Submission for Reclassification of the Combined Diphtheria-Tetanus-Acellular Pertussis Vaccine for use in Adults

Executive Summary

This application requests a reclassification for the combined diphtheria-tetanus-acellular pertussis vaccination allowing administration to people aged 16 years or over by pharmacists who have successfully completed the Immunisation Advisory Centre or a New Zealand Qualifications Authority approved vaccinator's course, and are complying with the immunisation standards of the Ministry of Health.

The primary intention of this application is to improve vaccination rates of people 16 years or over in close contact with infants, in an internationally recommended practice to cocoon infants,[1-5] preventing transmission of *Bordetella pertussis*, or whooping cough. This requires use of the booster shot containing tetanus, diphtheria and acellular pertussis (Tdap). Tdap in adults is usually unfunded, and public awareness of and access to this vaccination is likely to improve with pharmacist vaccinators, reducing the potential for infants to be infected with pertussis. The role of pharmacist vaccinators administering Tdap for cocooning has been recognised by public health in the US and Canada in recent pertussis outbreaks.[3,4,6,7]

Internationally, certified pharmacists are increasingly administering vaccinations. Pharmacist-administered vaccinations have been occurring in the US since the 1990s, including millions of influenza vaccines,[8] and other vaccines.[9] Pharmacist-administered vaccinations are also occurring in the UK,[10] Ireland,[11] Canada,[12] and Portugal.[10] The increasing use of pharmacists recognises the accessibility and convenience of pharmacy and the advocacy of pharmacists as health professionals to increase consumer awareness and vaccination opportunities. Vaccination rates improve[13,14] and healthcare consumers and pharmacists support this strategy.[11,15] In the US, pharmacist-administered vaccinations have the support of the American College of Physicians and American Society of Internal Medicine,[16] and the Centers of Disease Control and Prevention (CDC).[9]

Changing the classification of Tdap vaccinations will help protect infants from pertussis. Increasing the number of pharmacists administering vaccinations will provide public health benefits for NZ, through greater accessibility (location, opening hours, usually no appointment), increased promotion of vaccinations, increased advocacy, and better coverage in epidemics or pandemics. Pharmacy can collaborate with General Practice to facilitate an increased public awareness in vaccines and reminding patients to get their funded vaccinations on time.

The comprehensive pharmacy process will include 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 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

Important note: We have taken information from IMAC, the Ministry of Health Immunisation Handbook 2011, and CDC in the US in preference to datasheets of products registered on the NZ market owing to the need to follow latest best practice in this field.

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

Diphtheria, Tetanus and Pertussis (Acellular, Component) Vaccine (Adsorbed) (Tdap)

2. Proprietary name(s)

Three vaccinations are combined in a single injection called combined diphtheria-tetanus-acellular pertussis (dTap or Tdap) vaccine. Products on the market for people who have already received the primary vaccinations include Boostrix®, and Adacel®.

Note: The booster vaccination is commonly known as Tdap or dTap (showing full strength of tetanus and low strength diphtheria and acellular pertussis). The primary vaccination is known as DTaP showing all three vaccinations are in high strength.

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

Diphtheria vaccine (also classified as diphtheria toxoid)
Pertussis (whooping cough) vaccine (also classified as pertussis antigen)
Tetanus vaccine (also classified as tetanus toxoid)

Adacel contains (in a single dose):
2.5 mcg pertussis toxoid
5 mcg pertussis filamentous haemagglutinin
5 mcg pertussis fimbriae types 2 and 3
3 mcg pertussis pertactin
≥ 2 IU diphtheria toxoid
≥ 20 IU tetanus toxoid

Boostrix contains (in a single dose):
≥ 2 IU diphtheria toxoid
≥ 20 IU tetanus toxoid
8 mcg pertussis toxoid
8 mcg pertussis filamentous haemagglutinin
2.5 mcg pertussis pertactin

The strengths for Adacel and Boostrix (Tdap) are reduced for diphtheria and pertussis antigens compared to the paediatric diphtheria-tetanus-acellular pertussis formulations used for primary immunisation (DTaP). Given that the strength and content can vary slightly (as seen above), we suggest not specifying the strength, but specifying the age of consumer.

