



Northern Territory of Australia

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Northern Territory of Australia

Medicines, Poisons and Therapeutic Goods Act

**Revocation of Approval and Approval of
Scheduled Substance Treatment Protocol**

I, Hugh Crosbie Heggie, Acting Chief Health Officer:

- (a) under section 254(1)(f) of the *Medicines, Poisons and Therapeutic Goods Act* and with reference to section 43 of the *Interpretation Act*, revoke the approval of the Scheduled substance treatment protocol entitled "Pharmacist-Led Administration of Vaccines to Adults at Pharmacy Premises in the Northern Territory – January 2016"; and
- (b) under section 254(1)(f) of the *Medicines, Poisons and Therapeutic Goods Act*, approve the protocol entitled "Pharmacist-Led Administration of Vaccines to Adults at Pharmacy Premises in the Northern Territory" and dated February 2017 for possessing, supplying or administering a Schedule 4 substance at a pharmacy.

Dated 13 March 2017


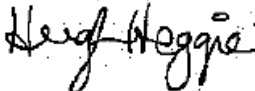
H. C. Heggie
Acting Chief Health Officer

Schedule Substance Treatment Protocol (SSTP)

Title	Pharmacist-Led Administration of Vaccines to Adults at Pharmacy Premises in the Northern Territory(NT)
Areas Applicable	Pharmacists administering vaccinations at pharmacy premises
Drug	Influenza Vaccine Measles/Mumps/Rubella (MMR) Vaccine Diphtheria/Tetanus/Pertussis Vaccine Adrenaline
Indication	Vaccination according to the 'Australian Immunisation Handbook' (electronic version)
Contraindications and/or Exclusions*	<p>The following persons who have a reason for exclusion after completing the pre-vaccination must be referred to their general medical practitioner or primary health care provider:</p> <ul style="list-style-type: none"> • Persons under 16 years of age; • Persons with contraindications to vaccinations as listed in the current edition of the Australian Immunisation Handbook; • Persons with a previous history of Guillian Barré syndrome; • Persons with immune-compromising conditions from medications or diseases who require measles, mumps, rubella vaccine. <p>For all vaccines: Please follow any additional vaccine specific contraindications described in the relevant chapters in the 'Australian Immunisation Handbook' (electronic version).</p>
Dose & Route*	As per the Australian Immunisation Handbook (electronic version) both intramuscular or subcutaneous administration, but <u>not</u> for intradermal administration of influenza vaccine.
Dose frequency*	As per Australian Immunisation Handbook (electronic version)
Administration*	As per Australian Immunisation Handbook (electronic version)
Drug Interactions*	<p>As per the Australian Immunisation Handbook (electronic version)</p> <ul style="list-style-type: none"> • Refer to the Australian Immunisation Handbook for specific vaccines and their interactions with immunoglobulins and blood products. • MMR vaccine must be given at the same time as other live vaccines or at least 4 weeks after another live vaccine such as yellow fever, varicella vaccine. • Mantoux testing should not be done until 4 weeks after the administration of measles containing vaccines. • Refer to vaccine specific chapters in the Australian Immunisation Handbook for specific drug interactions with each vaccine.
Monitoring requirements	<ul style="list-style-type: none"> • Ensure that patients who qualify for the National Immunisation Program must be offered referral to their local clinic or general practitioner but can be vaccinated in the pharmacy if they choose that service and understand the cost. • Ensure vaccines are stored according to National Storage Guidelines "Strive for Five". • Assess patient suitability for vaccination at the pharmacy with pre-vaccination screening questionnaire. • Contact NT Immunisation Register (NTIR) - Phone: 8922 8315 or Australian Immunisation Register - for previous immunisation record if required. • Obtain patient consent to be vaccinated. • Provide advice to the patient on action to take if adverse reaction detected once leaving the pharmacy.

