases however, irreversible paralysis can develop resulting in sequelae of various intensity and sometimes death.

No specific antiviral treatment is available.
Rabies is a vaccine-preventable viral disease transmitted to humans by infected animals, occurring in more than 150 countries and territories. Once clinical symptoms appear, it is always fatal. An average of 60,000 people die from rabies annually, and more than 15 million people receive post-exposure treatment every year. Four out of every ten deaths due to rabies are in children younger than 15 years old.

In developing countries, rabies is transmitted mainly by rabid stray dogs through a bite, scratch or licking of damaged skin or mucosa, and is still considered a major public health concern, causing tens of thousands deaths each year.

The WHO recommends vaccination for individuals at high risk including sub-populations in highly endemic settings, those at occupational risk, and travelers who may be at risk for exposure.

Since 1977, Sanofi Pasteur has offered life-saving vaccines for this disease. To date, vaccination remains the only effective treatment against rabies and acts by neutralizing the virus before it actually reaches the central nervous system. We manufacture vaccines to help protect against rabies in more than 80 countries each year.

**SYMPTOMS AND TREATMENT**

Following infection, the virus replicates and spreads through the entire body; first signs include pain or an abnormal sensation at or around the wound, followed by other non-specific symptoms such as fever, anorexia, nausea, vomiting, headaches, malaise, and lethargy.

Vaccination is the only effective treatment, and acts by neutralizing the virus before it reaches the central nervous system.
VIRAL DISEASES

YELLOW FEVER

Yellow fever is a viral hemorrhagic fever that is transmitted by mosquitoes. Each year, 200,000 cases of yellow fever occur of which 30,000 are fatal. The disease is a threat for over three million travelers visiting endemic regions each year.

Yellow fever was once one of the most feared epidemic diseases in the world with the capacity to bring devastation to almost every continent. Mass vaccination campaigns in the mid-20th century succeeded in bringing the disease under control for over 40 years. However, since the late 1980s, this deadly disease has returned, putting a new generation at risk in West and Central Africa and threatening to erupt into devastating urban epidemics.

In 2016, Sanofi Pasteur shipped more than 15 million vaccine doses to Africa to respond to yellow fever outbreaks on the continent, with more than 415 million doses distributed worldwide since vaccine launch in 1979. Currently, we have yellow fever vaccines registered in more than 100 countries. According to the WHO, a single dose of yellow fever vaccine can provide lifelong protection.

SYMPTOMS AND TREATMENT

The first signs of the disease typically include fever, chills, muscle pain, and headaches, suggestive of influenza, dengue or malaria. In the most severe forms of the disease, a transient remission is followed by the onset of a hemorrhagic syndrome associated with vomiting of black blood, jaundice, renal failure. The outcome is fatal in 20 to 50% of cases.

Aside from vaccination, no specific antiviral treatment is available against yellow fever.
Sanofi Pasteur’s Journey

HELPING PROTECT THE WORLD AGAINST SEVERAL INFECTIOUS AND SEVERE DISEASES AT EVERY STAGE OF LIFE FOR MORE THAN ONE HUNDRED YEARS.
Louis Pasteur's work revolutionized modern medicine. By establishing a link between infections and microorganisms in 1857, Louis Pasteur left his mark on science and medicine with one of the most important breakthroughs in the history of medicine.

His discoveries paved the way for the development of the first vaccines, namely the rabies vaccine. Louis Pasteur also helped to improve hospital practices, thereby increasing control over infectious diseases.

A scientific visionary

Louis Pasteur spearheaded a fundamental breakthrough in food and hygiene with pasteurization, a process that kills pathogenic microorganisms in perishable foodstuffs.

Pasteur devoted the latter years of his life to founding Institut Pasteur, a non-profit organization geared towards disease prevention and treatment.

Sanofi Pasteur is still a partner with Institut Pasteur to this day.

Sanofi Pasteur has a proud history of innovation in vaccination. We continue to draw inspiration from the pioneers who laid the foundations of our company.
A vaccine technology trailblazer

In 1897, Richard Slee founded the Pocono Laboratories in Swiftwater, Pennsylvania, to house the production of a new breed of smallpox vaccine. Dr. Slee learned this innovative method of production from vaccine pioneer Louis Pasteur.

