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ANMF (Vic Branch) Submission to the Victorian Pharmacist Administered Vaccination Program Expansion Consultation Paper November 2019

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1 Introduction

The Australian Nursing and Midwifery Federation (Victorian Branch) (ANMF) was established in 1924. The ANMF (Vic Branch) is the largest industrial and professional organisation in Australia for nurses and midwives, with Branches in each state and territory of Australia.

The ANMF (Vic Branch) represents more than 87,000 nurses, midwives and personal care workers (the latter predominantly in the private residential aged care sector). Our members are employed in a wide range of enterprises in urban, rural and community care locations and the public and private health and aged care sectors. Relevantly, ANMF (Vic Branch) represents registered nurses and midwives who have Secretary Approval as a Nurse Immuniser and/ or who are involved in the administration of vaccinations to the Victorian community.

The core business for the ANMF (Vic Branch) is the representation of the professional and industrial interests of our members and the professions of nursing and midwifery.

The ANMF (Vic Branch) participates in the development of policy relating to nursing and midwifery practice, professionalism, regulation, education, training, workforce, and socio-economic welfare, health and aged care, community services, veterans' affairs, occupational health and safety, industrial relations, social justice, human rights, immigration, foreign affairs and law reform.

The ANMF (Vic Branch) is delighted to make submission to *Victorian Pharmacist Administered Vaccination Program Expansion Consultation Paper November 2019.* Our submission is directly aligned with questions contained within the Consultation Response Template.

2 Executive Summary

ANMF (Vic Branch) welcomes the opportunity to provide feedback regarding the *Victorian Pharmacist Administered Vaccination Program Expansion Consultation Paper November 2019* (the Expansion Consultation Paper). In doing so, we have given due regard to the *Evaluation of the Victorian Pharmacist Administered Vaccination* [the Final Evaluation Report] prepared by HealthConsult for the Department of Health and Human Services (HealthConsult, March 2018) and the extensive feedback we have received on this matter from Nurse Immunisers within the Immunisation Nurses Special Interest Group (ANMF Vic Branch).

We note that whilst identifying the potential to increase the types of vaccines that could be administered by a pharmacist or to increase the age profile, the Final Evaluation Report recommended against expansion of the Program at that point. The Final Evaluation Report identified a range of issues within the existing Pharmacist Administered Vaccination Program and concluded that:

> *Until these issues are addressed, an increase in the program scope is not recommended and would likely compound these issues* (page 9, HealthConsult, 2018).

In the absence of any formal subsequent Evaluation which might otherwise give confidence that the significant issues identified in the Final Evaluation Report have been resolved, ANMF (Vic Branch) has significant apprehension regarding the further proposed expansion.

Additionally, we note the findings (including the benefits and shortfalls of the existing scheme) within the Final Evaluation Report are consistent with the written feedback provided to ANMF (Vic Branch) via a recent survey of over 400 members of the Immunisation Nurses Special Interest Group (INSIG) ANMF (Vic Branch) [the ANMF 2019 Consultation Survey]. This written feedback is incorporated into this submission and aligned with the Consultation Response Template together with written feedback previously provided to ANMF (Vic Branch) via the 2018 survey of Immunisation Nurses Special Interest Group (INSIG) ANMF (Vic Branch) [the ANMF 2018 Consultation Survey.

ANMF (Vic Branch) is a committed supporter of implementing all safe and reasonable measures to promote and increase the vaccination rates within the Victorian Community. At the same time, we believe it is critical that the issues identified within the Final Evaluation Report and those outlined below, be addressed prior to any further expansion.

3 Do you support pharmacist immunisers in Victoria being able to administer the influenza vaccine to people aged 10-15 (Proposal 1 - announced by Minister Mikakos on 10 October 2019)?

No

If no, please provide an explanation of your reasons for this.

