Part A

1. International Non-proprietary Name of the medicine.

Cholera vaccine
COVID-19 vaccine
Diphtheria, tetanus and pertussis (acellular, component) vaccine (Tdap)
Diphtheria toxoid
Diphtheria vaccine
Haemophilus influenzae vaccine
Hepatitis A vaccine
Hepatitis B vaccine
Human papillomavirus vaccine (HPV)
Influenza vaccine
Japanese encephalitis vaccine
Measles vaccine
Meningococcal vaccine
Mumps vaccine
Pertussis (whooping cough) vaccine
Pneumococcal vaccine
Poliomyelitis vaccine (polio)
Rabies vaccine
Recombinant varicella zoster virus glycoprotein E antigen
Rotavirus vaccine
Rubella vaccine
Staphylococcus aureus vaccine
Streptococcus beta-haemolyticus vaccine
Tetanus toxoid
Tetanus vaccine
Triple antigen vaccine
Tuberculosis vaccine
Typhoid vaccine
Vaccinia virus vaccine
Varicella vaccine[1]
Yellow fever vaccine

[1] [1] Note Medsafe Classification database holds two entries for varicella - varicella (shingles) vaccine and varicella (chickenpox) vaccine. Medicines Regulations 1984 only lists varicella vaccine.

2. Name and contact details of the company / organisation / individual requesting a reclassification.

Martin Chadwick – Chief Allied Health Professions Officer. Ministry of Health

Main contacts
Harry Zheng – Advisor, Pharmacy. Te Whatu Ora, Health New Zealand
Email: harry.zheng@health.govt.nz,

Andi Shirtcliffe – Clinical Chief Advisor. Ministry of Health
Email: andi.shirtcliffe@health.govt.nz

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

All dose forms and strengths of all the vaccines listed in Part A, Section 1. Except only injectable haemophilus influenzae, pneumococcal, staphlycoccus aureus, and streptococcus beta-haemolyticus vaccines

4. Pack size, storage conditions and other qualifications.

Pack sizes of vaccines is varied amongst each product. Providers will still need to maintain cold chain accreditation[2]. Vaccines will be distributed and stored according to the National Standards for Vaccine Storage and Transportation for Immunisation Providers 2017[3] and the 2021 Addendum[4].

5. Indications for which change is sought.

All approved indications.

6. Present classification of the medicine.

All prescription-only, unless stated

Cholera vaccine

Prescription-only except in the form of an oral liquid containing vibrio cholerae when sold in a pharmacy by a registered pharmacist.

[2] https://www.health.govt.nz/our-work/preventative-health-wellness/immunisation/national-immunisation-programme-cold-chain-management
[3] https://www.health.govt.nz/publication/national-standards-vaccine-storage-and-transportation-immunisation-providers-2017
[4] https://www.health.govt.nz/publication/2021-addendum-national-standards-vaccine-storage-and-transportation-providers-2017-2nd-edition

COVID-19 vaccine

Prescription-only except when administered by vaccinators, registered pharmacists, or registered intern pharmacists who have successfully completed the COVID-19 Vaccinator Education Course (or any equivalent training course on COVID-19 vaccination approved by the Ministry of Health) and who comply with the immunisation standards of the Ministry of Health (but excluding vaccinators who have completed the Provisional Vaccinator Foundation Course or the COVID-19 Vaccinator - Working under Supervision Course).

Diphtheria, tetanus and pertussis (acellular, component) vaccine

Prescription-only except when administered in a single dose to a person 18 years of age or over or to a pregnant woman aged 13 years or over by a registered pharmacist who has successfully completed the Vaccinator Foundation Course (or any equivalent training course approved by the Ministry of Health) and who complies with the immunisation standards of the Ministry of Health (but excluding a vaccinator who has completed the Provisional Vaccinator Foundation Course)

Haemophilus influenzae, pneumococcal, staphylococcus aureus and streptococcus beta-haemolyticus vaccines

Prescription-only except in oral vaccines for the prophylaxis of bacterial complications of colds

Human papillomavirus vaccine

Prescription-only except when administered by a registered pharmacist or registered intern pharmacist who has successfully completed the Vaccinator Foundation Course (or any equivalent training course approved by the Ministry of Health) and who complies with the immunisation standards of the Ministry of Health (but excluding a vaccinator who has completed the Provisional Vaccinator Foundation Course)

