

**sanofi pasteur**

The vaccines division of sanofi-aventis Group

**sanofi aventis**

Because health matters



# Press Kit

**Sanofi Pasteur – world leader in vaccines**

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CIRC.07/05/COM/087

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## **SANOFI PASTEUR – LEADING PROVIDER OF VACCINES**

**Sanofi Pasteur is the vaccines division of sanofi-aventis Group, a leading global pharmaceutical company that discovers, develops and distributes therapeutic solutions to improve the lives of everyone.**

**Sanofi Pasteur is the largest company entirely dedicated to vaccines. The company produced more than 1.6 billion doses of vaccine in 2008, making it possible to immunize more than 500 million people across the globe.**

**A world leader in the vaccine industry, sanofi pasteur offers the broadest range of vaccines, protecting against 20 infectious diseases.**

**Sanofi Pasteur's vision is a world in which no one suffers or dies from a vaccine-preventable disease.**

**Sanofi Pasteur's mission is to protect and improve human health worldwide by:**

- **Providing superior, innovative vaccines for the prevention and treatment of disease**
- **Playing an active role in the immunization community to maximize vaccination**

## **SANOFI PASTEUR: A GLOBAL COMPANY**

- **Headquarters: Lyon, France**
- **Revenue: 2,861 million euros in 2008, a 9.6% increase from 2007\***  
(\*on a comparable basis)
- **Market share: approximately a quarter of the world's vaccine market**
- **R&D and industrial sites worldwide**
  - France (Marcy l'Etoile, largest industrial site dedicated to vaccines worldwide, and Val de Reuil)
  - United States (Swiftwater, PA; Cambridge and Canton, MA; Rockville, MD)
  - Canada (Toronto)
  - Argentina (Pilar), China (Shenzhen), Thailand (Chachoengsao)

## **SANOFI PASTEUR: PEOPLE**

- **Wayne Pisano: President and Chief Executive Officer**
- **11,000 employees worldwide (December 2008)**

## **SANOFI PASTEUR: INVESTMENT IN RESEARCH AND PRODUCTION CAPACITY**

- **Largest product range available, against 20 infectious diseases**
- **R&D investment: 425 million euros invested in 2008**
  - 18 vaccines in development or submitted (entirely new vaccines or improved versions of existing vaccines)
- **Production capacity: nearly 1.5 billion euros invested in the last 5 years (2004 -2008)**
  - In 2008 sanofi pasteur inaugurated a high-tech, 100-million euro vaccine-production facility in Val de Reuil, France. This facility is part of a 200-million euro investment plan at this site

- The construction of a new vaccine production facility in China began in 2008 with the aim of producing seasonal influenza vaccine for the Chinese market starting in 2012
- In 2007, sanofi pasteur completed the construction of a new influenza vaccine production facility in the USA, with an investment of 150 million dollars
- Other key investments include:
  - Increased production capacity for inactivated polio vaccine (IPV) to help polio-free countries implement international health standards
  - Increased production capacity for quadrivalent conjugate vaccine against four different types of meningococcal meningitis (serogroups A, C, Y and W-135)
  - A new building for visual inspection of vials and syringes

**GLOBAL COMMITMENT TO IMPROVE PUBLIC HEALTH****BROADEST RANGE OF VACCINES**

**Today, according to the World Health Organization, vaccines are available to protect against more than 26 infectious diseases.**

**Sanofi Pasteur has the broadest range of vaccines around the world, protecting against 20 infectious diseases:**

- **World's largest provider of seasonal influenza vaccines: over 170 million doses in 2008**
- **Leading provider of poliomyelitis vaccine and the largest corporate donor to the Global Polio Eradication Initiative (GPEI)**
- **Range of modern pediatric combination vaccines for children throughout the world**
- **World's largest provider of vaccines against meningococcal infections; Sole international provider of vaccine against meningococcal meningitis to fight epidemics in Africa**
- **Largest portfolio of vaccines for travelers and people living in endemic areas**

**INFLUENZA: MEETING ESCALATING DEMAND**

The WHO estimates that influenza causes up to 500,000 deaths worldwide every year<sup>1</sup>; and demand for influenza vaccines is increasing. Sanofi Pasteur is the world's largest provider of influenza vaccines, providing more than 170 million doses of influenza vaccine in 2008. In July 2007, sanofi pasteur announced the completion of a new influenza vaccine production facility that is expected to double its production capacity in the United States, upon FDA approval.

**INTRADERMAL INFLUENZA VACCINE**

Current influenza vaccines are generally administered intramuscularly (IM). The intradermal (ID) route represents a promising alternative: the vaccine is administered into the dermis, or the top layer of the skin. In 2009, sanofi pasteur was granted marketing authorization for the first intradermal microinjection influenza vaccine in the European Union.

