

## Direct Healthcare Professional Communication

10<sup>th</sup> January 2023

**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 15 months to 18  
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 *06<sup>th</sup> January 2023* a new shelf-life at Ultra-Low-Temperature storage conditions (-90 °C to -60 °C) has been approved in the UK 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 15 months to 18 months. The storage conditions remain unchanged (-90 °C to -60 °C).

Within the 18-month shelf-life, unopened vials may be stored and transported at -25 °C to -15 °C for a single period of up to 2 weeks and can be returned to -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:

<u>Approved Shelf Life at Packaging</u>	<u>Printed Date</u>		<u>Updated Expiry Date</u>
6 Months	December 2021	→	December 2022 <sup>a</sup>
6 Months	January 2022	→	January 2023 <sup>a</sup>
6 Months	February 2022	→	February 2023 <sup>a</sup>
6 Months	March 2022	→	March 2023 <sup>a, b</sup>
9 Months	April 2022	→	January 2023 <sup>c</sup>
9 Months	May 2022	→	February 2023 <sup>d</sup>
9 Months	June 2022	→	March 2023 <sup>b</sup>
9 Months	July 2022	→	April 2023

9 Months	August 2022	→	May 2023
9 Months	September 2022	→	June 2023
9 Months	October 2022	→	July 2023
9 Months	November 2022	→	August 2023
9 Months	December 2022	→	September 2023

<sup>a</sup> - Expiry date update combining 9, 12- and 15- and 18-months shelf-life extension

<sup>b</sup> - Due to implementation of the change in shelf-life from 6 to 9 months in October 2021, two different printed expiry dates could be extended to March 2023.

<sup>c</sup> - Applicable to batch with printed expiry date April 2022 corresponding to 9-months shelf-life; two different printed expiry date could be extended to January 2023

<sup>d</sup> - Applicable to batch with printed expiry date May 2022 corresponding to 9-months shelf-life; two different printed expiry dates could be extended to February 2023

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

**Therefore, vaccine with an expiry date of December 2021 through December 2022 printed on the label may remain in use for 9 or 12 months beyond the printed date (expiry date update combining 15- and 18-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 at 2 °C to 8 °C, with up to 48 hours used for transportation, should remain within the 18-month expiry date.**

**All vials in cartons with the original Pfizer label with an expiry date beyond May 2024 will already reflect the 18 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 19<sup>th</sup> August 2022.

### **Further information**

For product information please refer to  
[www.comirnatyeducation.co.uk](http://www.comirnatyeducation.co.uk).



### **Reporting of suspected adverse reactions**

**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.

Healthcare professionals and patients are asked to report any suspected adverse reactions associated with the use of COVID-19 vaccines to the Coronavirus Yellow Card reporting site at <https://coronavirus-yellowcard.mhra.gov.uk/> or via the free Yellow Card App (available from the Apple App Store or Google Play Store).

When reporting, please provide as much information as possible, including vaccine brand name and batch number, vaccination date, previously received doses, onset and description of the reaction, and information about medical history and any concomitant medication.

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

Other suspected adverse drug reactions (ADRs) should be reported via the Yellow Card scheme. Report via the website <https://www.gov.uk/yellowcard>, the Yellow Card app, and some clinical IT systems (EMIS, SystemOne, Vision, MiDatabank) for healthcare professionals.

***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



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