COVID-19 Vaccination: Building Global Capacity

Q&A for Session 05: Regulatory and Procurement Aspects for COVID-19 Vaccines

Tuesday, March 09, 2021

Thank you for attending the above session for National, regional and global stakeholders. Many questions were submitted by participants, either in the Zoom chat during the session itself, or in the two Telegram channels managed by Technet-21 supporting regions, countries, and partners in preparing for COVID-19 vaccine introduction. In this document, we share the answers from presenters to each question.

Links to the session recordings in all languages and presentations can be found on the Project ECHO website.

More information on COVID-19 vaccine introduction can be found in the resources listed below.

- General questions regarding the COVID-19 vaccines
- Preparing for COVID-19 vaccination
- WHO Coronavirus disease (COVID-2019) technical guidance
- TechNet-21 – The Technical Network for Strengthening Immunization Services
- OpenWHO COVID-19 vaccine trainings:
  - Orientation to national deployment and vaccination planning for COVID-19 vaccines

In addition, TechNet-21 manages two Telegram channels supporting regions, countries, and partners in preparing for COVID-19 vaccine introduction. In these two spaces - one anglophone and one francophone - you will be able to share your experiences, discuss key questions, and connect with experts from around the world. We'll also share new information and global guidance as it becomes available. Join us today:

- COVID-19 Vaccine Introduction – TechNet-21 (English)
- Introduction des vaccins contre la Covid-19 – TechNet-21 (Français)

Is there a link for the COVAX tracker?

The data of COVAX tracker is not available publicly.

In Latin America, which countries have sent requests to the manufacturers for the test, because in PERU, it takes time, and it is not done yet.

We don't have such information and requests submitted to the manufacturers. WHO is only aware of regulatory requirements for authorization or approval of vaccines that have been submitted to WHO. Most of the countries in America are going to receive their vaccine through revolving fund mechanism and therefore testing is not required.

Please see the below links for additional information:

https://www.paho.org/en/revolvingfund

https://www.paho.org/immunization-toolkit/?page_id=25

https://www.paho.org/en/covid-19-vaccines

By not allowing or supporting testing by NRAs not creating a perception issue? If so, how is communication done to allay the anxiety in countries that may not be comfortable on this?

Testing of the vaccines is not the only way to ensure their quality. The assurance on quality, safety and effectiveness of medical products including vaccines are achieved through a series of controls and regulatory oversights. Although WHO is not advising countries not to test the vaccines, however, this is at the end the decision of the country to test the vaccine. The National Regulatory Authority (NRA) may explain to public that the vaccines are already tested by the manufacturer and later on by competent authorities and have been released through sophisticated regulatory controls.

Please see the below explanation that is provided in Chapter 2 of NDVP.
Link: https://www.who.int/publications/i/item/WHO-2019-nCoV-Vaccine_deployment-2020.1

During the COVID-19 pandemic, the allocated COVID-19 vaccines should be released to the immunization programme in the shortest possible time without compromising safety.

Testing of vaccines requires sophisticated and complex analytical methods and equipment that should be managed by trained staff. WHO advises that vaccines procured from assured sources, e.g. WHO prequalified vaccines, vaccines listed as EUL, or vaccines approved by SRAs, are not tested again by receiving countries as they have been tested and released already by NRAs with stable, formal approaches for vaccine approval. If countries are required by law to review the summary lot protocols, vaccine release should be done quickly and through the review of the minimum documents as advised by WHO. Countries may also want to explore if there can be any law or exception granted in the case of emergency use of a vaccine with existing SRA approval.

For further reading please see the WHO Guidelines for independent lot release of vaccines by regulatory Authorities. Link: https://www.who.int/biologicals/TRS_978_Annex_2.pdf

Some NRAs have granted emergency use of the COVID-19 vaccines but continue to take samples of the vaccine in-country for testing. Are we saying NRAs shouldn't test all?

The added value of such exercise should be questioned and evaluated properly. Please see the below explanation that is provided in Chapter 2 of NDVP. Link: https://www.who.int/publications/i/item/WHO-2019-nCoV-Vaccine_deployment-2020.1

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In addition, most probably the NRAs may not be able to perform the most important test such as potency related ones and they may just perform some tests that they can perform. At the end again I would like to emphasis on what can be the added value of sampling and testing of the vaccines?

Any list of the 48 PIP countries available?

Yes, the list of PIP countries is available here:
https://www.who.int/influenza/pip/partnership_contribution/hlipii_2020_21_countrylist.pdf?ua=1

Are vaccines being approved for safety and quality by the manufacturing site (as is usual with usual medicines following Good Manufacturing Practice etc), or is the approval for emergency use and listing just by product? The concern is from partners at country level that different manufacturing sites (for the same product) will have different quality assurance mechanisms, and indeed for FCV countries may receive those which are sub-standard/ of poorer quality.

The PQ or EUL is based on data on the commercial scale, in the manufacturing facility used to supply to COVAX.

All information on the dossier, including process, stability, etc is assessed as indicated above. The EUL takes in consideration the actual manufacturing site where the product will be manufactured as listed in the EUL application.. The WHO Inspection team pronounces on the GMP status of the manufacturing site as listed in the product dossier. Therefore the GMP status for the actual site as per the product dossier is considered. This information is considered when WHO lists the product.