ATTACHMENT 1: BACKGROUND AND CONSULTATION RESPONSE TEMPLATE
Pharmacist-Administered Vaccination Program

1. Background
On 26 November 2015, the Minister for Health announced implementation of a Pharmacist-Administered Vaccination Program (the program) in Victoria commencing in 2016.

The program will enable pharmacists with general registration to administer funded influenza vaccines under the National Immunisation Program and funded pertussis-containing vaccines under the Victorian Government’s Parent Whooping Cough Vaccine Program to eligible adults 18 years of age and over, subject to a pharmacist’s service fee. Adults across Victoria will also be able to receive the influenza and pertussis-containing vaccinations from their pharmacist for a fee.

The program is based on robust evidence, both from Australia and internationally, that pharmacist-administered vaccination is safe and effective. Studies of pharmacist-administered vaccination models internationally have demonstrated that these services have the capacity to not only increase access to vaccination, but to also increase immunisation rates1,2,3,4. Patients accessing these services have also reported high levels of satisfaction5,6,7,8 and have indicated that they are willing to pay for the convenience of accessing vaccination services from their pharmacist9.

The establishment of a Pharmacist-Administered Vaccination Program will increase access to influenza and pertussis-containing vaccines for all Victorians. This will help to improve overall immunisation rates, protecting those most at risk of vaccine-preventable diseases, reducing preventable hospitalisations and workplace productivity losses resulting from pertussis and influenza-related illness, and giving new parents more options to be vaccinated against pertussis to protect their newborn infant.

For a complete scope of the program, refer to Attachment 2: Scope of the Pharmacist-Administered Vaccination Program.

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3 Ibid
7 Ernst ME, Bergus GR, Sorofman BA. Patients’ acceptance of traditional and non-traditional immunisation providers. *JAPhA*. 2001; 41: 53-59.
9 Ibid
2. Rationale

Declining vaccination rates and disease prevalence:

- Influenza vaccinations for persons at risk of complications of infection are the single most important measure to prevent or attenuate influenza infection and prevent mortality\(^\text{10}\).
- There has been a decline of vaccination rates for Victorians aged over 65 years and eligible for the National Immunisation Program; falling from 81.6% in 2004 to 75% in the most recent Adult Vaccination Survey in 2009. There was also a decline in the vaccination of Victorians predisposed to severe influenza (i.e. people with circulatory, respiratory and immune-suppressant conditions) aged 18 years and older; falling from 65.1% in 2004 to 55.1% in 2009\(^\text{11}\).
- 90,000 flu cases were reported across Australia in 2015, which is 25,000 higher than the previous record\(^\text{12}\). 11,455 of these cases were reported in Victoria\(^\text{13}\).
- There was a 57.7% increase in notifications of pertussis cases in Victoria, from 2,926 in 2013 to 4,617 in 2014. There has also been an increase in cases among children less than one year old – 115 notifications of cases in 2014, compared to 74 in 2013. In 2015, pertussis cases continued to increase, peaking at 4,745.
- Free pertussis vaccinations are now available to all pregnant women and expectant parents from 28 weeks gestation, and all parents of newborn babies less than six months of age and who are born on, or after, the 1 June 2015 funded vaccine program start date. This expanded eligibility is based on new international evidence which shows that the vaccine is safe and effective when administered to pregnant women in the third trimester.

A policy environment that has recognised the opportunities and benefits of expanding the role of pharmacists in primary and preventive care:

- In 2014 the Victorian Legislative Council Legal and Social Issues Legislation Committee released its report on the *Inquiry into Community Pharmacy in Victoria* which recommended the establishment of a pharmacy immunisation trial targeting Victorian adults\(^\text{14}\).
- Pharmacist-administered vaccination programs and pilots have already been established in most other Australian jurisdictions (Queensland, New South Wales, South Australia, Western Australia, Tasmania and the Northern Territory).
- Pharmacist-administered vaccination programs are also well established in the United Kingdom, New Zealand and many European counties. The range of vaccines that can be administered varies from country to country, but includes influenza, whooping cough, pneumococcal, hepatitis A and B, meningococcal, measles, mumps and rubella, and tetanus\(^\text{15}\).

