Submission for Reclassification of Influenza Vaccination

Executive Summary

This application requests a reclassification for influenza vaccination allowing administration to adults by pharmacists who have completed an approved vaccinator's course and comply with the immunisation standards of the Ministry of Health.

Internationally, there is an increasing trend to allow certified pharmacists to administer vaccinations, particularly influenza vaccinations. Pharmacist-administered vaccinations have been occurring in the US since the 1990s, with millions of doses having been pharmacist-administered there.[1] Other countries in which pharmacist-vaccinations are occurring include the UK,[2] Ireland,[3] Canada,[4] and Portugal.[2] This move recognises the accessibility and convenience of pharmacy and the advocacy of pharmacists as health professionals, both of which increase awareness of and opportunities for consumers to become vaccinated. Vaccination rates improve[5,6] and pharmacist-vaccinators have been received well by both healthcare consumers and pharmacists.[3,7] In the US, pharmacist-administered vaccinations have the support of the American College of Physicians and American Society of Internal Medicine.[8]

Changing the classification of influenza vaccinations will reduce the barriers for pharmacists to deliver these services. The benefit-risk profile of the influenza vaccination given by an appropriately trained health professional is clearly consistent with (or better than) other pharmacist-only medicines or medicines with exemption to supply through pharmacists. Benefits of influenza vaccination in reducing influenza cases, reducing hospitalisations and reducing mortality are well-known.[9] Risks using trained vaccinators with first aid training and appropriate set-up are extremely low.[3]

Increasing the number of pharmacists trained in this area and administering and advocating for use of vaccinations will provide public health benefits for NZ. These benefits arise from increased accessibility (location, opening hours, no appointment), increased promotion of vaccinations, increased advocacy, and ability to use the strong functionality of the pharmacy computer software for recall of patients. Pharmacy can collaborate with General Practice to facilitate an increase in awareness for the public around all vaccines and the importance of discussing funded vaccinations (not just influenza) with their practitioners.

The pharmacy process will be comprehensive including thorough screening, record-keeping, notification to the healthcare consumer's GP (with consent), and reporting of adverse events to the GP and the Centre for Adverse Reactions Monitoring (CARM). The pharmacy process will meet the standards in Appendix 3 of the Immunisation Handbook 2011 (see Appendix 3 of this application), including use of a private area and a 20 minute observation period.

Pharmacy is willing and able to play a greater role in public health.

Part A

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

Influenza vaccination (split virion, inactivated)

2. Proprietary name(s)

Products on the market vary (according to funding for example), and currently include Intanza®, Fluarix®, Vaxigrip® and Fluvax®.

3. Name of company/organisation/individual requesting reclassification

Pharmacybrands Ltd, the parent company for Life, Unichem, Amcal, Radius and Care Chemist Pharmacies in New Zealand.

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

Single dose injection.

The strains selected change (usually annually) to reflect the requirements of the Australian Influenza Vaccine Committee and the New Zealand Ministry of Health for the winter. Strains are selected by the World Health Organisation (WHO) see http://www.medsafe.govt.nz/regulatory/flu.asp

5. Pack size and other qualifications

The pack size varies with each product.

The product is for injection.

6. Indications for which change is sought

For the prophylaxis against influenza in adults.

7. Present classification of medicine

Prescription only medicine

8. Classification sought

Exemption to Prescription Medicine when administered to an adult by a pharmacist who has successfully completed the NZQA approved vaccinator's course and is complying with the immunisation standards of the Ministry of Health.

Please note that exemption to Prescription Medicine is sought not a Pharmacist-Only Medicine. The primary reason for using this mechanism is because estimates of usage are difficult with a product which has differing constituents each year and where uptake can

change. At short notice companies may need to pull in stock from elsewhere (e.g. Australia where they may have a harmonised label). Thus, an exemption to Prescription Medicine retains flexibility for companies in ensuring the market needs can be met. This clearly has public health benefits in ensuring people can continue to access the medicine.

