

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: 7 August 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 (epinephrine)	Mumps vaccine
Diphtheria toxoid	Pertussis antigen 'Pertussis vaccine'
Haemophilus influenzae vaccine	Pneumococcal vaccine
Hepatitis A vaccine	Poliomyelitis vaccine
Hepatitis B vaccine	Specified <i>vaccine</i> for human therapeutic use, namely: <ul style="list-style-type: none"> • 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
Specified <i>vaccine</i> for human therapeutic use, namely: Modified vaccinia Ankara– Bavarian Nordic (MVA-BN) vaccine	Recombinant Respiratory Syncytial Virus pre-fusion F protein vaccine
Respiratory syncytial virus monoclonal antibodies	Japanese encephalitis vaccine
SARS-COV-2 (COVID-19) vaccine	Specified vaccine for human therapeutic use, namely: Tuberculosis (BCG) vaccine
Tuberculin	

2) Conditions

A. Limitation on supply

An Authorised Registered Nurse or Registered Midwife may supply and administer a vaccine listed in clause 1 subject to the condition that the Authorised Registered Nurse or Registered Midwife complies with the conditions outlined in the NSW Authorised Registered Nurses and Midwives Vaccination Standards (Annexure A).

3) Publication

This instrument will be published on the NSW Health website.

4) Commencement

This authority commences on publication on the NSW Health website and expires on a date this authority is revoked.

5) Revocation

The previous authorisation to supply certain vaccines that are poisons and restricted substances dated 17 April 2024 is hereby revoked.

NSW AUTHORISED REGISTERED NURSES AND MIDWIVES VACCINATION STANDARDS

A. APPROVED VACCINES AND MONOCLONAL ANTIBODIES SCHEDULES

Name	Abbreviated/ alternate name	Limitations of use
Adrenaline (epinephrine)		
Diphtheria toxoid [†]		
Haemophilus influenzae vaccine [†]	Haemophilus influenzae type b (Hib) vaccine	
Hepatitis A vaccine [†]	Hep A	
Hepatitis B vaccine [†]	Hep B	
Human papillomavirus vaccine [†]	HPV	
Influenza and coryza vaccine 'Influenza vaccine' [†]		
Japanese encephalitis vaccine [†]	JE	Mandatory completion of the additional training module: Japanese encephalitis -
Modified vaccinia Ankara– Bavarian Nordic (MVA-BN) vaccine [#]	Known as JYNNEOS vaccine [#]	In accordance with the NSW Health State-wide Protocol for the Supply and Administration of JYNNEOS Vaccine (https://www.health.nsw.gov.au/Infectious/factsheets/Pages/mpxv-protocol.aspx) or as otherwise directed by the NSW Chief Health Officer Subcutaneous injection (S/C) formulation only
Measles vaccine [†]		
Meningococcal vaccine [†]	MenACWY (quadrivalent) conjugate vaccine; or MenC – monovalent meningococcal serogroup C	
Meningococcal B vaccine [†]	MenB	
Mumps vaccine		
Pertussis antigen 'Pertussis vaccine' [†]		
Pneumococcal vaccine [†]		
Poliomyelitis vaccine [†]	Polio	
Recombinant respiratory syncytial virus pre-fusion F protein vaccine [†]	RSV vaccine	In accordance with Australian Technical Advisory Group on Immunisation (ATAGI) recommendations [^]
Respiratory syncytial virus monoclonal antibodies [†]	RSV mAbs	In accordance with Australian Technical Advisory Group on Immunisation (ATAGI) recommendations [^]
Recombinant varicella zoster virus glycoprotein e antigen vaccine [†]	Zoster vaccine	Shingrix vaccine brand only
Rubella vaccine [†]		

SARS-COV-2 (COVID-19) vaccine†		Mandatory completion of the additional ATAGI guidance on the use of multi-dose vials for COVID-19 vaccination module and reviewed the NSW Health guidance on management of COVID-19 vaccines
Tetanus toxoid†		
Tuberculin	Purified protein derivative (PPD)	Mandatory completion of the Tuberculosis Management (TST/BCG) course (Australian College of Nursing); and undertake supervised training and competency assessment
Specified vaccine for human therapeutic use, namely: Tuberculosis (BCG†) vaccine	Tuberculosis (BCG) vaccine	
Typhoid vaccine†		Intramuscular injection (IMI) formulation only
Varicella vaccine†	VZV	

^ Monoclonal antibody recommendations for individuals and administration processes must be in accordance with ATAGI advice or the TGA approved Product Information, where advice differs, the advice of ATAGI must be followed.