The booster vaccination is commonly known as Tdap or dTap (showing full strength of tetanus and low strength diphtheria and acellular pertussis). The primary vaccination is known as DTaP showing all three are in high strength.

5. Pack size and other qualifications

A single dose contains 0.5mL in a glass vial (Adacel) or in a glass single dose syringe (Boostrix).

The product is for IM injection.

6. Indications for which change is sought

For the prophylaxis against whooping cough, tetanus and diphtheria in people 16 years of age or older.

Please note: we have chosen 16 years or older rather than adult to maximise coverage of household contacts of infants, and noting that parents can be teenagers, and an infant could have a sibling or caregiver aged 16 or over. Children should get a booster at age 11 years from the doctor, which should take them through until around this time.[17] This booster is funded for children below the age of 16 years.

7. Present classification of medicine

Prescription only medicine

8. Classification sought

Exemption to Prescription Medicine when administered to a person aged 16 years or over by a pharmacist who has successfully completed the Immunisation Advisory Centre vaccinator course and is complying with the immunisation standards of the Ministry of Health.

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, pertussis vaccine, and diphtheria and tetanus toxoid have been Schedule II since December 1998, equivalent to NZ's Pharmacist-Only Medicine.[18] This vaccination is administered by trained vaccinator pharmacists,[3] and was recently funded through pharmacists for administration during a pertussis outbreak in British Columbia (Appendix 2).[3,4]

In the USA, vaccinations have been available from pharmacies in some States since the 1990s,[19] extended to all states in 2009. Following completion of the American Pharmacists Association Certification Program, pharmacists are able to administer vaccinations[15] through various practices, mostly a practice which has some similarities with standing orders or the UK's patient group directions. All 50 states now allow influenza vaccination, and 43 States allow pharmacists to administer Tdap.[20] Pharmacist-administered Tdap vaccinations are considered an important mechanism to help get adults in contact with young babies to be immunised against whooping cough. "Drug Store News", an on-line publication for drugstores and pharmacies has around 60 articles mentioning whooping cough. These articles show drugstores and pharmacies increasing stocks and communication about Tdap immunisation in States where pertussis incidence has risen, including Kansas, Washington, Illinois and Milwaukee, helping immunise adults in close contact with infants.[6] See Appendix 1 for a CDC letter to pharmacists and community providers.[9]

In the UK, influenza vaccination by accredited pharmacists in pharmacies under Patient Group Direction (PGD) is common.[21] Other vaccinations are given in some pharmacies, for example travel vaccinations and cervical cancer, but a literature review from 2010 did not specifically identify pertussis or Tdap as vaccinations given or not given in pharmacy in the UK,[10] and a google search using *pertussis*, *pharmacy* and *UK* did not reveal any relevant articles.

Vaccinations in community pharmacies are also available in Portugal[10] and Ireland,[11] although it is unclear if the vaccinations available include Tdap.

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

Sales figures for Tdap are unknown. Given this is used for a funded booster at 11 years, and the NZ birth cohort is around 65,000 but it is used for other booster shots; it is expected that the sales would be over 70,000 units per year.

According to the Medsafe website, Adacel® was first consented for use on 31 May 2007 and Boostrix® on 9 November 2000. Diphtheria vaccine was first available in NZ in 1926, tetanus vaccine in 1940, and pertussis in 1945[5] (but initially was whole-cell; the acellular vaccine is associated with less adverse effects).[5]

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

Labelling would not change for the proposed reclassification. This medicine is not going to be self-administered so consumer labelling is unnecessary.

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 vaccination containing tetanus, diphtheria or pertussis antigens without other prescription medicine ingredients that is registered on the NZ market will be affected by the change suggested in this application. However, given that we are suggesting administration for 16 years or above, the primary vaccinations (DTaP) is not expected to be administered by pharmacists.

