Reclassification of a Medicine for consideration by the Medicine Classification Committee

This form should be completed in conjunction with the directions in the guidance: How to change the legal classification of a medicine in New Zealand.

Once completed, this application should be sent to committees@moh.govt.nz by the deadline indicated on the Dates and Deadlines page on the Medsafe website.

By submitting this form, you are confirming that all information is true and accurate, and understand that this information and any appendices and/or supporting information that is not considered commercially confidential under the Official Information Act 1982 criteria will be published on the Medsafe website.

Part A

1. **International Non-proprietary Name of the medicine.**

   Influenza vaccine.

2. **Proprietary name(s).**

   Influvac, Influvac Tetra, Fluvax, FluQuadri, Vaxigrip

3. **Name and contact details of the company / organisation / individual requesting a reclassification.**

   [redacted] Pharmaceutical Society of New Zealand

   Note: Contact details will be removed from the form prior to publication on the Medsafe website.

4. **Dose form(s) and strength(s) for which a change is sought**

   Single dose

5. **Pack size, storage conditions and other qualifications.**

   Could vary by product

6. **Indications for which change is sought.**

   For the prevention of influenza caused by influenza virus, types A and B in a person 13 years of age or over in accordance with the recommendations in the National Immunisation Guideline.

7. **Present classification of the medicine.**

   Influenza vaccine is currently a prescription medicine except when administered to a person 13 years of age or over by a registered pharmacist who has successfully completed a vaccinator training course approved by the Ministry of Health and who is complying with the immunisation standards of the Ministry of Health.

8. Classification sought.

Prescription medicine except when administered to a person 13 years of age or over by a registered pharmacist or **registered intern pharmacist** who has successfully completed a vaccinator training course approved by the Ministry of Health and who is complying with the immunisation standards of the Ministry of Health.

9. **Classification status in other countries (especially Australia, UK, USA, Canada).**

Influenza vaccine is a prescription medicine in Australia, UK, USA and carries a schedule 2 listing in Canada. However, pharmacist-delivered vaccinations are happening through different mechanisms in all of these countries, as well as Switzerland and Australia.[1,2,3]

10. Extent of usage in New Zealand and elsewhere (eg, sales volumes) and dates of original consent to distribute.

There is good evidence that pharmacists administering vaccines in the community setting is both safe and effective.[3,4,5]

11. Local data or special considerations relating to New Zealand (if applicable).

Currently there are 843 pharmacist vaccinators in New Zealand administering vaccines in the community. It would be ideal if New Zealand could enable intern pharmacists to undertake influenza vaccination as part of their training in a similar way to other jurisdictions. This would also help building on and addressing public health needs across the country.

12. Labelling or draft labelling for the proposed new presentation(s).
N/A.

13. Proposed warning statements (if applicable).
N/A

14. Other products containing the same active ingredient(s) and which would be affected by the proposed change.

All registered products containing influenza vaccine will be affected by the proposed change.

Part B

1. Indications and dose

Single dose treatment for the prevention of influenza caused by influenza virus, types A and B in a person 13 years of age or over in accordance with the recommendations in the National Immunisation Guideline.

2. Presentation

Single dose treatment in a prefilled syringe

3. Consumer benefits

Influenza vaccine is a prescription medicine in Australia, UK, USA and carries a schedule 2 listing in Canada. However, pharmacist-delivered vaccinations are happening through different mechanisms in all of these countries, as well as Switzerland and Australia.[1,2,3]
This medicine is only used for the proposed indication and is a single dose vaccination. The proposed change will increase patients access to treatment, the total number of patients receiving their influenza vaccine through a community pharmacy and continue to help in reaching vulnerable populations.

4. Contraindications and precautions

Contraindications

- Hypersensitivity to the active substances, to any of the excipients and to residues of eggs, chicken protein, formaldehyde, cetrimonium bromide, polysorbate 80, or gentamicin. The Ministry of Health Immunisation Handbook (2017) recommends "that individuals with hypersensitivity to eggs may receive influenza vaccination – but those with an anaphylactic component should be vaccinated in a closely monitored environment such as a hospital or outpatient clinic."
- Anaphylaxis following a previous dose of any influenza vaccine.
- Immunisation should be postponed in patients with an acute febrile illness.

