

Reclassification of Medicines

**Submission to Medicines Classification Committee,
New Zealand Medicines and Medical Devices Safety
Authority (MEDSAFE)**

Contact

ANGELA CLARK, PROFESSIONAL NURSING ADVISOR

0800 283 848 | WWW.NZNO.ORG.NZ

NEW ZEALAND NURSES ORGANISATION | PO BOX 2128 | WELLINGTON 6140

About the New Zealand Nurses Organisation

The New Zealand Nurses Organisation is the leading professional and industrial organisation for nurses in Aotearoa New Zealand, representing over 46,000 nurses, midwives, students, kaimahi hauora and health workers on a range of employment-related and professional issues. Te Runanga o Aotearoa comprises our Māori membership and is the arm through which our Te Tiriti o Waitangi partnership is articulated.

NZNO provides leadership, research and support for professional excellence in nursing, negotiates collective employment agreements on behalf of its members and collaborates with government and other agencies throughout the health sector. Nurses are the largest group of health professionals comprising half the health workforce.

The NZNO vision is "Freed to care, Proud to nurse". Our members enhance the health and wellbeing of all people of Aotearoa New Zealand and are united in their professional and industrial aspirations to achieve a safe, sustainable and accessible system of public health care for all New Zealanders.

EXECUTIVE SUMMARY

1. The New Zealand Nurses Organisation (NZNO) welcomes the opportunity to comment on reclassification of the following medicines at its 49th meeting, 30th April 2013.
 - Diphtheria, tetanus and pertussis (acellular component) vaccine: Agenda item 5.3
 - Meningococcal vaccine: Agenda item 6.1Each vaccine will be responded to separately within the discussion of this submission.
2. NZNO has consulted its members and staff in the preparation of this submission, in particular, Industrial, Policy, and members of our specialist College, NZ College of Primary Health Care Nurses.
3. NZNO supports the reclassification of these medicines.
4. However, NZNO **recommends** that the reclassification of both of the above vaccines includes **ALL AUTHORISED VACCINATORS**
5. NZNO **recommends** the committee reclassify diphtheria, tetanus and pertussis (acellular, component) vaccine (Tdap), in a single dose from prescription medicine to prescription medicine except when administered to a person aged over 18 years or over by **an authorised vaccinator** who has successfully completed a vaccinator training course approved by the Ministry of Health and is complying with the immunisation standards of the Ministry of Health.

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6. NZNO **notes** that the agenda of the forty-ninth medicines classification committee states that the additional data, to reconsider this application, has been received. This data has not been attached to the agenda and as such NZNO is not able to give a full opinion on supporting the original application.
7. NZNO **recommends** the committee reclassify meningococcal vaccine from prescription medicine to prescription medicine except when administered to a person aged over 18 years or over by **an authorised vaccinator** who has successfully completed a vaccinator training course approved by the Ministry of Health and is complying with the immunisation standards of the Ministry of Health.

Diphtheria, Tetanus and Pertussis (acellular component) vaccine (Tdap)

8. The Application for Reclassification of Tdap Vaccination July 2012, by Pharmacybrands Limited, presented to the agenda of the 48th meeting has been reviewed by NZNO and we agree with the rationale for reclassification
 - 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
 - Community pharmacies are accessible to most of the population, healthy and unwell, and all ages.
 - Trained pharmacists provides the community with another health professional group actively involved in immunisation and advocating for its use in both funded (schedule vaccines provided by a medical practitioner or authorised vaccinator) and unfunded groups.
9. NZNO acknowledges and approves the recent reclassification of influenza vaccine from a prescription medicine to an adult in a pharmacy by a registered pharmacist who has successfully completed an Authorised Vaccinator Training Course and is complying with the immunisation standards of the Ministry of Health.
10. In approving this recent reclassification, NZNO understands that the Medicines Classification Committee has already given consideration to the safety of administering a vaccine within a pharmacy, the management of adverse events, the training of administering medication by injection, the environment around administration and cold chain management

11. NZNO **does** support the following aspects of the discussion of reclassification of Tdap that occurred at the 48th meeting.

- A proposal to lift the age to 18 in line with the reclassification for influenza.
- Community pharmacists providing influenza vaccination have shown they work closely with general practice informing them of vaccinations delivered and any other health concerns.
- The notification to the general practice of administering Tdap is essential.
- Community pharmacists will remind and refer consumers to receive their primary funded vaccination from their well child provider.
- Pharmacists will receive the same training requirements as all other authorised vaccinators.
- Community pharmacists are a convenience place for vaccination.
- Community pharmacists have an important role in managing the current pertussis outbreak.

12. NZNO **agrees** with the medicines classification committee decision that further information was required because the application by Pharmacybrands Limited, July 2012;

- Did not provide adequate information about the amount of training a pharmacist would receive in giving intramuscular injection as other authorised vaccinators (nurses) have this within their undergraduate nursing training.
- Further consideration needed to be given to who would receive booster doses of Tdap and how would pharmacists identify them.
- The ability to access the National Immunisation Register needed further investigation.
- Because Tdap is not funded and this not within the National Immunisation Register there is not the current ability to accurately record in a central repository the immunisations received to maintain protection of an illness already initiated in a primary course. This is also an issue for all other vaccinators. Accessing this information from the general practice is not always accurate as adults also receive opportune vaccines from other places – particularly in relation to treatments of wounds and opportune tetanus. We agree that further information on the management of the booster dose is required.