As detailed above, in the absence of any formal subsequent Evaluation which might otherwise give confidence that the significant issues identified in the Final Evaluation Report have been resolved, ANMF (Vic Branch) has significant apprehension regarding the further proposed expansion. We are concerned that a further expansion in this context runs the unacceptable risk of compounding the significant issues identified in the Final Evaluation Report including for example:

a) Inadequate/suboptimal collaboration between the pharmacist and general practitioner
b) Unacceptable time pressures in administering vaccinations

c) Significant deficiencies in entering data on the Australian Immunisation Register (AIR)
d) Inadequate facilities and infrastructure to otherwise facilitate high quality client consultation, comprehensive client assessment, vaccine administration and monitoring in an environment which affords privacy and client comfort in each of the stages outlined above

Additionally, we are concerned that Section 3.1 of the *Victorian Pharmacist Administered Vaccination Program Expansion Consultation Paper November 2019* introduces new risks through a failure to articulate what systems would be in place to manage potential adverse events (including a vasovagal episode) arising from the administration of the influenza vaccine to this young cohort and does not adequately address matters relating to obtaining consent or making assessments in regards to whether the child is a 'mature minor'.

Specifically, we note that *Victorian Pharmacist Administered Vaccination Program Expansion Consultation Paper November 2019* does not clearly stipulate whether:

1) The child receiving the influenza vaccine must be accompanied by a parent and/ or guardian; and /or,
2) The child receiving the influenza vaccine must have the consent of his or her parent and or guardian before receiving the vaccination; or
3) The child receiving the influenza vaccine can be administered the influenza vaccine based on being assessed as a 'mature minor' and without being accompanied a parent and /or guardian.

Given the Expansion Consultation Paper identifies that the *most common immediate, or soon after vaccination, adverse event in older children is a vasovagal episode (fainting)* (page 3), robust systems must be in place to reduce clinical risk associated with such episodes, including in particular the requirement that the child receiving the influenza vaccine be accompanied by a parent and/ or guardian – and that facilities and infrastructure are adequate and provide for the safe care and monitoring of a child who has experienced a vasovagal episode.

Furthermore, as detailed in the *ANMF (Vic Branch) Submission to the Victorian Pharmacist Administered Vaccination Program Expansion Consultation Paper August 2018*, expansion of the Pharmacist Administered Vaccination program to clients under 18 years of age introduces complexities regarding obtaining informed consent and raises concerns regarding the capacity of the Pharmacist to adequately assess whether or not the client is a 'mature minor'.

The Department of Education and Training (DET) describes in regards to assessing whether or not an adolescent is a mature minor that:

> *Mature minors are young people under the age of 18 years who are deemed capable by a GP of seeking and obtaining health care for their particular issue. To give informed consent, a young person must be able to understand what treatment involves, what it is for, why it is needed and why it applies to them as an individual. The young person must also appreciate the risks associated with the treatment and be aware of the other options available, as well as the consequences of not pursuing treatment*

(DET 18/5/2017 https://www.education.vic.gov.au/Documents/about/programs/health/Consent%20and%20confidentiailty%20School%20information%20sheet%20Revised%20May%202017.pdf last accessed 6.12.12)

Deficiencies identified in the Final Evaluation Report do not auger well for further expansion including unresolved concerns that there is inadequate time for the pharmacist to make a comprehensive assessment of the young person's immunisation history and health record, to assess whether or not the young person is a mature minor and to ensure facilities and resources are adequate to provide optimal care and monitoring of a young child who has experienced an adverse event from the Influenza vaccine.

The feedback below from participants of the ANMF 2019 Consultation Survey elaborates on these concerns.