Special warnings and precautions for use

- As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of a rare anaphylactic event following the administration of the vaccine.
- Influenza vaccine should not be administered intravascularly.
- Patients with impaired immune responsiveness, whether due to the use of immunosuppressive therapy, a genetic defect, human immunodeficiency virus (HIV) infection, or other causes, may have a reduced antibody response in active immunisation procedures.
- Patients with a history of Guillain-Barre syndrome (GBS) with an onset related in time to influenza vaccination may be at increased risk of again developing GBS if given influenza vaccine. While this risk should be weighed against the benefits to the individual patient of influenza vaccination, it would seem prudent to avoid subsequent influenza vaccination in this group. Because patients with a history of GBS have an increased likelihood of again developing the syndrome, the chance of them coincidentally developing the syndrome following influenza vaccination may be higher than in individuals with no history of GBS.
- Anxiety-related reactions, including vasovagal reactions (syncope) hyperventilation or stress related reactions can occur following, or even before, any vaccination as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints.

Interactions with other medicines
From the NZ-approved datasheet the following interactions are possible:

- Although inhibition of hepatic clearance of phenytoin, theophylline and warfarin has been reported after influenza vaccination, subsequent studies have not shown any evidence of undesirable effects related to this phenomenon.
- The immunological response may be diminished in patients taking immunosuppressant treatment.
- Influenza vaccine should not be mixed with other vaccines in the same syringe.
- Influenza vaccine may be given at the same time as other vaccines. Immunisation should be carried out in separate limbs. Adverse reactions may be intensified.

These contraindications and precautions will be managed by the pharmacy intern working under the direct supervision of the pharmacist vaccinator using the approved patient consent forms and training developed for pharmacist vaccinator training.

5. Undesirable effects

The Ministry of Health Immunisation Handbook (2017) states:

"Trivalent influenza vaccines are generally well tolerated. Placebo-controlled trials of influenza vaccines have shown that influenza vaccine is not associated with systemic reactions (e.g., fever, malaise, myalgia) in older persons and healthy young adults.[6] A large post-licensure study in the US, which reviewed more than 250,000 children aged under 18 years given influenza vaccine, showed no increase in clinically important medically attended events for two weeks after vaccination compared to control periods.[7] In early 2010 there were reports of children in both Australia and New Zealand who had received the influenza vaccine and experienced febrile seizures. All of the cases were linked to the Fluvax brand of vaccine.

Vaccinators need to emphasise to recipients that:

- it is an inactivated vaccine and cannot cause influenza
- local reaction and mild systemic symptoms may occur within a day or two of Immunisation
- respiratory viral infections are common, and many individuals will develop one coincidentally following immunisation, and these should not be falsely attributed to the vaccine.

Influenza local reactions, including redness and induration at the injection site, may persist for one to two days in 10–64 percent of adult recipients, but these effects are usually mild.[6] Passive reporting of local and systemic reactions to influenza vaccines is more frequent for females (both young and older adults) than males.[8]
The safety profile of quadrivalent inactivated vaccines is comparable to that of trivalent inactivated vaccines.[6]"

In accordance with the NZ approved datasheets:

- As clinical trials are conducted under widely varying conditions, adverse event rates observed in the clinical trials of a vaccine cannot be directly compared to rates in the clinical trial of another vaccine and may not reflect the rates observed in practice.

- No serious adverse reactions attributable to vaccine administration were reported. Local and general symptoms were recorded for a period of 3 days following vaccination and reactions usually disappeared within 1-2 days without treatment.

- During clinical studies, local and general signs and symptoms reported by the vaccine were recorded. The events are categorised by frequency according to the following definitions:
    - *Very common*: (frequency ≥ 10%)
    - *Common* (frequency ≥ 1 and < 10%)
    - *Uncommon* (frequency ≥ 0.1% and < 1%)
    - *Rare* (frequency ≥ 0.01% and < 0.1%)
    - *Very rare* (frequency < 0.01%)

- Local reactions *Very common:* redness, swelling, pain.
  Common: ecchymosis, induration.