Influenza vaccine

Prescription-only except when administered by vaccinators, registered pharmacists, or registered intern pharmacists who have successfully completed the Vaccinator Foundation Course (or any equivalent training course approved by the Ministry of Health) and who comply with the immunisation standards of the Ministry of Health (but excluding vaccinators who have completed the Provisional Vaccinator Foundation Course)

Measles, mumps, and rubella vaccines

Prescription-only except when administered, in combination with [other active components of the MMR vaccine] vaccines in a combination product the supply of which the Minister of Health has consented to, by vaccinators, registered pharmacists, or registered intern pharmacists who have successfully completed the Vaccinator Foundation Course (or any equivalent training course approved by the Ministry of Health) and who comply with the immunisation standards of the Ministry of Health (but excluding vaccinators who have completed the Provisional Vaccinator Foundation Course)

Meningococcal vaccine

except when administered to a person 16 years of age or over by a registered pharmacist who has successfully completed the Vaccinator Foundation Course (or any equivalent training course approved by the Ministry of Health) and who complies with the immunisation standards of the Ministry of Health (but excluding a vaccinator who has completed the Provisional Vaccinator Foundation Course)

Varicella vaccine

Prescription-only except when administered for the prevention of herpes zoster (shingles) to a person 50 years of age or over by a registered pharmacist who has successfully completed the Vaccinator Foundation Course (or any equivalent training course approved by the Ministry of Health) and who complies with the immunisation standards of the Ministry of Health (but excluding a vaccinator who has completed the Provisional Vaccinator Foundation Course)

7. Classification sought.

Cholera vaccine

Prescription-only EXCEPT when sold by a vaccinator who has successfully completed the Vaccinator Foundation Course (or equivalent course) approved by the Ministry of Health and who is complying with the immunisation standards of the Ministry of Health, but excluding COVID-19 Vaccinators Working Under Supervision, Provisional Vaccinators, Provisional Pharmacist Vaccinators, and Vaccinating Health Workers, OR in the form of an oral liquid containing vibrio cholerae when sold in a pharmacy by a registered pharmacist.

COVID-19 vaccine

Prescription-only EXCEPT when administered, by a vaccinator who has successfully completed a Vaccinator Foundation Course and a COVID-19 Vaccinator Education Course (or any equivalent training course on COVID-19 vaccination approved by the Ministry of Health) and who is complying with the immunisation standards of the Ministry of Health, but excluding COVID-19 Vaccinators Working Under Supervision, Provisional Vaccinators, Provisional Pharmacist Vaccinators, and Vaccinating Health Workers.

Diphtheria, tetanus and pertussis (acellular, component) vaccine (Tdap)

Prescription-only EXCEPT when administered by a vaccinator who has successfully completed the Vaccinator Foundation Course (or equivalent course) approved by the Ministry of Health and who is complying with the immunisation standards of the Ministry of Health, but excluding COVID-19 Vaccinators Working Under Supervision, Provisional Vaccinators, Provisional Pharmacist Vaccinators, and Vaccinating Health Workers.

Diphtheria toxoid

Prescription-only EXCEPT when administered by a vaccinator who has successfully completed the Vaccinator Foundation Course (or equivalent course) approved by the Ministry of Health

and who is complying with the immunisation standards of the Ministry of Health, but excluding COVID-19 Vaccinators Working Under Supervision, Provisional Vaccinators, Provisional Pharmacist Vaccinators, and Vaccinating Health Workers.

Diphtheria vaccine

Prescription-only EXCEPT when administered by a vaccinator who has successfully completed the Vaccinator Foundation Course (or equivalent course) approved by the Ministry of Health and who is complying with the immunisation standards of the Ministry of Health, but excluding COVID-19 Vaccinators Working Under Supervision, Provisional Vaccinators, Provisional Pharmacist Vaccinators, and Vaccinating Health Workers.

Haemophilus influenzae vaccine

Prescription-only EXCEPT when injected by a vaccinator who has successfully completed the Vaccinator Foundation Course (or equivalent course) approved by the Ministry of Health and who is complying with the immunisation standards of the Ministry of Health, but excluding COVID-19 Vaccinators Working Under Supervision, Provisional Vaccinators, Provisional Pharmacist Vaccinators, and Vaccinating Health Workers, or when specified elsewhere in this schedule.

