SANOFI PASTEUR, LEADING PROVIDER OF SEASONAL INFLUENZA VACCINES

WORLD’S LEADING INFLUENZA VACCINE MANUFACTURER

- Annual production capacity of Sanofi Pasteur seasonal influenza vaccines have doubled over the past ten years.

In 2012, Sanofi Pasteur confirmed its leadership by completing a record production of over 200 million seasonal influenza vaccine doses, i.e., approximately 40% of the influenza vaccines distributed worldwide, representing:
  - more than one third of the Northern Hemisphere’s seasonal influenza vaccine production,
  - approx. 50% of the seasonal influenza vaccines distributed in the U.S.,
  - and approx. 75% of the Southern Hemisphere’s seasonal influenza vaccine total production.

- Sanofi Pasteur produces the vaccine against seasonal influenza on its two historic sites in the United States, in Swiftwater (Pennsylvania), Val-de-Reuil (France) and more recently Ocoyoacac (Mexico City, Mexico) and Shenzhen (China).

All Sanofi Pasteur production sites have been designed and built according to standards for Sanofi Pasteur to switch production of vaccine against seasonal influenza vaccine against pandemic influenza.

- Sanofi Pasteur’s seasonal influenza vaccines are licensed and distributed in more than 150 countries.
- More than 2.5 billion doses of Sanofi Pasteur seasonal influenza vaccines have been administered worldwide over the past 60 years.

According to the World Health Organization (WHO), seasonal Influenza is a serious public health problem that causes severe illnesses and deaths mainly among high-risk groups. Worldwide, these annual epidemics result in about three to five million cases of severe illness, and about 250,000 to 500,000 deaths.  

As the world leader in the research, development and manufacturing of influenza vaccine, Sanofi Pasteur is working to develop new and improved influenza vaccines to save lives.

- In April 2012, the European authorities have agreed to review the decentralized authorization application on the market for a quadrivalent formulation (including four strains) of Vaxigrip®, seasonal trivalent inactivated influenza vaccine that Sanofi Pasteur produces on the Val de Reuil production site (France).

- Sanofi Pasteur filed in October 2012, an additional application of Biologics License (Supplemental Biologics License Application sBLA) with the Food and Drug Administration (FDA) for a quadrivalent formulation of influenza vaccine Fluzone® produced in the Swiftwater site (United States). The sBLA application has been accepted by the FDA for a comprehensive review and a response date is scheduled for the second quarter of 2013.

- In May 2011, the U.S. FDA licensed Fluzone® ID 9 µg, Sanofi Pasteur’s new micro-needle seasonal influenza vaccine produced at Swiftwater, Pennsylvania, Sanofi Pasteur’s facility in the U.S. This vaccine is indicated for adults 18 to 64.

- Fluzone® High-Dose was licensed by the U.S. Food and Drug Administration (FDA) in December 2009.
  - This new influenza vaccine strengthens the immune response in people 65 years of age and older, an age group that suffers disproportionately from influenza and its complications.

- In February 2009, Sanofi Pasteur was granted marketing authorization by the European Commission for the first micro-needle seasonal influenza vaccine, Intanza® (also commercialized under the brand name of IDflu® in some countries of the world) produced at Val-de-Reuil Sanofi Pasteur’s facility in France.

The vaccine was launched in 2010 in more than 30 countries in Asia, Europe, Latin America and Oceania. It is being marketed under two dosages:

- 9µg (or IDflu® 9µg) for adults 18 to 59.
- 15µg (or IDflu® 15µg) for adults 60 and over.

- Sanofi Pasteur’s trivalent seasonal vaccines are formulated based on the WHO yearly recommendations. Since 2010, both-Southern and Northern Hemisphere-seasonal vaccines include the A(H1N1) 2009 pandemic strain.
An influenza pandemic represents a potential major risk for the global public health. To help as much as possible the health authorities address A(H1N1) 2009 pandemic threat, Sanofi Pasteur committed to producing as many doses of monovalent pandemic vaccines as fast as possible. Sanofi Pasteur’s teams worked around the clock, 7 days a week, and produced over 250 Million doses of non-adjuvanted A(H1N1) 2009 vaccine in 2009-2010.