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- The change in the wording from “...who has successfully completed the Immunisation Advisory Centre course and is complying with the Immunisation Standards of the Ministry of Health” to “a vaccinator training course approved by the Ministry of Health...” This facilitates the intent of the Immunisation Standards and 2011 Protocol for authorisation of vaccinators in NZ (MOH. 2011, Appendix 4.)
 - The submission focussed on pertussis and did not provide adequate data on tetanus and diphtheria and supports the request for data on this along with detailed information on patient selection and information on how to find out if a patient had received the primary vaccination.
13. NZNO **strongly** urges the Medicines Classification Committee to communicate to the Ministry of Health that the dissolution of the National Immunisation Register to Primary Health Organisations (PHO's) will have a significant impact on the way in which authorised vaccinators will record immunisation data for adults 18 and over, who over a lifetime, will change their residence several times and will move in and out of PHO's.
 14. NZNO **notes** that the agenda of the forty-ninth medicines classification committee states that the additional data has been received. This data has not been attached to the agenda and as such NZNO is not able to give a full opinion on supporting the original application.
 15. NZNO **recommends** Dtap be reclassified to include prescription except when administered by **All Authorised Vaccinators**, including registered nurses who are authorised. Nurses are already supplying and administering medicines under a Standing Order or prescribing by proxy (the nurse assesses the patient and determines the medicine to be prescribed but the doctor signs the prescription. as a result of consumers need for more time and convenient access to medicines, a desire to better use nurses skills' and knowledge, and because of doctor shortages (particularly in remote areas) and workload. (NCNZ, 2013)
 16. Nurses report that much time is wasted in both nursing staff and patients' time in waiting for a prescription to become available prior to then going ahead and administering this vaccine.
 17. Nurses' access to administer Tdap, without a Standing Oder or prescription, creates a greater efficiency to a current practice and improves access for those patients where Standing Orders or access to a prescription is not available.
 18. The future aging population of NZ will create both a demand for adult booster doses of Tdap and further demand on existing health

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professionals. It is imperative that reclassification of Tdap provides improved access for both the consumers and health professionals and there is not a piecemeal approach to reclassification and access to this vaccine.

Meningococcal vaccine

19. NZNO **supports** the intent of the application to reduce the incidence, morbidity and mortality from meningococcal invasive disease, primarily in at-risk adolescents. Effectively, reducing risk of hospitalisation, permanent disability or death from the disease.
20. NZNO believes that the ability of **ALL Authorised Vaccinators** to provide Meningococcal Vaccine to people aged over 16 years is critical in improving access to the vulnerable population whom this is intended.
21. Many Authorised Vaccinators (registered nurses) currently practice in environments where this population **already resides** or accesses health care currently – general practices, school health clinics (prior to entering 1st year youth hostel accommodation), tertiary student health centres, youth health centres, tertiary study halls of residence, youth justice, sexual health clinics, family planning clinics, defence force establishments.
22. Reclassifying this vaccine to prescription only except when administered by a pharmacist vaccinator ignores the current relationship that youth have with both existing authorised vaccinators and health providers.
23. Mathias,K. (2002) reported high levels of utilisation of current youth-specific primary care services
24. Comprehensive literature reviews of school based health services evidences their effectiveness through the youth focus, engagement with the local education environment and community, youth participation in planning and service delivery, high quality comprehensive health care with multidisciplinary providers, and effective administrative and clinical systems to support service delivery. (Winnard.D,et.al 2005)
25. The philosophy, structure and functioning of tertiary education health centres, halls of residence and youth health centres can be likened to the effective school health services. They are open for most of the time that students are at school / on the campus, have been shown to increase access to health care, and more likely to offer youth friendly care than health services not specifically for youth (Fleming & Elvidge, 2010)

26. Consideration needs to be given to young people who do not live in hostel type accommodation but their risk of meningococcal illness is high due to their home living environments. Denny et. al (2013) report the reasons youth do not access health care when needed. Therefore, utilisation of current providers in the community is essential. Examples include public health nurses visiting the home, a primary health care nurse within a WINZ centre or general practice, an immunisation outreach nurse or faith community nurse within a church/parish setting alongside other health promotion activities. Many of these nurses are **already** authorised vaccinators working alongside this vulnerable population.
27. NZNO **recommends** the committee reclassify meningococcal vaccine from prescription medicine to prescription medicine except when administered to a person aged over 18 years or over by **an authorised vaccinator** who has successfully completed a vaccinator training course approved by the Ministry of Health and is complying with the immunisation standards of the Ministry of Health.
28. NZNO **supports** the application that pharmacists (and applicability to ALL Authorised Vaccinators) would be administering conjugate vaccinations, either Group C alone, or the quadrivalent vaccine.
29. NZNO **strongly** urges the Medicines Classification Committee to communicate to the Ministry of Health that the dissolution of the National Immunisation Register to Primary Health Organisations (PHO's) will have a significant impact on the way in which authorised vaccinators will record immunisation data for youth and young adults youth whose residence and regular health provider change frequently and are less likely to be enrolled with a PHO.

CONCLUSION

30. The aging population creates further demand for vaccinations.
31. An aging workforce creates a need to reorient health services across health providers to meet the workload demand and improved access and choice for consumers.
32. Nurses are already providing these vaccines by Standing Order or prescribing by proxy draining the health system of nurses' time to provide services and wasting consumers' time in unnecessary delays.
33. Nurses, who are authorised prescribers, are already in communities and residences where these targeted populations are and limiting a reclassification of these medicines to only pharmacists who are authorised vaccinators is limiting patient's access and choice in health providers.

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34. However, NZNO **recommends** that the reclassification of both of the above vaccines includes **ALL AUTHORISED VACCINATORS**

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