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• The National Immunisation Committee has approved the development of a National Immunisation Education Framework for Health Professionals\(^{16}\) (the national framework). The national framework is currently in draft form and provides the minimum curriculum for immunisation education to support consistency in quality and effective immunisation programs in Australia for all relevant health professionals, including pharmacists.

The development of resources, guidelines and standards to govern and support the practice of pharmacist-administered vaccination in Australia:

• The Pharmacy Board of Australia has indicated that vaccination is within the scope of practice of a pharmacist\(^ {17}\) and has released the *Mapping of pharmacists’ competency standards for the administration of vaccines*\(^ {18}\).

• Training programs have been developed to support pharmacist administration of vaccines and standards have been established for the accreditation for these programs by the Australian Pharmacy Council.

• Standards for ‘Facilities for immunisation services’ have been included in the Victorian Pharmacy Authority’s Guidelines.\(^ {19}\)

• Professional guidelines have also been reviewed and updated to include vaccination by pharmacists.

3. Consultation information

(i) *Drugs, Poisons and Controlled Substances Amendment (Pharmacist-Administered Vaccination) Regulations 2016*

The Department of Health & Human Services (the department) is working with the Office of the Chief Parliamentary Counsel to draft amendments to the Drugs, Poisons and Controlled Substances Regulations 2006 (the Regulations), which will enable pharmacists to administer a Schedule 4 poison in certain circumstances and administer Schedule 3 poisons in certain circumstances.

The proposed amendments are in draft form only at this stage and have not been finalised. Specific conditions that relate to pharmacists’ administration of vaccines will be included in a Secretary Approval (refer to 3.(ii) Conditions proposed for Secretary Approval). This will include conditions such as the poisons pharmacists will be approved to administer, the competence or qualifications of the pharmacist, and the suitability of proposed premises or facilities.

(ii) Conditions proposed for Secretary Approval: Pharmacist-administered vaccination

It is proposed that amendments to the Drugs, Poisons and Controlled Substances Regulations 2006 will allow the Secretary of the Department of Health & Human Services to approve a Schedule 4 poison for administration by a pharmacist without an instruction from a registered medical practitioner, dentist, nurse practitioner or an authorised registered midwife.

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The Health Workforce Innovation & Reform Unit is preparing a submission to the Secretary of the Department of Health & Human Services (the department) seeking approval for pharmacists to administer two Schedule 4 poisons without an instruction from a registered medical practitioner, dentist, nurse practitioner or an authorised registered midwife. The approval will identify the following poisons:

- Influenza vaccines\(^\text{20}\); and
- Pertussis-containing vaccines\(^\text{21}\).

As a Schedule 3 poison, 1:1000 adrenaline (for the treatment of anaphylactic reactions to the vaccines) will not be identified in the approval. The proposed regulations will include new conditions related to the administration of a Schedule 3 poison by a pharmacist.

The approval will be subject to the following conditions:

- Pharmacists will be required to hold general registration (i.e. not provisional or non-practising registration).
- Pharmacists will be required to hold current first aid certificate and a current cardiopulmonary resuscitation certificate.
- Pharmacists will be required to administer Schedule 4 poisons in accordance with the Australian Immunisation Handbook (current edition).
- Pharmacists will be required to complete a training course which has been recognised by the Chief Health Officer as an Immuniser program of study and is accredited against the Australian Pharmacy Council’s Standards for the accreditation of programs to support pharmacist administration of vaccinations\(^\text{22}\). and.
- Pharmacists will be required to nominate a responsible pharmacist and register with the department before they begin providing vaccinations.
- Pharmacists will be required to ensure the premises on which they vaccinate, and facilities available on that premises, meet standards described in the Victorian Pharmacy Authority Guidelines\(^\text{23}\) (current version).

\(^\text{20}\) The term 'influenza vaccines' is used in this paper to refer to the following vaccine brand names: Influvac, Fluvax, Fluvarix, FluQuadri, and Fluvarix Tetra.

\(^\text{21}\) The term 'pertussis-containing vaccines' is used in this paper to refer to the following vaccine brand names: Adacel and Boostrix.


reporting requirements where necessary i.e. Surveillance of Adverse Events Following Vaccination In the Community (SAEFVIC).