**POLIOMYELITIS: WORKING TOWARDS ERADICATION**

Sanofi Pasteur is a committed partner in the fight against polio. The company is the world's leading provider of poliomyelitis vaccine, with nearly 400 million doses

supplied each year to UNICEF and other international organizations and is the largest corporate donor to the Global Polio Eradication Initiative (GPEI). Since the creation of GPEI in 1988, cases of the disease have fallen by 99%<sup>2</sup>, with an estimated 5 million people escaping paralysis.

Sanofi Pasteur developed a monovalent oral polio vaccine (mOPV) per WHO's request as part of its strategy to eradicate polio. Fifty million doses of mOPV were used in Egypt, helping the country to attain polio-free status in 2006. In Saudi Arabia sanofi pasteur is the main provider of polio vaccine and recognized as a key contributor to polio eradication efforts in the country, declared polio-free in 2007. Russia, which has been polio-free since 2002, adopted IPV (inactivated polio vaccine) for its national immunization program for 2008, through a collaboration between the Chumakov Institute and sanofi pasteur.

**PEDIATRIC COMBINATION VACCINES: PROTECTING AGAINST CHILDHOOD DISEASES**

Sanofi Pasteur is committed to providing the same standard-of-care combination vaccines throughout the world, offering

protection against major childhood diseases such as diphtheria, tetanus, pertussis (whooping cough), polio, hepatitis B, and *Haemophilus influenzae* type b (Hib). Since 2007, a pentavalent pediatric combination vaccine (diphtheria, tetanus, acellular pertussis, inactivated poliomyelitis vaccine, and *Haemophilus influenzae* type b conjugate vaccine) from sanofi pasteur, is available to infants in Mexico and Turkey through the countries' national immunization programs.

On December 2008, Sanofi Pasteur was the first international vaccine company to launch a pediatric vaccine in Japan.

### **BOOSTERS: PROVIDING LONGER-LASTING PROTECTION**

A booster vaccine is a repeat shot that is used, at intervals, to maintain immunity. Sanofi Pasteur's latest booster vaccine is a combination against tetanus, diphtheria, pertussis (whooping cough), and polio. This booster vaccine allows parents and relatives to protect unvaccinated newborns from pertussis by stopping the transmission cycle of the disease.

### **MENINGOCOCCAL MENINGITIS: TACKLING MAJOR OUTBREAKS**

Sanofi Pasteur is the world's leading provider of vaccines to fight meningococcal infections. Sanofi pasteur has supplied vaccines for meningitis outbreak control in Africa for over 30 years and is today the sole international provider of meningitis A and C vaccines used to combat devastating annual epidemics occurring in sub-Saharan countries ("African meningitis belt" is the name given to the 17 countries most affected by the disease). Sanofi Pasteur is also the only company to provide a quadrivalent conjugate vaccine protecting against four different types of meningococcal meningitis (serogroups A, C, Y and W-135). The vaccine is licensed in the U.S. and Canada for people 2–55 years old.

### **PUBLIC HEALTH EMERGENCY**

In February 2008, 6 million doses of yellow fever vaccine were shipped in record time to help curb the epidemic devastating Brazil and Paraguay.

**VACCINES FOR TRAVELERS AND PEOPLE IN ENDEMIC AREAS: OFFERING A BROAD VACCINE PORTFOLIO**

Sanofi Pasteur provides the broadest range of vaccines for travelers, military personnel, and populations living in tropical areas where infectious diseases are endemic. The portfolio includes vaccines against cholera, diphtheria, hepatitis A and B, Japanese encephalitis, meningococcal diseases, rabies, tetanus, typhoid, yellow fever, and a range of antivenoms.

Over the past 20 years, nearly 20 million people in 100 countries have been treated

against rabies with sanofi pasteur vaccines and immunoglobulins.

With regard to yellow fever, its reemergence results in an estimated 200,000 cases and 30,000 deaths every year<sup>3</sup>. Sanofi Pasteur has been the primary supplier of yellow fever vaccine for Africa for 60 years. In the past 20 years, over 200 million doses of yellow fever vaccines were procured. Sanofi Pasteur has provided 6 million doses of vaccine for the stockpile funded by the Global Alliance for Vaccines and Immunization (GAVI) to control yellow fever outbreaks in Africa.