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

Internationally pharmacist-administration of vaccines is becoming common through various mechanisms. In most countries the vaccines remain prescription medicines.

In Canada, influenza vaccinations have been Schedule II since December 1998, equivalent to NZ's Pharmacist-Only Medicine.[10] Trained pharmacists in British Columbia, Alberta and New Brunswick administer vaccinations, and Manitoba, Ontario and Nova Scotia are finalising regulations to allow trained pharmacists to administer vaccinations.[11] Pharmacist training includes an eight-hour online session and practicum.[4]

In the USA, vaccinations have been available from pharmacies in some states since the 1990s,[12] extended to all states in 2009. Following completion of the American Pharmacists Association Certification Program, pharmacists are able to administer influenza vaccinations[7] through a practice which has some similarities with standing orders or the UK's patient group directions.

In the UK, influenza vaccination by accredited pharmacists in pharmacies under Patient Group Direction (PGD) is common. Chemist and Druggist reported in November 2010 administration of more than 100,000 flu vaccinations in pharmacies through the Novartis Vaccines in-pharmacy flu vaccination programme.[13]

Vaccinations in community pharmacies are also available in Portugal[2] and Ireland.[3] Pharmacist-administered influenza vaccinations have been trialled in Australia, and at least one pharmacy school is training students to immunise.[14]

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

Based on Healthcare Logistics and Ministry of Health figures, from 2005 to 2008 influenza vaccinations distributed were very stable at 717,000 – 760,000 distributed each year, of which 55-60% were funded claims (e.g. for people over 65 years or with chronic conditions). This increased in 2009 and 2010 probably because of the influenza A (H1N1) pandemic with over 900,000 per year distributed, approximately 60% of which were funded.

According to the Medsafe website, Fluvax® was first consented for use 31 December 1969. Other brands of influenza vaccination have received consent subsequent to that time.

11. Labelling or draft labelling for the proposed new presentation(s)

There would be no change to labelling for the proposed change in classification. This medicine is not going to be self-administered so consumer labelling is unnecessary. Additionally, some companies have packaging harmonised with Australia.

12. Proposed warning statements if applicable

Current packaging would remain.

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

Any influenza vaccination that is registered on the NZ market will be affected.

Part B

1. A statement of the benefits to both the consumer and to the public expected from the proposed change

The primary aim of reclassification is to increase the access and convenience of influenza vaccination in order to increase uptake by the general population and reduce the healthcare burden of influenza.

In having more pharmacists trained in immunisation there are further follow-on benefits. Firstly, pharmacists will be better informed to be advocates for all immunisations on the current NZ programme. And secondly, should mass vaccination be required (e.g. future pandemic or certain epidemics), there is a larger workforce already skilled in this area.

Benefits of influenza vaccination

Influenza causes:

- Illness, including secondary infections
- Hospitalisations (average 327/year 1989-2004, but under-reported)[9,15]
- Deaths (5 – 14 deaths per year, 49 in 2009; modelling suggests an average of 400 deaths per year that are attributable to influenza)[9]
- Emergency department over-loading (by contagious patients)
- Time off work or other important non-work activities
- Cost to the taxpayer through the health system costs and reduced productivity

Influenza vaccination prevents cases of influenza with efficacy of 60-95% when vaccination strains are well matched with strains in the community.[9] Although efficacy is lower in older people, it has been estimated that over half of respiratory illnesses, pneumonia cases, hospitalisations and deaths in older people may be prevented by influenza vaccination.[9] The National Influenza Strategy Group (NISG) reports research in elderly people showing a 26% reduction in risk of hospitalisation for influenza or pneumonia, and 42% reduction in mortality.[15] Influenza-related mortality declined after introduction of routine influenza vaccination among the NZ elderly.[16]

Expected benefits of widening access to vaccinations through pharmacy in NZ

Benefits of widening access to vaccinations through pharmacy include:

- Increasing uptake in influenza and other vaccinations
- Reducing illness in the community
- Reducing complications from the illnesses (decreasing antibiotic use)
- Reducing time off work (with influenza)
- Reducing cost to the taxpayer (loss in productivity, healthcare costs).

