THE ONLY FULLY-LIQUID, READY TO USE 6-IN-1 PEDIATRIC VACCINE

ONE VACCINE, A PROTECTION AGAINST SIX DISEASES

- Sanofi Pasteur’s hexavalent vaccine protects children against six World Health Organization (WHO) priority diseases:
  - Poliomyelitis
  - Diphtheria
  - Tetanus
  - Pertussis (whooping cough)
  - Invasive infections caused by Haemophilus influenzae type b
  - Hepatitis B

- The treatment will permit the expansion of immunization coverage for these 6 diseases.
  According to WHO, more than 1,200,000 deaths (mainly children) are linked every year to these 6 diseases.

Sources: OMS website, accessed on 07/09/2012:
NUMEROUS ADVANTAGES

- The vaccine is the only fully liquid, ready to use 6-in-1 vaccine; no reconstitution is needed prior to administration which improves convenience for health care professionals.
- The vaccine expands the protection against six childhood diseases; it reduces the number of vaccination visits for infants, thus the vaccination coverage will increase.
- By reducing the number of consultations and injections necessary for the infants’ vaccination, it will allow to reduce the cost bearing by public health and parents.
- By combining six vaccines into one, the vaccine reduces the number of injections, improving comfort and vaccination compliance for infants and reducing parental anxiety. It is more convenient for parents to complete the recommended vaccination schedule and thus better protect their children against 6 major childhood diseases.
THE FIRST VACCINE RECEIVING A POSITIVE OPINION FROM EUROPEAN MEDICINES AGENCY (EMA) (ARTICLE 58)

- First vaccine registered under European’s article 58, allowing Sanofi Pasteur to licence and distribute the vaccine rapidly all over the world.

- What is Article 58? It allows the Agency's Committee for Medicinal Products for Human Use (CHMP) to give opinions on medicinal products for human use that is intended exclusively for markets outside of the European Union (EU). Medicines eligible for this procedure are used to prevent or treat diseases of major public health interest. The EMA assessment was conducted with the participation of experts from the World Health Organization (WHO) according to the same quality, safety and efficacy criteria as vaccines authorized for the European Union.

- As of May 2016, Sanofi Pasteur’s hexavalent vaccine is now registered in more than 100 countries.

INNOVATIVE PEDIATRIC VACCINES FOR PUBLIC HEALTH

- Sanofi Pasteur is still searching for new pediatric combination vaccines to improve childhood vaccination.

Development of pediatric combination vaccines of Sanofi Pasteur

- The hexavalent vaccine is the result of ten years of work and leads to multi-center clinical studies involving approximately 4,000 infants.

- The acellular pertussis vaccines have been distributed in over 100 countries with more than 450 million doses.

- Since first launch in 2013, we delivered 15 million doses of our hexavalent vaccine.
6 PRIORITY DISEASES

- Poliomyelitis is a contagious disease caused by three different serotypes of poliovirus (types 1, 2, and 3). It is responsible for incapacitating paralysis and death.

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

- Tetanus is an often fatal infectious disease caused by the toxigenic strains of the tetanus bacillus. Tetanus is a devastating disease in developing countries and has not yet entirely disappeared from industrialized countries.

- Pertussis is a highly contagious infection of the lower respiratory tract caused by the bacterium Bordetella pertussis. Pertussis is a slowly progressing disease (several weeks) that is particularly severe among young infants.

- Haemophilus influenzae type b infections are widespread throughout the world. Hib infections may develop under various forms but meningitis is the most frequent one. Hib infections occur in children under the age of five years, and mostly during the first year of life.

- Hepatitis B is a virus (HBV) that causes an inflammation of the liver. Severe outcomes may be observed following acute hepatitis, but they mainly result from the complications of chronic HBV infection (e.g., liver cirrhosis and cancer).

References:

1 EMA website - European Medicines Agency gives first opinion for a vaccine for use outside the EU, accessed on 09/07/2012.

2 EMA website - Article 58 applications, accessed on 09/07/2012.

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