**PRODUCTION CAPACITY**

Sanofi Pasteur has the industrial-scale manufacturing ability to produce vaccines in large quantities, with the highest quality standards, to help fulfill public health needs. To meet the growing demand for vaccines, which should double by 2017, sanofi pasteur is continuously investing to increase production capacity. Over 1.5 billion euros have been invested between 2004 and 2008. For example, investments will enable sanofi pasteur's influenza vaccine production capacity to increase from 170 million doses in 2008 to nearly 400 million doses in 2016.

**SANOFI PASTEUR VACCINE PORTFOLIO**

- Cholera
- Diphtheria
- *Haemophilus influenzae* type b (Hib) infections
- Hepatitis A
- Hepatitis B
- Influenza
- Japanese encephalitis
- Measles
- Meningococcal infections
- Mumps
- Pertussis
- Pneumococcal infections
- Poliomyelitis
- Rabies
- Rubella
- Tetanus
- Tuberculosis
- Typhoid fever
- Varicella
- Yellow fever

And against one eradicated disease:

- **Smallpox** (vaccine produced in response to the threat of bioterrorism using strains of the smallpox virus)

**GLOBAL COMMITMENT TO IMPROVE PUBLIC HEALTH****AT THE FOREFRONT OF PANDEMIC INFLUENZA PREPAREDNESS**

**Sanofi Pasteur's leadership position in developing and producing influenza vaccines places the company at the forefront of readiness against the threat of pandemic influenza.**

**The company is committed to playing a leading role in the event of a pandemic by producing as many doses of sanofi pasteur's most advanced vaccine in the shortest possible timeframe.**

**A WORLD LEADER**

Sanofi Pasteur is the world's leading manufacturer of vaccines against seasonal influenza, a disease responsible for up to half-a-million deaths worldwide each year, according to WHO estimates. Sanofi Pasteur has two influenza vaccine production facilities worldwide in the United States and in France, where large investments have been made to increase production capacity. New vaccine production centers are under construction in China and Mexico to meet local needs.

This greater production capacity for seasonal influenza vaccines brings both immediate and long-term public health benefits. It enables the expansion of current influenza immunization programs and enhance sanofi pasteur's ability to respond effectively to the

current influenza pandemic. All influenza production sites have been designed to switch from production of seasonal influenza vaccine to pandemic vaccine.

**INDUSTRIAL-SCALE CAPACITY**

Sanofi Pasteur was the first company to employ its industrial-scale capabilities for the manufacture of a vaccine against an H5N1 influenza pandemic. Since 2004, millions of doses have been industrially produced, using different strains. In the current pandemic situation, the company is ready to produce large amounts of vaccine against the virus identified by the WHO as quickly as possible. Industrial and scientific expertise have enabled sanofi pasteur to produce H5N1 vaccines for several countries, including the

United States, France, and Italy for their national pre-pandemic stockpiles, as part of their pandemic preparedness programs. The production of A (H1N1) vaccine is under way.

### **CONTINUAL NEW RESEARCH**

Sanofi Pasteur invests heavily to support a priority research program for influenza.

This program has yielded unprecedented results showing that the lowest dose known today of a prototype H5N1 influenza vaccine, containing a new adjuvant, induces a strong immune response, thus allowing for the production of a large number of doses in the event of a pandemic. In collaboration with international health authorities, results from this program are being applied to the development of a pandemic vaccine against A (H1N1).

Sanofi Pasteur is also testing the ability of its vaccines to generate immune responses against other types (or strains) of influenza virus.

### **LEADING THE WAY IN PANDEMIC PREPAREDNESS**

Sanofi Pasteur is bringing its worldwide vaccine expertise to governments, international organizations, and working groups on all aspects of influenza pandemic preparedness and supports

dialogue between all partners to define vaccination strategies before a pandemic is declared.

Sanofi Pasteur supports the WHO initiative announced in June 2007 for the establishment of an international pandemic vaccine stockpile for developing countries.

In 2007, sanofi pasteur was the first to receive a license for a vaccine against avian influenza in humans from the U.S. Food and Drug Administration (FDA). Sanofi Pasteur is also a member of FLUPAN, a European Union-funded collaboration to improve the level of pandemic preparation in the EU. In March 2009, sanofi pasteur's prototype pandemic vaccine was approved by the Australian Therapeutic Goods Administration (TGA).

### **CONTINUITY OF ACTIVITIES**

Sanofi Pasteur has developed an internal preparedness plan in order to ensure the continuity of its industrial activities for large-scale production of a pandemic vaccine and for production of other key vaccines for public health needs should a pandemic be declared.

Sanofi Pasteur's response to the emergence of a new A(H1N1) influenza strain is to maintain maximum flexibility in its influenza vaccine production. The company has been continuing to manufacture its seasonal influenza vaccine for the 2009/2010 Northern Hemisphere influenza season as recommended by the World Health Organization (WHO). Production of both Northern and Southern hemisphere seasonal influenza vaccines is still a priority as seasonal influenza is a very serious illness causing 250,000 to 500,000 deaths per year.

