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Europe Suspends Sales of Sanofi Merck Vaccine - Hexavac

Sep 20, 2005 - LONDON (Reuters) - The European Medicines Agency has suspended sales of Sanofi Pasteur MSD's childhood vaccine Hexavac because of concerns it may not offer adequate protection, the drugs watchdog said on Tuesday.

The vaccine - which accounts for around 10 percent of sales by the joint venture between Sanofi Aventis SA and Merck & Co. Inc. - is designed to protect infants and children against diphtheria, tetanus, whooping cough, hepatitis B, polio and Haemophilus influenzae type B.

But experts at the London-based agency have identified a problem with the hepatitis B element of the shot, resulting in decreased immunogenicity, or the ability of a vaccine to stimulate an immune response.

This could lead to reduced long-term protection against the hepatitis B virus.

The problem does not affect the vaccine's protection against other diseases and there is no immediate concern for children already vaccinated with Hexavac.

The issue is related to variations in the production process used to make the vaccine and the medicines agency has asked the manufacturers to design a follow-up program to assess if children will need to be revaccinated at a later stage.

Mike Watson, European director of clinical affairs and epidemiology at Sanofi Pasteur MSD, said the company hoped the suspension would be relatively short term but it was not possible to put a figure on it.

The active ingredient for the hepatitis B element of the vaccine is manufactured in the United States by Sanofi's partner Merck but Hexavac itself is not sold in the U.S. market.

The agency noted that alternative vaccines were available throughout Europe and GlaxoSmithKline Plc, which makes the rival product Infanrix hexa, said it was stepping up supplies to meet any shortfall.

Vaccination against hepatitis B is widely recommended by health authorities during the first year of life to protect children against the disease, which can eventually lead to cirrhosis or liver cancer.

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