Hepatitis A vaccine

Prescription-only EXCEPT when administered by a vaccinator who has successfully completed the Vaccinator Foundation Course (or equivalent course) approved by the Ministry of Health and who is complying with the immunisation standards of the Ministry of Health, but excluding COVID-19 Vaccinators Working Under Supervision, Provisional Vaccinators, Provisional Pharmacist Vaccinators, and Vaccinating Health Workers.

Hepatitis B vaccine

Prescription-only EXCEPT when administered by a vaccinator who has successfully completed the Vaccinator Foundation Course (or equivalent course) approved by the Ministry of Health and who is complying with the immunisation standards of the Ministry of Health, but excluding COVID-19 Vaccinators Working Under Supervision, Provisional Vaccinators, Provisional Pharmacist Vaccinators, and Vaccinating Health Workers.

Human papillomavirus vaccine (HPV)

Prescription-only EXCEPT when administered by a vaccinator who has successfully completed the Vaccinator Foundation Course (or equivalent course) approved by the Ministry of Health and who is complying with the immunisation standards of the Ministry of Health, but excluding COVID-19 Vaccinators Working Under Supervision, Provisional Vaccinators, Provisional Pharmacist Vaccinators, and Vaccinating Health Workers.

Influenza vaccine

Prescription-only EXCEPT when administered by a vaccinator who has successfully completed the Vaccinator Foundation Course (or equivalent course) approved by the Ministry of Health and who is complying with the immunisation standards of the Ministry of Health, but

excluding COVID-19 Vaccinators Working Under Supervision, Provisional Vaccinators, Provisional Pharmacist Vaccinators, and Vaccinating Health Workers.

Japanese encephalitis vaccine

Prescription-only EXCEPT when administered by a vaccinator who has successfully completed the Vaccinator Foundation Course (or equivalent course) approved by the Ministry of Health and who is complying with the immunisation standards of the Ministry of Health, but excluding COVID-19 Vaccinators Working Under Supervision, Provisional Vaccinators, Provisional Pharmacist Vaccinators, and Vaccinating Health Workers.

Measles vaccine

Prescription-only EXCEPT when administered by a vaccinator who has successfully completed the Vaccinator Foundation Course (or equivalent course) approved by the Ministry of Health and who is complying with the immunisation standards of the Ministry of Health, but excluding COVID-19 Vaccinators Working Under Supervision, Provisional Vaccinators, Provisional Pharmacist Vaccinators, and Vaccinating Health Workers.

Meningococcal vaccine

Prescription-only EXCEPT when administered by a vaccinator who has successfully completed the Vaccinator Foundation Course (or equivalent course) approved by the Ministry of Health and who is complying with the immunisation standards of the Ministry of Health, but excluding COVID-19 Vaccinators Working Under Supervision, Provisional Vaccinators, Provisional Pharmacist Vaccinators, and Vaccinating Health Workers.

Mumps vaccine

Prescription-only EXCEPT when administered by a vaccinator who has successfully completed the Vaccinator Foundation Course (or equivalent course) approved by the Ministry of Health and who is complying with the immunisation standards of the Ministry of Health, but excluding COVID-19 Vaccinators Working Under Supervision, Provisional Vaccinators, Provisional Pharmacist Vaccinators, and Vaccinating Health Workers.

Pneumococcal vaccine

Prescription-only EXCEPT when injected by a vaccinator who has successfully completed the Vaccinator Foundation Course (or equivalent course) approved by the Ministry of Health and who is complying with the immunisation standards of the Ministry of Health, but excluding COVID-19 Vaccinators Working Under Supervision, Provisional Vaccinators, Provisional Pharmacist Vaccinators, and Vaccinating Health Workers, or when specified elsewhere in this schedule.

Poliomyelitis vaccine (polio)

Prescription-only EXCEPT when administered by a vaccinator who has successfully completed the Vaccinator Foundation Course (or equivalent course) approved by the Ministry of Health and who is complying with the immunisation standards of the Ministry of Health, but

excluding COVID-19 Vaccinators Working Under Supervision, Provisional Vaccinators, Provisional Pharmacist Vaccinators, and Vaccinating Health Workers.

Rabies vaccine

Prescription-only EXCEPT when administered by a vaccinator who has successfully completed the Vaccinator Foundation Course (or equivalent course) approved by the Ministry of Health and who is complying with the immunisation standards of the Ministry of Health, but excluding COVID-19 Vaccinators Working Under Supervision, Provisional Vaccinators, Provisional Pharmacist Vaccinators, and Vaccinating Health Workers.