The company operates influenza vaccine production facilities in Swiftwater, Pennsylvania, U.S.A., and Val de Reuil, France. All Sanofi Pasteur influenza vaccine facilities have been designed and built to be able to switch from seasonal influenza vaccine production to pandemic influenza vaccine production.

Sanofi Pasteur produces approximately 40 percent of the influenza vaccines distributed worldwide. For the 2008-2009 influenza season, the company produced more than 45 percent of the influenza vaccines distributed in the U.S.

Sanofi Pasteur's pandemic Influenza A(H1N1) 2009 vaccines are manufactured using the same production process as Sanofi Pasteur's seasonal influenza virus vaccines licensed by authorities:

- ✓ In Europe, Sanofi Pasteur developed two A(H1N1) 2009 pandemic vaccines: Panenza® (a 15 microgram-dose non-adjuvanted vaccine) approved in France on November 2009 and Humenza® (a 3.8 microgram-dose adjuvanted dose-sparing vaccine – Centralized European Licensure process on track).
- ✓ In the US, the company developed a 15 microgram-dose non-adjuvanted vaccine that was licensed by the U.S. Food and Drug Administration in September 2009 and that is indicated for active immunization of persons six months of age and older against influenza disease caused by pandemic A(H1N1) 2009 virus.

Sanofi Pasteur has signed agreements with many governments for the supply of A(H1N1) 2009 influenza vaccine:

- ✓ With the French Ministry of Health: agreement signed in July 2009 providing for the initial supply of 28 million doses. This agreement includes an option for an additional 28 million doses.
- ✓ With the U.S. government: agreements signed in May, July and September 2009, for the supply of a cumulated total of 75.3 million doses of FDA-licensed influenza A (H1N1) 2009 vaccine.
- ✓ With the Brazilian Ministry of Health: agreement signed in September 2009 in partnership with Butantan Institute (Sao Paulo, Brazil) providing for the supply of 18 million doses of A(H1N1) 2009 influenza virus vaccine. The agreement includes an option for an additional 15 million doses of A(H1N1) 2009.

In June 2009, the company announced its commitment to donate 100 million doses of pandemic influenza vaccine to the World Health Organization (WHO) and to reserve 10 percent of its output for the WHO as a donation to help the most vulnerable countries face the influenza pandemic.

Sanofi Pasteur remains in continuous communication with the WHO and health authorities around the world to help develop a tailored response to local public health needs.

More information about Sanofi Pasteur's pandemic preparedness efforts can be found at [www.pandemic.influenza.com](http://www.pandemic.influenza.com)

**GLOBAL COMMITMENT TO IMPROVE PUBLIC HEALTH****VACCINES FOR TOMORROW**

The process to develop a new vaccine can take between 14 to 25<sup>4</sup> years with an overall cost of US\$300 million to US\$1 billion<sup>5</sup>.

Sanofi Pasteur invests more than €1 million in research and development every day:

- 1,700 people working in research and development
- 18 vaccines in development or submitted for market authorization, including:
  - New vaccines against endemic diseases, such as dengue, and against hospital-acquired infections (*C. Difficile*), for which no vaccines exist yet
  - Next-generation vaccines such as a single-dose Japanese encephalitis vaccine
  - New vaccines or new generation vaccines for every stage of life

**DENGUE FEVER**

Dengue fever is a mosquito-borne disease caused by four types of dengue viruses (type 1 to 4). The disease is a threat to almost half of the world's population — more than 100 tropical and subtropical countries. Of the estimated 230 million people infected annually, two million, mostly children, develop dengue hemorrhagic fever<sup>6</sup>. The WHO has warned that the Western Pacific Region may be heading for a major dengue outbreak. Outbreaks recently have been observed in

Paraguay and the Middle East. In addition, dengue affects countries such as Australia (Queensland) and the United States (Puerto Rico, Texas-Mexico border, Hawaii and the US-affiliated Pacific Islands). A substantial number of people traveling to endemic regions are also infected each year.

Clinical studies of sanofi pasteur's tetravalent dengue vaccine are underway in endemic regions such as Asia and Latin America to determine the efficacy of the vaccine against the disease.