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 Tdap vaccination in order to increase uptake by adults in close contact with infants including parents, grandparents, health workers and caregivers, to reduce the risk of whooping cough in infants in their first year of life, the most vulnerable age group for this disease.[5] In whooping cough epidemics, this will increase accessibility and convenience of Tdap vaccination, and increase promotion to the core group outlined above via the pharmacist.

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 pandemics or epidemics), there is a larger workforce already skilled in this area.

Whooping cough is deadly for infants. Before immunisation, whooping cough killed more infants than measles, diphtheria, scarlet fever and poliomyelitis together.[1] A comprehensive paper written about pertussis in NZ by Associate Professor Cameron Grant and Dr Stewart Reid in 2010 is attached (Appendix 3). See also the Immunisation Handbook attached (Appendix 4).

Whooping cough is a common, easily-transmissable illness in adults and adolescents caused by *Bordetella pertussis*. Each primary case can cause 12 to 17 secondary cases (often asymptomatic).[1] Epidemics occur in two to five year cycles, with up to 500 hospitalisations in peak years.[5] Infants under three months have the highest rates of notification and hospitalisation, particularly in the Māori and Pacific Island communities. Young infants are worst affected with 70% of infants under six months old with pertussis hospitalised.[1] Of those hospitalised, around 7% will go into intensive care, of whom around 14% will die or have brain damage.[1] Prolonged apnoea can cause cyanosis, anoxic encephalopathy, seizures and death. The Immunisation Handbook reports a fatality rate in infants of 2 in 1000 in countries such as NZ, but the US reports a 0.77% fatality rate in infants, with 90% younger than 4 months.[2] Five deaths occurred in NZ during 2000-2010.[5] During epidemic years, NZ hospitalisations have reached around 250 (2004) and 500 (2000). Pertussis hospitalisation rates in NZ are considerably higher than the UK, Australia and the US.[5]

The classic infection includes a one to two week catarrhal stage (symptoms similar to the common cold), followed by a four to six week paroxysmal stage (intense coughing that can cause rib fractures in some cases), then a two week to six month or longer convalescent stage during which symptoms gradually resolve.[2] Infection may be asymptomatic, or cause mild to severe symptoms, increasing the chances of spreading the disease.

Benefits of pertussis vaccination

Whooping cough causes:

- Hospitalisations (250-500 in a bad year)[5]
- Deaths – five in 2000-2010 period[5]
- Illness, including secondary infections[5]
- Cost to the taxpayer through the health system costs and reduced productivity

Primary immunisation in infants (dosed at four weeks, three months and five months of age) provides 84% efficacy against whooping cough, with protection delayed until the third dose.[5] Immunisation in adults is expected to have 92% efficacy, with antibodies present five years after immunisation.[5] A difficulty is that infection in adults and adolescents may present without classic symptoms and thus they may be undiagnosed and exposing an infant unknowingly, and vaccination in adults over 19 years is rare.[22] A CDC Epidemic Intelligence Service Officer, Dr Ann Acosta, is reported as considering adult infection may be under-reported by 100-fold.[2] A further problem may have arisen from the change from whole cell to acellular vaccine for pertussis to reduce side effects. This change may have reduced the duration of coverage of the vaccine, and has been speculated to be the cause of the recent outbreak of pertussis in the US.[23]

The 'cocooning strategy' is used to protect infants, given their vulnerability and lack of early protection prior to the third immunisation at five months.[2,5] Potential sources of *B. pertussis* for infants are immunised with Tdap, i.e. those in closest contact, including parents, grandparents (living in the household or caring for the infant), early childhood service workers and healthcare workers.[2,5]

