Poisons and Therapeutic Goods Act 1966 – Section 9
Poisons and Therapeutic Goods Regulation 2008 – Clause 162 and 163
Licence to supply by wholesale certain restricted substances

Licence No Covidvax 007

1. This licence is issued to the following persons (***the licensee***) who have been supplied the restricted substance (specified at Schedule 1) by the Commonwealth Department of Health or, in respect of a responsible person at a residential care facility, from an authorised person at a GP clinic:
   a) An *authorised person* at a NSW Health vaccination clinic
   b) An *authorised person* at an Aboriginal Community Controlled Health Service that has registered to participate in the COVID-19 vaccination program; and
   c) An *authorised person* at a GP clinic that has registered to participate in the COVID-19 vaccination program
   d) An *authorised person* registered to participate in the COVID-19 vaccine program in NSW under the Commonwealth's Vaccine Administration Partners Program
   e) An *authorised person* at a community pharmacy approved under Schedule 5F of the *Health Practitioner Regulation National Law* (NSW) that has registered to participate in the COVID-19 vaccination program; or
   f) A *responsible person* at a residential care facility.
2. This licence only authorises the supply by wholesale of the restricted substances specified in Schedule 1.
3. This licence is subject to the conditions set out in Schedule 2.
4. This licence commences at the beginning of 23 September 2024 and remains in force until the beginning of **23 September 2025** unless earlier cancelled by the Secretary, NSW Health, and is not transferrable.

In this instrument:

- An *Authorised person* means a person licensed or authorised to supply, dispense or be in possession of the restricted substance (specified at Schedule 1) under the *Poisons and Therapeutic Goods Act 1966* (**the Act**) or *Poisons and Therapeutic Goods Regulation 2008* (**the Regulation**) in accordance with the provisions of the Act and Regulation.
- *Responsible person* has the same meaning as in the Regulation.

Schedule 1 – restricted substances for supply by wholesale

SARS-COV-2 (COVID-19) vaccine (all brands).

Delegate of the Secretary, NSW Health
19 September 2024

Schedule 2 — Schedule of conditions

1. The Schedule 1 restricted substances can only be supplied by wholesale to an: a) *authorised person* at NSW Health vaccination clinics; b) *authorised person* at Aboriginal Community Controlled Health Services in New South Wales that have registered to participate in the COVID-19 vaccination program; c) *authorised person* at GP clinics in New South Wales that have registered to participate in the COVID-19 vaccination program; d) *authorised person* at community pharmacies approved under Schedule 5F of the *Health Practitioner Regulation National Law* (NSW) that have registered to participate in the COVID-19 vaccination program; e) *responsible person* at a residential care facility; and f) *authorised person* who is registered to participate in the COVID-19 vaccine program in NSW under the Commonwealth's Vaccine Administration Partners Program.
2. The Schedule 1 restricted substances must only be supplied in the unopened ARTG registered packs or, in the alternative, unopened vials as received from the supplier.
3. The licensee must notify the Secretary, NSW Health, of any requests for supply of the Schedule 1 restricted substances in quantities which appear to be inconsistent with the activities of the business for which it is being supplied.
4. Records of supply related to the supply of the Schedule 1 restricted substance can only be issued in the name of the authorised person supplying and supply must be made to the authorised person receiving the supply.
5. The licensee must make, and hold for a period of at least 2 years, a record of the supply of the Schedule 1 restricted substance, and provide a copy to the recipient.
6. The licensee must comply with any record keeping requirements imposed by the Commonwealth Department of Health.
7. The licensee must comply with storage and any cold chain requirements, including during transit of the product, in accordance with the Product Information Sheet for the Schedule 1 restricted substance.
8. Appropriate cold chain records that comply with the Product Information sheet for the Schedule 1 restricted substance must be maintained during transit and at storage sites and shared to verify cold chain storage as needed.

Delegate of the Secretary, NSW Health
19 September 2024