POISONS AND THERAPEUTIC GOODS REGULATION 2008

AUTHORITY

Supply of poisons and restricted substances

I, Kerry Chant, Chief Health Officer, a duly appointed delegate of the Secretary, NSW Health, make this instrument pursuant to clause 170 of the *Poisons and Therapeutic Goods Regulation 2008* (NSW) [the Regulation] for the purposes of clause 17 and clause 53 of the Regulation and section 10(2)(b) and section 10(4)(d) of the *Poisons and Therapeutic Goods Act 1966*. Pursuant to clause 171(1) of the Regulation, the authorisation is granted subject to conditions.

KERRY CHANT
Chief Health Officer
(Delegation Numbers PH427, PH380 & PH381)

Date: 8 February 2024

Authorisation to Supply Poisons and Restricted Substances

1 Authorisation

This order authorises the Authorised Person to supply the following poisons and restricted substances:

Poison or Restricted Substance	
Adrenaline	Mumps vaccine
Diphtheria toxoid	Pertussis antigen 'Pertussis vaccine'
Haemophilus influenzae vaccine	Pneumococcal vaccine
Hepatitis A vaccine	Poliomyelitis vaccine
Hepatitis B vaccine	Specified *vaccine* for human therapeutic use, namely: • Rotavirus vaccine
Recombinant varicella zoster virus glycoprotein e antigen	Rubella vaccine
Human papillomavirus vaccine	Tetanus toxoid
Influenza and coryza vaccine 'Influenza vaccine'	Typhoid vaccine
Measles vaccine	Varicella vaccine

Meningococcal vaccine	Meningococcal Group B vaccine

This order also authorises an Authorised Person who has completed additional training referred to at clause 2(2), clause 2(3), and 2(4) respectively, to supply:

Poison or restricted substance	
Japanese Encephalitis vaccine	SARS-COV-2 (COVID-19) vaccine
Tuberculin	Specified *vaccine* for human therapeutic use, namely: • Tuberculosis (BCG) vaccine

2 Authorised Person or Class of Persons

(1) An Authorised Person is a Registered Nurse or Registered Midwife who has successfully completed:

a. The NSW Department of Health Immunisation Accreditation Program for Registered Nurses prior to 2001, or
b. The immunisation education program administered by the Australian College of Nursing or its predecessors prior to 1 December 2020, or
c. An interstate immunisation education program, as approved by the Australian College of Nursing prior to 1 December 2020, or
d. An immunisation course for registered nurses and midwives that conforms to the National Immunisation Education Framework for Health Professionals, following accreditation by Health Education Services Australia (HESA) and published on the list of approved courses on the HESA website, or
e. An interstate immunisation education program that conforms to the National Immunisation Education Framework for Health Professionals, as approved by an education provider following the accreditation of their course by HESA and listing of their course on the HESA website.

(2) For the purposes of supply and administration of a SARS-COV-2 (COVID-19) vaccine, an Authorised Person is a Registered Nurse or Registered Midwife who, in addition to the requirements at clause 2(1) ensures at a minimum that they have read the Australian Technical Advisory Group on Immunisation (ATAGI) guidance on the use of multi-dose vials for COVID-19 vaccination (https://www.health.gov.au/sites/default/files/documents/2022/08/atagi-guidance-on-the-use-of-multi-dose-vials-for-covid-19-vaccination.pdf) and reviewed the NSW Health guidance on management of COVID-19 vaccines specific to each of the vaccines that the immuniser will be administering (https://www.health.nsw.gov.au/Infectious/covid-19/vaccine/Pages/document-centre.aspx#administration-downtime).

3) For the purposes of supply and administration of Tuberculin (purified protein derivative) and Tuberculosis (Bacille Calmette Guèrin – BCG) vaccine, an Authorised Person is a Registered Nurse or Registered Midwife who, in addition to the requirements at clause 2(1), has successfully completed:
    a. a HESA accredited immunisation course for registered nurses and midwives (or completion of the immunisation education program administered by the Australian College of Nursing prior to 1 December 2020;

    AND

    b. the Tuberculosis Management (TST/BCG) course (Australian College of Nursing); and undertake supervised training and competency assessment in conjunction with a NSW TB Service; or
    c. the Immunisation: Tuberculosis Tuberculin Skin Test (TST) course for Tuberculin; the Immunisation: Tuberculosis Bacille Calmette-Guèrin (BCG) course for the Tuberculosis vaccine (Australian College of Nursing); or
    d. the NSW Health Department Immunisation Accreditation Course for Registered Nurses prior to 2001 and, who undertook additional specialist training in the administration of Tuberculin Skin Test (TST) or Bacille Calmette-Guèrin (BCG).

4) For the purposes of supply and administration of Japanese Encephalitis vaccine, an Authorised Person is a Registered Nurse or Registered Midwife who in addition to the requirements at clause 2(1) has successfully completed the:
    a. Japanese encephalitis: A learning resource for registered nurses and midwives, developed and hosted by the National Centre for Immunisation Research and Surveillance (NCIRS).

3. Conditions

a. The Authorised Person is employed or engaged to provide immunisation services, and

b. The Authorised Person administers a vaccine only while employed or engaged to provide immunisation services, and only as specified in the digital *Australian Immunisation Handbook* and in accordance with the Therapeutic Goods Administration approved Product Information or Australian Technical Advisory Group on Immunisation (ATAGI) advice, and

c. The pre- and post-vaccination assessment and administration of each vaccine is undertaken in accordance with the procedures specified in the digital *Australian Immunisation Handbook*, or for the COVID-19 vaccination in accordance with the Therapeutic Goods Administration approved Product Information or Australian Technical Advisory Group on Immunisation (ATAGI) advice, and

d. The poisons and restricted substances are stored in accordance with the requirements under the *Poisons and Therapeutic Goods Regulation 2008, National Vaccine Storage Guidelines 'Strive for 5'* or as stated on the respective manufacturer's pack, or for the COVID-19 vaccination in accordance with the Therapeutic Goods Administration approved Product Information or Australian Technical Advisory Group on Immunisation (ATAGI) advice, and

e. During each vaccination clinic the Authorised Person carries a complete anaphylaxis kit with in-date adrenaline (epinephrine) for use in the treatment of anaphylaxis, and

f. The Authorised Person ensures that procedures for the administration of adrenaline (epinephrine) comply with the procedures specified in the digital *Australian Immunisation Handbook*, and

g. The Authorised Person must report each adverse event following immunisation to the local Public Health Unit, and

h. The Authorised Person ensures that a designated medical officer is contactable for medical advice during the vaccination clinic, and

i. All vaccinations administered must be recorded on the Australian Immunisation Register (AIR), and

j. To maintain authority to immunise, the Authorised Person must annually review best practice policy for immunisation. This may be, but is not limited to, attendance at seminars on current practices. An annual statement of proficiency in cardio-pulmonary resuscitation must also be obtained.

4. Revocation

The previous authorisation to supply certain vaccines that are poisons and restricted substances dated 27 September 2023 is hereby revoked.

5. Validity

This authority commences on the day it is signed and dated, and expires on the date 21 October 2024, or otherwise on a date that this authority is revoked.