While there is not a lot of evidence for cocooning as yet, it is recommended in NZ by the Ministry of Health,[5] and IMAC,[24] and in the US is encouraged by the American Academy of Paediatrics and the Advisory Committee on Immunization Practices (ACIP).[2] Additionally, it is logical, with up to 83% of infant pertussis infections coming from a household contact.[2] In California, comprehensive cocooning was considered to have reduced deaths from pertussis from 10 (all infants under 3 months) in 2010 to zero in 2011 for the first time since 1991.[2] See Appendix 5 for a further discussion of the evidence around cocooning.[2]

The Ministry of Health also recommends considering pertussis boosters in other vulnerable people, such as those with an underlying respiratory illness.[25]

We anticipate that most vaccinations through pharmacy will be incremental gains, e.g. people who never get around to booking in with their doctor, or who may be unaware of the importance of being vaccinated for the protection of their baby. 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. 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.[26] Awareness of need for vaccination may be low in adults in contact with infants. Pharmacy availability will increase this awareness, particularly during an epidemic.

Current NZ epidemic

There is an outbreak of whooping cough in NZ that started in August 2011, with 3400 cases reported nationwide between then and 8 June 2012.[27] In the year to June 2012, the highest rates have been in the South Island, and 96 hospitalisations had been reported throughout NZ.[28] In May 2012 a midwife from Middlemore Hospital is likely to have contributed to the current Auckland epidemic.[29] The IMAC website includes the following news articles:

- Counties Manukau DHB has free whooping cough booster vaccinations for pregnant women (from 20 weeks) and women up to two weeks post-partum (June and July 2012).
- South Canterbury District Health Board has free whooping cough booster vaccinations for parents and caregivers of infants under six months of age (April 2012).
- Whooping cough vaccinations are free for pregnant women from 30 weeks pregnancy and women up to two weeks post-partum (April 2012).

US physician support of pharmacist-vaccinations

The American College of Physicians and American Society of Internal Medicine stated in 2002: [16]

> *"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

Working with the GP

Pharmacist-led Tdap vaccination will be complementary to general practice, offering another option of administration and promoting the need for vaccination. With patient consent the GP is notified of the vaccination. 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. Trained vaccinator pharmacists will be able to remind parents of the importance of vaccinating children (particularly infants) on time (as delayed vaccinations increases risk of hospitalisation from whooping cough),[5] and the importance of ensuring older siblings are up-to-date with their vaccinations. Trained vaccinator pharmacists will also be able to have a conversation about immunisations with people

purchasing folic acid and ovulation kits pre-pregnancy, pregnancy testing kits, obviously pregnant women, or parents with new babies.

Pharmacist immunisations of Tdap in USA and Canada

In the US, pharmacist-administered vaccinations play an important role in whooping cough epidemics. Washington state has recently had a ten-fold increase in reported whooping cough causing Rite Aid and Walgreens to increase shipments of vaccine to their store to cover adults in contact with infants.[7] The Washington state Department of Health communications director Tim Church said: *"We've been pleased with what's been happening with pharmacies in Washington state, they're promoting the whooping cough vaccine like never before. Pharmacists are among the most trusted health providers out there, so we sure would love to see pharmacists ask people coming through if they're aware there's a whooping cough outbreak. If people hear those things from pharmacists, it'll help get more people vaccinated. Retail pharmacies have a lot of resources we don't have."*

In British Columbia this year Canadian vaccinator pharmacists were used as a key part of the pertussis outbreak strategy, administering funded Tdap immunisations to adults and youth who have not had a booster for more than five years and have contact with young children.[4]

Other 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.[19] 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.[19] 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.[8]

Advocacy by GPs and practice nurses is an important motivator for people to have an influenza vaccination.[30] Pharmacist advocacy, even without vaccination administration, also significantly increases influenza vaccination rate in at-risk populations.[31-34] For example, in Japan pharmacist advocacy significantly increased vaccination rate in people over 65 years from 65% (controls) to 82% (intervention).[31] We anticipate that pharmacist encouragement of immunisation will assist in uptake by adults in close contact with infants, as well as reminding parents to get their children immunised on time.