## HOSPITAL-ACQUIRED INFECTIONS

*C. difficile* is an anaerobic spore-forming bacterium, present asymptotically in approximately 60% of infants but only ~3% of healthy adults. Hospital-acquired infections caused by *C. difficile* bacteria are a major concern for public health in many industrialized countries. It is estimated that *C. difficile* infection (CDI) causes about 500,000 cases in the US alone, with annual costs to the healthcare system of \$3.2bn. In the EU, the healthcare costs of CDI are estimated to be around \$4.4bn per year. Sanofi Pasteur's candidate vaccine uses a toxoid-based approach, which has been used extensively in sanofi pasteur's licensed vaccines against tetanus, diphtheria and pertussis (whooping cough). This candidate vaccine has successfully completed Phase I clinical trials in more than 200 participants to evaluate its safety and immunogenicity. A Phase II study of a vaccine against *Clostridium difficile* is under way.

## JAPANESE ENCEPHALITIS

Approximately 30,000 to 50,000 people<sup>7</sup> suffer from Japanese encephalitis annually, mostly in Asia. Sanofi Pasteur is committed to the fight against this disease in endemic regions with the development of a next-generation, single-dose (only one injection to be immunized) Japanese encephalitis vaccine. Submission for registration of this vaccine to health authorities is planned for 2009.

## HUMAN IMMUNODEFICIENCY VIRUS (HIV)

Sanofi Pasteur is taking part in the global effort to develop an HIV vaccine. In the nearly 20 years since sanofi pasteur's HIV vaccine development program was established, the company has been collaborating with a number of leading governmental agencies and pharmaceutical companies. These partnerships have led to major advances in research, clinical study design, and implementation. An HIV prophylactic vaccine is currently in Phase III clinical trials in Thailand; the results will be announced in 2009.

**NEW AND IMPROVED VACCINES FOR EVERY STAGE OF LIFE**

- For **infants**, sanofi pasteur is continuing efforts toward polio eradication and preventing respiratory and meningeal infections that cause severe sequelae in infants; new **pediatric** combination vaccines are developed to immunize against up to six childhood diseases simultaneously, reducing the number of injections required, increasing coverage, and improving public health.
- For **adolescents**, sanofi pasteur scientists are making strides in four directions: combating sexually-transmitted infections, increasing protection against the devastating effects of meningitis, and developing booster vaccines against polio and pertussis.
- For **adults** and the **elderly**, sanofi pasteur is developing vaccines focused on the fight against respiratory tract infections such as influenza and pneumonia.

**AT THE CUTTING EDGE OF VACCINE DEVELOPMENT**

Sanofi Pasteur continually works to remain at the forefront of vaccine research and development. In 2008, the company invested 100 million Canadian dollars in an R&D centre in Toronto to boost innovation in vaccine research for global health. Whether alone or in collaboration with partners, sanofi pasteur is seeking new approaches to combat infectious

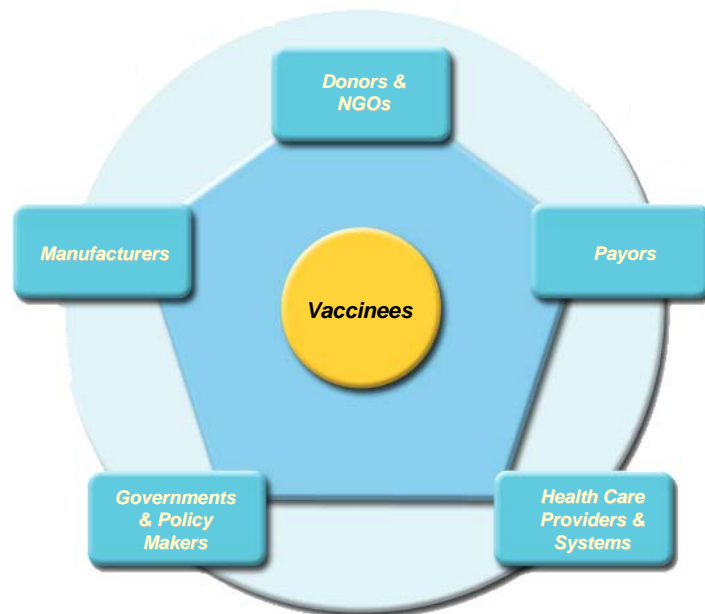
diseases. Several vaccines are under development stemming from agreements signed between sanofi pasteur and biotechnology industry partners. Research into disease epidemiology and basic immunology is also supported, underpinning the scientific rationale for vaccine development and improving knowledge of when and where vaccines are required most.

In the areas of research and knowledge sharing, sanofi pasteur maintains privileged partnerships with Fondation Mérieux (a non-profit organization founded in 1967 by Dr. Charles Mérieux). The Foundation contributes to medicine and the improvement of public health by organizing scientific events and training courses, publishing reports, and funding research. Since its inception, sanofi pasteur has supported many of the Foundation's events, such as the International Vaccinology Program.

