World Health Organization

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In reply please refer to: I8-370-43
PQT-OL/rg (2021-365)

Your reference:

Dr Etleva Kadilli
Director
Supply Division UNICEF
Oceanvej 10-12
2150 Nordhavn
Danemark

28 December 2021

Dear Dr Kadilli,

Managing Pfizer "Label Expiry" Risk – Clarification of WHO-PQ's statement

This is to provide further clarification on the message in the World Health Organization Emergency Use Listing (WHO EUL) letter to UNICEF (dated 20 September 2021); the letter should have separated the message on the general shelf-life extension of Comirnaty® vaccine from 6 to 9 months granted by both European Medicines Agency (EMA) and US Food and Drug Administration (FDA) from the vaccines donated by US Government (USG) (with retroactive shelf-life).

General shelf-life extension

- The WHO EUL recommendation for Comirnaty® (based on EMA's approval as WHO's regulatory authority of record) included the extended shelf-life of the vaccine from 6 to 9 months at -90^0 C to -60^0 C as of 10 September 2021 (the date of EMA approval)
- This applies only to lots that have been released after this date with appropriate shelf-life labeling and not retro-actively
- USFDA approved this shelf-life extension on 22 August 2021 https://www.fda.gov/media/151731/download

USG Donation

- The USG decided to donate bilaterally 500M doses of Comirnaty® vaccine through the COVAX facility
- The WHO EUL listing with USFDA (as NRA of record for the donation) was based on the request from USG/COVAX to facilitate the donation of USG Comirnaty® vaccine through COVAX under the terms of USA Emergency Use Authorization (EUA) (reference EUL letter to UNICEF of 16 July 2021)
- Based on the scientific data available, the USFDA allowed a three-month extension of the shelf-life to be applied retroactively to the vaccines stored at -90^0 C to -60^0 C, so that the vaccines would not go wasted

Please note that per standard regulatory principles, WHO does not recommend use of vaccines beyond their labelled expiry date and the shelf-life extension under EUL was not retro-active.

ENCL.: As stated.

cc: Pfizer Ltd. (Attention: Dr Matthew J. Marsden and Dr James Philip Smith)
UNICEF Supply Division (Attention: Mrs Ann Ottosen, Dr Andrew Jones and Mr Soren Hansen)
GAVI (Attention: Mr Seth Berkley, Dr. Mike Brison and Mrs Aurelia Nguyen)

However, in this particular case, it was a bilateral donation to countries and given the exceptional nature of this retroactive approval, the recipient countries have to make their own decision, based on the USFDA assessment, to accept (or not) these donations, including the retroactive shelf-life extension for some batches under the terms of USFDA EUA.

The USFDA approval confirms the quality of the batches covered by the retroactive approval. Therefore, there are no safety or efficacy risks, but there is a regulatory issue and reputation risk related to the use of vaccine lots beyond their labelled expiry date. This may be exploited by the antivaccinists with more long-term consequences. This is the risk each country needs to assess in order to make a decision.

Thank you for your continued collaboration.

Yours sincerely,

Dr Rogério Gaspar
Director
Regulation and Prequalification Department