His work vastly improved smallpox vaccination in the U.S. More than 100 years later, his legacy remains. The World Health Organization (WHO) declared smallpox officially eradicated in 1980. The facility that housed his former laboratory has become the U.S. location of Sanofi Pasteur.

Three generations of innovators

Marcel, his son, Charles, and his grandson, Alain – dedicated their lives to protecting people from infectious diseases. The most important contribution of the Mérieux Institute was the development of industrial-scale vaccine production methods, allowing large numbers of people to be vaccinated in a relatively short period of time.

In 1974, techniques developed by the Institute prevented an epidemic of meningococcal meningitis in Brazil, where 90 million people were immunized in nine months.

Canada’s public health pioneer

John FitzGerald had a vision of producing life-saving public health products at prices within everyone’s reach. Founded by FitzGerald in 1914, Connaught Laboratories grew rapidly, producing vaccines and serums against diphtheria, smallpox, tetanus, and meningitis. The Laboratories also made important contributions to the battle against polio.

After he developed the first injectable polio vaccine, Dr. Jonas Salk used techniques developed by Connaught scientists to produce his vaccine on a large scale, helping to bring an end to the epidemic in North America in the 1950s.
SANOFI PASTEUR’S LEGACY

We partner with the public health, medical and scientific communities to improve access to life-protecting vaccines and increase vaccination coverage, while striving to develop new and improved vaccines to enhance health and well-being.

- **Over half a billion people** vaccinated with Sanofi Pasteur vaccines worldwide
- **A world leader** in influenza and pediatrics vaccines, first worldwide supplier of polio injectable vaccine
- **World-class partnerships** that span major universities, research institutes, government bodies, biotechnology companies and contract research organizations
- More than **15,000 employees** globally, 60% of them dedicated to manufacturing and quality operations
- **€5,101 million in sales** (as of December, 2017)
- Sanofi Pasteur supplies **500 million doses** of vaccine to UNICEF or other international organizations annually

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OUR VACCINES: A HISTORY OF INNOVATION

At Sanofi Pasteur, we work every day to realize our vision of a world in which no one suffers or dies from a vaccine preventable disease. This requires high-quality, well-tolerated and innovative vaccines to combat infectious diseases, a reliable supply, and collaboration with the public health community to ensure vaccines are available for generations to come.

Since the beginning of the 20th century, many discoveries have been made in vaccines. Innovation is crucial. Combination vaccines (which reduce the total number of injections), those that protect against multiple diseases, are one of the strengths of our product range. They offer the advantage of simplifying vaccination schedules, decreasing health-related costs, and ensuring better comfort as a result of reduced injections.

These dates are of first license for Sanofi Pasteur’s major products. After 1996, dates correspond to when marketing authorization was first obtained. Some vaccines listed on the timeline are no longer available. Please refer to your local health authorities for information on current vaccines.

### Timeline

- **1907**
  - Sera production

- **1922**
  - First tetanus vaccine

- **1939**
  - New application of the percutaneous reaction
  - First use of the Mérieux tuberculine

- **1946**
  - Anti-pertussis serum

- **1953**
  - Yellow fever vaccine

- **1955**
  - First Salk (inactivated) polio vaccine (injectable)

(a) or from the companies which preceded it in its current legal status

(b) Institut Biologique Mérieux

(c) Institut Mérieux

(d) By Connaught Laboratories, bought by Institut Mérieux

(e) Merger of Institut Mérieux & Institut Pasteur Production created in 1973: Pasteur Vaccins is founded

(f) By Pasteur Mérieux Sérum & Vaccins, created in 1990

(g) Pasteur Mérieux Connaught

(h) By Aventis Pasteur, new name of Pasteur Mérieux Connaught after the merger of Rhône-Poulenc and Hoechst Life Sciences activities in 1999, to form a single company, Aventis
Improving the world’s health entails developing new solutions to illnesses that affect people around the globe. Sanofi Pasteur makes innovation the heart of its strategy and spends more than €500 million a year on researching and developing new vaccines.

Sanofi Pasteur’s R&D teams closely follow the latest technological advances around the world in an effort to develop vaccines against new infectious disease targets (diseases for which there is still no means of prevention) and improve existing ones to advance global access.

Our Team’s Latest Developments:

• An influenza vaccine containing a fourth strain for broader coverage. The quadrivalent influenza vaccine formulation includes 2 A strains and 2 B strains to better fit the current epidemiology as per the World Health Organization recommendations.