**GLOBAL COMMITMENT TO IMPROVE PUBLIC HEALTH**

**PARTNERING WITH THE IMMUNIZATION COMMUNITY**

**Sanofi Pasteur works in partnership within the immunization community, including policy makers, donors, and non-governmental organizations (NGOs), to ensure that the largest number of people benefit from vaccination.**



**Immunization Community:** Partnerships and co-operation between members of the immunization community are essential if vaccines are to be supplied to those who need them most. Sanofi Pasteur works with many of the institutions represented in this diagram.

## **INTERNATIONAL ORGANIZATIONS**

Sanofi Pasteur supports the GAVI Alliance, a public-private partnership focused on increasing children's access to vaccines in poor countries. Partners include national governments, UNICEF (United Nations Children's Fund), WHO, The World Bank, the Bill & Melinda Gates Foundation, the vaccine industry, public health institutions, and non-governmental organizations (NGOs).

Sanofi Pasteur has ongoing partnerships with a number of international organizations, including UNICEF, to supply vaccines where they are needed most. In 2008, the company provided nearly 400 million doses of vaccine to UNICEF and other international organizations. Since 2003, sanofi pasteur provides 6 million doses of yellow fever vaccine each year for the stockpile funded by the GAVI Alliance to control outbreaks in Africa. For over 30 years, sanofi pasteur has supplied vaccines for meningitis outbreak control in Africa and is today the sole international provider of meningitis A and C vaccines used to combat devastating annual epidemics occurring in sub-Saharan countries (African meningitis belt).

The Pediatric Dengue Vaccine Initiative (PDVI) and sanofi pasteur have initiated a partnership to help develop and make widely available a dengue vaccine for the global prevention of dengue fever, the second most-widespread tropical disease after malaria<sup>8</sup>.

## **SUPPORTING IMMUNIZATION INFRASTRUCTURE**

The cost of vaccine administration, weak healthcare infrastructure, and in some cases conflict mean that many people living in the world's poorest countries do not have access to vaccines.

Sanofi Pasteur has developed specially adapted packaging and established tiered pricing policies in order to widen access to vaccines in developing countries. This strategy helps provide access to vaccines in countries supported by the GAVI Alliance.

Sanofi Pasteur and the partners of the GAVI Alliance have begun a major initiative to fight against the high epidemiological risk of yellow fever. In December 2006, 56 health officials from eight African countries at high-risk of yellow fever attended seminars and were educated about the use of vaccines to prevent infection. In December 2007,

these seminars were followed up by the first yellow fever technical conference in Ouidah, Benin.

Created and funded by sanofi pasteur, EPIVAC is a program designed by AMP (Agence pour la Médecine Préventive) to train doctors and healthcare workers involved in the implementation of immunization programs in 11 sub-Saharan countries. Since 2002, EPIVAC has trained nearly 350 doctors.

## PHILANTHROPIC INITIATIVES

Sanofi Pasteur's philanthropic activities are consistent with its core business and demonstrate—in an efficient and concrete way—the company's contributions to better health and unity for all, worldwide.

For the most vulnerable, sanofi pasteur donates large amounts of vaccines. This involves working with established NGOs to ensure vaccines are delivered to the targeted population.

Sanofi Pasteur is the principal corporate donor to the Global Polio Eradication Initiative (GPEI), the premier public health initiative in the world. Between 1997 and 2005, sanofi pasteur donated 120-million doses of oral polio vaccine for the immunization of children in five war-

ravaged African countries: Angola, Liberia, Sierra Leone, Somalia, and Southern Sudan.

Sanofi Pasteur supports Handicap International with a three-tiered program. The company funds two permanent Handicap International volunteers working in communities providing emergency relief and long-term development support. It supplies vaccines to Handicap International in response to urgent needs. Sanofi Pasteur has a policy of matching donations from its own employees to this NGO.

Sanofi Pasteur works closely with Health Partners International, a non-governmental organization specializing in the distribution of donated medicines, medical supplies and vaccines to developed or developing countries. Sanofi Pasteur also has a long-term relationship with the Ontario March of Dimes. The Ontario March of Dimes was founded in 1951 to raise funds to eradicate polio in Canada. For 12 years sanofi pasteur has sponsored an award presented annually to a Canadian scientist, physician or researcher who has made an outstanding contribution in science or medicine to prevent, alleviate or eliminate a physical disability.

## RECENT DONATIONS

In 2009, sanofi pasteur supplied Mexican authorities with nearly 250,000 doses of vaccine against influenza.