We anticipate that most vaccinations through pharmacy will be incremental gains, e.g. people who never get around to booking in with their doctor. Most community pharmacies are open at least 6 days a week, and many are open long hours. An appointment will often not be necessary. There are over 900 pharmacies around the country, conveniently located for most of the population. A European survey found only 67% of those intending to have a vaccination actually received a vaccination.[17] In Australia, time and inconvenience were cited by a quarter of adults under 65 years with chronic medical conditions who did not get an influenza vaccination.[18]

This reclassification would increase the potential pool of vaccinators which would help managing a pandemic or important epidemic. In British Columbia, Canada allowing pharmacist-administration of vaccinations was prompted by the Influenza A(H1N1) pandemic 09.[4] Pharmacists were generally positive about this expanded role, including many being willing to offer vaccination services in the evenings and weekends, and subsequently participated in administration of the pandemic vaccination.

US physician support

The American College of Physicians and American Society of Internal Medicine stated in 2002: [8]

> *"ACP-ASIM supports the use of the pharmacist as immunization information source, host of immunization sites and immunizer, as appropriate and allowed by state law. ACP-ASIM will work with pharmacy organizations to increase immunization awareness."*

No concerns about pharmacist-immunisation were outlined by these doctor groups who noted:

- The potential benefit of non-physician immunisation
- Pharmacists increase access to immunisation through extended opening hours and locations
- Benefits expected include decreased antibiotic resistance and increased adult immunisation

Collaboration with GPs

The delivery of influenza vaccine in pharmacy has raised some significant opportunities to increase the collaborative approach to patients. Feedback from general practice indicates that the ability to "Recall" patients each year has some system challenges. Pharmacy has the ability to manage this through the dispensary system and work together with GPs to facilitate this communication and increase the awareness of influenza and the benefits of vaccination for those over 65 years of age but more so with those patients with a chronic condition under the age of 65 years which has been raised as a potentially key area to increase uptake (with only 35% uptake by this group in 2008)[19]. In the Netherlands vaccination increased significantly when pharmacy records were used by GPs,[20] and pharmacist advocacy improves vaccination uptake (see below).

Pharmacist-led influenza vaccination programmes do not replace general practice but offer another option for patients. With patient consent the GP is notified of the vaccination. This will improve further when the National Immunization Register can include influenza vaccine reporting. As is usual in pharmacy, the pharmacist will refer patients onto their GP where they feel appropriate, and as identified through the history taking/consent process.

International research and experience of pharmacist-administered vaccinations

In the US, pharmacists have administered vaccinations to adults since the 1990s, expanding to all states in 2009.[12] Pharmacists administer influenza vaccinations through a practice which has some similarities with standing orders or the UK's patient group directions. This has lead to 18% of influenza vaccinations in adults being given in the US through pharmacy, versus 40% through doctors and 17% at workplaces.[12] In Walgreens alone (a large community pharmacy chain) more than 4.5 million seasonal influenza vaccinations were pharmacist-administered in the 2009/2010 season, including 1.7 million in medically underserved areas.[1]

Advocacy by GPs and practice nurses is an important motivator for people to have an influenza vaccination.[21] Pharmacist advocacy even without vaccination administration also significantly increases influenza vaccination rate in at-risk populations.[22-25] For example, in Japan pharmacist advocacy significantly increased vaccination rate in people over 65 years from 65% (controls) to 82% (intervention).[22]

Other promotion of influenza vaccination increases with pharmacy involvement. In the UK, pharmacies have had in-store posters and other materials, in Washington DC in autumn 2011 pharmacies had posters at the entrance and large signs on the street outside. In NZ, advertising by Pharmacy 547 may have assisted in the uptake by consumers.[26] Such promotion at a point where they can immediately act on the message will be important for increasing vaccination amongst consumers who do not normally get vaccinated.

