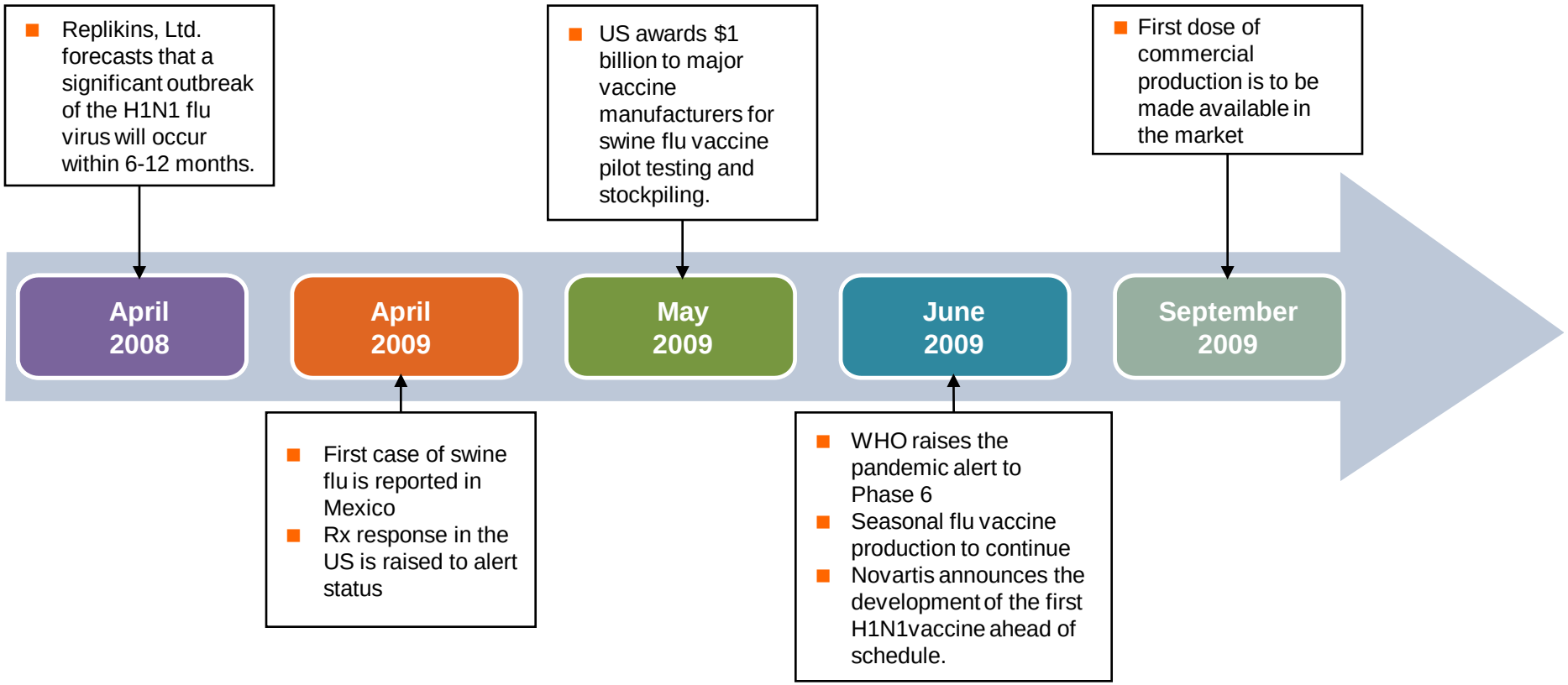
Impact of Swine Flu on the Pharmaceutical Industry

