

**On the localization of production of Infanrix Hexa<sup>1</sup> and Synflorix<sup>2</sup> vaccines in the Russian Federation\*\***

The international biopharmaceutical research company GlaxoSmithKline (hereinafter – GSK) informs healthcare specialists about the progress of the GSK vaccinal portfolio production localization in Russia with this letter.

GSK obtained the updated registration certificates for vaccine Infanrix Hexa for simultaneous prevention of 6 (six) infections and vaccine Synflorix for prevention of pneumococcal infections. Infanrix Hexa is a combined adsorbed vaccine for prevention of diphtheria, tetanus, pertussis (acellular), poliomyelitis (inactivated) and hepatitis B with a conjugated adsorbed vaccine for prevention of the infection induced by *Haemophilus influenzae* type B.

Synflorix is an adsorbed 10-valent pneumococcal polysaccharide vaccine conjugated with D-protein of the nontypeable *Haemophilus influenzae*, tetanus and diphtheria anatoxins.

The updated registration certificates include an additional production space – LLC “SmithKline Beecham – Biomed” (hereinafter – SB-Biomed).

SB-Biomed was founded in 1997 and immediately started operation according to the international standards of the Good Manufacturing Practice (GMP). The enterprise develops on the basis of cooperation with Russian producer of vaccines OJSC “Mechnikov Biomed”. SB-Biomed has been gradually implementing production of innovative vaccines in Russia and exercising release quality control for the last 15 years. The vaccines produced by SB-Biomed are used for many purposes, including provision of the National vaccination calendar in the Russian Federation.

Right to manufacture vaccines is certified by the license #FS-99-04-000848 for production of medicinal agents of 25 November 2010 (Appendices 1, 2) issued by the Federal Service on Surveillance in Healthcare.

According to the National RF standard “Policy GOST R 52249-2009 for production and quality control of medicinal drugs” approved by the Order #159-st of 20 May 2009 of the Federal Agency on Technical Regulating and Metrology, cl. 31, 32 of article 4 and cl. 1-3 of article 45 of the Federal Law of the Russian Federation #61-FL “On the circulation of medicinal agents” of 12 April 2010, **SB-Biomed is a Russian manufacturer**, which conducts production processes and exercises release quality control according to the legal requirements and the approved manufacturing policies.

Thus, as a Russian manufacturer, SB-Biomed produces and controls quality of 8 immunobiological drugs (vaccines) with the status “Made in the Russian Federation”:

1. Engerix B – recombinant vaccine for prevention of hepatitis B.
2. Havrix – vaccine for prevention of viral hepatitis A.
3. Hiberix – vaccine for prevention of the infection induced by *H. influenzae* type B.
4. Fluarix – vaccine for prevention of seasonal influenza.
5. Poliorix – inactivated vaccine for prevention of poliomyelitis.
6. Infanrix – 3-component vaccine for prevention of diphtheria, tetanus and pertussis (acellular).

---

\* - Advertorial. The information is intended for the medical staff. For the detailed information, consult CJSC “GlaxoSmithKline” at: Russia, Moscow, Krylatskaya Str. 17/3, Business Park “Krylatsky Hills”, floor 5, 121614. Tel.: (495) 777-89-00; fax: (495) 777-89-04.

<sup>1</sup> - Infanrix® Hexa is a combined adsorbed vaccine for prevention of diphtheria, tetanus, pertussis (acellular), poliomyelitis (inactivated) and hepatitis B with a conjugated adsorbed vaccine for prevention of the infection induced by *Haemophilus influenzae* type B

<sup>2</sup> - Synflorix is an adsorbed 10-valent pneumococcal polysaccharide vaccine conjugated with D-protein of the nontypeable *Haemophilus influenzae*, tetanus and diphtheria anatoxins.

\*\* - read the instructions on medical application of medicinal agents carefully before use.

## INFORMATION OF A PHARMACEUTICAL COMPANY\*

7. Infanrix Hexa – combined vaccine for prevention of diphtheria, tetanus, pertussis, poliomyelitis, hepatitis B and the infection induced by *H. influenzae* type B.
8. Synflorix – vaccine for prevention of pneumococcal infections.

Procurement of permission for local production and quality control of vaccines Infanrix Hexa and Synflorix is an important stage of the project of production localization of the GSK vaccines in Russia. **The first lots of these vaccines will be produced by SB-Biomed in the end of 2013.** The company is planning to complete registration and start serial production of other innovative GSK vaccines.

GSK is committed to the strategy of long-term investments in Russia. The company has been working in Russia following its mission – improvement of life quality of people so they could do more, feel better and live longer – persistently.