The Exciting Journey of Vaccines

SECURING SUPPLY THROUGH SHARED UNDERSTANDING

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THE COMPLEX JOURNEY OF A VACCINE

Safe & effective by a regulatory authority.



Vaccine manufacturing involves (Each step can be performed in different sites situated in different countries.





RECEPTION

All incoming raw materials are checked for conformance with the quality specifications.



MANUFACTURING

The active ingredient of the vaccine is manufactured. This is the most critical step in the production of high quality, safe and efficacious vaccines.



FORMULATION

The active ingredient is mixed with other ingredients to enhance the immune response and ensure product stability.



The vaccine is filled into the final container. This could be a vial or a prefilled syringe.



The vaccine in the final container is labeled in accordance with regulatory requirements and packed, ready for shipping to the customer.



LOT RELEASE

Quality assurance confirms the product has been manufactured and tested in accordance with the correct procedures. The national regulatory authority gives final authorization to distribute the vaccine.



Vaccine of consistent quality.





Quality Control represents up to 70% of manufacturing time.



 Testing done by the manufacturer ■ Testing done by the exporting country

> A vaccine typically travels through several different sites before being ready for shipment.



A vaccine undergoes up to several hundred quality control tests during its manufacturing journey.





Leaving no-one behind with immunization is a shared goal of Gavi, the Vaccine Alliance, IFPMA*, and DCVMN* and contributes to the advancement of Sustainable **Development Goals.**

Member companies are proud to contribute to Gavi's vision 2025 by ensuring that timely demands for life-saving vaccines are met for Gavi-eligible countries, as it is a critical enabler of success.

We recognize the important work Gavi has done to move towards greater demand visibility, however there remain a number of aspects that still contribute to uncertainty:

- Vaccine manufacturing is a challenging, specialized process, with inherent variability;
- Vaccines require a long lead time due to stringent quality control, taking from several months up to 3 years from the time production is initiated;
- Vaccine manufacturing is capital intensive. It can take up to 5-10 years for new facilities to be built and certified, with upfront financial investment of \$10 to \$100 million, or more;

- Highly skilled and trained personnel are essential to ensure a consistent manufacturing process;
- Compliance with diverging local and international regulations. For example, post marketing approvals can take up to 2-4 years to process and can cause further delays.

*DCVMN: Developing Countries Vaccine Manufacturers Network

SECURING SUPPLY THROUGH SHARED UNDERSTANDING

- Foster and sustain early dialogue with manufacturers to help align Gavi's goals with industry strategic planning.
- Ensure we can anticipate policy changes together to ensure supply.
- Support prioritization of future vaccine innovations with significant public health impact.
- Ensure sustainability and diversity of vaccines supply within healthy market framework.

^{*}IFPMA: International Federation of Pharmaceutical Manufacturers and Associations