US studies have shown increased uptake of influenza vaccination and pneumococcal vaccination in states with community pharmacist-vaccination versus states without.[13,14,35] Pharmacist input in hospitals has also improved rates of vaccination. [36,37,38] 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."*[39] 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.[11]

NZ government strategy

Administration of Tdap 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.

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,[40] and preventive care – keeping people out of hospital. 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 Tdap 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. US experience 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, particularly with respect to reducing the pertussis burden on infants.

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

The only pharmacists able to provide Tdap vaccinations will have successfully completed the IMAC or a NZQA approved vaccinator's course and clinical assessment and meeting the requirements in standards set by the Ministry of Health (see Appendix 4). Establishing appropriate persons to vaccinate will be straight-forward for these trained pharmacists. The pre-vaccination checklist and consent form attached (Appendix 6) will be used by the pharmacist, recording each consultation. While created by Pharmacybrands, these materials will available to any pharmacist vaccinator. Those fulfilling referral criteria would be referred to the GP, those answering no to all questions (except for the question on whether they have or are about to have close contact with infants which would require a "yes" answer) will be vaccinated if they consent.

3. Relevant comparative data for like compounds

Two vaccinations have been recommended by the MCC for availability through the pharmacist: Dukoral®, an oral vaccination for prevention of cholera and ETEC travellers' diarrhoea, and influenza vaccination. For the latter vaccination the pharmacist needs to have undergone appropriate training first, and the vaccination should only be provided to adults.

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

The above information on benefits provides local data and considerations for NZ. Tdap is generally unfunded in NZ in adults. For further information, see the Grant and Reid paper attached (Appendix 3), the Immunisation Handbook attached (Appendix 4), and Reid and Wilson's paper (Appendix 7).

Reminder: Please note that throughout this submission and in preparing the checklist and information sheet we have used information from IMAC, Ministry of Health and CDC rather than datasheets. This is because this area evolves quickly and information from these organisations is latest best practice.

5. Interactions with other medicines

Tdap vaccination is not a live vaccine, and therefore does not cause disease in people on immunosuppressants.[5] However, immunosuppression can affect response, and therefore we recommend doctor referral.

Tdap should not be mixed with any other vaccinations. Pharmacists would not be mixing vaccinations.

6. Contraindications

The Immunisation Handbook (p117 and p145) reports that the only contraindication for Tdap vaccination is immediate, severe anaphylactic reaction to any of the vaccination components previously.[5] However, it also states children with an evolving neurological disorder (e.g. uncontrolled epilepsy or deteriorating neurological state) there is confusion about vaccination while clinically unstable. As pharmacists will not be vaccinating children, this does not apply.

CDC states (24 January 2012):[41]

- *"Anyone who has had a life-threatening allergic reaction after a dose of any tetanus, diphtheria, or pertussis containing vaccine should not get Td or Tdap.*
- *Anyone who has a severe allergy to any component of a vaccine should not get that vaccine.*
- *Anyone who had a coma, or long or multiple seizures within 7 days after a dose of DTP or DTaP should not get Tdap, unless a cause other than the vaccine was found. These people may get Td."*

CDC further recommends talking to the doctor if the person to be vaccinated has epilepsy or another nervous system problem, had severe swelling or severe pain after a previous dose of Tdap or other vaccines for tetanus, or diphtheria, or has had Guillain Barré Syndrome (GBS). Thus we will screen for these and recommend doctor vaccination, to be conservative.

Moderate or severe illness on the day of vaccination will be screened for and vaccination postponed. A mild illness or low fever (< 38°C) will not be excluded. This is in line with CDC and IMAC recommendations.

Please see the Immunisation Handbook (Appendix 4) and attached CDC Vaccination Information Sheet (Appendix 9).

Contraindications will be covered in the vaccination checklist (Appendix 6), 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 8), 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 post vaccination.