Recombinant varicella zoster virus glycoprotein E antigen

Prescription-only EXCEPT when administered by a vaccinator who has successfully completed the Vaccinator Foundation Course (or equivalent course) approved by the Ministry of Health and who is complying with the immunisation standards of the Ministry of Health, but excluding COVID-19 Vaccinators Working Under Supervision, Provisional Vaccinators, Provisional Pharmacist Vaccinators, and Vaccinating Health Workers.

Rubella vaccine

Prescription-only EXCEPT when administered by a vaccinator who has successfully completed the Vaccinator Foundation Course (or equivalent course) approved by the Ministry of Health and who is complying with the immunisation standards of the Ministry of Health, but excluding COVID-19 Vaccinators Working Under Supervision, Provisional Vaccinators, Provisional Pharmacist Vaccinators, and Vaccinating Health Workers.

Rotavirus vaccine

Prescription-only EXCEPT when sold by a vaccinator who has successfully completed the Vaccinator Foundation Course (or equivalent course) approved by the Ministry of Health and who is complying with the immunisation standards of the Ministry of Health, but excluding COVID-19 Vaccinators Working Under Supervision, Provisional Vaccinators, Provisional Pharmacist Vaccinators, and Vaccinating Health Workers

Staphylococcus aureus vaccine

Prescription-only EXCEPT when injected by a vaccinator who has successfully completed the Vaccinator Foundation Course (or equivalent course) approved by the Ministry of Health and who is complying with the immunisation standards of the Ministry of Health, but excluding COVID-19 Vaccinators Working Under Supervision, Provisional Vaccinators, Provisional Pharmacist Vaccinators, and Vaccinating Health Workers, or when specified elsewhere in this schedule.

Streptococcus beta-haemolyticus vaccines

Prescription-only EXCEPT when injected by a vaccinator who has successfully completed the Vaccinator Foundation Course (or equivalent course) approved by the Ministry of Health and who is complying with the immunisation standards of the Ministry of Health, but excluding COVID-19 Vaccinators Working Under Supervision, Provisional Vaccinators, Provisional

Pharmacist Vaccinators, and Vaccinating Health Workers, or when specified elsewhere in this schedule.

Tetanus toxoid

Prescription-only EXCEPT when administered by a vaccinator who has successfully completed the Vaccinator Foundation Course (or equivalent course) approved by the Ministry of Health and who is complying with the immunisation standards of the Ministry of Health, but excluding COVID-19 Vaccinators Working Under Supervision, Provisional Vaccinators, Provisional Pharmacist Vaccinators, and Vaccinating Health Workers.

Tetanus vaccine

Prescription-only EXCEPT when administered by a vaccinator who has successfully completed the Vaccinator Foundation Course (or equivalent course) approved by the Ministry of Health and who is complying with the immunisation standards of the Ministry of Health, but excluding COVID-19 Vaccinators Working Under Supervision, Provisional Vaccinators, Provisional Pharmacist Vaccinators, and Vaccinating Health Workers.

Triple antigen vaccine

Prescription-only EXCEPT when administered by a vaccinator who has successfully completed the Vaccinator Foundation Course (or equivalent course) approved by the Ministry of Health and who is complying with the immunisation standards of the Ministry of Health, but excluding COVID-19 Vaccinators Working Under Supervision, Provisional Vaccinators, Provisional Pharmacist Vaccinators, and Vaccinating Health Workers.

Tuberculosis vaccine

Prescription-only EXCEPT when administered, by a vaccinator who has successfully completed a Vaccinator Foundation Course (or equivalent course) approved by the Ministry of Health, and who is complying with the immunisation standards and any other requirements of the Ministry of Health, but excluding COVID-19 Vaccinators Working Under Supervision, Provisional Vaccinators, Provisional Pharmacist Vaccinators, and Vaccinating Health Workers.

Typhoid vaccine

Prescription-only EXCEPT when sold in an oral liquid form, OR when administered by a vaccinator who has successfully completed a Vaccinator Foundation Course (or equivalent course) approved by the Ministry of Health, and who is complying with the immunisation standards and any other requirements of the Ministry of Health, but excluding COVID-19 Vaccinators Working Under Supervision, Provisional Vaccinators, Provisional Pharmacist Vaccinators, and Vaccinating Health Workers.