> *The proposal requires additional safeguards:*
>
> *Competency assessment of the pharmacist's ability to vaccinate children. There has been an increase in reports of shoulder injury related to vaccine administration. These injuries can result in long term disability. While all pharmacist courses have been assessed to meet a minimum standard, it is incorrect to say that all courses offer similar training. For example, five courses aimed at registered nurses require a competency assessment and vary in hours from 130-170, 3 have compulsory study days. In addition, the course without a clinical placement requires 70-150 hours of study. These courses recommend students seek clinical supervision if they do not have competency in giving vaccinations. In contrast, the pharmacist course consists of a six-hour online study package and a one-day workshop. Injection practice is performed on simulators, pharmacists are free to vaccinate live people with no further supervision in the field. I think the general public would be shocked at this and would expect that any one performing a procedure that has the potential to injure would have had supervised practice on a patient*
>
> *Child to be accompanied by a parent to age 15. Faint and near faint are a frequent occurrence in young people and recovery time can be prolonged, parents should be in attendance to age 15 not only to provide consent but also to provide supervision and care post vaccination. Fainting can occur up to 30 mins post vaccine when the child would have left the pharmacy*
>
> *All vaccines to be reported to AIR, this is noted on the pharmacy guild to be a mandated requirement in some states. The reporting of vaccination simply is not happening. Effective immunisation programs rely on more than just giving vaccines. Records help to inform public health management and research of vaccine-preventable diseases, monitoring of vaccination coverage is essential to help to identify at risk populations and to help measure vaccine effectiveness (Participant 6, 2019)*
>
> *Expansion of the program will compound the problems with under reporting. A well child who attends for a preventive vaccine could be disabled by incorrect vaccine technique. Unaccompanied children could be injured from a fall due to fainting. Fractured skull related to fainting after vaccination has been recorded in the literature (Braun, Patriarca & Ellenberg, 1997) (Participant 6, 2019)*
>
> *(Pharmacists) Need to have adequate training. Need to carry out pre immunisation assessment and ensure wait 15 mins after immunisation. Need to have adrenaline on site and be able to administer. need to be able to perform CPR and have emergency trolley available. A pharmacy is not a health professional office with designated areas for privacy - it is a business selling products (participant 15, 2019)*

I fully support opportunistic vaccination for all ages however will the pharmacists have the time to monitor the client post vaccination for 15 minutes without them wandering around or leaving the pharmacy. Pharmacies tend to be quite busy and the spaces they use can be quite small (Participant 19, 2019)

Additionally, in regard to matters relating to reliable entry of data onto the AIR, ANMF (Vic Branch) notes an apparent disconnect between the data distributed by the Pharmacy Guild and information kindly provided separately to ANMF (Vic Branch) from of the Department of Health and Human Services. For example, ANMF (Vic Branch) notes that the Pharmacy Guild has identified that

Over 13 million Australians have been vaccinated against the flu this year, with over 2 million having received their vaccination from a community pharmacy (Media Release Pharmacy Guild, 10 October 2019 https://www.guild.org.au/news-events/news/2019/victorian-pharmacists-able-to-protect-more-people-against-the-flu

This does not align with subsequent information provided by to ANMF (Vic Branch) by representatives of the Department of Health and Human Services who on 6 December 2019 advised, *that more than 200,000 Australians received their flu vaccination from a pharmacy between April 2018 and August 2018.*

Furthermore, the data contained within Appendix 1 of the *Victorian Pharmacist Administered Vaccination Program Expansion Consultation Paper November 2019* does not provide clarity in regard to how many vaccines were administered in a community pharmacy versus how many were recorded on the AIR.

In the context of the concerns raised within the Final Evaluation Report – and to identify measures to reduce risk and improve quality and safety - it is important that reliable data be collected to measure how many vaccinations are administered in a community pharmacy versus how many are recorded on the AIR. It is implausible that 82,500 vaccinations were administered in a community pharmacy and that 100% of these were recorded in the AIR, yet this is implied within the data provided within Appendix 1 of the *Victorian Pharmacist Administered Vaccination Program Expansion Consultation Paper November 2019.*

4) Are there any unintended consequences of allowing pharmacist immunisers in Victoria to administer the influenza vaccine to people aged 10-15 (Proposal 1 - announced by Minister Mikakos on 10 October 2019)?

Yes

If yes, please state what you consider these potential unintended consequences might be.