Sanofi Pasteur's response to the emergence of the new A(H1N1) 2009 influenza strain was to maintain maximum flexibility in its influenza vaccine production. In close contact with world health authorities, the company had, in particular, accomplished concomitantly two key public health missions:

- To develop, produce and supply the A(H1N1) monovalent pandemic flu vaccine, in accordance with regulatory timeframes
- To produce and supply in 2009 and in 2010 the committed number of doses of seasonal influenza vaccines for the 2009/2010 Northern Hemisphere influenza season and for the 2010 Southern Hemisphere influenza season, in accordance with WHO and Health authorities recommendations.

The continuation of the seasonal flu vaccine production, as well for the northern and southern hemisphere, in parallel of the pandemic vaccine, remained a priority for the WHO and the world authorities of health, throughout pandemic alarm A (H1N1) 2009.

Sanofi Pasteur’s non-adjuvanted A(H1N1) monovalent pandemic influenza vaccines have been manufactured in the U.S. (no trade mark) and in France (Panenza®).

These two vaccines:

- were licensed in their country of origin in September 2009 [Sanofi Pasteur’s A(H1N1) vaccine manufactured in the U.S.] and November 2009 [Panenza®],
- were prequalified for global use by the WHO in January 2010.

As a WHO requisite for vaccine distribution through the WHO, prequalification:

- is a key step towards ensuring the vaccine can be distributed in developing countries,
- and is an aid provided by the WHO to facilitate access to medicines that meet unified standards of quality, safety and efficacy.

Sanofi Pasteur signed in December 2009 a donation letter with the WHO, in line with the Company’s June 2009 commitment to donate to the WHO up to 100 million doses of A(H1N1) pandemic vaccine for distribution by the WHO to requesting eligible countries in need.

The donation was tailored to contribute to respond to the A(H1N1)2009 influenza pandemic to help protect the most vulnerable populations against the risk of pandemic influenza and comprised a previous commitment made by the company in 2008 in the context of the A(H5N1) pandemic threat.
First influenza vaccine was created in 1947 by the Pocono Biological Laboratories (founded in 1897) in Swiftwater, Pennsylvania (USA), now Sanofi Pasteur USA.

1968 and 1969: commercial launch of seasonal influenza vaccines by Institut Pasteur Production and by Institut Mérieux (France), now Sanofi Pasteur France.

In 1973: construction of the vaccine production facility in Val-de-Reuil, France, to date the world’s leading seasonal influenza vaccine production plant.

For the last five years, Sanofi Pasteur has been consistently investing in major expansions of its influenza vaccine production capacity in the United States, France, China, and Mexico.

- In May 2009, the U.S. Food and Drug Administration (FDA) licensed a new Sanofi Pasteur state-of-the-industry influenza vaccine manufacturing facility in Swiftwater, Pa., USA representing a 150 million dollar capital investment.
  - The new facility has approximately twice the capacity of the company’s existing facility in the US.
  - In total, Sanofi Pasteur produces a capacity of approximately 150 million doses of trivalent seasonal influenza vaccine per year in the U.S., comprised of:
    - 50 million doses from the existing facility,
    - and 100 million doses from the new facility when it is operating at full capacity.

- The company has finalized the construction of two new high-tech influenza vaccine manufacturing facilities located in Ocoyoacac, Mexico (operational since January 2012) and Shenzhen in China (operational in 2013), with the aim of producing seasonal influenza vaccine for the Chinese and Mexican national markets.

- Recent investments (€250 million) were also made in Val de Reuil, France, to build new high-tech centers:
  - a filling and packaging facility came online in 2008 and helped respond to soaring influenza and other vaccine demand worldwide,
  - and a formulation facility, operational since 2012.
  - Investments also include continuous quality improvement and regulatory updates.
  - These new facilities incorporate the latest technology in vaccine production and will enable Sanofi Pasteur to fulfill its commitment to provide vaccines that meet the highest standards of quality to protect people from infectious diseases wherever they live.
SANOFI PASTEUR’S COMMITMENT TO PRODUCE VACCINES OF THE HIGHEST QUALITY

- Sanofi Pasteur is committed to providing its customers with vaccines of the highest purity, potency and safety.

- All Sanofi Pasteur influenza vaccines:
  - are manufactured in accordance with current Good Manufacturing Practices (GMP),
  - and comply with the Company’s specifications, and with the specifications approved by the Food and Drug Administration of the United States of America for vaccines manufactured in the US and by the Agence Française de Sécurité Sanitaire des Produits de Santé (Afssaps, France) for vaccines manufactured in France as well as the Mexican and Chinese regulatory authorities for vaccines produced respectively in Mexico and China.

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