- Pharmacists will be required to ensure that they are appropriately trained and that at least one other staff member with current First Aid and CPR Certificates is on duty in the pharmacy when the vaccination service is being delivered. Protocols, equipment and drugs necessary for the management of anaphylaxis, including an anaphylaxis response protocol identifying assigned roles and responsibilities, should be checked and available before each vaccination session, and each person’s roles and responsibilities in relation to the anaphylaxis response protocol clarified before commencing the vaccination session.

(iii) Process for Recognition by the Chief Health Officer of a program of study for Immunisers

Immuniser program of study

As a condition of approval, pharmacists will be required to complete a training program that has been recognised by the Chief Health Officer as an Immuniser program of study and complies with the Australian Pharmacy Council’s Standards for the accreditation of programs to support pharmacist administration of vaccinations.

The Department of Health & Human Services has an existing process in place for recognition by the Chief Health Officer of a program of study for Nurse Immunisers. Seven programs of study have already been recognised. This process will be broadened to include programs of study for all immunisers, including pharmacists.

The draft document, Recognition by the Chief Health Officer of a program of study for Immunisers, is attached at Attachment 3. This provides information about the recognition process, program standards and learning outcomes required for all courses offered to immunisers in Victoria.

It is anticipated that the programs of study will provide context around the National Immunisation Program and core curriculum for safe and effective practice as an immunisation provider.

National work is also occurring to develop a National Immunisation Education Framework for "Health Professionals", including pharmacists. This will outline the core areas of knowledge and skills encompassing clinical theory and practice of immunisation. Once the national framework has been finalised, it is anticipated that the existing process of recognition will be either complemented or superseded by the national process. Although learning outcome requirements of the existing Victorian program of study for immunisers largely aligns with the draft national framework, future processes for recognition against the framework are yet to be established.

Review process

An expert panel of reviewers is responsible for evaluating all documentation requested from the education provider as part of the recognition process. The panel comprises:

- at least one representative from a relevant group of clinical specialists or individual practitioners with recognised expertise in the health profession for which the course is intended for delivery;
- one representative with significant expertise and clinical practice experience in immunisation; and
- a representative with appropriate curriculum development knowledge.

Although one individual may have skills or experience in a number of the domains defined above, the panel will consist of no less than two reviewers.

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The review panel provides feedback to the Chief Health Officer including either a positive or negative recommendation for recognition of the program of study.

**Providers**

Before providing a program of study to health professionals for which they are not already recognised, existing providers will be required to demonstrate that they meet the revised criteria, program standards and learning outcomes, including ensuring that the program complies with and/or is accredited against any current professional guidelines and standards for immunisation training relevant to the health professionals to whom the course will be delivered\(^27\).

New providers will also be required to demonstrate that they meet all criteria, program standards and learning outcomes described in the attached document, including ensuring that the program complies with and/or is accredited against any current professional guidelines and standards for immunisation training relevant to the health professionals to whom the course will be delivered\(^28\).

\(^{27}\) These include the *National Guidelines for Immunisation Education for Registered Nurses and Midwives – A guide for courses, assessors, educators and training organisations* and the Australian Pharmacy Council’s *Standards for the accreditation of programs to support pharmacist administration of vaccinations*.

\(^{28}\) These include the *National Guidelines for Immunisation Education for Registered Nurses and Midwives – A guide for courses, assessors, educators and training organisations* and the Australian Pharmacy Council’s *Standards for the accreditation of programs to support pharmacist administration of vaccinations*. 
**Consultation response**

Do you have any concerns with pharmacists being able to administer the recommended Schedule 4 poisons (influenza vaccines and pertussis-containing vaccines) without an instruction from a registered medical practitioner, dentist, nurse practitioner or an authorised registered midwife?

*Please specify:*

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Do you have any other comments/suggestions about the *Pharmacist-Administered Vaccination Program*?

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Please use the above template to provide your feedback on the submission by email to [jessica.malone@dhhs.vic.gov.au](mailto:jessica.malone@dhhs.vic.gov.au) by **Thursday 25 February 2016**.