

# Proposed amendments to Secretary Approvals for nurse immunisers and pharmacist immunisers

Consultation paper – September 2022

**OFFICIAL**

## 1. Consultation and timeline

The Department of Health (the department) is currently partnering with select sexual health centres, health services and Local Public Health Units to provide access to the monkeypox vaccine, counselling and advice for people recommended for vaccination as part of its state-wide response to the emergence of the monkeypox virus.

Authorisation and training of nurse immunisers to administer the monkeypox vaccine to people recommended for vaccination will build workforce capacity in these existing models and allow them to scale up as more monkeypox vaccine becomes available.

Authorisation and training of pharmacist immunisers to administer the monkeypox vaccine to people recommended for vaccination, aged five years and older. This will align with the minimum age group that is within the pharmacist immuniser's scope of practice in case of an expansion to the groups recommended for vaccination, and ensure that Victoria is prepared and well positioned when more vaccine becomes available and it is determined that additional models of care involving partnerships with primary care partners (including community pharmacies) need to be established.

It is therefore proposed that the Secretary Approvals for nurse immunisers and pharmacist immunisers are amended to enable these workforces to administer the monkeypox vaccine to people recommended for vaccination as listed on the department's [Monkeypox webpage](#) as amended from time to time. Successful completion of a new Monkeypox vaccination eLearning module (and a clinical skills competency assessment where intradermal monkeypox vaccination will occur) will be a condition of the authorisation.

Authorisation of these immunisation workforces does not equate to participation in Victoria's monkeypox response.

**Please confirm whether your organisation supports the proposed changes detailed in this consultation paper. If your organisation does not support these proposed amendments, please advise why, or suggest amendments.**

Please email your response to [Immunisation@health.vic.gov.au](mailto:Immunisation@health.vic.gov.au) by the close of business **14 September 2022**.

If you have any questions, please contact Sarah Bird, Principal Policy Adviser, Immunisation Unit via email at [Immunisation@health.vic.gov.au](mailto:Immunisation@health.vic.gov.au).

## 2. Background

The *Drugs, Poisons and Controlled Substances Regulations 2017* (the Regulations) enable the Secretary of the department to approve a Schedule 4 poison for administration by a nurse immuniser or pharmacist immuniser, and to specify the conditions in which nurse immunisers or pharmacist immunisers are authorised to administer the Schedule 4 poison.

Nurse immunisers and pharmacist immunisers have administered a range of vaccines in Victoria for many years and have recently made a vital contribution to Victoria's COVID-19 Vaccination Program.

Nurse immunisers and pharmacist immunisers are required to complete an 'Immuniser program of study' that has been recognised by the Chief Health Officer and aligns with the National Immunisation Education Framework for Health Professionals. This training includes administration of all vaccines on the National Immunisation Program Schedule to all vaccine-recommended age groups. The 'Immuniser program of study' does not include the monkeypox vaccine as it is not on the National Immunisation Program Schedule, and therefore it is currently not within the scope of any Victorian recognised 'Immuniser program of study'.

Authorisation of nurse immunisers and pharmacist immunisers, and provision of additional training to ensure they have the knowledge and skills required to administer the monkeypox vaccine, will ensure that there is sufficient vaccination workforce available to meet demand for the monkeypox vaccine when additional vaccine supply becomes available.

Under the proposed changes, nurse immunisers and pharmacist immunisers must continue to adhere to current standards, guidelines and protocols to support safe vaccination, appropriate management of adverse events and must comply with requirements relating to documentation and reporting.

**Please note: this is a separate process to the consultation process currently underway to support a proposed expansion to the Victorian Pharmacist-Administered Vaccination Program.**

## 3. Proposal: Authorisation of nurse immunisers and pharmacist immunisers to administer the monkeypox vaccine

### 3.1 Monkeypox

Monkeypox is a viral zoonosis (an infection spread from animals to humans) and is part of the same family of viruses as the variola virus which causes smallpox. It is a rare viral illness that while usually mild, can become serious. For most people, symptoms will clear on their own after 2-4 weeks.

Common signs of monkeypox infection can include a new rash and/or lesions, swollen lymph nodes, fever, headache, muscle aches, joint pain, back pain, chills or exhaustion<sup>1</sup>.

While smallpox was declared eradicated in 1980 by the World Health Organization<sup>2</sup>, monkeypox spread has recently increased in both number of cases and geographic reach. This is likely due to the cessation of smallpox vaccination, which has been proven to be protective against monkeypox, resulting in waning vaccine-induced population immunity and no protection for younger age groups.