IMAC recommends immunisation of pregnant women after 20 weeks gestation to maximise benefit for the baby. On advice of Associate Professor Cameron Grant and IMAC, we have included immunisation of pregnant women without first requiring dialogue with the LMC or doctor. Both will be advised with the patient's consent. As the LMC's address is unlikely to be known, information for the LMC will be given to the patient to pass on at next visit.

7. Possible resistance

Not applicable.

8. Adverse events - nature, frequency etc.

Adverse events of Tdap are generally mild and self-limiting, rarely requiring medical attention and include:[42]

- Pain, redness and/or swelling at the site of injection
- Headache (about 3 in 10 adults)
- Mild tiredness (about 1 in 4 adults)
- Nausea, vomiting, diarrhoea, stomach ache (up to 1 in 10 adults)
- Fever (about 1 or 2 in 100 adults)
- Chills, body aches, sore joints, rash, swollen glands
- Extensive swelling of the arm where the shot was given (up to 3 in 100)
- Severe allergy is estimated to occur in less than one in a million vaccinations

After immunisation the healthcare consumer will be given an information sheet for managing adverse events (Appendix 6).

9. Potential for abuse or misuse.

There is no potential for abuse.

Misuse is unlikely. Possibly someone could get two Tdap 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. Given there is no minimum time between tetanus-diphtheria and Tdap,[43] there is probably little risk if this occurred, higher incidence of local reactions being the main concern. If the consumer is unsure he or she can be referred to their GP for vaccination instead. Pharmacists will notify doctors of 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 Tdap vaccination is important for viability of the vaccination, currently 2-8 degrees C. 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. Pharmacists will be familiar with this also from supplying influenza vaccinations as well as from the multitude of current pharmaceuticals that are cold chain managed.

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 4)

IM Injection

Pharmacists currently administering the influenza vaccination may only be administering this by sub-cutaneous injection with Intanza. In contrast, Tdap is administered by IM injection. Loretta Roberts, Training Manager of IMAC, has confirmed that pharmacists have been taught how to do this on the IMAC course, and does not believe any further training is required. If pharmacists have only been signed off in clinical assessment for Intanza (sub-cutaneous) a further clinical assessment would be required for providing IM injections. We would ask the Pharmacy Guild and the Pharmaceutical Society to include information about this requirement in communications about this reclassification, in addition to our communication to Pharmacybrands members. We will also ask Pharmacy Today to include it in their media article about the reclassification.

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.