August 2009

Swine Flu Outbreak – Major Events

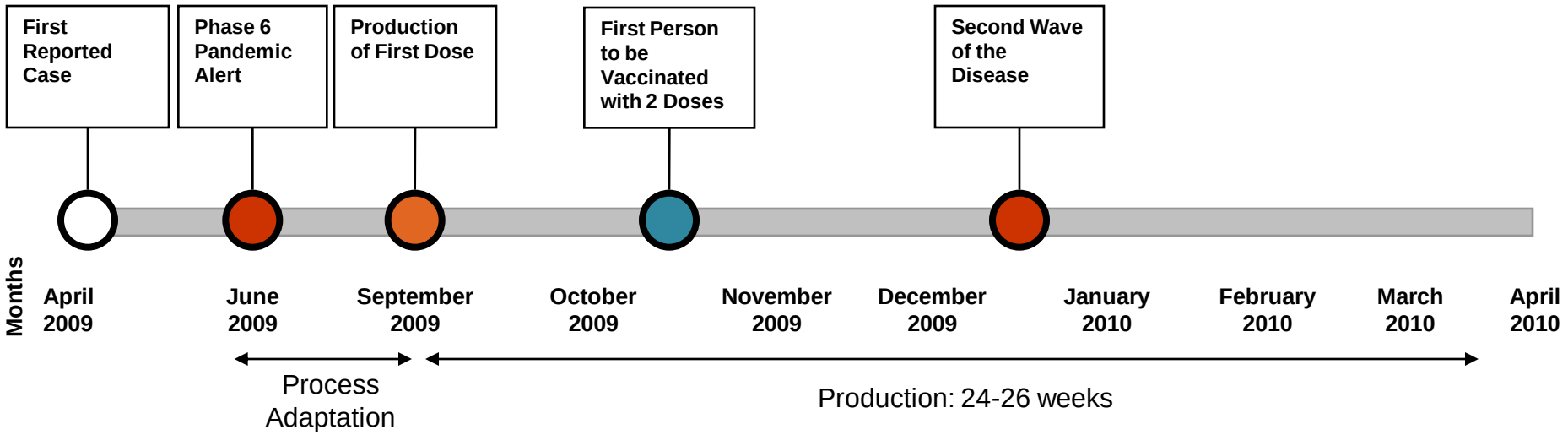
- The first case of swine flu was reported in April 2009 in Mexico. This was approximately a year after Replikins, Ltd forecast a major outbreak of flu within 6-12 months in April 2008.
- WHO raised the pandemic alert status to Phase 6 for the first time in 46 years. Novartis announced the development of the first H1N1 vaccine well ahead of schedule. Two major technologies – using egg and cell culture are under development.
- Despite the pandemic alert due to the spread of swine flu, seasonal flu vaccine production is expected to continue as scheduled, to avoid imminent shortage of common flu shots.
- Swine flu shots for commercial use are expected to be available in the market by September 2009.



Source: BioResearch Online, MedicalNews Today

Swine Flu Vaccine Production - Timeline

- The swine flu vaccine is expected to be available in the market by September 2009.
- A **second surge of swine flu** is expected **during the 2009-2010 flu season**.



- It takes around 3-4 months to generate a seed strain, 4 to 6 weeks for a manufacturing set-up, and 18 weeks of production, including 2 to 3 weeks of quality assurance and regulatory approval.
- Considering the above stages, a vaccine is expected to arrive in the market around the time when the pandemic's second wave is likely.

Source: BioPharm International, WHO

Overview

- The demand for the swine flu vaccine and the anticipated increase in production is expected to amplify the demand for process equipments, new technology instruments and chemical ingredients used in the manufacture of the vaccine.
- The following table lists the various vaccine components and the raw materials for which an increased demand is expected with the commercial production of swine flu vaccines.

Components/ Ingredients	Raw Materials
Egg Proteins	Egg
Squalene	Shark Liver Oil, Olive Oil
Polysorbate 80	Corn, Oleic Acid sources like Olives
Thimerosal	Ethyl Mercury/ Mercury
Syringes, Filters & Cartridges and Plastic Disposables *(depending on the type of filter/ cartridges used)	Polyethylene, Polypropylene, Polycarbonate, Polyurethane, Polyvinylidene Fluoride (PVDF), Inorganic Cellulose, Silicone and Nylon
Needles	Aluminum, Steel
Equipments	Bio Reactors, Autoclaves, Laboratory Incubators
Shikimic Acid used in Tamiflu	Star Anise Seed
Vials	Glass, Rubber Stopper, Aluminum foils, Labels
Cold Chain	Refrigerated Storage and Transport

Source: PE1, WHO, FDA, Product Catalogs

Overview

The following tables list the medical care devices and the professionals expected to be in shortage with the spread of the pandemic swine flu across the globe.