In addition to the clinical risks outlined above in regards to managing a child who has experienced a vasovagal episode and the potential increase in the incidence of in Shoulder Injury Related to Vaccine Administration (SIRVA), accessing vaccination in this way may serve as a disincentive for a child and /or adolescent to visit a general practitioner where they might otherwise receive opportunistic assessment of their overall health and wellbeing including health promotion, early identification of health issues or disease and referral. This is particularly important in the context of emerging health issues for adolescents and the potentially missed opportunity to undertake health assessments, interventions and /or education regarding sexual health and mental health.

5) Do you support pharmacist immunisers in Victoria being able to administer the meningococcal ACWY vaccine to persons aged 15 years and older (Proposal 2)?

No

If no, please provide an explanation of your reasons for this.

Expansion of the program in this way would require close collaboration with the client's general practitioner, timely and reliable access to the AIR and adequate time, expertise and physical environment to undertake a comprehensive assessment of a client's vaccination history, health records.

In the absence of any formal subsequent Evaluation which would otherwise give confidence that the significant issues identified in the Final Evaluation Report have been resolved, ANMF (Vic Branch) is apprehensive regarding this further proposed expansion.

6) Are there any unintended consequences of allowing pharmacist immunisers in Victoria to administer the meningococcal ACWY vaccine to persons aged 15 years and older (Proposal 2)?

Yes, in addition to the clinical risks outlined above in regards to managing a child who has experienced a vasovagal episode, the potential increase in the incidence of in SIRVA, and the potentially missed opportunity for a general practitioner to undertake health assessments, interventions and /or education regarding sexual health and mental health, allowing pharmacist immunisers in Victoria to administer the meningococcal ACWY vaccine to persons aged 15 years unavoidably draws attention away from improving access to those identified at being at risk and eligible for Government funded vaccines, to those who are considered to be at low risk and not eligible for Government funded vaccines. This creates perverse incentives to target those at lowest risk and militates against implementing measures to improve access to vaccinations for those at higher risk.

7) Do you support pharmacist immunisers in Victoria being able to administer the measles-mumps-rubella and pertussis-containing (whooping cough) vaccines to persons aged 15 years and older (Proposal 3)?

Not at this point

The administration of live vaccines requires assessing vaccination history and preparing a catch-up schedule. This is a complex activity requiring time, expertise and access to reliable information and data regarding a client's vaccination history. As identified in the ANMF (Vic Branch) Victorian Pharmacist Administered Vaccination Program Expansion Consultation Paper August 2018:

> *Any person requiring an MMR vaccine … should have their entire immunisation history examined by a very experienced immuniser who is familiar with the skills required to create an immunisation catch up plan. These clients are usually immigrants/refugees with complex overseas immunisation histories. It takes a highly skilled and experienced practitioner to analyse these histories and work out what the client needs. MMR is only one of the vaccines they may require. Will pharmacists be exposed to the regular networking and education required to maintain the skills necessary for creating immunisation plans MMR is a live vaccine and therefore has many more contraindications.* (Participant 31, 2018)

Knowledge of the patient's vaccine history - how will this be determined? This includes factors such as whether the patient has had a live vaccine in the previous month and any previous adverse reactions to vaccines. (Participant 17, 2018)

Additionally, it is important to and assess whether contraindications exist for the administration of a live vaccine. This management of the MMR live vaccine requires additional precaution thorough assessment and follow up:

Most people in the cohort they wish to vaccinate are already immune. If a person does require MMR vaccine, they will probably require additional vaccines that the pharmacists cannot give. If they also require a varicella vaccine or other live vaccine this must be given on the same day as MMR or one month later necessitating a visit to another vaccine provider. Do pharmacists have the current IT infrastructure to upload vaccines onto AIR? If a person requires catch up due to No Jab No pay can this be uploaded in a timely manner in order for client to have payments reinstated. Can pharmacists tick the box on AIR to state that person is on a catch up even though they cannot deliver all of the catch-up vaccines? Other vaccine providers (GP's and Council run vaccine clinics) are already able to attend to catch up vaccines and provide catch up plans. Live vaccines must be given under specific guidelines and clients e.g. must be counselled not to become pregnant following vaccine for 4 weeks after vaccine. (Participant 4, 2018)

