World Health Organization

Manufacturing, safety and quality control of vaccines

8 December 2020

This document is part three in a series of explainers on vaccine development and distribution. Part one focused on how vaccines work to protect our bodies from disease-carrying germs. Part two focused on the ingredients in a vaccine and the three clinical trial phases.

This document outlines the next part of the vaccine journey: the steps from completing the clinical trial phases through to distribution.

How a vaccine is approved for production

For more information on the three phases of vaccine clinical trials, click here.

Once a vaccine has reached pre-approval stage following clinical trials, it is assessed by the relevant regulatory body for compliance with quality, safety and efficacy criteria. Following regulatory approval, manufacturers can submit a vaccine to WHO for prequalification (PQ), an assessment process that ensures quality, safety and efficacy and helps the UN and other international procurement organizations determine the programmatic suitability of a vaccine.

During global health emergencies, the WHO Emergency Use Listing Procedure (EUL) may be used to allow emergency use of the vaccine. The EUL exists because, in a pandemic situation, products that could benefit the lives of people all over the world may be prevented from coming to market with sufficient speed. The EUL is a fast-tracked but rigorous process, designed to bring impactful products to all those in need, as quickly as possible, on a time-limited basis and based on a risk-versus-benefit evaluation. The WHO PQ/EUL recommendation may be used by UN agencies such as UNICEF and the Pan American Health Organization Revolving Fund for procurement decisions in low- and middle-income countries. Gavi also relies on WHO EUL/PQ to specify which vaccines its funds may be used to purchase.

How it's made

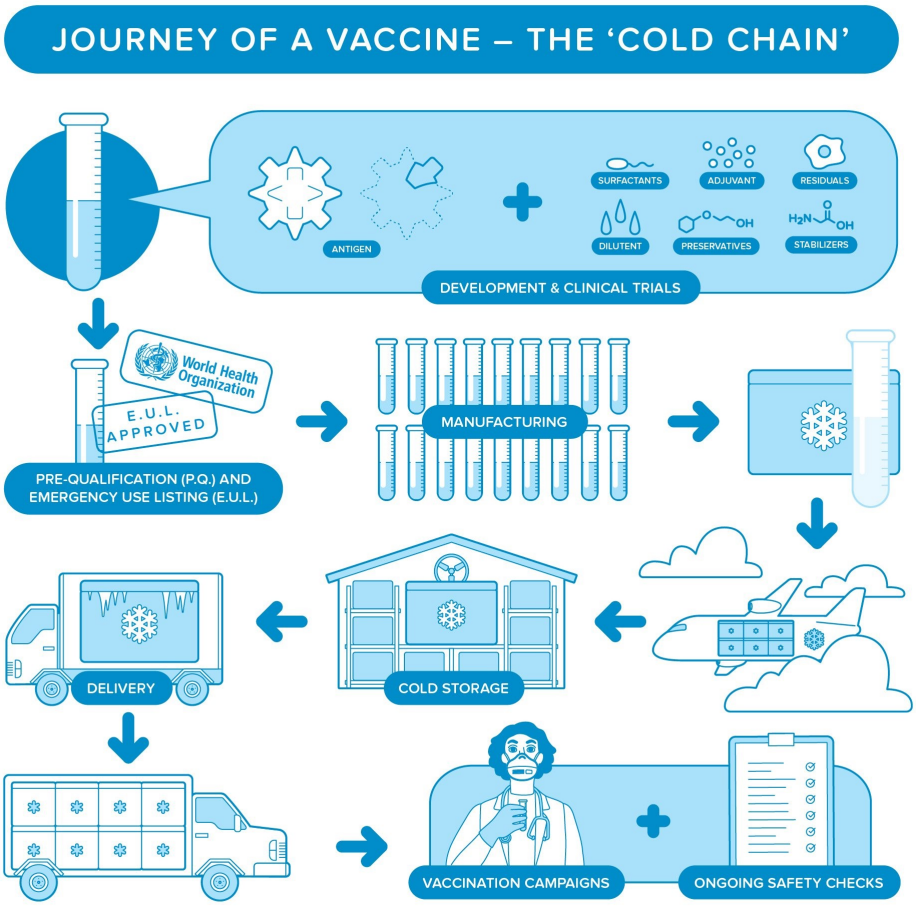
Typically, companies will work independently to complete clinical development plans for a vaccine. Once a vaccine is authorized, manufacturing begins to scale up. The antigen (part of the germ that our immune system reacts to) is weakened or deactivated. To form the full vaccine, all ingredients are combined.

The whole process, from preclinical trial to manufacture, can sometimes take over a decade to complete. In the search for a COVID-19 vaccine, researchers and developers are working on several different phases in parallel, to speed up results. It is the scale of the financial and political commitments to the development of a vaccine that has allowed this accelerated development to take place. Also, nations and international health organizations are working together through COVAX to invest in development capacity upfront to streamline the process, as well as to ensure equitable distribution of vaccines.

How it's packaged

Once the vaccine has been made in bulk quantities', it is bottled in glass vials and then carefully packaged for safe cold storage and transport.

Vaccine packaging must be able to withstand extreme temperatures, as well as the risks involved in being transported globally. Therefore, vaccine vials are most commonly made from glass, as it is durable and able to maintain its integrity in extreme temperatures.



How it's stored

When a vaccine is too hot or too cold, it becomes less effective or even inactive. If stored at the incorrect temperature, vaccines can be ruined or unsafe for use. Most vaccines require refrigerated storage at between 2 and 8 °C. Some vaccines require temperatures as cold as -20°C. Some of the newer vaccines need to be kept ultra cold at -70°C. For frozen vaccines some of them can be safely stored for a limited time between 2 and 8°C.

Regular refrigerators cannot maintain an even temperature consistently, so specialized medical refrigerators are required for these precious products.

How it's shipped

To maintain this cold chain, vaccines are shipped using specialized equipment that does not compromise the integrity of the product. Once shipments land in the destination country, refrigerated lorries transport the vaccines from the airport to the warehouse cold room. From there, portable iceboxes are used to transport vaccines from the cold room to regional centres where they're stored in refrigerators. If vaccination takes place outside of the regional facility, the

final step often requires portable iceboxes to transport the goods to local areas for vaccination campaigns. New technologies have invented some portable devices that can keep vaccines at ther cold temperature for several days without needing electricity.

Quality control

Once vaccines start being administered, national authorities and WHO constantly monitor for – and establish the severity of – any possible adverse side effects and responses from people who have received the vaccine. The safety of the vaccine is paramount, with regular assessments and post-approval clinical studies to report on its safety and effectiveness.

Studies are often conducted to determine how long a given vaccine remains protective.

Read previous 'Vaccines Explained' topic: "How are vaccines developed?"

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