

19th August 2022

Direct Healthcare Professional Communication

Important shelf-life update for COMIRNATY®▼30 micrograms/dose concentrate for dispersion for injection (tozinameran), COVID-19 mRNA Vaccine (nucleoside-modified) Marketing Authorisation number: PLGB 53632/0002
- Important shelf-life update from 12 months to 15 months when stored at Ultra-Low-Temperature storage conditions (-90°C to -60 °C).

Dear Healthcare Professional,

We would like to inform you that on 15 August 2022 a new shelf-life at Ultra-Low-Temperature storage conditions (-90 °C to -60 °C) has been approved by the Medicines and Healthcare products Regulatory Agency (MHRA) for COMIRNATY®▼30 micrograms/dose concentrate for dispersion for injection (tozinameran), COVID-19 mRNA Vaccine (nucleoside modified) in the UK.

The Product Information has been updated with the new shelf-life for the frozen vial, that has been extended from 12 months to 15 months. The storage conditions remain unchanged (-90 °C to -60 °C).

In addition to this being applied to future batches, the 3-month extension may be applied retrospectively to vials manufactured prior to this approval.

Updated expiry dates are shown below for COMIRNATY®▼30 micrograms/dose concentrate for dispersion for injection (tozinameran), purple cap:

<u>Printed Expiry Date</u>		<u>Updated Expiry Date</u>
June 2022	→	December 2022
July 2022	→	January 2023
August 2022	→	February 2023
September 2022	→	March 2023
October 2022	→	April 2023

November 2022 → May 2023
December 2022 → June 2023

Footnote: All dates refer to the end of the calendar month.

Therefore, vaccine with an expiry date of June 2022 through December 2022 printed on the label may remain in use for 6 months beyond the printed date (expiry date update combining 12- and 15-months shelf-life extension), as long as approved storage conditions between -90 °C to -60 °C have been maintained before thawing. The approved storage conditions are unchanged but the allowed 1 month storage and transportation at 2 °C to 8 °C should remain within the 15-month expiry date.

All vials in cartons with the original Pfizer label with an expiry date beyond August 2023 will already reflect the 15 months shelf-life and their shelf-life should not be extended further.

Please note that all of the supplementary information on COMIRNATY impacted by this change is being updated accordingly.

This letter supersedes the communication dated 29 April 2022.

Further information

For product information please refer to
www.comirnatyeducation.co.uk.



Call for reporting

COMIRNATY® ▼ 30 micrograms/dose concentrate for dispersion for injection (tozinameran), COVID-19 mRNA vaccine (nucleoside-modified) is subject to additional monitoring. This will allow quick identification of new safety information.

Suspected adverse reactions associated with COVID-19 vaccines should be reported to the MHRA through the MHRA's Coronavirus Yellow Card reporting site at <https://coronavirus-yellowcard.mhra.gov.uk> or via the Yellow Card app.

When reporting please provide as much information as possible, including information about medical history, any concomitant medications, onset, treatment dates, and vaccine product brand name and batch number.

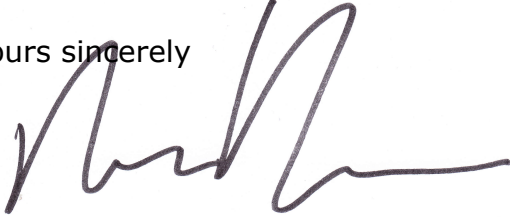
Alternatively, adverse events of concern in association with Comirnaty can be reported to Pfizer Medical Information on 01304 616161 or via www.pfizersafetyreporting.com.

Please do not report the same adverse event(s) to both systems as all reports will be shared between Pfizer and MHRA (in an anonymized form) and dual reporting will create unnecessary duplicates.

Company contact point

If you have any questions about this letter or for more information about COMIRNATY please contact Pfizer Medical Information at Pfizer Limited, Walton Oaks, Dorking Road, Tadworth, Surrey, KT20 7NS or Telephone: 01304 616161.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Ruben Rizzi', with a long horizontal flourish extending to the right.

Ruben Rizzi, MD
Vice President Global Regulatory Affairs
BioNTech Manufacturing GmbH