CM H23/59207-1

POISONS AND THERAPEUTIC GOODS REGULATION 2008

EXEMPTION

I, MONIQUE REYES, Acting Deputy Chief Pharmacist and a duly appointed delegate of the Secretary of the Ministry of Health, pursuant to clauses 133(2) and 133 (3) of the *Poisons and Therapeutic Goods Regulation 2008* (**the Regulation**), do hereby exempt:

- Australian Red Cross Society and *Approved Health Providers* from compliance with the Wholesaling Code of Practice, but only to the extent that the supply by wholesale of a substance is made under and in accordance with Licence No Lifeblood 001 annexed to this instrument.

In this instrument:

- Licence No Lifeblood 001 means the annexed licence signed 8 August 2023.
- Wholesaling Code of Practice means the *Australian Code of Good Wholesaling Practice for Therapeutic Goods for Human Use*, published by the Commonwealth Government, as in force from time to time or a code of practice that replaces that Code.

Monique Reyes
Acting Deputy Chief Pharmacist
(Delegation Number: PH524)

8 August 2023

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

CM H23/59207

Licence No Lifeblood 001

1. This licence is issued to Australian Red Cross Society (ABN 50 169 561 394) and an *Approved Health Provider* (collectively, the ***licensee***) in relation to the substances listed at Schedule 1.
2. This licence is subject to the conditions set out in Schedule 2.
3. This licence remains in force until cancelled by the Secretary, NSW Health and is not transferrable.

In this licence:

- *Approved Health Provider* means a person or entity (including a pathology/transfusion laboratory on behalf of a public hospital or private health facility, a private infusion clinic, and a private pathology provider lab located outside a public hospital or private health facility) that is registered with the National Blood Authority to hold blood and blood products having demonstrated to the Australian Red Cross Society or the NSW Ministry of Health that it is able to meet the expectations of the Australian Health Ministers' Statement on National Stewardship Expectations for the Supply of Blood and Blood products issued on 12 November 2010.
- 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.
- *National Blood Authority*, means a non-corporate Commonwealth entity established under the *National Blood Authority Act 2003* (Cth).
- A *public hospital* takes the same meaning as in the *Health Services Act 1997* (NSW).
- A *private health facility* takes the same meaning as in the *Private Health Facilities Act 2007* (NSW).

Schedule 1

• IMMUNOGLOBULINS for human parenteral use.

Schedule 2 — Schedule of conditions

1. The licensee must only supply a substance listed in Schedule 1 by wholesale to an *Approved Health Provider* or an *Authorised person*.
2. The substance listed in Schedule 1 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 substance listed in Schedule 1 in quantities which appear to be inconsistent with the activities of the business for which it is being supplied.

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4. The licensee must make and keep records of supply related to the supply of the substance listed in Schedule 1 issued in the name of the person supplying and receiving the supply.
5. The licensee must make, and hold for a period of at least 2 years, a record of supply of the substance listed in Schedule 1, and provide a copy to the recipient.
6. 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 substance listed in Schedule 1.
7. Appropriate cold chain records that comply with the Product Information sheet for the substance listed in Schedule 1 must be maintained during transit and at storage sites and shared to verify cold chain storage as needed.
8. The licensee must have policies and procedures in place that address: • safety and security of the facility and scheduled substances held in the facility • prevention of diversion, theft, misuse and illegal distribution of scheduled substances; and • reporting of theft or misuse of substances.

Delegate of the Secretary, NSW Health
8 August 2023