

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

Licence No LHD 005

1. The licence signed on 5 August 2022 and annexed to this licence is cancelled.
2. This licence is issued to the following specified public health organisations:
 - A local health district
 - A specified affiliated health organisation, namely:
 - St Vincent's Hospital Sydney Limited
 - Calvary Health Care (Newcastle) Limited
 - Calvary Health Care Sydney Limited
 - A specified statutory health corporation, namely:
 - The Sydney Children's Hospitals Network (Randwick and Westmead) (incorporating The Royal Alexandra Hospital for Children)
 - Justice Health and Forensic Mental Health Network(collectively, **the licensee**) in relation to the substances listed at Schedule 1.
3. This licence is subject to the conditions set out in Schedule 2.
4. This licence remains in force until **20 December 2024** unless earlier cancelled by the Secretary, NSW Health and is not transferrable.

In this instrument:

- *Public health organisation, local health district, statutory health corporation, and affiliated health organisation* have the same meaning as in the *Health Services Act 1997* (NSW)
- An *Authorised person* means a person licensed or authorised to supply, dispense or be in possession of the poison or 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
- *Responsible person* has the same meaning as in the Regulation
- *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

- Any *poison or restricted substance*

Schedule 1B

- sotrovimab

Schedule 1C

- molnupiravir
- nirmatrelvir with ritonavir



Schedule 1D

- casirivimab with imdevimab
- remdesivir
- tocilizumab

Schedule 1E

- oseltamivir

Schedule 1F

- the following specified vaccine, namely:
 - smallpox vaccine.

Schedule 2 — Schedule of conditions

1. Any substance listed in Schedule 1A can only be supplied by wholesale:
 - a. to a Chief Pharmacist of the following public health organisations or the Director of Nursing on behalf of the public health organisation at which a Chief Pharmacist is not employed:
 - A local health district
 - A specified affiliated health organisation, namely:
 - St Vincent's Hospital Sydney Limited
 - Calvary Health Care (Newcastle) Limited
 - Calvary Health Care Sydney Limited
 - A specified statutory health corporation, namely:
 - The Sydney Children's Hospitals Network (Randwick and Westmead) (incorporating The Royal Alexandra Hospital for Children)
 - Justice Health and Forensic Mental Health Network.
2. A substance listed in Schedule 1B can only be supplied by wholesale to:
 - a. An *Authorised Person* on behalf of the Royal Flying Doctor Service
 - b. An *Authorised Person* on behalf of a GP clinic
 - c. An *Authorised Person* on behalf of an Aboriginal Community Controlled Health Service or Aboriginal Medical Service
 - d. The director of nursing on behalf of a private health facility licenced under the *Private Health Facility Act 2007*; and
 - e. A *responsible person* on behalf of a residential care facility
 - f. A *responsible person* on behalf of a managed correctional centre.
3. A substance listed in Schedule 1C can only be supplied by wholesale to:
 - a. A *responsible person* on behalf of a residential care facility
 - b. A master of a ship
 - c. An *Authorised Person* on behalf of an Aboriginal Community Controlled Health Service or Aboriginal Medical Service
 - d. A *responsible person* on behalf of a managed correctional centre.
4. A substance listed in Schedule 1D can only be supplied by wholesale to:
 - a. The director of nursing on behalf of a private health facility licenced under the *Private Health Facility Act 2007*
 - b. A *responsible person* on behalf of a managed correctional centre.

