



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 s.43 of the *Interpretation Act 1987* do hereby:

1. revoke the approval instrument signed on 14 July 2021 and published in the NSW Government Gazette Number 320 on 16 July 2021; and
2. approve the SARS-CoV-2 (COVID-19) AstraZeneca (ChAdOx1-S) vaccine (the *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 the approved vaccine to a person who is under the age of 18 years old.
 - b. The pharmacist must obtain written or other electronic evidence of consent from each patient to whom the 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 the approved vaccine to a patient who is not able to consent to the treatment on their own behalf.
 - d. The pharmacist must not supply or administer the approved vaccine to a person who has experienced a serious adverse event after the first administration of the approved vaccine.
 - e. The pharmacist must not supply or administer the 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.
 - f. The pharmacist must provide each patient with the Australian Government advice in relation to what to expect following vaccination with the 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 the approved vaccine.
 - h. An intern pharmacist is not authorised to administer or supply the approved vaccine.

In this instrument:

- 'pharmacist' means a registered pharmacist who administers the approved vaccine in:
 - a pharmacy business approved under Schedule 5F of the *Health Practitioner Regulation National Law* that has registered to participate in the COVID-19 vaccination program
 - a residential care facility (as defined under the *Poisons and Therapeutic Goods Regulation 2008*)
 - a general practice clinic registered to participate in the COVID-19 vaccination program; and
 - an Aboriginal Medical Service that has registered to participate in the COVID-19 vaccination program.

This approval can be revoked at any time.

Kerry Chant

Chief Health Officer

Dated 28th July 2021