References

1. Grant CC, Reid S. Pertussis continues to put New Zealand's immunisation strategy to the test. *New Zealand Medical Journal.* 2010;123(1313):46-61.
2. Adamson Fryhofer S. Pertussis and cocooning strategies: the latest from ACIP. *Medscape J Med.* 2012. http://www.medscape.com/viewarticle/759891. Accessed 12 July 2012.
3. Pharmacist and Immunization: Frequently Asked Questions, Fraser Health Pertussis Outbreak 2012. 2012; http://www.health.gov.bc.ca/pharmacare/pdf/fha-faqs.pdf. Accessed 12 July 2012.
4. Medical Health Officer. Pertussis outbreak continues and spreading west in Fraser Health. 2012; http://www.fraserhealth.ca/your_health/mhoupdates/2012/pertussis-outbreak-continues-and-spreading-west-in-fraser-health. Accessed 12 July 2012.
5. Ministry of Health. *Immunisation Handbook 2011*. Wellington: Ministry of Health; 2011.
6. Dearment A. Walgreens boosts pertussis vaccine supply amid Kan. outbreak. *Drug Store News.* 2012. http://drugstorenews.com/article/walgreens-boosts-pertussis-vaccine-supply-amid-kan-outbreak. Accessed 11 July 2012.
7. Dearment A. Pharmacists play role in Wash. pertussis epidemic. *Drug Store News.* 2012. http://drugstorenews.com/article/pharmacists-play-role-wash-pertussis-epidemic-0. Accessed 12 July 2012.
8. Murphy PA, Frazee SG, Cantlin JP, Cohen E, Rosan JR, Harshburger DE. Pharmacy provision of influenza vaccinations in medically underserved communities. *J Am Pharm Assoc.* Jan 1 2012;52(1):67-70.
9. Schuchat A. Letter to Pharmacists and Community Vaccinators Health and Human Services, Public Health Service: Centers for Disease Control and Prevention (CDC) 26 June 2012; 2012.
10. Francis M, Hinchliffe A. Vaccination services through community pharmacy: a literature review. In: Wales PH, ed2010.
11. *Seasonal influenza vaccination programme in pharmacies - evidence base and framework*: The Pharmaceutical Society of Ireland;2011.
12. Marra F, Kaczorowski JA, Marra C. Assessing pharmacists' attitudes regarding delivery of the pandmic influenza vaccine in British Columbia. *CPJ.* 2010;143(6):278-284.
13. Grabenstein JD, Guess HA, Hartzema AG, Koch GG, Konrad TR. Effect of vaccination by community pharmacists among adult prescriptoin recipients. *Medical Care.* 2001;39(4):340-348.
14. Steyer TE, Ragucci KR, Pearson WS, Mainous Iii AG. The role of pharmacists in the delivery of influenza vaccinations. *Vaccine.* 2004;22(8):1001-1006.
15. Bowles S. Learning to reach new levels. *CPJ.* 2007;140(Suppl 2):S4-5.
16. American College of Physicians, American Society of Internal Medicine. Pharmacist scope of practice. *Ann Intern Med.* 2002;136(1):79-85.
17. Reid S. The further and future evolution of the New Zealand Immunisation Schedule. *New Zealand Medical Journal.* 2012;125(1354):86-99.
18. Search National Drug Schedule. http://napra.ca/pages/Schedules/Search.aspx. Accessed 11 July 2012.
19. Place of influenza vaccination among adults - United States, 2010-11 influenza season. *Morbidity and Mortality Weekly Report.* 2011;60(23):781-785. http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6023a3.htm?s_cid=mm6023a3_w. Accessed 26 January 2012.
20. Pharmacist Administered Vaccines: Types of vaccines authorized to administer. 2012; http://www.pharmacist.com/AM/Template.cfm?Section=Pharmacist_Immunization_Center1&ContentID=26931&Template=/CM/ContentDisplay.cfm. Accessed 11 July 2012.

21. Flu vaccinations: top tips to boost your service this season. *Chemist and Druggist.* 2010. http://www.chemistanddruggist.co.uk/feature-content/-/article_display_list/4394854/4394850. Accessed 26 January 2012.

22. Basco WT. Protecting infants from pertussis: are we making progress? *Medscape J Med.* 2012. http://www.medscape.com/viewarticle/764349. Accessed 12 July 2012.

23. Fox M. CDC: Whooping cough epidemic worst in 50 years. 2012; http://vitals.nbcnews.com/_news/2012/07/19/12835335-cdc-whooping-cough-epidemic-worst-in-50-years?lite&__utma=238145375.828847914.1342757222.1342757222.1342757222.1&__utmb=238145375.1.10.1342757222&__utmc=238145375&__utmx=-&__utmz=238145375.1342757222.1.1.utmcsr=(direct)|utmccn=(direct)|utmcmd=(none)&__utmv=238145375.|8=Earned%20By=msnbc%7Chealth=1^12=Landing%20Content=External=1^13=Landing%20Hostname=www.msnbc.msn.com=1^30=Visit%20Type%20to%20Content=Earned%20to%20External=1&__utmk=30622332. Accessed 20 July 2012.

24. Quick answers to frequent Tdap questions: Factsheet for vaccinators. 2012; http://www.immune.org.nz/sites/default/files/factsheets/AdministrationTdapQA20120523V03Final.pdf. Accessed 13 July 2012.

25. Hunt D. Current advice on the public health management of pertussis [letter]. 2012; http://www.immune.org.nz/sites/default/files/MoH%2C%20Pertussis%20guidelines%2020120405.pdf. Accessed 12 July 2012.