Do they know rules about spacing of live vaccines? Do they know to ask about planned pregnancy and that no pregnancy can be planned for a month? Do they know disease contraindications for live vaccines Anaphylactic training? (Participant 7, 2018)

Being that MMR is a live vaccine, will the pharmacists be able to medically assess whether there are contraindications to that person safely receiving the vaccine? Also, my extensive experience of adolescents and adults who require "catch-up" vaccinations has shown that anyone requiring MMR often has other vaccines that are required to be given. Will there then be a situation where the client is missing out on other vaccines that would have been given had the client visited a G.P or nurse- immuniser? (Participant 28, 2018)

If MMR is mistakenly given within 4 weeks of another live vaccine, it may alter the effectiveness of the immunisations. If MMR is mistakenly given during pregnancy or within 4 weeks of pregnancy it may cause problems to the unborn child/pregnancy. MMR is a live vaccine, so there are more contraindications e.g. cannot be given to immunocompromised clients or within 3 months of blood transfusion. Will pharmacists spend time on collating the patient's history? Clients will miss out on other important vaccinations. (Participant 31, 2018).

In the absence of any formal subsequent Evaluation there is not confidence that clinical risks associated with inadequate skill, knowledge or capacity to comprehensively assess a client's vaccination history and to develop a catch-up schedule have been addressed. In this context, ANMF (Vic Branch) is apprehensive regarding this further proposed expansion.

8) Are there any unintended consequences of allowing pharmacist immunisers in Victoria to administer the measles-mumps-rubella and pertussis-containing (whooping cough) vaccines to persons aged 15 years and older (Proposal 3)?

Yes

If yes, please state what you consider these potential unintended consequences might be.

Yes, in addition to the clinical risks outlined above in regards to managing a child who has experienced a vasovagal episode, the potential increase in the incidence of in SIRVA, and the potentially missed opportunity for a general practitioner to undertake health assessments, interventions and /or education regarding sexual health and mental health, where comprehensive assessments are not made in regard to immunisation history, delays can occur in administering additional vaccinations which in turn result in delayed immunity.

9) Do you support a variation to the restrictions on where pharmacists can administer vaccinations in Victoria (Proposal 4)?

ANMF (Vic Branch) recognises the public health benefit of expanding the relevant settings to aged care facilities however consider the other expanded settings will either:

a) result in duplication of service (medical centre or GP practice and workplaces)
b) result in clinical risk (in people's homes)
c) gives tacit acknowledgement that facilities and infrastructure are not always adequate to otherwise facilitate high quality client consultation, comprehensive client assessment, vaccine administration and monitoring in an environment which affords privacy and client comfort
d) are not aligned to the identified focus of the expansion such as to cohorts identified within the *Victorian Pharmacist Administered Vaccination Program Expansion Consultation Paper November 2019* including for example improving access to vaccinations for:
    I. members of the community experiencing vulnerability
    II. Aboriginal and Torres Strait Islander People
    III. Children and adolescents.

In addition, vulnerable citizens such as refugees and Aboriginal and Torres Strait Islander People often have other requirements (for example, assessment of Hepatitis B status prior to vaccination and as assessment of any clinical indication for administration of the Pneumococcal vaccine) which require a health practitioner to comprehensively assess a client's vaccination history, undertake pathology (Hepatitis B serology) and to develop a catch-up schedule. Administration of these additional vaccinisations fall outside of the scope of practice of the Pharmacist Immuniser and given the lack of evidence to support that the significant deficiencies identified within the Final Evaluation Report have been resolved, there is not confidence that the Pharmacist Immuniser will reliably refer the client to their general practitioner to undertake this comprehensive assessment.

In considering lifting restrictions in regard to where pharmacists can administer approved vaccinations, concentration should be on meeting the needs of the vulnerable such as the homeless, in soup kitchens and shelters, aged care facilities, home visits for the disabled.