† Vaccination recommendations for individuals and administration processes must be in accordance with the digital edition of the Australian Immunisation Handbook or recommendations from the Australian Technical Advisory Group on Immunisation (ATAGI).

Must be supplied and used only at the direction of the Chief Health Officer (CHO), as set out under the Therapeutic Goods (Medicines – MVA-BN) (Emergency) Exemption (No. 3) 2022. As at the date of this instrument, the requirements set out in the [State-wide Protocol for the Supply and Administration of JYNNEOS Vaccine](#) are the directions of the CHO for the purposes of the Therapeutic Goods (Medicines – MVA-BN) (Emergency) Exemption (No.3) 2022.

B. COMPETENCY, TRAINING AND SCOPE OF PRACTICE

Authorised registered nurse/midwife immunisers must practice within their scope of practice, professional knowledge and expertise when undertaking vaccination (including management related to adverse events).

The authorised registered nurse/midwife immuniser must only administer a vaccine or monoclonal antibody treatment while employed or engaged in a role where immunisation services are provided (which may be part of general nursing roles) or are otherwise engaged in a role to provide immunisation services. Nurses and midwives must only administer substances listed in the NSW Authorised Registered Nurses and Midwives Vaccination Standards when acting in their capacity as an authorised registered nurse/midwife immuniser.

The authorised registered nurse/midwife immuniser must have the required knowledge for all authorised vaccines and monoclonal antibodies that they intend to administer. For all vaccines and monoclonal antibody treatments, authorised registered nurse/midwife immuniser must ensure their practice is consistent with the digital Australian Immunisation Handbook and, if relevant, the Therapeutic Goods Administration (TGA) approved product information or Australian Technical Advisory Group on Immunisations (ATAGI) recommendations.

The authorised registered nurse/midwife immuniser must have access to, and comply with, the following: -

- *The digital 'Australian Immunisation Handbook* – Australian Government Department of Health; and
- *'National Vaccine Storage Guidelines – Strive for 5'* (current edition) – Australian Government Department of Health.

If supplying and using the JYNNEOS vaccine, the authorised registered nurse/midwife immuniser must also have access to the [State-wide Protocol for the Supply and Administration of JYNNEOS Vaccine](#) – NSW Health.

General training

To become an authorised registered nurse/midwife immuniser, a registered nurse / midwife must have successfully completed:

- The NSW Department of Health Immunisation Accreditation Program for Registered Nurses prior to 2001, or
- The immunisation education program administered by the Australian College of Nursing or its predecessors prior to 1 December 2020, or
- An interstate immunisation education program, as approved by the Australian College of Nursing prior to 1 December 2020, or
- 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
- 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.

COVID-19 vaccine training

- For the purposes of supply and administration of any COVID-19 vaccine, an authorised registered nurse/midwife immuniser, in addition to the general training requirements, must also have read the ATAGI guidance on the use of multi-dose vials for COVID-19 vaccination (<https://www.health.gov.au/resources/publications/atagi-guidance-on-the-use-of-multi-dose-vials-for-covid-19-vaccination?language=en>) 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>).

Japanese encephalitis vaccine training

In addition to the general training requirements, an authorised registered nurse/midwife immuniser must also have successfully completed the Japanese encephalitis learning resource for registered nurses and midwives, developed and hosted by the National Centre for Immunisation Research and Surveillance (NCIRS).

Tuberculin and Tuberculosis vaccine training

In addition to the general training requirements, for the purposes of supply and administration of Tuberculin (purified protein derivative) and Tuberculosis (Bacille Calmette Guérin – BCG) vaccine, an authorised registered nurse/midwife Immuniser must successfully complete:

- The Tuberculosis Management (TST/BCG) course (Australian College of Nursing);

and:

- undertaken supervised training and competency assessment in conjunction with a NSW TB Service [as per the NSW Health TST/BCG Competency Assessment: Process for Authorised Nurse Immunisers](#); or
- the Immunisation: Tuberculosis Tuberculin Skin Test (TST) course for Tuberculin; the Immunisation: Tuberculosis Bacille Calmette-Guérin (BCG) course for the Tuberculosis vaccine (Australian College of Nursing); or
- 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-Guérin (BCG).

The authorised registered nurse/midwife immuniser must hold a cardio-pulmonary resuscitation (CPR) certificate issued within the last 12 months, including paediatric basic life support where relevant for practice.

To maintain authority to immunise, the authorised registered nurse/midwife immuniser must annually review best practice policy for immunisation and ensure their competence for each vaccine they administer. This may be, but is not limited to, attendance at seminars on current practices, or formal immunisation update courses.