In 2008, sanofi pasteur donated over 660,000 doses of vaccine and financially supported over 500 projects:

- Vaccine donated to Azerbaijan and Armenia against mumps, rubella and measles.
- Hepatitis A vaccine donated to Brazil after a flood.
- 350,000 vaccine doses donated to Health Partners International of Canada (HPIC) for people most in need.

In Indonesia, sanofi pasteur is committed to donating 1.5 million doses of IPV within 5 years (2007-2011) for a pilot program under the patronage of WHO and the Indonesian government. The goal is to evaluate the switch from OPV to IPV in a tropical setting. Approximately 50,000 newborns will be vaccinated with IPV each year.

## VACCINATION BASICS

### THE VALUE OF VACCINES

Apart from clean, safe drinking water, no human action rivals immunization in preventing infectious diseases and reducing mortality rates<sup>9</sup>. Vaccination saves lives: more than 2.5 million lives every year<sup>10</sup>, thanks to the vast range of vaccines providing protection from over 26 infectious diseases.

Vaccination also saves money, being one of the most cost-effective healthcare investments available. For instance, in the United States, a cost-benefit analysis indicates that every dollar invested in a vaccine dose saves up to US \$27 in health-care expenses<sup>11</sup>.

However, it remains important to develop improved vaccines and increase access to these vaccines, enabling even more lives to be saved. It is also important to recognize that vaccination is an ongoing challenge. History shows that a decrease in immunization coverage sets the stage for the reappearance of disease in previously protected populations. The resurgence of diphtheria in the 1990s in certain Eastern European countries, with more than 125,000 cases and 4,000 deaths reported<sup>12</sup>, illustrates that continued vigilance is crucial to controlling and eradicating some infectious diseases in the future.

### REDUCING THE BURDEN OF DISEASE

Since 1988, reported cases of polio have fallen by 99% with an estimated 5 million people escaping paralysis<sup>11</sup>.

## WHAT IS IMMUNIZATION?

Infectious diseases are a major cause of death, in particular among children and young adults. Infectious diseases are caused by microorganisms such as viruses, bacteria, parasites or fungi. They are present everywhere and may survive in many types of environments (soil, water, food) or hosts (humans, animals).

Vaccination can protect against these diseases. It provides an individual with protection from an infection by stimulating an immune reaction and thereby boosting the natural defenses of the body.

Vaccines are produced from whole bacteria or viruses, from their components (polysaccharides, proteins), or the substances they secrete (toxins), in which their capacity to provoke a disease has been eliminated while keeping intact their ability to induce a specific immune response. The immune response stimulated by a vaccine is vital to ensure that enough antibodies are made and that the body's natural defenses are able to fight off any infection in the future.

## MAIN VACCINE TYPES

### Live attenuated vaccines

The bacteria or virus is weakened. Its ability to cause disease is removed, either by growing it in a certain way or by using physical or chemical treatments. But the pathogen is still able to produce an immune response.

**Examples:** Mumps, measles, rubella, polio (oral), yellow fever, tuberculosis.

### Inactivated vaccines

Inactivated vaccines can be produced from the whole microorganism or only parts of it. Whole germ vaccines are made from the entire pathogenic agent, which is killed using chemicals or heat, without altering its immunogenicity. Sub-unit vaccines only comprise those parts of the infectious agent necessary to obtain an immune response (antigens).

**Examples:** Diphtheria, tetanus, pertussis, Hib, meningococcal infections, Typhoid fever, pneumococcal infections, influenza, rabies, polio (injectable), hepatitis A, Japanese encephalitis.

### Recombinant vaccines

Recombinant vaccines are produced by genetic engineering. Other animal cells or yeasts can be used as 'antigen-factories' producing large amounts of vaccine antigen, which are then used to produce an immune response.

**Example:** Hepatitis B.

## THE VACCINE DEVELOPMENT CYCLE

Vaccine research is long, complex and costly. Because a vaccine is a biological product made from living microorganisms, its development cycle is quite different from that of a pharmaceutical product:

- **Exploratory stage:** to understand the disease, its epidemiological data and the right proteins (antigens) to use in preventing or treating the disease
- **Pre-clinical stage:** to assess antigen safety and select the best candidate vaccine
- **Clinical development:** a dozen (Phase I) to thousand people (Phase III) are involved in clinical trials and the first batches are produced (clinical batches and industrial batches for compliance)
- **Regulatory approval:** all the data collected through the preceding stages are submitted to the relevant health authorities for approval
- **Manufacturing process:** takes 6–22 months to produce a single batch of vaccine
- **Quality control:** approximately 70% of production time is dedicated to quality control and pharmacovigilance procedures in the clinical development and production phases

## HISTORY AND HERITAGE

### FOUR PATHS, ONE DESTINY

The origin of sanofi pasteur dates back more than a century and is closely linked with the achievements of Louis Pasteur, the Mérieux family, John FitzGerald and Richard Slee. Although each followed a unique path, they shared one goal – protecting people from infectious diseases.