	<ul style="list-style-type: none"> • Observe the patient post administration for 15 minutes for adverse reaction and • If an adverse event occurs, an 'Adverse event following vaccination' form must be completed and sent to the Centre for Disease Control (CDC).
<p>Pharmacist Accreditation Requirements</p>	<p>Before 1 January 2017 Successful completion of</p> <ul style="list-style-type: none"> ➤ APPIMM806A - Manage the delivery and administration of injections and immunisations - Pharmaceutical Society of Australia; or ➤ 10455NAT - Course in conduct immunisation services within a community pharmacy environment - Pharmacy Guild of Australia; <p>Or</p> <p>After 1 January 2017 Successful completion of</p> <ul style="list-style-type: none"> ➤ a training program accredited to meet the standards set by the Australian Pharmacy Council's 'Standards for the accreditation of programs to support Pharmacist Administration of vaccines'. ➤ This course must include training for the influenza, measles, mumps, rubella and diphtheria, tetanus, pertussis vaccines. <p>All</p> <ul style="list-style-type: none"> • General registration with the Pharmacy Board of Australia with no conditions or undertakings which may limit delivery of clinical services directly to patients; • Maintain continuing professional development in the delivery of immunisation services; • Current certificate Australasian Society of Clinical Immunology and Allergy (ASCIA) 'Anaphylaxis e-training for pharmacists'; • Current first aid certificate • Current cardiopulmonary resuscitation (CPR). • Consumers should be able to observe copies of these certificates if needed.
<p>Pharmacy requirements</p>	<p>Premises and equipment</p> <ul style="list-style-type: none"> • Facilities comply with the NT Pharmacy Premises Committee's 'Premises and Equipment Standard for Pharmacy Based Immunisation Programs'; and • Access to appropriate record management storage that can send records to the Australian Immunisation register <p>Staffing</p> <ul style="list-style-type: none"> • Immunisations can only be administered when an additional pharmacist or pharmacy assistant with current First aid and CPR certificates can assist if needed for emergencies at the premises; and • The immunisation pharmacist must have uninterrupted time to conduct the pre-vaccination assessment and vaccination procedures. <p>Audit requirements Participate in periodic audits of premises and educational requirements by the NT Department of Health.</p>

<p>Documentation (including necessary information to the patient)</p>	<p>Documentation, policies and procedures must be kept for the following</p> <ul style="list-style-type: none"> • Pre-vaccination checklist; • Storage and handling of vaccines and cold chain monitoring • Patient exclusion and referral to general practitioner or other clinics • Obtaining and documenting patient consent • Disposal of sharps and infection control procedures • Post vaccination patient monitoring • Responses to emergencies including anaphylaxis • Clinical record and provision of information to the Australian Immunisation Register • Management of staff training records • Completion of NT Adverse Event following Immunisation form if required. • Required documentation to be sent to Australian Immunisation Register within 14 days of vaccine administration; • All records must be kept for a minimum of seven years from vaccine administration date, be available for inspection on demand by an authorised officer under the <i>Medicines, Poisons and Therapeutic Goods Act</i> and be managed following data security and privacy standards. • The records must include the following information: <ul style="list-style-type: none"> ○ Vaccine brand, batch number and expiry date, patient name, address, date of birth, contact details, date the vaccines was given and pharmacist name and signature.
<p>Related Documents</p>	<p>This protocol is to be used in conjunction with:</p> <ul style="list-style-type: none"> • Australian Immunisation Handbook electronic version on http://www.health.gov.au/internet/immunise/publishing.nsf/Content/Handbook10-home • 'National Vaccine Storage Guidelines Strive for 5' (2nd edition) electronic version http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/59F63C79DAFAFB38CA257B020002C371/\$File/strive-for-5-guidelines.pdf • <u>NT Immunisation Program website</u> https://health.nt.gov.au/professionals/centre-for-disease-control/immunisation-health-professionals • '<u>Premises and Equipment Standard for Pharmacy Based Immunisation Programs</u>' as published by the NT Pharmacy Premises Committee https://health.nt.gov.au/health-governance/department-of-health/committees-regulations-advisory-groups/pharmacy-premises-committee • Pharmaceutical Society of Australia 'Practice Guidelines for the provision of Immunisation Services within a Pharmacy' http://www.psa.org.au

Head of Immunisation (Medical Officer)	Signature 	Print name Rosalind Webby	Date 10 March 2017
Chief Health Officer	Signature 	Print name Hugh Heggie	Date 13 March 2017
Date for Review	3 years from date of approval by Chief Health Officer		
References: *The drug information provided is to act as a guide only, for further information reference should be made to the full manufacturer's product info and other reliable sources of medicines information. If contraindications or interactions are present refer to medical officer before administration			