Monkeypox virus can be transmitted from infected animals to people, or from person to person. Monkeypox does not spread easily between people, but can be transmitted via close contact with lesions, body fluids, respiratory droplets in prolonged face-to-face contact or through contact with contaminated objects, surfaces and/or materials (such as clothing or linen)<sup>3</sup>.

Since May 2022, there has been a global increase in monkeypox infections in multiple countries where the illness is not usually seen. Monkeypox was first reported in Australia in May 2022 and declared by the World Health

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<sup>1</sup> [Monkeypox \(MPX\) | Australian Government Department of Health and Aged Care](#)

<sup>2</sup> WHO (2022), Smallpox – accessed at <https://www.who.int/health-topics/smallpox>

<sup>3</sup> [atagi-clinical-guidance-on-vaccination-against-monkeypox-atagi-clinical-guidance-on-vaccination-against-monkeypox\\_0.pdf \(health.gov.au\)](#)

Organization as a Public Health Emergency of International Concern on 23 July 2022. On 28 July 2022, Australia's Chief Medical Officer declared monkeypox a Communicable Disease of National Significance<sup>4</sup>.

Further information about monkeypox in Victoria can be found on the department's [Monkeypox webpage](#).

## 3.2 Monkeypox vaccine

There are two vaccines available for use in Australia:

- JYNNEOS®
- ACAM2000™.

JYNNEOS® is the preferred vaccine for use in Australia based on its safety profile and because it is easier to administer.

JYNNEOS® can be injected subcutaneously (under the skin, preferably into the upper arm) or intradermally (into the outer layers of skin). However, intradermal administration of this vaccine is not recommended for anyone with a weakened immune system or a history of keloid scarring. Intradermal injection is not preferred as the route for the first dose for post-exposure vaccination.

The Australian Technical Advisory Group on Immunisation (ATAGI) has advised that that vaccination with JYNNEOS® in children can be considered, especially for people in high-risk groups aged 16 years and older, after discussing the risks and benefits with their vaccine provider.

There is a globally limited supply of the JYNNEOS® vaccine and high international demand. Given vaccine supply is limited, access to vaccines is being prioritised to support strong outbreak management<sup>5</sup>.

## 3.3 Monkeypox vaccine priority cohorts

A comprehensive Victorian response to monkeypox virus is currently underway, which includes distribution of the monkeypox vaccine to people recommended for vaccination through select sexual health centres, health services, and Local Public Health Units.

In Victoria, the monkeypox vaccine is available free-of-charge at specified locations for specific priority groups. Monkeypox vaccination of at-risk, priority individuals will play a key role in controlling the disease and preventing future outbreaks. People recommended for vaccination are included on the department's [Monkeypox webpage](#) and will be subject to change in response to changing circumstances and vaccine availability.

At 5 September 2022, people recommended for vaccination include the following:

- Post exposure prophylaxis for high-risk close contacts of monkeypox cases (within 4 days)
- Laboratory workers who analyse specimens from monkeypox cases
- Sexually active HIV positive gay, bisexual, and other men, trans people or non-binary people assigned male at birth who have sex with men (including cis and trans men)
  - With a sexually transmitted infection (STI) in the last 12 months OR
  - Who will be travelling to North America or Europe before 31 October 2022\* OR
  - Who attend sex on premises venues including saunas, adult cinemas/lounges, beats and sex parties.

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<sup>4</sup> [Monkeypox \(MPX\) | Australian Government Department of Health and Aged Care](#)

<sup>5</sup> [Monkeypox \(MPX\) vaccines | Australian Government Department of Health and Aged Care](#)

- Sexually active HIV negative gay, bisexual, and other men, trans people or non-binary people assigned male at birth who have sex with men (including cis and trans men)
  - With an STI in the last 12 months OR
  - Who will be travelling to North America or Europe before 31 October 2022\* OR
  - Who attend sex on premises venues including saunas, adult cinemas/lounges, beats and sex parties.
- Sexually active gay, bisexual, and other men, trans people or non-binary people assigned male at birth who have sex with men (including cis and trans men) who are homeless, or have significant drug use or psychiatric illness
- Sex workers who engage in sex with the sexually active groups listed above.

\*A person will start to build protection in the days after their first dose with antibodies providing protection within 2 weeks.

### 3.4 Scope of proposed authorisation

Nurse immunisers and pharmacist immunisers are not currently authorised to administer the monkeypox vaccine in Victoria.