### LOUIS PASTEUR: A SCIENTIFIC VISIONARY

Louis Pasteur made a series of discoveries throughout his career that revolutionized modern medicine and laid the groundwork for the practice of microbiology. His contributions stem from his “germ theory of disease” – proving that infectious diseases are caused by microorganisms.



Further to this theory, Pasteur found that injecting a weakened form of a microorganism could protect the body from the diseases that it causes. This discovery led to the development of a number of vaccines, including the rabies vaccine, first

administered to a human in 1885. Pasteur dedicated the final years of his life to the establishment of Institut Pasteur, a non-profit organization that continues to work on protecting people from infectious diseases. Sanofi Pasteur has maintained a privileged relationship with the Institute.

### THE MÉRIEUX FAMILY: THREE GENERATIONS OF INNOVATORS

Profoundly influenced by the teaching of Louis Pasteur, Marcel Mérieux established the Institut Biologique Mérieux. Three generations of the Mérieux family—Marcel, son Charles and grandson Alain—dedicated their lives to protecting people from infectious diseases. The most important contribution of the Institut Mérieux was the development of industrial-scale vaccine production, allowing large numbers of people to be vaccinated in a relatively short period of time. In 1974, techniques developed by the Institute stopped an epidemic of meningococcal meningitis in Brazil, where 90 million people were immunized in nine months.



**JOHN FITZGERALD:  
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 an important contribution to the battle against polio.

After he developed the first injectable polio vaccine, Dr. Jonas Salk used techniques developed by Connaught scientists to produce polio vaccine on a large scale, bringing an end to the epidemics in North America in the 1950s.



**RICHARD SLEE:  
A VACCINE TRAILBLAZER**

In 1897, Richard Slee founded the Pocono Biological Laboratories in Swiftwater, Pennsylvania, to house the production of a new breed of smallpox vaccine. More than 100 years later, his legacy remains intact—smallpox has been officially eradicated globally since 1980, and his laboratory has grown to become the location of sanofi pasteur in the United States.



## SANOFI PASTEUR'S HISTORY

- 1885** Louis Pasteur creates the rabies vaccine.
- 1897** Profoundly influenced by the teachings of Louis Pasteur, Marcel Mérieux establishes Institut Biologique Mérieux. Across the Atlantic, Richard Slee opens the Pocono Biological Laboratories, which today houses the U.S. headquarters of Sanofi Pasteur.
- 1914** In Toronto, John Fitzgerald establishes a laboratory for the production of a diphtheria antitoxin. Formerly known as Connaught Laboratories, this is now the headquarters of sanofi pasteur in Canada.
- 1937** Charles Mérieux succeeds his father, Marcel. He develops a foot and mouth vaccine, which saves six million cattle during a severe epidemic in 1952. Industrial virology is born and applied to human medicine.
- 1967** Alain Mérieux succeeds his father, Charles, and Institut Mérieux becomes a worldwide player in the field of applied immunology.
- 1968** Rhône-Poulenc acquires a majority stake in Institut Mérieux.
- 1973** Institut Pasteur production site is created in Val de Reuil, France. The site will be acquired by Institut Mérieux in 1985.
- 1985** Institut Mérieux acquires Institut Pasteur production.
- 1989** Institut Mérieux acquires Connaught Laboratories and becomes the world leader in vaccines.
- 1990** Institut Mérieux becomes Pasteur Mérieux Sérums & Vaccins.
- 1994** Pasteur Mérieux Sérums & Vaccins becomes a wholly owned subsidiary of the Rhône-Poulenc Group.
- 1994** Pasteur Mérieux MSD is founded. Known today as Sanofi Pasteur MSD, it is a joint venture with Merck & Co. covering 19 countries in Europe.
- 1996** Pasteur Mérieux Sérums & Vaccins and Connaught Laboratories adopt the name Pasteur Mérieux Connaught.
- 1999** Rhône-Poulenc and Hoechst merge their life sciences activity—pharmaceuticals, animal health and crop science—to form a single company, Aventis. Pasteur Mérieux Connaught changes its name to Aventis Pasteur.
- 2004** Sanofi-synthelabo acquired Aventis, becoming sanofi-aventis Group. Aventis Pasteur becomes sanofi pasteur.
- 2008** Sanofi Pasteur acquired Acambis plc, a biotech company.
- 2009** Sanofi Pasteur acquired Shantha Biotechnics, a vaccine manufacturer based in India.

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