<p>5. A substance listed in Schedule 1E can only be supply by wholesale to:</p> <p>a. A <i>responsible person</i> on behalf of a residential care facility.</p>
<p>6. A substance listed in Schedule 1F can only be supplied by wholesale to:</p> <p>a. A medical practitioner authorised to prescribe Highly Specialised Drugs for the treatment of Hepatitis B and Human Immunodeficiency Virus under s.100 of the <i>National Health Act 1953 (Cth)</i>.</p>
<p>7. To the extent the substance is a Schedule 1F substance, the licensee must comply with any direction of the Chief Health Officer of the Ministry of Health in relation to the Schedule 1F restricted substance.</p>
<p>8. The poison or restricted substance must only be supplied in the unopened ARTG registered packs or, in the alternative, unopened vials as received from the supplier.</p>
<p>9. The licensee must notify the Secretary, NSW Health, of any requests for supply of the poison or restricted substance in quantities which appear to be inconsistent with the activities of the business for which it is being supplied.</p>
<p>10. Records of the supply of the poison or restricted substance can only be issued in the name of the Chief Pharmacist (or Director of Nursing where relevant) supplying, and supply must be made to the (as relevant):</p> <ul style="list-style-type: none"> a) Chief Pharmacist or Director of Nursing of the public health organisation b) Authorised person of the Royal Flying Doctor Service c) Authorised Person at the GP clinic d) Authorised Person at an Aboriginal Community Controlled Health Service or Aboriginal Medical Service e) Director of nursing on behalf of the private health facility f) Responsible person at the residential care facility g) The master of a ship h) A <i>responsible person</i> on behalf of a managed correctional centre; or i) The medical practitioner authorised to prescribe Highly Specialised Drugs for the treatment of Hepatitis B and Human Immunodeficiency Virus under s.100 of the <i>National Health Act 1953 (Cth)</i>.
<p>11. 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, and provide a copy to the recipient.</p>
<p>12. 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 each poison or restricted substance.</p>
<p>13. Appropriate cold chain records that comply with the Product Information sheet for the poison or restricted substance must be maintained during transit and at storage sites and shared to verify cold chain storage as needed.</p>

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

Licence No LHD 004

1. The licence signed on 17 July 2022 and annexed to this licence is cancelled.
2. This licence is issued to the following specified public health organisations:
 - A local health district
 - A specified affiliated health organisation, namely:
 - St Vincent's Hospital Sydney Limited
 - Calvary Health Care (Newcastle) Limited
 - Calvary Health Care Sydney Limited
 - A specified statutory health corporation, namely:
 - The Sydney Children's Hospitals Network (Randwick and Westmead) (incorporating The Royal Alexandra Hospital for Children)
 - Justice Health and Forensic Mental Health Network(collectively, **the licensee**) in relation to the substances listed at Schedule 1.
3. This licence is subject to the conditions set out in Schedule 2.
4. This licence remains in force until **5 August 2024** unless earlier cancelled by the Secretary, NSW Health and is not transferrable.

In this instrument:

- *Public health organisation, local health district, statutory health corporation, and affiliated health organisation* have the same meaning as in the *Health Services Act 1997* (NSW)
- An *Authorised person* means a person licensed or authorised to supply, dispense or be in possession of the poison or 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
- *Responsible person* has the same meaning as in the Regulation
- *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 <ul style="list-style-type: none">• Any poison or restricted substance
Schedule 1B <ul style="list-style-type: none">• sotrovimab
Schedule 1C <ul style="list-style-type: none">• molnupiravir• nirmatrelvir with ritonavir

<p>Schedule 1D</p> <ul style="list-style-type: none"> • casirivimab with imdevimab • remdesivir • tocilizumab
<p>Schedule 1E</p> <ul style="list-style-type: none"> • oseltamivir
<p>Schedule 1F</p> <ul style="list-style-type: none"> • the following specified vaccine, namely: <ul style="list-style-type: none"> ○ smallpox vaccine.