US studies have shown increased uptake of influenza vaccination, particularly in certain groups (e.g. over 65 and those not vaccinated the previous year) in states with community pharmacist-vaccination versus states without.[5] [6] This has carried over into pneumococcal vaccination with an observational study indicating pharmacists have a 68% higher rate of delivery in at-risk groups than traditional providers.[27] Pharmacist input in hospitals has also improved rates of vaccination. [28,29,30] In the UK when a Primary Care Trust in London allowed pharmacist-administered influenza vaccination, the vaccination rate in those over 65 years rose to 76% and in at risk under 65 years rose to 67% in 2008. The PCT reported that *"central to this success has been widening the range of venues where people can have the 'jab', including many pharmacies."*[31] Vaccinations by pharmacists have been well received by patients, e.g. in Portugal 99.5% satisfaction with immunisation provider, 98% with privacy, high satisfaction in Aberdeen.[3]

NZ case study

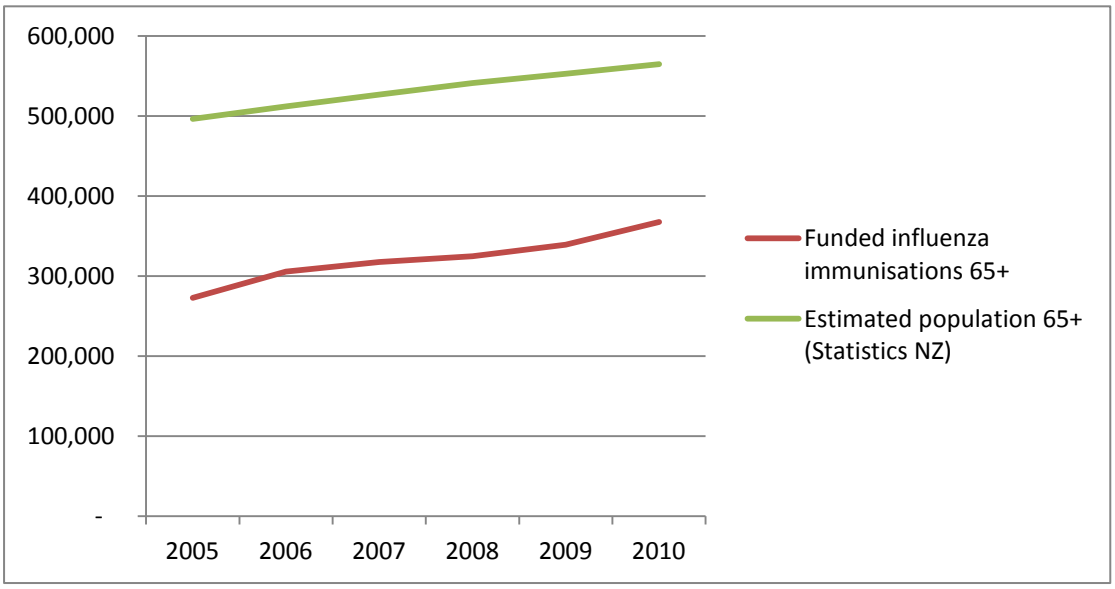
One community pharmacy in NZ has lead the way in this area.[26] After offering nurse-administered influenza vaccination through their pharmacy for two years, Ian McMichael

and Alice Littlewood at Pharmacy 547 in Hamilton had all pharmacists at their pharmacy trained and approved as independent vaccinators. From 15 March to 30 April 2010, 327 vaccinations were administered in the pharmacy, 57% of which were funded by the local DHB. Referrals occurred from some medical clinics when they ran out of supplies, (showing pharmacy supply can help ensure coverage at peak times), and 50 people were immunised at the local church at their weekly low cost lunch for homeless people (on suggestion from IMAC). Two-thirds of recipients who answered the questionnaire had not received an influenza vaccination in 2009, and a fifth of recipients who answered the questionnaire had never received an influenza vaccination before. Although this is experience in one pharmacy alone, it is encouraging that pharmacy appears to be attracting a different audience at least in part. Patient satisfaction was high.