Vaccinia virus vaccine

Prescription-only EXCEPT when administered by a vaccinator who has successfully completed the Vaccinator Foundation Course (or equivalent course) approved by the Ministry of Health and who is complying with the immunisation standards of the Ministry of Health, but

excluding COVID-19 Vaccinators Working Under Supervision, Provisional Vaccinators, Provisional Pharmacist Vaccinators, and Vaccinating Health Workers.

Varicella vaccine

Prescription-only EXCEPT when administered by a vaccinator who has successfully completed the Vaccinator Foundation Course (or equivalent course) approved by the Ministry of Health and who is complying with the immunisation standards of the Ministry of Health, but excluding COVID-19 Vaccinators Working Under Supervision, Provisional Vaccinators, Provisional Pharmacist Vaccinators, and Vaccinating Health Workers.

Yellow fever vaccine

Prescription-only EXCEPT when administered, by a vaccinator who has successfully completed a Vaccinator Foundation Course (or equivalent course) approved by the Ministry of Health, and who is complying with the immunisation standards and any other requirements of the Ministry of Health, but excluding COVID-19 Vaccinators Working Under Supervision, Provisional Vaccinators, Provisional Pharmacist Vaccinators, and Vaccinating Health Workers.

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

Canada

Classification of medicines in Canada is administered by the National Association of Pharmacy Regulatory Authorities (NAPRA). The medicines this submission is looking to reclassify fall into Schedule I or Schedule II (the equivalent to prescription and pharmacist-only in New Zealand) of the Canadian National Drug Schedules [1]. Authorisation of pharmacists to administer vaccines are determined by regulations of each province and territory (P/T).

Pharmacists in 11 out of 13 P/Ts can administer 17 vaccines[5] that are included in this submission [2]. From those P/Ts, 10 of them have authorised pharmacist vaccinators to also prescribe vaccines in a limited or whole manner. Access to publicly funded vaccines is variable across the P/Ts with British Columbia having the widest access. However, all P/Ts allow for publicly funded influenza and COVID-19 vaccines to pharmacist vaccinators. P/Ts that do not offer publicly funded vaccines allow pharmacists to provide them in the private market. Quebec is a notable exception as it offers the second widest range of publicly funded vaccines, but pharmacists cannot provide them privately.

Minimum patient age is variable across the P/Ts. However most have a minimum age of 2-5 years old.

[5] Influenza, COVID-19, pneumococcal, meningococcal, haemophilus influenzae, hepatitis A, hepatitis B, measles, mumps, rubella, diphtheria, tetanus, pertussis, varicella (chickenpox and shingles) HPV, and polio vaccines.

Australia

Classification of medicines in Australia is administered by the Therapeutic Goods Administration (TGA). Vaccines in this submission are classed as Schedule 4 medicines, the equivalent of prescription-only in New Zealand [3]. Authorised nurse and midwife vaccinators and pharmacist vaccinators can prepare and administer vaccines if they are appropriately qualified, trained, acting within their scope of practice and are authorised by relevant legislation in their jurisdictions [4].

Pharmacists in all eight states in Australia can administer influenza, Tdap, and MMR vaccines. Authorisation of other vaccines are variable in each state. The minimum age of the patient, and public funding status is also variable in each state [5].

United Kingdom

Classification of medicines in the UK is administered by the Medicines and Healthcare products Regulatory Agency (MHRA). All vaccines in the UK are classed as prescription-only medicines [6].

The Human Medicines Regulations 2012 permits non-prescribing registered health professionals to administer or supply prescription-only medicines pursuant to:

1. A signed prescription
2. A Patient Specific Direction (PSD)
3. A Patient Group Direction (PGD)
4. A National Protocol

A PGD allows a for the supply or administration of medicines to groups of patients who may not be individually identified before presentation for treatment [6]. They provide a legal framework that allows the supply and/or administration of a specified medicine(s), to a pre-defined group of patients needing prophylaxis or treatment for a condition described in the PGD, without the need for a prescription or an instruction from a prescriber. PGDs enable a wide range of immunisation programs in the UK.

United States

Most (47) states in the US have laws that explicitly state that pharmacists may administer vaccines [7]. Out of those, 44 states require pharmacists to vaccinate under third-party authorisation. Authorisation in 37 of those states can be a general authorisation (like a standing order or PGD), and 3 states require patient-specific authorisations. The remaining four states have ambiguous requirements [7].