It is proposed that nurse immunisers and pharmacist immunisers are authorised to administer the monkeypox vaccine to people that are recommended for vaccination as listed on the department's [Monkeypox webpage](#). These groups may be subject to change in response to emerging events.

The proposed training (see section 3.5 below) will not equip nurse immunisers or pharmacist immunisers to provide all the necessary care in the instances of **post exposure prophylaxis purposes for high-risk close contacts** of monkeypox cases. This process requires specialist counselling and comprehensive public health measures to be considered – including contact tracing. This process should be undertaken by appropriately trained specialist sexual health/public health/infectious disease clinicians. Authorised immunisers who are working within a clinical model and team that supports this specialist care, can perform the monkeypox vaccinations where the specialist care activities can be performed by an appropriately trained specialist clinician (i.e. a medical practitioner or nurse practitioner or infectious disease/sexual health expert, not the immuniser). Other models of care where a nurse immuniser or pharmacist immuniser can undertake post exposure prophylaxis vaccination activity may be specifically noted on the department's Monkeypox webpage, or within the clinical guidelines.

The proposed authorisations will permit the administration of the vaccine to individuals in line with the vaccination criteria tied to planned international travel as specified on the department's Monkeypox webpage, but it **will not include** the administration of the monkeypox vaccine for the **purpose of other international travel that is not specified**. Travel vaccinations require a medical consultation with a general practitioner or travel medicine specialist, which considers broader matters relating to travel beyond vaccination. Vaccination against monkeypox under this criterion should not be viewed as a substitute for obtaining a travel medicine assessment.

Authorising nurse immunisers and pharmacist immunisers to administer the monkeypox vaccine to people who are recommended for vaccination will support Victoria's response to the monkeypox virus by building workforce capacity and increasing vaccine access for at-risk individuals. Enhancing the number of trained and competent immunisers authorised to administer the monkeypox vaccine will ensure Victoria is prepared and well positioned to quickly scale to meet demand and ensure equitable access as more vaccine become available.

It is proposed that pharmacist immunisers are authorised to administer the monkeypox vaccine to individuals recommended for vaccination, aged five years and older. Although the vaccine is currently only recommended for people aged 16 years and older, the authorisation aligns with the minimum age group that is within the pharmacist immuniser's scope of practice. This age limit allows for the potential for expansion of criteria if required, to include younger cohorts of people.

ATAGI has recommended the preferred monkeypox vaccine be administered via either subcutaneous or intradermal injection<sup>6</sup>. Administration of the monkeypox vaccine intradermally requires 1/5 of the required vaccine dosage producing a similar immune response as compared with subcutaneous administration. This means that up to five times more people will be able to access the vaccine if administered intradermally. A trained and competent vaccination workforce will be required to manage this expansion.

### 3.5 Additional training requirements

The department has commenced development of a Monkeypox vaccination eLearning module that will be made available online to authorised immunisers through the [Victorian Immunisation Learning Hub \(vic-immunisation-learning.com\)](https://vic-immunisation-learning.com) free of charge. This will be a pre-requisite for all nurse immunisers and pharmacist immunisers prior to administering the monkeypox vaccine.

Note: The training will only include JYNNEOS<sup>®</sup> information as the preferred monkeypox vaccine in Victoria. As such, nurse immunisers pharmacist immunisers will only be trained in the delivery of JYNNEOS<sup>®</sup>. Patients requiring ACAM2000<sup>™</sup> should be referred to a medical practitioner or nurse practitioner.

In select organisations where intradermal monkeypox vaccination will occur, the department will have clinical competency training available for authorised immunisers. Authorised immunisers undertaking this activity will be required to successfully complete both the eLearning module and the associated clinical competency training and assessment prior to administration of the monkeypox vaccine intradermally, and will be a condition of the authorisation.

## 4. Next steps

Feedback received through this consultation process will be used to inform the scope of the final changes to the Secretary Approvals and will help to identify any issues that need to be addressed prior to implementation.

The proposals are subject to advice from the department's Health Professions Drug Access Committee and approval by the Director of Medicines and Poisons Regulation (as the Secretary's delegate).

It is anticipated that the changes will be published in the Victorian Government Gazette and in force by early October 2022. Relevant guidelines, websites and resources will also be updated to reflect the change.

As noted above, authorisation of these immunisation workforces does not equate to participation in Victoria's monkeypox response.

The department will continue work with key sector stakeholders to ensure the approved changes are clearly communicated.

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<sup>6</sup> [ATAGI clinical guidance on vaccination against Monkeypox | Australian Government Department of Health and Aged Care](#)