

Yellow Fever ACIP presentation  
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# Yellow Fever Vaccine: US Supply Update

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# YF-VAX<sup>®</sup> Supply History

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- In the past several years, intermittent production issues have resulted in temporary supply shortages
- To improve supply, we are transitioning manufacturing to a new state-of-the-art facility planned for mid-2018
- This transition was intended to be seamless and without impact on supply
- In Q1 2016, a manufacturing issue resulted in the loss of a large number of doses being produced to bridge supply until our new facility was online
- We immediately instituted ordering restrictions to extend supply to health care providers (HCPs)

# Stakeholder Coordination

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- **Given yellow fever outbreaks in other countries and global supply issues, we initiated stakeholder discussions in the Spring of 2016**
- **Key participants have included CDC, FDA, and DoD**
- **Our focus has been to assure continuous yellow fever vaccine supply for travelers, U.S. government employees, military, and other response groups**

# Multiple Paths to Ensure Supply

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**Sanofi Pasteur has pursued multiple paths to ensure continuous supply of yellow fever vaccine:**

- 1. Product ordering restrictions**
- 2. Additional production of YF-VAX vaccine in the existing facility**
- 3. Importation of Stamaril® via an Expanded Access IND Program (EAP)**

# 1. Product Ordering Restrictions

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**HCPs are required to verify that vaccine recipients are travelling within 30 days to:**

- **A yellow fever endemic country**  
or
- **A country that requires proof of vaccination for entry**

**Account order limits have been activated to avoid account over-ordering**

## 2. New Production of YF-VAX Vaccine

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- **Additional product was produced in the existing facility**
- **Further manufacturing issues limited new production thus not enough product could be made to fully bridge to the new facility**
- **Restrictions will enable continued use of YF-VAX vaccine through mid-2017**

### 3. Importation of Stamaril Vaccine

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- **Sanofi Pasteur worked closely with the FDA to rapidly develop and submit an EAP**
- **FDA rapidly reviewed the application and granted approval in October 2016**
- **EAP protocol allows product to be used at authorized facilities in a restricted format**

**By mid-2017 Sanofi Pasteur will supply Stamaril vaccine under an EAP to fulfill US yellow fever immunization demand**

# Stamaril Vaccine Product Profile

- **Yellow Fever vaccine manufactured by Sanofi Pasteur in France**
- **Yellow fever virus 17D-204 strain (live, attenuated)**
  - Same strain as in YF-VAX vaccine
- **Used globally in more than 100 countries**
- **Licensed for more than 30 years**
- **More than 430 million doses have been distributed**
- **Safety and efficacy comparable to YF-VAX vaccine**
- **Supplied as a vial of lyophilized powder and syringe prefilled with diluent**





# Stamaril Vaccine Supply Process

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- As an investigational product, there are protocol and tracking requirements for the sites that administer Stamaril
- Sanofi Pasteur plans to enroll ~150-170 high-volume centers that can dedicate resources and train personnel to counsel, administer, and monitor safety
- Outreach will begin in March in order for sites to review and accept the protocol and obtain approval from local Institutional Review Boards as needed
- Targeting end-of-May site readiness, including completion of training
- Yellow fever providers and travelers will be notified in May-June timeframe to direct them to Stamaril vaccine sites

# Partnering with CDC

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- **Working closely with CDC programs**
  - **Division of Global Migration and Quarantine**
  - **Division of Vector-Borne Diseases**
- **Sharing information and developing support for**
  - **Communications materials and plans**
  - **Product & logistics information**
  - **Stamaril site selection process**
  - **Stamaril site location information**
  - **Access to state health departments**

# Key Takeaways

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- **By mid-2017, Sanofi Pasteur will provide Stamaril vaccine under EAP**
- **Site enrollment and training will begin in March to ensure readiness**
- **Patients will be directed to designated clinics to receive Stamaril vaccine; HCPs will be notified to send their patients to these sites**
- **Stamaril vaccine will be supplied to sites until the new production facility is online mid-2018**

**Sanofi Pasteur will continue to work diligently to make yellow fever vaccine continuously available throughout this transition**