Influenza Vaccine Reclassification Application

Pharmaceutical Society of New Zealand

January 2018

Submission for Reclassification of Influenza Vaccine

Executive Summary

This application seeks the reclassification of influenza vaccine to:

A 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 immunization standards of the Ministry of Health.

Pharmacists have been providing vaccinations to patients in New Zealand since 2012 and the training is provided by the immunisation advisory centre.

Pharmacy interns are registered with the Pharmacy Council under the Health Practitioners Competence Assurance Act 2003.

It is proposed that registered intern pharmacists follow the same process for training and once qualified vaccinators they administer vaccinations **under the direct supervision** of **trained pharmacist vaccinator** and in accordance with their APC requirements.

Part A

1. International Non-proprietary Name (or British Approved Name or US Adopted Name) of the medicine

Influenza vaccine

2. Trade name(s)

Influvac, Influvac Tetra, Fluvax, FluQuadri, Vaxigrip

3. Name of company/organisation/individual requesting reclassification

Pharmaceutical Society of New Zealand

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

Single dose

5. Pack size 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 medicine

Influenza vaccine is current 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. 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. A statement of the benefits to both the consumer and to the public expected from the proposed change

The proposed change will increase the total number of patients receiving their influenza vaccine through a community pharmacy and continue to help reaching vulnerable populations.

This proposal will increase the number of health practitioners 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.

Intern pharmacists and pharmacy students have been administering influenza vaccine under supervision in Canada and the United States since 2012.[4,5,6]

The upskilling of registered intern pharmacists will also enable the pharmacy workforce to be working at the top of their scope of practice and potentially all pharmacists to become vaccinators.

The pharmacy vaccinator workforce will continue to grow year on year, as the number of intern pharmacists complete the training and qualifying as registered pharmacists.

2. Ease of self-diagnosis or diagnosis by a pharmacist for the condition indicated

Pharmacists have been administering vaccinations in New Zealand since 2012 and the training programmes are well established.
Interns will undertake the same training and work under the direct supervision of a pharmacist vaccinator. There should be no problem with diagnosis and administration by the intern pharmacist working under these conditions.

3. Relevant comparative data for like compounds

Not applicable.

4. Local data or special considerations relating to New Zealand

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 address public health needs across the country.

5. 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 potential medication interactions 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.

6. 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.

These contraindications and precautions will be 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.

7. Possible resistance

Not applicable

8. Adverse events - nature, frequency etc.

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 (eg, fever, malaise, myalgia) in older persons and healthy young adults.[7] 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.[8] 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.[7]
Passive reporting of local and systemic reactions to influenza vaccines is more frequent for females (both young and older adults) than males.[9]
The safety profile of quadrivalent inactivated vaccines is comparable to that of trivalent inactivated vaccines.[7]"

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.

International evidence

There is good evidence that pharmacists administering vaccines in the community setting is both safe and effective.[3,10,11]

9. Potential for abuse or misuse

Not applicable

10. References

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