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

Licence No NMS0125

1. The licence issued to the National Medical Stockpile dated 31 March 2022 and **annexed** to this instrument is cancelled.
2. This licence is issued to the National Medical Stockpile (**the licensee**).
3. This licence only authorises the supply by wholesale of the restricted substances specified in Schedule 1.
4. This licence is subject to the conditions set out in Schedule 2.
5. This licence remains in force until **5 August 2024** 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 Schedule 1 restricted substance 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
- *Residential care facility* and *responsible person* have the same meaning as in the Regulation
- *Local health district, statutory health corporation,* and *affiliated health organisation* have the same meaning as in the *Health Services Act 1997*
- *State Vaccine Centre* has the same meaning as under the *Health Practitioner Regulation National Law*
- *Restricted substance* means a substance specified in Schedule 4 of the Poisons List
- *Poison* is a substance specified in Schedule Two and Schedule Three of the Poisons List
- *Poisons List* has the same meaning as under the Act.

Schedule 1

• **Schedule 1A —** Molnupiravir and Nirmatrelvir plus Ritonavir
• **Schedule 1B —** Oseltamivir
• **Schedule 1C —** Any poison or restricted substance

Schedule 2 — Schedule of conditions

1. A Schedule 1A restricted substance can only be supplied by wholesale to: • an *Authorised person* on behalf of an Aboriginal Community Controlled Health Service; or • a responsible person at a residential care facility.
2. A Schedule 1B restricted substance can only be supplied by wholesale to:

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• a responsible person at a residential care facility.
3. A Schedule 1C poison or restricted substance can only be supplied by wholesale to: • An *Authorised person* at a State Vaccine Centre • A Chief Pharmacist on behalf of a local health district • A Chief Pharmacist on behalf of the following affiliated health organisations: o Calvary Health Care (Newcastle) Limited o Calvary Health Care Sydney Limited o St Vincent's Hospital Sydney Limited • A Chief Pharmacist on behalf of the following statutory health corporations: o Justice Health and Forensic Mental Health Network o The Sydney Children's Hospitals Network (Randwick and Westmead) (incorporating The Royal Alexandra Hospital for Children).
4. The poison or restricted substance must only be supplied in the unopened packs as received from the supplier.
5. The licensee must make, and hold for a period of at least 2 years, a record of the supply of the poison or restricted substance.
6. The licensee must comply with any record keeping requirements imposed by the Commonwealth Department of Health.
7. To the extent the substance is a Schedule 1C vaccine subject to a direction of the Chief Health Officer of the Ministry of Health, the licensee must comply with that direction in relation to the vaccine.
8. The licensee must comply with storage requirements, including during transit of the product, in accordance with the Product Information Sheet for the restricted substance.

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

Licence No NMS0124

1. The licence issued to the National Medical Stockpile dated 7 February 2022 and **annexed** to this instrument is cancelled.
2. This licence is issued to the following persons (**the licensee**):
    a. National Medical Stockpile; and
    b. A Local Health District.
3. This licence only authorises the supply by wholesale of the restricted substances specified in Schedule 1.
4. This licence is subject to the conditions set out in Schedule 2.
5. This licence remains in force until **31 March 2024** 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 Schedule 1 restricted substance 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
- *Residential care facility* and *responsible person* have the same meaning as the Regulation
- *Local Health District* has the same meaning as the *Health Services Act 1997*.

Schedule 1

• **Schedule 1A —** Molnupiravir and Nirmatrelvir plus Ritonavir
• **Schedule 1B —** Oseltamivir

Schedule 2 — Schedule of conditions

1. A Schedule 1A restricted substance can only be supplied by wholesale to: • an *Authorised person* on behalf of an Aboriginal Community Controlled Health Service; or • a responsible person at a residential care facility
2. A Schedule 1B restricted substance can only be supplied by wholesale to: • a responsible person at a residential care facility
3. The Schedule 1 restricted substance must only be supplied in the unopened packs as received from the supplier.
4. 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.
5. The licensee must comply with any record keeping requirements imposed by the Commonwealth Department of Health.
6. The licensee must comply with storage requirements, including during transit of the product, in accordance with the Product Information Sheet for the Schedule 1 restricted substance.

Judeth Madison
Delegate of the Secretary, NSW Health
31 March 2022