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In reply please I8-370-43 EURO
refer to: PQT-RD/ha (2021-280)

Your reference:

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

20 September 2021

Dear Dr Kadilli,

COMIRNATY® (Tozinameran - COVID-19 mRNA Vaccine), a World Health Organization (WHO) recommended vaccine through WHO Emergency Use Listing Procedure (EUL) Variation to extend the shelf-life from 6 to 9 months at -90°C to -60°C

We are pleased to inform you of the recommendation to extend the shelf-life of unopened vaccine vials from 6 to 9 months at -90°C to -60°C. In addition, unopened vaccine vials may be stored and transported at -25°C to -15°C for a single period of up to 2 weeks while thawed vaccine vials can be stored at 2°C – 8°C for up to one month (31 days) within the 9 months shelf-life.

This decision is based on the review of data by WHO and the positive opinion received from the European Medicines Agency (EMA), which is the WHO regulatory authority of record for this vaccine. The same positive opinion has been issued by Office of Vaccines Research and Review of the Center for Biologics Evaluation and Research (CBER) of the US Food and Drug Administration (FDA) via a concurrence letter dated 22 August 2021.

This 3-month extension applies to vials manufactured after EMA approval date (10 September 2021). In addition, this extension may be applied retroactively to vaccine vials manufactured prior to this approval. The EUL holder has submitted a Dear Healthcare Professional communication updating the cartons with an expiry date of June 2021 through March 2022, as long as approved storage conditions between -90 °C to -60 °C have been maintained.

cc: UNICEF Supply Division (Attention: Mrs Ann Ottosen, Dr Dorcas Noertoft, Dr Andrew Jones and Mr Soren Hansen)
BioNTech Manufacturing GmbH (Attention: Dr Ruben Rizzi)
Pfizer Ltd. (Attention: Dr Matthew J. Marsden and Dr James Philip Smith)
EMA (Attention: Dr Agnès Saint-Raymond)
US FDA (Attention: Dr Gopa Raychaudhuri)
GAVI (Attention: Mr Seth Berkley and Mrs Aurelia Nguyen)
AMRO (Attention: Dr James Fitzgerald, Dr Analia Porras, Ms Maria Pombo-Castro, Mr Murilo Freitas and Ms Alexandra Mata)

Please note that the EUL webpage will be updated to include the extension of the vaccine shelf-life as well as the updated version of the WHO Product Information.

Thank you for your continued collaboration.

Yours sincerely,



Dr Rogério Gaspar
Director
Regulation and Prequalification Department