April 2017

Dear Health Care Professional:

This letter is to provide an update on the status of YF-VAX® (Yellow Fever Vaccine) supply. Sanofi Pasteur is experiencing delays in the production process of YF-VAX vaccine and it is anticipated that the product will be unavailable from mid-2017 to mid-2018 as we transition production to a new state-of-the-art facility. Ordering restrictions have been implemented to responsibly manage the limited remaining supply of YF-VAX vaccine. YF-VAX vaccine will continue to be available while current supplies last.

As the sole manufacturer of yellow fever vaccine in the United States, we take our responsibility seriously and are making every effort to maintain access to yellow fever vaccine. We have worked with the Food and Drug Administration (FDA) to make another yellow fever vaccine available in the US. This vaccine, STAMARIL® (Yellow Fever Vaccine [Live]), manufactured by Sanofi Pasteur in France, is a live, attenuated yellow fever vaccine that is investigational/unlicensed in the US, but it is registered and currently distributed in over 70 countries. The mechanism by which we can make this vaccine available is called an Expanded Access Investigational New Drug Application (IND), made possible under US regulations.

An Expanded Access IND program is similar to a clinical trial and requires training of clinical site staff and monitoring of vaccine recipients. There are additional rigorous documentation and informed consent procedures. Further, only health care providers who are certified by state health departments to administer yellow fever vaccine will be eligible. Given all of these restrictions, a limited number of clinical sites can participate in this program. These locations have been selected to include sites that immunize the most patients with YF-VAX vaccine, and geographic location. The objective is to provide the broadest access possible to yellow fever vaccine, given the regulatory requirements of the Expanded Access IND program.

Once YF-VAX vaccine is no longer available, health care providers and patients will be able to find locations that will administer STAMARIL vaccine by visiting the CDC web page at http://wwwnc.cdc.gov/travel/yellow-fever-vaccination-clinics/search. They may also visit http://wwwnc.cdc.gov/travel/ for information about which countries require yellow fever vaccination for entry and for which countries the CDC recommends yellow fever vaccination.

Supply of YF-VAX vaccine from our new US facility is planned for mid-2018. A significant number of doses had been planned to bridge the gap between the former manufacturing facility and the new facility. However, there was an unavoidable equipment issue that resulted in halting production. This did not affect any doses of YF-VAX vaccine that are being shipped to customers. All doses shipped to customers received release clearance for safety and potency from the FDA Center for Biologics Evaluation and Research.

Sanofi Pasteur recognizes the challenge this supply disruption will cause for your practice and for patients in need of yellow fever vaccine. We are making every effort to see that yellow fever vaccination continues in the US during this YF-VAX vaccine supply disruption and we appreciate your understanding.

For more information on YF-VAX vaccine availability and our vaccine supply situation, you can contact Sanofi Pasteur by calling 1-800-VACCINE (1-800-822-2463). (Over)
IMPORTANT SAFETY INFORMATION FOR YF-VAX VACCINE

Indication
YF-VAX vaccine is indicated for active immunization for the prevention of yellow fever in persons 9 months of age and older in the following categories: persons living in or traveling to yellow fever endemic areas, persons traveling internationally through countries with yellow fever, and laboratory personnel who handle virulent yellow fever virus or concentrated preparations of the yellow fever vaccine virus strains.

Safety Information
The most common local and systemic adverse reactions to YF-VAX vaccine include edema and pain at the injection site; mild headache, myalgia, and fever. Other adverse reactions may occur. YF-VAX vaccine should not be administered to an individual with a history of acute hypersensitivity to eggs, egg products, or to any component of the vaccine. Anaphylaxis may occur following the use of YF-VAX vaccine, even in individuals with no prior history of hypersensitivity to the vaccine components. Infants younger than 9 months of age should not be vaccinated with YF-VAX vaccine. Vaccination with YF-VAX vaccine is also contraindicated in lactating women who are providing breast milk to infants younger than 9 months of age due to the potential for transmission of vaccine virus in breast milk. In addition, YF-VAX vaccine is contraindicated in immunosuppressed individuals. Yellow fever vaccine-associated viscerotropic and neurotropic diseases are known rare serious adverse events. Vaccination with YF-VAX vaccine may not protect all individuals.

Before administering YF-VAX vaccine, please see accompanying full Prescribing Information.

Sincerely,

[Signature]

Matthew Wilcox
Vice President Marketing, US

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