

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 HSD001

- This licence is issued to a medical practitioner authorised to prescribe Highly Specialised Drugs for the treatment of Hepatitis B and Human Immunodeficiency Virus under s.100 of the *National Health Act 1953* (Cth) (**the licensee**).
- This licence only authorises the supply by wholesale of the restricted substance specified in Schedule 1.
- This licence is subject to the conditions set out in Schedule 2.
- This licence remains in force until **5 August 2024** unless earlier cancelled by the Secretary, NSW Health and is not transferrable.

In this instrument:

- *local health district* has the same meaning as in the *Health Services Act 1997* (NSW).

Schedule 1

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

Schedule 2 — Schedule of conditions

1. A Schedule 1 restricted substance can only be supplied by wholesale to:
 - a medical practitioner authorised to prescribe Highly Specialised Drugs for the treatment of Hepatitis B and Human Immunodeficiency Virus under s.100 of the *National Health Act 1953* (Cth)
 - a Chief Pharmacist on behalf of:
 - a local health district
 - St Vincent's Hospital Sydney Limited.
2. The Schedule 1 restricted substance must only be supplied in the unopened packs as received from the supplier.
3. 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.
4. The licensee must comply with any record keeping requirements imposed by the Chief Health Officer of the Ministry of Health.
5. The licensee must comply with any direction of the Chief Health Officer of the Ministry of Health in relation to the Schedule 1 restricted substance.
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.