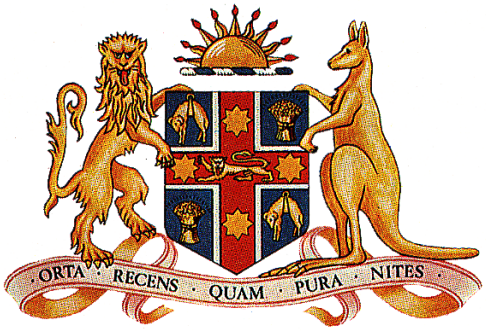

Government Gazette

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By Authority
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Approval
Poisons and Therapeutic Goods Regulation 2008 (NSW)

I, Kerry Chant, Chief Health Officer and delegate of the Secretary NSW Health, under clause 48A(1A)(d) of the *Poisons and Therapeutic Goods Regulation 2008* (NSW) and section 43 of the *Interpretation Act 1987* do hereby:

1. revoke the approval instrument signed on 14 February 2022 and published in NSW Government Gazette 55 on 18 February 2022.
2. approve the following vaccines, referred to in this instrument collectively as '***an approved vaccine***', for the purposes of clause 48A(1A)(d):
    - Vaxzevria (ChAdOx1-S) COVID-19 vaccine (ARTG ID 349072) '***AstraZeneca vaccine (ARTG ID 349072)'***
    - Comirnaty (tozinameran [mRNA]) COVID-19 vaccine (ARTG ID 346290) '***Pfizer vaccine (ARTG ID 346290)'***
    - Spikevax (elasomeran) COVID-19 vaccine (ARTG ID 370599) '***Moderna vaccine (ARTG ID 370599)'***
    - Comirnaty (tozinameran [mRNA]) COVID-19 vaccine (ARTG ID 377111) ***'Pfizer vaccine (ARTG ID 377111)'***
    - Nuvaxovid (SARS-CoV-2 rS (NVX-CoV2373) COVID-19 vaccine (ARTG ID 355139) ***'Novavax vaccine (ARTG ID 355139)'***
3. Pursuant to clause 48A(1B), this approval is subject to the following conditions:
    a. The pharmacist must **not** supply or administer the:
        i. AstraZeneca vaccine (ARTG ID 349072) to a person who is:
            1. under the age of 18 years old; or
            2. receiving a *booster dose*, unless the administration or supply of the booster dose occurs on the written direction of a medical practitioner.
        ii. Pfizer vaccine (ARTG ID 346290) to a person who is under the age of 12 years old.
        iii. Pfizer vaccine (ARTG ID 377111) to a person who is under the age of 5 years or is 12 years of age or older.
        iv. Moderna vaccine (ARTG ID 370599) to a person who is under the age of 6 years old.
        v. Novavax vaccine (ARTG ID 355139) to a person who is:
            1. under the age of 18 years old; or
            2. pregnant, unless the administration or supply occurs on the written direction of a medical practitioner.
    b. The pharmacist must obtain written or other electronic evidence of consent from each patient (or a parent, guardian or substitute decision-maker in the case of a person who cannot consent for themselves) to whom an approved vaccine is supplied and retain a copy of that consent. The Australian Government Department of Health *COVID-19 vaccination – Consent form for COVID-19 vaccination* is to be used in obtaining consent.
    c. The pharmacist must not supply or administer an approved vaccine to a person who has experienced a serious adverse event after the first administration of an approved vaccine.
    d. The pharmacist must not supply or administer an approved vaccine to a person with a contra-indication or precaution to vaccination listed in the 'The digital Australian

Immunisation Handbook', or in the Australian Technical Advisory Group on Immunisation (ATAGI) advice or guidance, or in the approved product information for the product unless the only contraindication or precaution:

i. For any approved vaccine: is that a person is on anti-coagulant therapy; or
ii. For Moderna vaccine (ARTG ID 370599), Pfizer vaccine (ARTG ID 346290), Pfizer vaccine (ARTG ID 377111); or 'Novavax vaccine (ARTG ID 355139): is that a person is pregnant.

e. The pharmacist must provide each patient (or a parent, guardian or substitute decision-maker) with the Australian Government advice in relation to what to expect following vaccination with an approved vaccine, and when to seek medical attention following each administration of the vaccine.
f. The pharmacist must ensure they remain up to date on any new advice from the Australian Technical Advisory Group on Immunisation (ATAGI) or Therapeutic Goods Administration (TGA) regarding additional precautions or consent requirements for an approved vaccine.

In this instrument:

- '***pharmacist***' means a registered pharmacist or a pharmacist who is provisionally registered and undertaking approved supervised practice
- ***primary course*** in relation to a COVID-19 vaccination, means 2 doses of a COVID-19 vaccine, or 3 doses for an immunocompromised patient
- ***booster dose*** in relation to a COVID-19 vaccination, means an additional dose to the *primary course*

This approval can be revoked at any time.

Kerry Chant
Chief Health Officer
Dated 24th February 2022

NSW GOVERNMENT | Health

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: 25/2/22

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 vaccine
Haemophilus influenzae (type b) vaccine	Pneumococcal vaccine
Hepatitis A vaccine	Poliomyelitis vaccine
Hepatitis B vaccine	Rotavirus vaccine
Human papillomavirus vaccine	Rubella vaccine
Influenza vaccine	Tetanus toxoid
Measles vaccine	Varicella vaccine
Meningococcal ACWY and B vaccines	

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

Poison or restricted substance	
Tuberculin (purified protein derivative)	Tuberculosis (BCG) vaccine
SARS-COV-2 (COVID-19) 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), has successfully completed:
   a. Core COVID-19 training modules from the *COVID-19 Vaccination Training Program* developed by the Commonwealth Department of Health in partnership with the Australian College of Nursing; and
   b. Additional COVID-19 vaccine specific training modules from the *COVID-19 Vaccination Training Program* developed by the Commonwealth Department of Health in partnership with the Australian College of Nursing, for each vaccine that the Authorised Person is administering.

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 Immunisation: Tuberculosis Tuberculin Skin Test (TST) course for Tuberculin; the Immunisation: Tuberculosis Bacille Calmette-Guèrin (BCG) course for the Tuberculosis vaccine;

or

c. 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)

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

Previous authorisation to supply poisons and restricted substances dated 19 February 2021 published in the New South Wales Government Gazette 86 on 5 March 2021 is hereby revoked.

5 Validity

This authority commences on the day it is signed and dated, and expires on the date 15 February 2024, or otherwise on a date that this authority is revoked.

INSTRUMENT

HEALTH SERVICES ACT 1997

REMOVAL OF MEMBER

SYDNEY CHILDREN'S HOSPITALS NETWORK BOARD

I, BRAD HAZZARD, Minister for Health, pursuant to the provisions of sections 26(2), 52F and 29(1)(a) of the *Health Services Act 1997,* do by this instrument, hereby remove **Dr Elizabeth McEntyre** as a member of the Sydney Children's Hospitals Network Board on and from 4 March 2022.

Signed and Dated: 28 February 2022

Brad Hazzard MP
Minister for Health