Schedule 2 – Schedule of conditions

<p>1. Any substance listed in Schedule 1A can only be supplied by wholesale:</p> <ol style="list-style-type: none"> a. to a Chief Pharmacist of the following public health organisations or the Director of Nursing on behalf of the public health organisation at which a Chief Pharmacist is not employed: <ul style="list-style-type: none"> • A local health district • A specified affiliated health organisation, namely: <ul style="list-style-type: none"> ▪ St Vincent's Hospital Sydney Limited ▪ Calvary Health Care (Newcastle) Limited ▪ Calvary Health Care Sydney Limited • A specified statutory health corporation, namely: <ul style="list-style-type: none"> ▪ The Sydney Children's Hospitals Network (Randwick and Westmead) (incorporating The Royal Alexandra Hospital for Children) ▪ Justice Health and Forensic Mental Health Network.
<p>2. A substance listed in Schedule 1B can only be supplied by wholesale to:</p> <ol style="list-style-type: none"> a. An <i>Authorised Person</i> on behalf of the Royal Flying Doctor Service b. An <i>Authorised Person</i> on behalf of a GP clinic c. An <i>Authorised Person</i> on behalf of an Aboriginal Community Controlled Health Service or Aboriginal Medical Service d. The director of nursing on behalf of a private health facility licenced under the <i>Private Health Facility Act 2007</i>; and e. A <i>responsible person</i> on behalf of a residential care facility f. A <i>responsible person</i> on behalf of a managed correctional centre.
<p>3. A substance listed in Schedule 1C can only be supplied by wholesale to:</p> <ol style="list-style-type: none"> a. A <i>responsible person</i> on behalf of a residential care facility b. A master of a ship c. An <i>Authorised Person</i> on behalf of an Aboriginal Community Controlled Health Service or Aboriginal Medical Service d. A <i>responsible person</i> on behalf of a managed correctional centre.
<p>4. A substance listed in Schedule 1D can only be supplied by wholesale to:</p> <ol style="list-style-type: none"> a. The director of nursing on behalf of a private health facility licenced under the <i>Private Health Facility Act 2007</i> b. A <i>responsible person</i> on behalf of a managed correctional centre.

<p>5. A substance listed in Schedule 1E can only be supply by wholesale to:</p> <p>a. A <i>responsible person</i> on behalf of a residential care facility.</p>
<p>6. A substance listed in Schedule 1F can only be supplied by wholesale to:</p> <p>a. A medical practitioner authorised to prescribe Highly Specialised Drugs for the treatment of Hepatitis B and Human Immunodeficiency Virus under s.100 of the <i>National Health Act 1953 (Cth)</i>.</p>
<p>7. To the extent the substance is a Schedule 1F substance, the licensee must comply with any direction of the Chief Health Officer of the Ministry of Health in relation to the Schedule 1E restricted substance.</p>
<p>8. The poison or restricted substance must only be supplied in the unopened ARTG registered packs or, in the alternative, unopened vials as received from the supplier.</p>
<p>9. The licensee must notify the Secretary, NSW Health, of any requests for supply of the poison or restricted substance in quantities which appear to be inconsistent with the activities of the business for which it is being supplied.</p>
<p>10. Records of the supply of the poison or restricted substance can only be issued in the name of the Chief Pharmacist (or Director of Nursing where relevant) supplying, and supply must be made to the (as relevant):</p> <ul style="list-style-type: none"> a) Chief Pharmacist or Director of Nursing of the public health organisation b) Authorised person of the Royal Flying Doctor Service c) Authorised Person at the GP clinic d) Authorised Person at an Aboriginal Community Controlled Health Service or Aboriginal Medical Service e) Director of nursing on behalf of the private health facility f) Responsible person at the residential care facility g) The master of a ship h) A <i>responsible person</i> on behalf of a managed correctional centre; or i) The medical practitioner authorised to prescribe Highly Specialised Drugs for the treatment of Hepatitis B and Human Immunodeficiency Virus under s.100 of the <i>National Health Act 1953 (Cth)</i>.
<p>11. 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, and provide a copy to the recipient.</p>
<p>12. 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 each poison or restricted substance.</p>
<p>13. Appropriate cold chain records that comply with the Product Information sheet for the poison or restricted substance must be maintained during transit and at storage sites and shared to verify cold chain storage as needed.</p>

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

Licence No LHD 003

1. The licence signed on 3 February 2022 and annexed to this licence is cancelled.
2. This licence is issued to a *public health organisation (the licensee)* in relation to the substances listed at Schedule 1.
3. This licence is subject to the conditions set out in Schedule 2.
4. This licence remains in force until **30 September 2024** unless earlier cancelled by the Secretary, NSW Health and is not transferrable.