Medical Care Devices
Ventilators
Mechanical Beds
Surgical Gloves
Face Masks
Respirators

Medical Care Professionals
Lab Technicians
Primary Care Doctors
Nurses

- The report identifies the timeline of the swine flu pandemic onset. It has been found that **Replikins Ltd forecasted the 2009 flu pandemic in April 2008 itself**.
- It is also observed that the **flu vaccine industry is affected by higher production costs**, **lower market prices** (as governments are the major buyers) and **overregulation**.
- Even though WHO has announced a pandemic alert for swine flu, it has asked companies **not to stop the production of seasonal flu vaccine** due to the fatalities involved and the upcoming winter season. Seasonal flu vaccine production is expected to be completed by July 31, 2009.
- According to WHO, **4.9 billion doses** of swine flu vaccine are expected to be manufactured **in 12 months**. The surge in the production of swine flu vaccine is expected to create increased demand for various equipments, instruments and vaccine ingredients.
- The report uses a **Scenario Analysis** to estimate the demand for various components or ingredients that are used in the production of swine flu vaccines (keeping the production capacity consistent)
  - **Scenario I – 4.9 billion doses will be manufactured in 12 months**
  - **Scenario II – 6.7 billion doses will be manufactured in 17-18 months** *(single dose for the world population)*
  - **Scenario III – 13.4 billion doses will be manufactured in 3 years** *(double dose for the world population)*

Source: PE1, WHO, FDA, Product Catalogs arial

Overview

- **Eggs** are the major raw material used in the production of antigens. Around 95% of flu vaccines produced uses eggs and the rest use cell culture technology. It is found that **billions of eggs** will be required for the manufacture of swine flu antigens.
- **Adjuvants** are used to enhance the immunity of antigens and reduce the number of eggs used**.** Flu vaccine manufacturers are expected to use **Squalene-based** adjuvants in the swine flu vaccines.
- The demand for **Surfactants** like **Polysorbate 80/ Tween 80** and **preservatives** like **Thimerosal** is also set to increase with the number of flu doses manufactured.
- Major flu vaccine manufacturers have announced the **use of cell-culture technology** in vaccine production. This has increased the **demand for single-use equipments, high throughput instruments and analytical tools.**
- The companies manufacturing vaccine consumables like **specialty filters, single-use bags and disposable components** for sterilization, filtration and storage have begun to receive huge orders from flu vaccine manufacturers.
- According to industry experts, the **number of vaccine doses manufactured** during a pandemic **increases ten-fold**. This affects the availability of **fill-finish capacity, syringes and vials** as the current supply is insufficient to meet the pandemic demand**.**
- According to the WHO Pandemic Preparedness Plan, the flu manufacturers have to double their existing capacity to meet the pandemic demand. Considering that at least 5 years are required to construct a vaccine-manufacturing plant, **a two-fold increase in the demand for process equipments** is expected.
- Since vaccine supply requires a cold chain, **a shortage of refrigerated storage and transport** is expected if WHO announces that the global population is to be vaccinated against swine flu.
- A **shortage of** the above mentioned **components** is expected if all the resources are diverted towards pandemic swine flu vaccine production.
- In the case of medical care services, a **shortage** in the availability of **lab technicians** is expected to cause a delay in diagnostic test results. With the spread of the disease, a shortage in **primary care professionals like doctors and nurses** is expected. The number of hospitalized patients will also increase the demand for intensive care wards, **mechanical beds and ventilators**.
- With the increase in safety and precautionary measures adopted by the countries, the demand for **surgical gloves, face masks and respirators** has also increased.
- **Recommendations:**
  - **Tracking the governments' response** to the swine flu outbreak such as the number of **doses ordered**, **funds allocated** to flu manufacturers for pandemic preparedness and **travel directives.**
  - **Coordinating with raw material suppliers** in swine flu-affected countries to avoid supply disruptions (during the SARS outbreak in 2003, the supply chains were affected with companies being forced to shutdown operations as the employees were affected by the disease).

Source: PE1, WHO, FDA, Product Catalogs

Thank You

Beroe has carried out a detailed analysis on the Industry and its impact.
For a more in-depth report contact our sales team.
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