NZ government strategy

Administration of influenza vaccinations by approved pharmacists both provides public health benefits and potential benefits to the taxpayer as outlined above. It is also clearly in line with the government strategy of better, sooner, more convenient healthcare.

Influenza vaccination is short of government targets of vaccinating 75% of people aged 65 years and over. Although a lot of ground has been made, particularly in those 65 years and over, only 35% of people with chronic illnesses and 64% of those 65 years and over received an influenza immunisation in 2008.[19] The graph below (Graph 1) shows that the growth of funded influenza immunisations for people 65 years and over approximately matches the underlying growth in the age-group, suggesting a plateau effect has been reached with current measures. To increase the uptake by people 65 years and over, and the low rate in those with chronic illnesses, training pharmacists in this area will increase advocacy for this group, and has been shown elsewhere to improve vaccination rates.[22]



Graph 1 Uptake of influenza immunisations in the population aged 65 years and over

Population growth, an aging population and developments in health are increasing demand for health services in a constrained fiscal environment. These require better use of the

existing health workforce, including extending existing roles.[32] Increasing the pool of vaccinators helps to meet the population needs now and in the future.

Community pharmacies are easily accessible to and used by most of the population, healthy and unwell, and all ages. Availability of influenza vaccination through trained pharmacists provides the community with another health professional group actively involved in immunisation and advocating for its use, both in funded groups (referred to the general practice) and unfunded groups. International experience (particularly from the US) indicates pharmacists can provide advocacy and accessibility that increase vaccinations. Increased advocacy plus convenience/accessibility provide a strong reason to reclassify this medicine, to provide public health benefits.

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

The only pharmacists able to provide influenza vaccinations will have successfully completed the approved vaccinator's course and clinical assessment and meeting the requirements in standards set by the Ministry of Health (see Appendix 3). Establishing appropriate persons to vaccinate will be straight-forward for these trained pharmacists. The pre-vaccination checklist and consent form attached (Appendix 1) will be used by the pharmacist, recording each consultation. Those fulfilling referral criteria would be referred to the GP, those answering no to all questions will be vaccinated if they consent.

3. Relevant comparative data for like compounds

There are no other influenza prevention medicines available other than influenza vaccination.

Dukoral®, an oral vaccination for prevention of cholera and ETEC travellers' diarrhoea received a recommendation from the last Medicines Classification Committee for reclassification providing training material addresses specific points.[33]

Oseltamivir (for treatment of influenza) became available without prescription in NZ in 2007, under an exemption from prescription when supplied by a pharmacist under certain criteria.[34] Accreditation was not required. Qualitative research indicated pharmacists took their responsibilities seriously, and kept the protocol and consultation pad ready for use, although non-prescription supply was low.[34]

Pharmacists provide other preventive medicines, e.g. low dose aspirin for prevention of cardiovascular disease, folic acid for pregnancy, insect repellents to travellers going to malarial areas.

4. Local data or special considerations relating to New Zealand

Based on Healthcare Logistics and Ministry of Health figures, from 2005 to 2008 influenza vaccinations distributed had little variation with 717,000 – 760,000 distributed each year, of which 55-60% were funded claims (e.g. for people over 65 years or with chronic conditions). This increased in 2009 and 2010 probably because of the influenza A (H1N1) pandemic with over 900,000 per year distributed, approximately 60% of which were funded. With a 4.4

million population, this represents approximately 17% of the population for the pre-pandemic years, and 22% for the subsequent years. Thus, 78-83% of the population is unvaccinated.

