



# *Government Gazette*

of the State of

New South Wales

**Number 542–Health and Education**

**Friday, 22 October 2021**

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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 28 September 2021 and published in NSW Government Gazette 496 on 1 October 2021.
2. approve the ***Vaxzevria ChAdOx1-S COVID-19 vaccine*** ('AstraZeneca vaccine'), ***Comirnaty (BNT162b2 [mRNA]) COVID-19 vaccine*** ('Pfizer vaccine') and the ***Spikevax (elasomeran) COVID-19 vaccine*** ('Moderna vaccine'), collectively '***an approved vaccine***', for the purposes of that clause. Pursuant to clause 48A(1B), this approval is subject to the following conditions:
  - a. The pharmacist must not supply or administer:
    - i. the AstraZeneca vaccine to a person who is under the age of 18 years old.
    - ii. the Pfizer vaccine to a person who is under the age of 12 years old.
    - iii. the Moderna vaccine to a person who is under the age of 12 years old.
  - b. The pharmacist must obtain written or other electronic evidence of consent from each patient (or 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 unless at least one other health practitioner or an appropriately trained person who is able to recognise signs of anaphylaxis and seek help, is onsite at the time of administration or supply.
  - e. 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 Pfizer vaccine or Moderna vaccine*: is that a person is pregnant.
  - f. The pharmacist must provide each patient (or 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.
  - g. 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.

**This approval can be revoked at any time.**



Kerry Chant PSM

**Chief Health Officer**

Dated 14<sup>th</sup> October 2021

**POISONS AND THERAPEUTIC  
GOODS REGULATION 2008**

ORDER

Withdrawal of Drug Authority

In accordance with the provisions of clause 175(1) of the *Poisons and Therapeutic Goods Regulation 2008* an Order has been made on **Dr Piyush Raj Sinha (MED0001181318)**, of STRATHFIELD NSW 2135, prohibiting him until further notice, as a medical practitioner, from supplying or having possession of drugs of addiction as authorised by clause 101 of the Regulation and issuing a prescription for a drug of addiction as authorised by clause 77 of the Regulation.

This Order is to take effect on and from 21 October 2021.

Dated at Sydney, 20 October 2021.

Elizabeth Koff  
Secretary, NSW Health

**POISONS AND THERAPEUTIC  
GOODS REGULATION 2008**

ORDER

Withdrawal of Drug Authority

In accordance with the provisions of clause 175(1) of the *Poisons and Therapeutic Goods Regulation 2008* an Order has been made on **Dr Prabhat Raj Sinha (MED0000968250)**, of SYDNEY NSW 2000, prohibiting him until further notice, as a medical practitioner, from supplying or having possession of drugs of addiction as authorised by clause 101 of the Regulation and issuing a prescription for a drug of addiction as authorised by clause 77 of the Regulation.

This Order is to take effect on and from 21 October 2021.

Dated at Sydney, 20 October 2021.

Elizabeth Koff  
Secretary, NSW Health