- Body as a whole Very common: headache.
  Common: fever, malaise.
  Uncommon: shivering, fatigue, sweating, myalgia, arthralgia.
  Very rare: neuralgia, paraesthesia, convulsions, transient thrombocytopenia, allergic reactions (such as angioedema) leading to shock.

6. Overdose

There is the potential for patients to receive more than one influenza vaccine from a health professional. However, this risk is mitigated by the consent process and use of electronic tools in the sector to confirm previous vaccines and current vaccination status.

7. Medication errors and abuse/misuse potential

Not applicable

8. Communal harm and / or benefit

This proposal will increase the number of registered health professionals in primary care who can administer influenza vaccines.

The proposal will ensure the early training of pharmacists and will become part of the Society's Intern Training Programme for all new pharmacists.

This proposal will enable registered intern pharmacists to become vaccinators and the training will be delivered during the Intern Training Programme.

This will enable the pharmacy vaccinator workforce to continue to grow year on year, as more registered intern pharmacists complete the training.

These proposed steps will help the Ministry of Health to deliver increased immunisation rates and greater heard immunity as a result of improved access to a communicable disease vaccine.

9. Integrated benefit-risk statement

Enabling registered intern pharmacists to administer influenza vaccine under the same circumstances as registered pharmacists will increase the number of health practitioners who can provide vaccination coverage, continue to help reaching vulnerable populations through ease of access to health services and improve herd immunity.

The training requirement and administration process will be the same as registered pharmacists so there is no increased risk of harm.

To include "registered intern pharmacist" in the reclassification statement will improve patients' access to treatment, increase the size of the available workforce to provide vaccinations and help achieve the Ministry of Health's targets and requirements around vaccination rates.

10. Risk mitigating strategies

The pharmacy intern will be working under the direct supervision of the pharmacist vaccinator using the approved patient consent forms and training developed for pharmacist vaccinator training

Council supports the proposal to include the term "intern pharmacist" in the gazette notice for the flu vaccine classification. There are several mitigators already in place to manage any risk associated with this reclassification:

Intern Pharmacists are registered as health professionals with the Pharmacy Council and are therefore subject to the same regulatory framework as pharmacists, with regard to standards of practice, ethical, cultural and professional obligations.

The potential to administer medicines (including vaccines) is already included in the intern scope of practice gazetted by the Pharmacy Council. As long as interns are supervised by a registered pharmacist, holding a current and valid Annual Practising Certificate, and who is currently certified as a vaccinator whilst administering a vaccine the intern will be supported in their learning, without increased risk to patient safety.

Interns must be deemed competent to administer the vaccine and this will be covered by undertaking vaccinator training that complies with the immunisation standards of the Ministry of Health.

The legal definition of “registered pharmacist” under the Health Practitioners Competence Assurance Act (HPCA Act 2003) does not incorporate those practising in the intern scope.
In order to administer the flu vaccine legally in New Zealand the gazette notice will need to be amended to include the term “intern pharmacist”.

With theses risk mitigators in place, the Pharmacy Council believes that any potential public safety concerns have been proactively addressed.

References

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3. Hattingh HL, Sim TF, Parsons R, et al. Evaluation of the first pharmacist administered vaccinations in Western Australia: a mixed methods study. *BMJ Open* 2016;**6**:e011948. URL: link [accessed 13 h June 2019].

4. Nissen, Lisa, Glass, Beverley, Lau, Esther, & Rosenthal, Michelle (2015). Queensland pharmacist immunisation pilot phase 1 pharmacist vaccination. Influenza final report. URL:link [accessed 13th June 2019].

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6. Centers for Disease Control and Prevention. 2016. Prevention and control of seasonal influenza with vaccines: recommendations of the Advisory Committee on Immunization Practices – United States, 2016–17 influenza season. Morbidity and Mortality Weekly Report: Recommendations and Reports 65(RR05): URL:link [accessed 13th June 2019].

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