• A combined pediatric vaccine, for the prevention of six major childhood diseases (diphtheria, tetanus, pertussis or whooping cough, polio, Haemophilus influenzae type B, hepatitis B). This vaccine is given as a single injection at each doctor’s visit throughout the recommended vaccination schedule.

• A dengue vaccine, the first one developed against the disease, which is transmitted by mosquitoes in tropical and subtropical areas around the world.

Our Programs in Development

• Vaccines against infectious diseases, such as respiratory syncytial virus (RSV), for which no vaccine exists.

• Vaccines against endemic diseases, such as HIV/AIDS, developed as part of the P5 public-private partnership.

• Improved existing vaccines, such as the second-generation rabies vaccine and a new meningitis vaccine.

• Vaccines to address the risk of pandemic influenza.
Sanofi Pasteur has implemented an ongoing investment program in building internal production capabilities.

The increasing population, efforts to improve health worldwide and emergence of new diseases all contribute to the mounting need for vaccines. **Sanofi Pasteur is continuously investing in state-of-the-art technologies to meet this growing demand.**

This diversification means we must optimize production capacities to meet anticipated demands for current and new vaccines, through a variety of capital improvement programs.

**We are investing in leading-edge manufacturing approaches, including:**

- Large-scale cell culture
- Large-scale viral production
- Bacterial conjugate vaccine production
- Inactivation and detoxification technologies
- Combination vaccine production technologies
Journey of a Vaccine

VACCINE RESEARCH IS LONG, COMPLEX AND COSTLY. OUR TOP PRIORITY IS TO PROVIDE VACCINES TO PROTECT PEOPLE’S HEALTH. IT TAKES BETWEEN 6 TO 36 MONTHS TO PRODUCE, PACKAGE AND DELIVER HIGH-QUALITY VACCINES.
**THE COMPLEX JOURNEY OF VACCINE**

**PRE-DEVELOPMENT STAGE:** 2 to 4 years - Identifying antigens to prevent or treat a disease. Selected candidate vaccines will continue development.

**PRE-ClinICAL STAGE:** 1 to 3 years - Assessment of antigen safety and selecting the best candidate vaccines to continue the process.

**CLINICAL:** 6 to 8 years - Being the candidate vaccines in humans.

**MANUFACTURING CHAIN**

1. **RAW MATERIAL RECEPTION**
   - All incoming raw materials are checked for conformance with the quality specifications.

2. **BULK ANTIGEN MANUFACTURING**
   - The active ingredient of the vaccine is manufactured. This is one of the most critical steps in the production of high-quality, safe and efficacious vaccines.

3. **FILLING**
   - The vaccine is filled into a vial or a syringe.

4. **PACKAGING**
   - The vaccine is labeled in accordance with regulatory requirements and packed, ready for shipping.

5. **LOT RELEASE**
   - Quality assurance confirms the product has been manufactured and tested in accordance with the correct procedures. The national regulatory authority gives the final authorization to release the product for distribution.

6. **SHIPTMENT**
   - Most vaccines require “cold chain” temperature control of 2-8°C from the warehouse to customers’ destinations.

**THE NEW VACCINE DEVELOPMENT PROCESS VARIES AND TAKES ON AVERAGE AT LEAST 10 YEARS**

**RESEARCH & DEVELOPMENT**

1. **RESEARCH**
   - All of the results that have been collected during the preclinical stage are analyzed and the regulatory assessment is made prior to approval for marketing authorization.

2. **APPREOVED: POSITIVE BENEFIT/RISK BALANCE**
   - Phase IV: Studies done post-licensure to gather additional information, including the vaccine’s performance in various populations.

**MANUFACTURING**

3. **FORMULATIONS**
   - The active ingredients are combined together with other vaccine ingredients.

4. **FILLING**
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**REGISTRATION**

6. **QUALITY ASSURANCE**
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**THE NEW VACCINE DEVELOPMENT PROCESS VARIES AND TAKES ON AVERAGE AT LEAST 10 YEARS**

**DEVELOPMENT**

1. **RESEARCH**
   - Design and support the development of novel vaccine candidates and demonstrates pre-clinical proof of concept.

2. **DEVELOPMENT**
   - Lifecycle management of vaccine candidates: development of project planning, clinical trial execution and sample testing, approval.