10) Do you have any comments in response to the questions and considerations identified in section 3.4.1 of the consultation paper?

What public health issues are experienced as a result of the current restrictions prohibiting pharmacists from delivering immunisation services outside the settings identified in the Secretary Approval: Pharmacist Immuniser

ANMF (Vic Branch) is not aware of any evidence base to support that the current restrictions create a 'public health issue'. Conversely, we note the significant issues identified within the Final Evaluation Report indicate clinical risk with expanding the Pharmacist Immuniser Program and the related recommendation that:

> *Until these issues are addressed, an increase in the program scope is not recommended and would likely compound these issues* (page 9, HealthConsult, 2018)

With this in mind, the weight of evidence is balanced against further expanding the Pharmacist Immuniser Program until such time there has been a transparent and robust evaluation to provide assurance that these issues have been resolved.

Do any restrictions (other than the Secretary Approval: Pharmacist Immuniser) prohibit pharmacists from delivering immunisation services outside of the pharmacy premises?

No additional comment

Do current program requirements require review / amendment to support this change e.g. Is there a need for a second person with CPR to be present and available in circumstances where pharmacists aren't required to dispense?

If considering a new model of care, consideration should be given towards undertaking a robust evaluation to provide assurance that these significant issues have been resolved. Consideration could also be given to implementing a Pilot Program to properly assess and manage risk and evaluate the clinical safety of expanding the scope of practice and settings which currently apply to the Pharmacist Immuniser Secretary Approval.

How will patients be monitored post-vaccination in expanded settings and by whom?

ANMF (Vic Branch) concurs that systems must be in place to safely care for and monitor patients post vaccination. There is not an evidence base to demonstrate this has been improved upon since the Final Evaluation Report and this does not auger well for further expansion at this point.

Will privately operating pharmacists (i.e. who are not linked to a particular pharmacy) be able to deliver immunisation services?

No additional comment

For mobile-type services:

How will cold chain requirements be met?

Through implementing reliable systems which ensure compliance with the National Vaccine Storage Guidelines Strive for 5 3rd Edition (Australian Government, Department of health, 2019 https://www.health.gov.au/sites/default/files/national-vaccine-storage-guidelines-strive-for-5_0.pd

How will access and timely reporting to the AIR be ensured?

No additional comment

How might patients be charged, and payment made for vaccination services outside the current premises?

No additional comment

In the event of an adverse event occurring after the pharmacist has left, what is the system for notifying the pharmacist in order for the pharmacist to report to Victoria's vaccine safety service.

As part of providing safe and high-quality care, a Pharmacist Immuniser would reasonably be expected to provide the client receiving the vaccination information and advice on reporting an adverse event. There are obvious limitations in expecting a child of 10 years of age to take on this responsibility which in turn highlights the inherent risks associated with expansion of the Pharmacist Immuniser Program to this young cohort.

Are there any settings/circumstances which should be excluded from this amendment?
Yes

No additional comment.

Conclusion - Do you have any other comments about the expansion of the Victorian Pharmacist-Administered Vaccination Program?

ANMF (Vic Branch) is a committed supporter of safe and effective means to improve vaccination rates within the Victorian Community.

However, we note the significant issues identified within the Final Evaluation Report indicate clinical risk and the related recommendation that:

> *Until these issues are addressed, an increase in the program scope is not recommended and would likely compound these issues* (page 9, HealthConsult, 2018).

With this in mind, the weight of evidence is balanced against further expanding the Pharmacist Immuniser Program until such time there has been a transparent and robust evaluation to provide assurance that these issues have been resolved.

The ANMF (Vic Branch) would welcome the opportunity to discuss the initiatives proposed by immunisation nurses as a means of contributing to improved vaccination rates within Victoria.

Reference List

ANMF (Vic Branch) Consultation Survey September 2018, ANMF (Vic Branch)

ANMF (Vic Branch) Consultation Survey November 2019, ANMF (Vic Branch)

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