

# Storage of COVID-19 vaccines in pharmacies

Community pharmacies approved to participate in the Commonwealth Government's COVID-19 vaccine rollout will need to be able to store quantities of vaccines under refrigeration, in readiness for administration. These pharmacies must comply with the <u>Australian Technical Advisory Group on Immunisation (ATAGI) site requirements</u> for COVID-19 vaccination in community pharmacies as well as any standards outlined in the <u>Australian Immunisation Handbook</u>, including the <u>National vaccine</u> storage guidelines (Strive for 5).

Normally, Schedule 4 medicines, which includes all vaccines, awaiting dispensing would be kept in the dispensary area, consistent with plans submitted as part of pharmacy registration under the *Pharmacy Act 2010*. Storage in the dispensary also ensures compliance with Regulation 90(1) of the Medicines and Poisons Regulation 2016, which requires Schedule 4 medicines in pharmacies be stored 'in an area or in a manner that prevents physical access to the medicine by any person other than a person who is employed in the pharmacy'.

## Can a community pharmacy store COVID-19 vaccines outside the dispensary area?

COVID-19 vaccines are different to other vaccines routinely administered within pharmacies as they are supplied in multi-dose vials. This means additional preparation prior to administration is required. ATAGI requirements are that pharmacies have a dedicated area, separate from areas that provide other pharmacy services at the same time, where vaccines from multi-dose vials may be drawn up, labelled, and prepared for administration.

Both space considerations and work flow associated with use of multi-dose vials mean pharmacies may wish to store COVID-19 vaccines outside the dispensary area. For many pharmacies, both preparation and administration (at separate times) will occur within their consultation room.

It is acceptable for pharmacies to store COVID-19 vaccines outside the dispensary provided the following conditions are met:

- Storage is within the area of the pharmacy where the vaccines will be prepared, such as a consultation room.
- There are handwashing facilities available in a location that allows standard aseptic technique to be maintained.
- A dedicated lockable vaccine refrigerator is used for storage.
- The pharmacy has procedures to ensure the temperature within the refrigerator is monitored and maintained within the required limits, in accordance with the national guidelines.
- The refrigerator is opaque (including the door) or the vaccines are stored such that their identity is not visible to those using the area for activities other than vaccine preparation and administration (such as when the consultation room is being used for patient counselling).

- Information about the area to be used for COVID-19 vaccine storage, including a plan (which can be hand-drawn), is submitted to the <a href="Pharmacy Registration Board of WA">Pharmacy Registration Board of WA</a>.
  - o Provision of information via a Premises Plan in place of a separate document.

If a suitable current Premises Plan is held by the Board, adding the location of a COVID-19 vaccine refrigerator is a simple process and preserves relevant information being shown on one document.

If not, the Board has the opportunity to update its records outside of an application or compliance activity.

It is not acceptable to store vaccines in the general retail area of the pharmacy, even when the refrigerator is lockable. This would not be considered to meet the requirements of the Medicines and Poisons legislation for storage of Schedule 4 medicines.

#### Can influenza vaccines be stored the same way?

No, influenza vaccines should continue to be stored in a vaccine refrigerator within the dispensary area. The following table describes factors that influence the different storage rules for these two types of vaccines.

#### Comparison between COVID-19 vaccines and influenza vaccines

Factor	COVID-19 vaccine	Influenza vaccine
Schedule	Schedule 4 (prescription only)	Schedule 4 (prescription only)
Responsibility for program rollout	Commonwealth Department of Health	WA Department of Health (National Immunisation Program, NIP stock) and private providers
Funding	Commonwealth, no fee to consumer	Commonwealth (NIP stock) or private, pharmacy can charge fees to consumer
Dosage form	Multi-dose vial	Pre-filled syringe (single dose)
Stock distribution	Via Commonwealth contracted logistics companies, additional requirements for reporting stock acceptance and stock management	Via standard pharmacy supply chain wholesalers
Risk of theft or damage	Higher, new product, limited amount available, potential target of anti-vaccination advocates	Lower, well established product with multiple brands available

### Acknowledgement

This Guideline has been jointly developed by the Medicines and Poisons Regulation Branch at the Department of Health and the Pharmacy Registration Board of Western Australia.

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