13 May 2022 - Updated Resources for Pharmacies | mRNA Shelf Life Extension | Decreasing the Minimum Orderable Quantity of Thawed Pfizer 12+ | Vaccine Administration Errors

Dear Service Provider,

This email provides information from the National COVID Vaccine Taskforce (the Taskforce) about a range of matters relevant to pharmacies participating in the COVID-19 Vaccination in Community Pharmacy Program (CVCP), as follows:

- Updated Resources for Pharmacies
- mRNA Shelf Life Extension
- Decreasing the Minimum Orderable Quantity of Thawed Pfizer 12+
- Vaccine Administration Errors.

Updated Resources for Pharmacies

Vaccine Comparison Poster and ATAGI COVID-19 vaccines and doses poster

- The COVID-19 vaccine comparison poster has recently been updated.
- The ATAGI COVID-19 vaccines and doses poster has been developed to help avoid vaccine administration errors.

ATAGI Pregnancy Update

- The COVID-19 vaccination decision guide for women who are pregnant, breastfeeding or planning pregnancy has been updated to include the following:
    - Updated information on Nuvaxovid (Novavax)
    - Booster dose information for those aged 16 and 17 years
    - Updated information on vaccine safety and effectiveness in pregnant individuals and infants.

mRNA Shelf Life Extension

Shelf Life Extension Applied Incorrectly to Thaw Expiry

- Recently the Therapeutic Goods Administration (TGA) approved a shelf-life extension for certain batch numbers of Moderna, Pfizer 12+ years (**purple cap**)

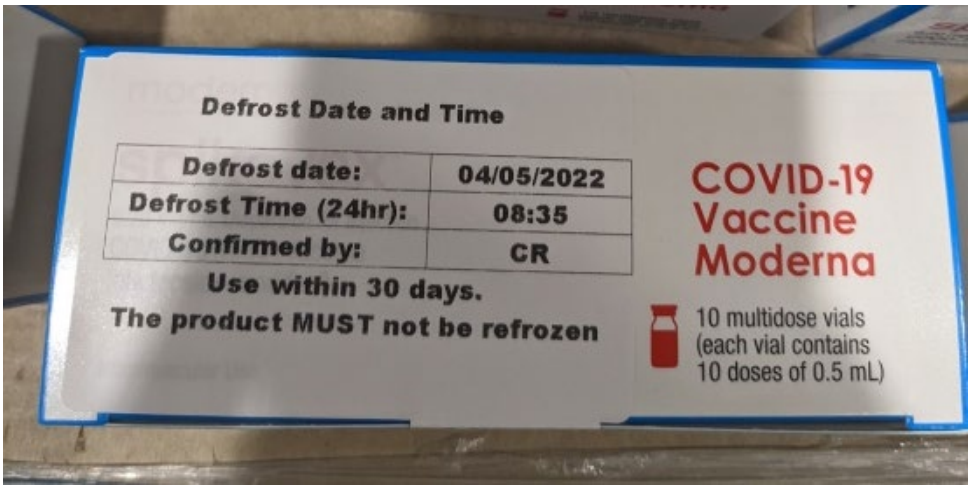
and Pfizer 5-11 years (**orange cap**) vaccines, when stored at frozen, prior to thawing.

- The **storage conditions for thawed deliveries,** however, **remain unchanged.**
- Within this extended **manufacturer expiry** date, unopened vials should be stored refrigerated at 2-8◦C, protected from light, for a maximum of:
    - 30 days after thawing for Moderna
    - 31 days after thawing for Pfizer 12+ years (**purple cap**)
    - 70 days (10 weeks) after thawing for Pfizer 5-11 years (**orange cap**)
- Both manufacturer expiry date and thaw use-by date should be checked prior to administration. The earliest of these dates should be considered the expiry date.

The **Pfizer 5-11 (orange cap)** defrost date will be shown on the box. This vaccine must be used within **10 weeks** of the defrost date shown.

The **Pfizer 12+ (purple cap)** defrost date will be shown on the box. This vaccine must be used within **31 days** of the defrost date shown.

The **Moderna** vaccine defrost date will be shown on the box. This vaccine must be used within **30 days** of the defrost date shown.



Decreasing the Minimum Orderable Quantity of Thawed Pfizer 12+

- Some pharmacies have requested to have the minimum orderable quantity for **Pfizer 12+ (purple cap)** reduced.
- Sites are now able to order **a minimum of 60 doses from Saturday 14 May 2022,** at the start of the new order window.
- The minimum orderable quantity for all other vaccines remains at 100 doses.

Vaccine Administration Errors (VAEs)

- The Vaccine Operations Centre (VOC) has noted several VAEs recently, where thaw use-by date has been disregarded. This has occurred following misinterpretation of the extension to the manufacturer expiry date.
- Best practice in handling and administering COVID-19 vaccines should always be followed, as detailed in:
    - the mandatory COVID-19 Vaccination Training modules;
    - the Australian Technical Advisory Group on Immunisation (ATAGI) advice on the Transporting, storing and handling COVID-19 vaccines webpage; and
    - in the relevant vaccine Product Information for Spikevax (Moderna), Comirnaty 12+ (Pfizer purple cap) and Comirnaty 5-11 years (Pfizer orange cap).

Case Study One

Pfizer 12+ years (purple cap) vaccine was administered over 100 days post thawing and well after the thaw use-by date to a large number of people.

- The Therapeutic Goods Administration (TGA) recently approved a new shelf-life extension for **Pfizer 12+ years (purple cap)** when stored at -90 to -60 degrees C.

- There was confusion at the site around this change and it was believed the extension was in relation to the thaw use-by date rather than the manufacturer expiry date while stored in ultra-cold temperatures.

How this can be prevented: Please read any communication around changes to COVID-19 vaccine administration and storage carefully. If there is uncertainty around any changes, refer to the mandatory COVID-19 Vaccination Training modules, the Australian Technical Advisory Group on Immunisation (ATAGI) Advice for COVID-19 vaccine providers and administrators webpage, the relevant vaccine Product Information or contact the VOC to clarify.

Case Study Two

Spikevax (Moderna) vaccine was administered to a patient within the thaw use-by date but after the manufacturer expiry date printed on the packaging.

- The thaw-use by date was checked upon vaccination but the manufacturer expiry date printed on the packaging was not checked until recording the vaccination in the Australian Immunisation Register (AIR).
- The site had not checked and updated the labelling on their vaccine stock when they received communication about the shelf-life extension of the manufacturer expiry date.
- The vaccine given was administered within the new shelf-life extension, so no vaccine administration error occurred on this occasion.

How this can be prevented: Sites should have detailed processes and procedures in place which detail how to store, label and maintain vaccines on site to avoid errors occurring, such as processes which require the clear labelling of each vial and vial box with the thaw use-by date. Providers should also check both thaw use-by date and manufacturer expiry date prior to each vaccination and the earliest expiry date should be used. If any communication is received specific to batches (e.g. shelf-life extensions, recalls, etc.) stock should be checked and identified with the relevant change.

Kind regards,
Pharmacy Programs Administrator