



17 February 2022- TGA Provisionally Approves Moderna for ages 6 years and older | Compliance Update - Pfizer Paediatric Vaccines

Dear Pharmacy,

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

- TGA provisional approval of Moderna for ages 6 years and older
- A compliance update regarding Pfizer paediatric vaccines.

TGA UPDATE

The TGA provisionally approves Moderna for ages 6 years and older

On 17 February 2022, the Therapeutic Goods Administration (TGA) provisionally [approved](#) Spikevax (Moderna COVID-19) as a primary course vaccine for individuals aged **6 years** and older.

The same vaccine preparation employed for older age groups will be used, however, a **lower dose of 0.25 mL (50 micrograms)** will be given to children 6-11 years, compared to the 0.5 mL (100 microgram) dose used for those 12 years and older.

The Australian Technical Advisory Group on Immunisation (ATAGI) is currently considering the regulatory approval and will provide their recommendations on the use of Moderna in coming days.

The National COVID Vaccine Taskforce will provide further advice on the implementation of Moderna for those aged 6 – 11 within the COVID-19 Vaccination Program once Government has considered ATAGI's final recommendations.

As part of this, the Moderna training modules will be updated in line with the ATAGI advice. Clinicians will be required to complete the updated training module prior to administering the Moderna vaccine to children in this age group.

Further advice will also be provided on surfacing on the Vaccine Clinic Finder.

Moderna for those aged 6 – 11 is not yet included for use within the COVID-19 Vaccination Program.

COMPLIANCE UPDATE

Following the recent commencement of Pfizer paediatric COVID-19 vaccinations for patients aged 5-11 years of age, the Taskforce advises that there have been a concerning number of vaccination errors received involving paediatric vaccinations, including in community pharmacies. Errors include administering:

- Too much or too little dosage of the Pfizer 5-11 years vaccine (ORANGE CAP)
- Pfizer adult vaccine (PURPLE CAP) to patients under 12 years of age
- Moderna vaccine to patients under 12 years of age
- Booster doses to patients aged under 12 years of age.

The Taskforce has requested that the PPA investigate these compliance cases as a priority. The Taskforce has indicated that where serious systemic issues are identified, action will be taken, including the **possible exclusion of individual pharmacies from delivering paediatric COVID-19 vaccinations.**

Paediatric Training Mandatory

The Taskforce reminds all pharmacies participating in the CVCP Program that **vaccinators must complete the relevant training for each COVID-19 vaccine they are administering prior to administering a vaccine.** This includes the module for the Pfizer 5-11 years (ORANGE CAP) vaccine. Vaccinators must not administer COVID-19 vaccines if they have not completed the [relevant training module for that specific vaccine](#). The Approved Pharmacist is responsible for ensuring pharmacists administering each vaccine have completed the relevant mandatory training modules.

Paediatric Dosage

The paediatric vaccine dose of Pfizer for children is one third of the dose for people aged 12 and over. **To deliver the smaller dose, a different ORANGE-CAPPED vial must be used to vaccinate children.** It is clearly differentiated from the product currently used to vaccinate those 12 years and older.

Children aged 5 to 11 years will receive a 2-dose primary course of vaccination, given 8 weeks apart. This interval can be shortened in special circumstances to a minimum of 3 weeks.

Further information regarding TGA Approval for the Pfizer vaccine for children aged 5 to 11 can be found [here](#).

Vaccine Separation

Pharmacies are strongly encouraged to separate administration of different vaccines by time, location, or vaccinator to reduce the likelihood of errors or confusion between vaccines. Techniques to separate vaccines include:

- Storing different COVID-19 vaccines in separate fridges (if possible) or on different shelves within the fridge
- If multiple consultation rooms are available, using different rooms for different vaccines
- Ensuring every vaccine in a drawn-up syringe is labelled with batch and vial expiry, as well as dose expiry
- If possible, having practitioners administer separate vaccines (e.g. a dedicated paediatric vaccinator)
- Use talkback and positive ID techniques (e.g. what vaccine are you here for, what is your DOB, reading out the expiry time).

The administration of COVID-19 vaccines continues to be an evolving and complex environment, as new vaccines emerge, coupled with TGA and ATAGI decisions regarding their use. It is imperative, therefore, for vaccinators to remain up to date in training for the vaccines they are administering and implement processes to separate vaccines to reduce confusion in their administration. The Taskforce advises that in circumstances where pharmacies are not able to keep abreast of the changing environment and as a result make serious or repeated compliance breaches, pharmacies may need to be excluded from the CVCP Program in the interest of patient safety.

The Taskforce does however acknowledge the enormous contribution that community pharmacies continue to make towards protecting our community from COVID-19 and that in the vast majority of cases vaccines are being administered appropriately. To date pharmacies have delivered over 5.5 million vaccinations, which is an outstanding achievement.

Kind regards,

Pharmacy Programs Administrator