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Northern Territory of Australia

Medicines, Poisons and Therapeutic Goods Act

Approval of Scheduled Substance Treatment Protocol for Pharmacist-Led Immunisation in Pharmacy Businesses and Pharmacy Departments

I, Dinesh Kumar Arya, Chief Health Officer:

(i) 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 notice titled 'Approval of Scheduled Substance Treatment Protocol for Pharmacist-Led Immunisation in Pharmacy Businesses and Pharmacy Departments' dated 14 April 2015 and published on pages 4 to 8 of *Gazette* No. S35, 21 April 2015; and

(ii) under section 254(1)(f) of the *Medicines, Poisons and Therapeutic Goods Act*, and with reference to section 42 of the *Interpretation Act*, approve the protocol specified in Schedule A for possessing, supplying or administering a Schedule 4 substance that is a vaccine at a pharmacy (***Scheduled substance treatment protocol***); and

In this instrument:

Schedule 4 substance, see section 7(2) of the *Medicines, Poisons and Therapeutic Goods Act*.

Scheduled substance treatment protocol, see section 5 of the *Medicines, Poisons and Therapeutic Goods Act*.

Dated 25 January 2016

D. K. Arya
Chief Health Officer

Schedule A

Protocol for Pharmacist-Led administration of vaccines to adults at pharmacy premises in the Northern Territory - January 2016

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 Injection
Indication	Public health 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"> • Pregnant women or women suspected of being pregnant; • Persons under 16 years of age; • Persons with immunosuppression conditions or on immunosuppressant medication; • Persons with allergies or anaphylaxis to previous vaccines or any vaccine components; and • Persons with a previous history of Guillain–Barré syndrome. <p>For all vaccines:</p> <p>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. • 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.

	<ul style="list-style-type: none"> • 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 correct storage and handling of vaccines according to the 'National Storage Guidelines - Strive for 5'; • Ensure only a pharmacist with current training in immunisation according to this SSTP administers vaccines; • Assess patient suitability for vaccination at the pharmacy with pre-vaccination screening questionnaire; • Contact NT Immunisation Register (NTIR) - Phone: 8922 8315 - for immunisation status if required; • Obtain patient consent to be vaccinated and for vaccination information to be sent to NTIR; • Provide advice to the patient on action to take if adverse reaction detected once leaving the pharmacy; • Request patient to complete a participant satisfaction/evaluation questionnaire, • 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).
Pharmacist Accreditation Requirements	<ul style="list-style-type: none"> • General registration with the Pharmacy Board of Australia with no conditions; • Completed immunisation training with NT modifications and maintain 3 yearly updates: <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; or ➤ NT About Giving Vaccines (AGV) – NT Department of Health (prior to March 2015); or ➤ Other courses which meet the Australian Pharmacy Council accreditation standards as approved by the Chief Health Officer; • Current certificate Australasian Society of Clinical Immunology and Allergy (ASCIA) 'Anaphylaxis e-training for health professionals or pharmacists' - maintain yearly update; • HLTAID003 Provide first aid (includes HLTAID001) - maintain 3 yearly update; • HLTAID001 Provide cardiopulmonary resuscitation - maintain yearly update; and • Current professional indemnity insurance for immunisation scope of practice.

<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 Guildcare® software (for clinical information recording) or equivalent. <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 is present at the premises; and • The immunisation pharmacist must have uninterrupted time to conduct the pre-vaccination assessment and vaccination procedures. <p>Documentation</p> <ul style="list-style-type: none"> • Completion of registration form for the NT pharmacy immunisation pilot; • Completion of the pre-vaccination checklist; and • Completion of NT Adverse Event following Immunisation form if required. <p>Pilot audit requirements</p> <ul style="list-style-type: none"> • Participate in periodic audits of premises and educational requirements by the Department of Health; and • Participate in the evaluation of the NT pilot by administering participant questionnaire and pharmacist feedback forms. <p>Other</p> <ul style="list-style-type: none"> • Accreditation with Quality Care Pharmacy Program (QCPP) (Quality Care Pharmacy Program - www.qcpp.com) or equivalent (as immunisations may occur in 'pharmacy services' eg hospital and Defence pharmacies as well as 'pharmacy businesses'); and • Appropriate indemnity cover for the business for immunisation.
<p>Documentation <i>(including necessary information to the patient)</i></p>	<ul style="list-style-type: none"> • Completion of the pre-vaccination checklist and obtain consent for immunisation to occur; • The patient's names, date of birth, address, date vaccine given, site of injection; batch number of the vaccination, signature and name of administering pharmacist to be recorded on clinical information database. This information is sent to NTIR only for persons who have given consent for information to be sent to NTIR; • Documentation for NT Immunisation register submitted, within 14 days of vaccine administration; • Completion of documentation related to any review of pharmacist vaccinations conducted in the NT; • Provision of vaccination receipt form(s) to the patient; • Information about the vaccination to be provided to the usual primary health care provider (if the patient has one) unless the patient specifically requests otherwise; • Provision of information to patient on action to be taken in the event of an adverse event once leaving the pharmacy; and

	<ul style="list-style-type: none"> All records must be kept for a minimum of two years from last entry, and be available for inspection on demand by an authorised officer under the <i>Medicines, Poisons and Therapeutic Goods Act</i>. 		
Related Documents	<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 NT Immunisation Program website http://health.nt.gov.au/Centre_for_Disease_Control/Immunisation/index.aspx 'Premises and Equipment Standard for Pharmacy Based Immunisation Programs' as published by the NT Pharmacy Premises Committee http://health.nt.gov.au/Agency/Advisory_Groups_and_Taskforces/Pharmacy_Premises_Committee/index.aspx 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 R. Webby	Print name Rosalind Webby	Date 25 January 2016
Chief Health Officer	Signature D. Arya	Print name Dinesh Arya	Date 25 January 2016
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			