In this instrument:

- *Public health organisation* has the same meaning as in the *Health Services Act 1997* (NSW)
- An *Authorised person* means a person licensed or authorised to supply, dispense or be in possession of the poison or 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
- A *responsible person* for a managed correctional centre has the same meaning as in the Regulation
- *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
- *Managed correctional centre* has the same meaning as in the *Crimes (Administration of Sentences) Act 1999*.

Schedule 1

<p>Schedule 1A</p> <ul style="list-style-type: none"> • Any <i>poison or restricted substance</i>
<p>Schedule 1B</p> <ul style="list-style-type: none"> • sotrovimab
<p>Schedule 1C</p> <ul style="list-style-type: none"> • molnupiravir • nirmatrelvir with ritonavir
<p>Schedule 1D</p> <ul style="list-style-type: none"> • specified monoclonal antibodies namely: <ul style="list-style-type: none"> ○ casirivimab with imdevimab • remdesivir • tocilizumab

Schedule 2 — Schedule of conditions

<p>1. A substance listed in Schedule 1A can only be supplied by wholesale to:</p> <ul style="list-style-type: none"> a. A Chief Pharmacist on behalf of a public health organisation or the Director of Nursing on behalf of a public health organisation at which a Chief Pharmacist is not employed; and b. A <i>responsible person</i> for a managed correctional centre.
<p>2. A substance listed in Schedule 1B can only be supplied by wholesale to:</p> <ul style="list-style-type: none"> a. An <i>Authorised Person</i> on behalf of the Royal Flying Doctor Service; b. An <i>Authorised Person</i> on behalf of a GP clinic; c. An <i>Authorised Person</i> on behalf of an Aboriginal Community Controlled Health Service or Aboriginal Medical Service; d. The director of nursing on behalf of a private health facility licenced under the <i>Private Health Facility Act 2007</i>; and e. A <i>responsible person</i> on behalf of a residential care facility.
<p>3. A substance listed in Schedule 1C can only be supplied by wholesale to:</p> <ul style="list-style-type: none"> a. A <i>responsible person</i> on behalf of a residential care facility; and b. A master of a ship.
<p>4. A substance listed in Schedule 1D can only be supplied by wholesale to:</p> <ul style="list-style-type: none"> a. The director of nursing on behalf of a private health facility licenced under the <i>Private Health Facility Act 2007</i>.
<p>5. The poison or restricted substance must only be supplied in the unopened ARTG registered packs or, in the alternative, unopened vials as received from the supplier.</p>
<p>6. The licensee must notify the Secretary, NSW Health, of any requests for supply of the poison or restricted substance in quantities which appear to be inconsistent with the activities of the business for which it is being supplied.</p>
<p>7. Records of the supply of the poison or restricted substance can only be issued in the name of the Chief Pharmacist (or Director of Nursing where relevant) supplying, and supply must be made to the (as relevant):</p> <ul style="list-style-type: none"> a) Chief Pharmacist or Director of Nursing of the public health organisation b) Responsible person for a managed correctional centre c) Authorised person of the Royal Flying Doctor Service d) Authorised Person at the GP clinic e) Authorised Person at an Aboriginal Community Controlled Health Service or Aboriginal Medical Service f) Director of nursing on behalf of the private health facility; g) Responsible person at the residential care facility; or h) A master of a ship.
<p>8. 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, and provide a copy to the recipient.</p>
<p>9. 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 each poison or restricted substance.</p>



10. Appropriate cold chain records that comply with the Product Information sheet for the poison or restricted substance must be maintained during transit and at storage sites and shared to verify cold chain storage as needed.