C. REQUIREMENTS IN DELIVERING IMMUNISATION SERVICES

Authorised nurse/midwife immunisers must document pre- and post-vaccination assessments and administration of vaccines (including monoclonal antibody treatments) in accordance with procedures specified in the digital [Australian Immunisation Handbook \(AIH\)](#). *If advice is not available in the AIH, the* Australian Technical Advisory Group on Immunisations (ATAGI) recommendations must be followed or if relevant, as indicated in the Therapeutic Goods Administration (TGA) approved product information.

Authorised registered nurses/midwife immunisers supplying or administering the JYNNEOS vaccine must do so in accordance with [the State-wide Protocol for the Supply and Administration of JYNNEOS Vaccine](#) issued by NSW Health or as otherwise directed by the NSW Chief Health Officer.

Storage of schedule 4 vaccines, and monoclonal antibodies must be in accordance with each of the requirements under the Poisons and Therapeutic Goods Regulation 2008, and the current edition of the [National Vaccine Storage Guidelines – “Strive for 5”](#).

Authorised registered nurse/midwife immuniser must carry a complete anaphylaxis response kit, and be competent to administer adrenaline (epinephrine), as specified in the digital [Australian Immunisation Handbook](#) for the treatment and management of anaphylaxis during each immunisation clinic.

All adverse events following immunisation (AEFIs) must be reported to the local Public Health Unit (by telephone on 1300 066 055), as required under the NSW Public Health Act 2010.

All administered vaccines must be recorded on the Australian Immunisation Register (AIR), preferably within 24 hours of administration but no later than 10 business days.

D. IMMUNISATION CLINIC REQUIREMENTS

Vaccine and monoclonal antibody cold chain storage equipment must be monitored and comply with the current edition of the [National Vaccine Storage Guidelines – “Strive for 5”](#) or if relevant, as indicated in the Therapeutic Goods Administration (TGA) approved product information or The [State-wide Protocol for the Supply and Administration of JYNNEOS Vaccine](#) issued by NSW Health.

The anaphylaxis response kit must be checked for completeness and currency of contents and placed in a readily accessible location prior to each immunisation clinic.

Emergency response protocols must be developed and include (but are not limited to), anaphylaxis response kit contents, phone access (particularly in rural / remote areas) and pre-identified roles and responsibilities during a severe adverse event following immunisation.

Informed consent requires that the authorised registered nurse/midwife immuniser provides information in relation to the benefits and risks of the specific vaccine or monoclonal antibody, explaining the rationale and purpose of the vaccine to the patient (or parent / guardian).

The authorised registered nurse/midwife immuniser must obtain informed written or verbal consent from the patient (or parent / guardian) before the vaccination and must retain proof of consent for seven years (in accordance with the *Health Records and Information Privacy Act 2002*), for all medications listed in this document.

The authorised registered nurse/midwife immuniser must not administer a vaccine or monoclonal antibody to a person with a contra-indication to any vaccine or monoclonal antibody as listed in the:

- I. The digital Australian Immunisation Handbook
- II. TGA approved Product Information
- III. [State-wide Protocol for the Supply and Administration of JYNNEOS Vaccine](#) or as otherwise directed by the NSW Chief Health Officer.

Should the patient have a contraindication or precaution to the vaccine, refer the patient to a medical or nurse practitioner.

Resources – digital [Australian Immunisation Handbook](#) and the [National Vaccine Storage Guidelines – Strive for 5](#) must be accessible during each immunisation clinic.

If supplying or using the JYNNEOS vaccine, the [State-wide Protocol for the Supply and Administration of JYNNEOS Vaccine](#) issued by NSW Health must be accessible during the immunisation clinic.

The authorised registered nurse/midwife immuniser must advise the person (or their parent/guardian) to remain at the clinic premises for 15 minutes post vaccination.

The authorised registered nurse/midwife immuniser must either observe, (or direct an appropriately trained staff member to observe), the person for 15 minutes post vaccination to monitor for acute adverse events or anaphylaxis.

The authorised registered nurse/midwife immuniser must provide each patient (and/or parent/guardian) with post-vaccination care as per the advice in the digital [Australian Immunisation Handbook](#) or the latest TGA Product Information in relation to what to expect following vaccination, and provide advice on when to seek medical attention, following each administration of a vaccine.

The authorised registered nurse/midwife immuniser must have access to the Australian Immunisation Register (AIR) for checking previous vaccinations as well as recording of further vaccinations.



Dr Kerry Chant AO PSM
Chief Health Officer and Deputy Secretary Population and Public Health

7 August 2024