26. Influenza Specialist Group. *Influenza and influenza vaccination - myths & misconceptions among at-risk Australians 18-64 years of age*2008.

27. Crispe I. Vaccines crucial in whooping cough epidemic. 2012; http://www.3news.co.nz/Vaccines-crucial-in-whooping-cough-epidemic/tabid/423/articleID/257162/Default.aspx.

28. Whooping cough epidemic rapidly escalating. 2012; http://www.nzherald.co.nz/nz/news/article.cfm?c_id=1&objectid=10811494. Accessed 22 July 2012.

29. Maas A. Whooping cough numbers continue to rise. 2012; http://www.stuff.co.nz/auckland/local-news/6934552/Whooping-cough-numbers-continue-to-rise. Accessed 12 July 2012.

30. Jennings LC. Influenza vaccination among New Zealand healthcare workers: low rates are concerning. *New Zealand Medical Journal.* 2006;119(1233).

31. Usami T, Hashiguchi M, Kouhara T, Ishii A, Nagata T, Mochizuki M. Impact of community pharmacists advocating immunization on influenza vaccination rates among the elderly. *Yakugaku Zasshi.* Sep 2009;129(9):1063-1068.

32. Fera T, Bluml BM, Ellis WM. Diabetes ten city challenge: final economic and clinical results. *Journal of the American Pharmaceutical Association.* 2009;49:383-391.

33. Grabenstein JD, Harzema AG, Guess HA, Johnston WP. Community pharmacists as immunization advocates: a clinical pharmacoepidemiologic experiment. *International Journal of Pharmacy Practice.* 1993;1993(2):5-10.

34. Grabenstein JD. Pharmacists as vaccine advocates: roles in community pharmacies, nursing homes, and hospitals. *Vaccine.* Nov 1998;16(18):1705-1710.

35. Taitel M, Cohen E, Duncan I, Pegus C. Pharmacists as providers: Targeting pneumococcal vaccinations to high risk populations. *Vaccine.* 2011;29(45):8073-8076.

36. Loughlin SM, Mortazavi A, Garey KW, Rice GK, Birtcher KK. Pharmacist-managed vaccination program increased influenza vaccination rates in cardiovascular patients enrolled in a secondary prevention lipid clinic. *Pharmacotherapy.* May 2007;27(5):729-733.

37. Sokos DR, Skledar SJ, Ervin KA, et al. Designing and implementing a hospital-based vaccine standing orders program. *American Journal of Health-System Pharmacy.* May 15 2007;64(10):1096-1102.

38. Rees S, Stevens L, Drayton J, Engledow N, Sanders J. Improving inpatient pneumococcal and influenza vaccination rates. *J Nurs Care Qual.* Oct-Dec 2011;26(4):358-363.

39. City and Hackey PCT. Annual report and accounts 2008-09. 2009; http://www.cityandhackney.nhs.uk/pdf/Version%207%20Final_Outline%20annual%20report%2008-09%20-%20v10%20on%2011%20June%2009%20FINAL.pdf. Accessed 31 January 2012.

40. Health Workforce New Zealand: Annual Review 2010/11. In: Health Workforce New Zealand, ed. Wellington: Ministry of Health; 2011.

41. Vaccine Information Statement: Td or Tdap (Tetanus-Diphtheria or Tetanus-Diphtheria-Pertussis) Vaccine: What you need to know. 2012; http://www.cdc.gov/vaccines/pubs/vis/downloads/vis-td-tdap.pdf. Accessed 13 July 2012.

42. Possible Side-effects from Vaccines: Td and Tdap. 2012; http://www.cdc.gov/vaccines/vac-gen/side-effects.htm#td. Accessed 20 July 2012.

43. Spacing of Tdap after a Td vaccine: factsheet for health professionals. Auckland: Immunisation Advisory Centre (IMAC); 2012.