Johnson & Johnson Supply Chain

COVID-19 Vaccine Manufacturing

At Johnson & Johnson (J&J), we take seriously our responsibility to supply our COVID-19 vaccine candidate around the world upon authorization, and are confident we have the capabilities, collaborations, and rigorous safety and quality standards to do so.

Vaccine Production and Distribution Process

1
In the production process, **cells are grown** and replicated in a controlled environment to generate "drug substance."

Quality control: Collect samples and perform testing.

2
The drug substance is **frozen at -60 °C** in bottles to preserve stability before drug product manufacturing.

3
Those bottles are **transported at -70 °C to production/ fill-finish sites,** often in a different country.

4
The drug substance is **thawed and diluted** into the vaccine formulation.

5
The vials are then **filled and finished with labels, then packaged**.

6
Those vials are frozen at -20 °C, and **shipped to J&J warehouses** for storage and distribution.

7
J&J ships the vaccine for distribution using the **same cold chain technologies** we use today to transport other innovative medicines.

With Janssen's AdVac® technology platform, the vaccine **is estimated to remain stable for two years at -20 °C (-4 °F)**. It can be kept at temperatures of 2-8 °C (36-46 °F) for a maximum of **4,5** months of that two-year period, based on local labeling requirements.

Each pallet of our vaccine will include **track-and-trace technologies** that will provide real-time location, temperature and other information needed to maintain the vaccine's quality.

The general timeframe to produce a batch of vaccine, from drug substance to fill and finish, is **60–70 days, plus 18–22 days** for final product quality testing and release.

Global Manufacturing Collaborations

Given the unprecedented nature of the pandemic, Johnson & Johnson is expanding its global manufacturing capacity. We have established new U.S. vaccine manufacturing capabilities and are scaling up capacity in other countries.

In addition to our existing manufacturing capacity in Leiden, the Netherlands, we have entered into multiple agreements to expand our manufacturing capability of our COVID-19 vaccine candidate.

Manufacturing Partners

Due to the global interconnectivity of our production and supply chain processes, one batch of the J&J COVID-19 vaccine **will likely visit multiple countries** through the course of various manufacturing stages in its journey from drug substance to a finished vial for injection.

For more information on Johnson & Johnson's approach to help combat COVID-19, **visit www.jnj.com/coronavirus**.

The Janssen COVID-19 Vaccine has not been approved or licensed by the U.S. Food and Drug Administration (FDA) but has been authorized by FDA through an Emergency Use Authorization (EUA) for active immunization to prevent Coronavirus Disease 2019 (COVID-19) in individuals 18 years of age and older.

The emergency use of this product is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of the medical product under Section 564(b)(1) of the FD&C Act, unless the declaration is terminated or authorization revoked sooner.

Please read Emergency Use Authorization (EUA) Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) including full EUA Prescribing Information available at www.JanssenCOVID19Vaccine.com/EUA-factsheet.

The COVID-19 vaccine has also been granted a Conditional Marketing Authorization from the European Commission for use in 27 member states of the European Union (EU), plus Norway, Iceland and Liechtenstein, and has been issued an Emergency Use Listing by the World Health Organization.

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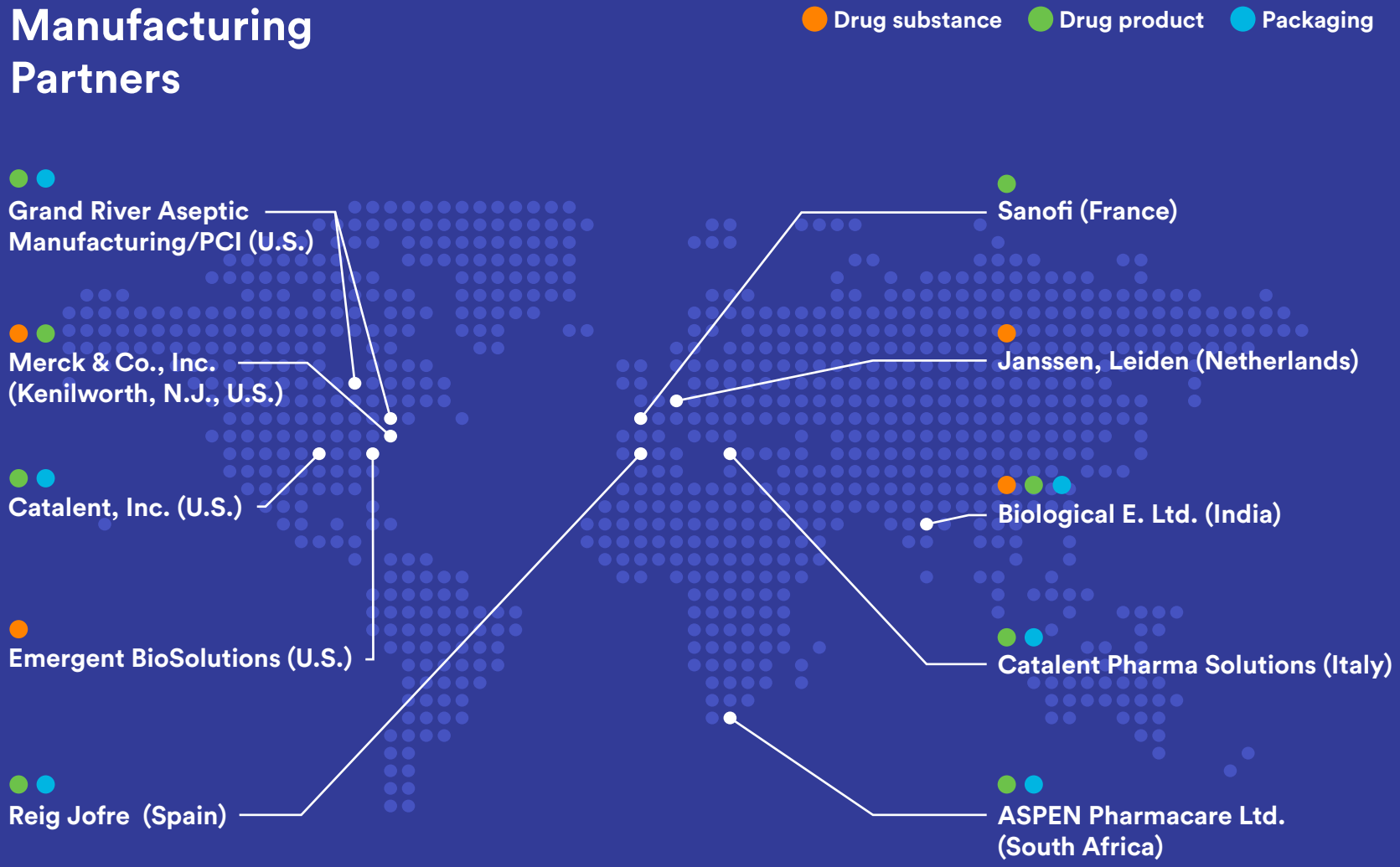

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