Funding claims for influenza vaccination in people over 65 show an increase from 272,715 in 2005 to 367,540 in 2010, possibly partly because of the influenza A(H1N1) 2009 pandemic. Usage in 2010 represents 64% of the over 65 year population (based on September 2010 estimated population over 65 years).[35]

Provision of vaccinations through community pharmacy in NZ has been limited, with Pharmacy 547 having pharmacist-vaccinators in 2010, and 22 pharmacists authorised mid 2011 administering 400 vaccines in this short period of time.

5. Interactions with other medicines

The immunological response may be reduced if the patient is taking corticosteroids or immunosuppressants.[36]

6. Contraindications

The Immunisation Handbook reports that a history of anaphylaxis to egg has been considered a contraindication to influenza vaccination, but that evidence suggests it can be given safely.[9] However, anyone with allergy to eggs, egg products or chicken proteins will be referred to the doctor.

Anaphylactic hypersensitivity to previous influenza vaccination is a clear contraindication.

Contraindications are vaccine specific also, e.g. Fluvax® includes anaphylactic hypersensitivity to neomycin, polymyxin B sulphate, or any constituents or trace residues.[36]

These will be covered in the vaccination checklist (Appendix 1), and pharmacists will have received the comprehensive training and completed vaccinator requirements including first aid training to level 3. Pharmacies offering the vaccinations will have a private area for consultation available and will have the necessary emergency equipment available (see Appendix 2), and the pharmacist-administered vaccination would be advised to the patient's GP as previously discussed. Patients will wait within line of sight in the pharmacy for 20 minutes after being dosed. They will also be given details of a process to be followed should they become unwell in the following 24 hours post vaccination.

7. Possible resistance

Not applicable.

8. Adverse events - nature, frequency etc.

The adverse events are compatible with availability without prescription. About a third of people will get pain and redness (usually mild) at the injection site.[15] Systemic reactions include fever, malaise, and myalgia, which are generally short in duration and mild, and

occur in about 1% of adults.[9,15] Anaphylaxis is very rare and managed as outlined in 6. Contraindications, above. Guillain-Barré syndrome is rare and possibly related to influenza vaccination in certain years.[9]

In the US pharmacist-administration of vaccinations is very common, for example in Walgreens in 2009-2010 4.5 million influenza vaccinations were carried out.[1] While initially in a small number of states in the 1990s, since 2009 all states allow this,[12] indicating strong confidence in pharmacist competence in this area.

After immunisation the healthcare consumer will be given an information sheet for managing adverse events (Appendix 4).

9. Potential for abuse or misuse.

There is no potential for abuse.

Misuse is unlikely. Possibly someone could get two influenza vaccinations in error – e.g. one from their doctor and one from the pharmacy. A vaccination is usually reasonably memorable, so this seems highly unlikely; this problem already exists with workplace immunisations. Pharmacists will notify doctors of the administration of the vaccination (with consent of the healthcare consumer) which minimises this unlikely risk.

10. Further information

Cold Chain

Appropriate storage and handling of the influenza vaccination is important for viability of the vaccination. Pharmacy currently manages the supply of cold chain products and has efficient cold chain Standard Operating Procedures to manage this. The cold chain and potential resulting issues are covered within the assessment of the pharmacist. During assessment cold chain SOP's are reviewed together with contingency plans in the event of a cold chain failure. Fridges are currently monitored within pharmacy and are also subject to the pharmacy Medsafe audit process.

Compliance with standards

Pharmacists will comply with immunisation standards of the Ministry of Health, as described in Appendix 3 of the Immunisation Handbook 2011 (attached to this application as Appendix 3)

Pharmacists will be well-informed by the Pharmacy Guild, the Pharmaceutical Society of NZ, Pharmacybrands and from news articles about a reclassification that will be published in Pharmacy Today, so chances of inadvertent administration by a pharmacist who is not accredited is highly unlikely. However, Healthcare Logistics is able to ensure pharmacies without accredited pharmacists are unable to order stock of the vaccination. IMAC will forward an approval list through to Healthcare Logistics that authorizes them as a supplier of Influenza Vaccines. Due to the computer system Healthcare Logistics has in place they are able to control access to the product.

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