Yellow Fever ACIP presentation
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Yellow Fever Vaccine: US Supply Update

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YF-VAX® Supply History

- 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

- 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

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

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

- 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

- 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

- 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

- 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

- 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