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7. **CONCLUSION**
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**THE COMPLEX JOURNEY OF VACCINE**

**THE NEW VACCINE DEVELOPMENT PROCESS VARIES AND TAKES ON AVERAGE AT LEAST 10 YEARS**

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Sources & glossary
SOURCES


64. WHO. *Pertussis vaccines.* WHO position paper. Weekly Epidemiological Record. 28 Jan. 2005; No.4, 80; 29-40.


**Adjuvant**
An added substance in a vaccine to enhance the immune response.

**Antibody**
Antibodies are large Y-shaped proteins. They are recruited by the immune system to identify and neutralize foreign objects like bacteria and viruses. They are also known as immunoglobulins.

**Antigen**
A foreign substance in the organism, identified by the immune system which produces antibodies specifically to attack it. Antigens are usually proteins contained in foreign bodies or cells (transfused red blood cells, transplanted organs, bacteria, viruses, etc.) or present in the environment (pollen, waste produced by dust mites, cat hair, etc.).

**Attenuated**
Weakened; in the field of immunization, this refers to the weakening of a virus or a bacterium in order to neutralize its capacity to cause disease, while inducing an immune response.

**Bacteremia**
The transient presence of bacteria in the body's bloodstream.

**Bacterium**
A single-cell microorganism without a nucleus (prokaryote) whose genome is composed of DNA (1 single chromosome).

**Booster injection**
Administration of a vaccine in a subject having previously received an initial vaccination (with one or several vaccine doses). The booster is designed to top the immunity acquired during prior vaccine administration.

**Encephalitis**
Inflammation of the brain (composed of the cerebrum, the brain stem and the cerebellum).

**Epiglottitis**
Inflammation of the epiglottis. The epiglottis is a flap of tissue that sits beneath the tongue at the back of the throat. Its main function is to close over the windpipe while eating, to prevent food entering the airways.

**Erythema**
Redness of the skin.

**FDA**
Abbreviation for the Food and Drug Administration, the American government body in charge of examining the efficacy and safety of drugs and vaccines.

**Immune protection**
Describes a sufficient level of immunity to protect an individual against infection. Immune protection is built through immunization or after a specific disease.

**Lymph node**
A small knot of lymphatic tissue designed to filter, attack and destroy harmful microbes. Part of the network of nodes spread throughout the organism to fight infection.

**Macrophage**
A phagocytic tissue cell of the immune system that may be fixed or freely motile, is derived from a monocyte, functions in the destruction of foreign antigens (such as bacteria and viruses), and serves as an antigen-presenting cell.

**Memory cell**
T and B lymphocytes which control the immune system's capacity to recall a specific invader and prevent it from causing future infection.

**Mutate**
To change shape, quality or any other characteristic.

**Non-specific immune system**
Set of defense mechanisms nonspecific to a given microorganism (the skin, macrophages, etc.), in other words, which exists in the absence of prior contact with the microorganism.

**Pancreatitis**
Inflammation of the pancreas.

**Polysaccharide**
A carbohydrate polymer or sugar found in bacteria capsules.

**Prodromal fever**
Fever marking the onset of a disease.

**Septicemia**
Serious infection of the organism characterized by the presence of pathogenic organisms in the bloodstream (liable to cause disease).
Specific immune system

Set of defense mechanisms specific to a given agent (microorganism). In the absence of prior contact, the response will be delayed by several days. Includes cell immunity (via T lymphocytes) and humoral immunity (via B lymphocytes).

Stabilizer

Chemical additive which helps to maintain a vaccine’s properties during transportation and storage.

Sterile

Free from living organisms or contaminants.

Toxin

Toxic substance secreted by a bacterium to which it confers its pathogenic power.

Toxoid

A toxin which has lost its toxic properties through physical or chemical treatment but which retains its antigenic power.

Virus

Tiny microorganism (100nm) composed of RNA or DNA which relies on the components of a host cell in order to multiply.
This booklet is a reference guide that provides you with an overview of our commitment to developing high-quality vaccines and our vision of a world in which no one suffers or dies from a vaccine-preventable disease.

Sharing Our Passion for vaccines means understanding the history of vaccination and its **value to public health**. It also means understanding **how vaccines work with your body’s natural immune system** and the **complex development cycle**. By sharing and building on our passion, we continue to lead the way in maximizing the impact of vaccination to build a healthier future for everyone.