9. Extent of usage in New Zealand and elsewhere (eg, sales volumes) and dates of original consent to distribute.

Dates of original consent to distribute

Dates of original consent to distribute for various products containing the vaccines in this submission is available on the Medsafe Product/Application Search website[6].

Sales Volumes – childhood immunisations

The table below shows the immunisation coverage of children who turned one of the milestone ages during the 12-month period from 1 April 2021 to 31 March 2022, and who have completed their age-appropriate immunisations [8].

Table 1. National childhood immunisation coverage 1 April 2021 – 31 March 2022

Milestone age	Number Eligible	Fully Immunised for age		Opt-Offs		Declines	
		No.	%	No.	%	No.	%
6 month	61,699	44,960	72.9%	378	0.6%	2841	4.6%
8 month	61,375	53,088	86.5%	393	0.6%	2941	4.8%
12 month (1 year)	59,717	53,674	89.9%	362	0.6%	3089	5.2%
18 month	59,384	42,087	70.9%	345	0.6%	3541	6.0%
24 month (2 years)	60,143	50,757	84.4%	322	0.5%	3412	5.7%
54 month (4.5 years)	62,797	44,623	71.1%	438	0.7%	3634	5.8%
5 year	63,421	53,117	83.8%	424	0.7%	3748	5.9%

Notes:

- 'Number eligible' is the number of children who turned one of the milestone ages in the three-month or 12-month reporting period.
- 'Fully immunised for age' is the number of eligible children who have completed all of their age-appropriate immunisations by the time they turned the milestone age.
- 'Opt-offs' is a count of individuals who have opted off the NIR.

[6] Available at: https://www.medsafe.govt.nz/regulatory/DbSearch.asp

- 'Declines' is a count of individuals who have declined any one vaccination.

Sales volumes – COVID-19 immunisation

The Ministry of Health publishes COVID-19 vaccine data with daily updates [9]. As of 19 July 2022, 10,917,135 COVID-19 vaccines were administered.

10. Local data or special considerations relating to New Zealand (if applicable).

The New Zealand regulatory setting

New Zealand's legislation allows for two major groups of vaccinators - authorised vaccinators and pharmacist vaccinators. Both groups of vaccinators undergo the same Ministry of Health-approved clinical training, but the process of attaining and maintaining vaccinator status differ.

Authorised vaccinators are healthcare professionals enabled to administer vaccines without a prescription by Medicines Regulations 1984 reg 44A. A significant limitation of the authorised vaccinator is they can only administer vaccines as part of an immunisation program that is approved by the Director-General of Health, or a Medical Officer of Health. Although within the legislative capacity of the Director-General of Health, authorisation is normally granted by local medical officers of health. One significant limitation of this is authorisation is it's only granted in the geographical area where the medical officer of health has jurisdiction. Should the vaccinator practice outside of that area, authorisation must be sought from the medical officer of health of the new area. This duplicates processes and bureaucracy for vaccinators and medical officers of health.

Pharmacist vaccinators are enabled to administer vaccines through classification statements of specific vaccines. These classification statements usually include a limitation on what populations pharmacist vaccinators can administer vaccines to. For example, pharmacists can only administer the meningococcal vaccine to people aged 16 years or over.

Authorised prescribers such as medical practitioners, nurse practitioners, and midwives can administer any vaccine, provided it is within their scope of practice. However, this is enabled through their prescribing authority, which is beyond the scope of this submission.

While there is some overlap in what populations both groups of vaccinators can vaccinate, there is inconsistency in access due to the different rules governing different vaccinator types. Currently it is possible for one family to visit multiple providers to meet all their vaccination needs.

National data

National immunisation data from the Ministry of Health highlight many Te Whatu Ora districts (DHBs) were unable to reach the former health target of 95% of eight-month-olds receiving their primary course of immunisation on time [10]. In eight quarterly periods

between 2019-2021, there were only 13 instances of DHBs reaching that target, out of a possible 160.

An analysis of vaccination rates by the Health Quality and Safety Commission on two-year-olds who have received their age-appropriate scheduled vaccines showed no ethnic group reached 95% in any quarter since July 2019 [11].

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

Affected vaccines will not need to be relabelled as they are not available for purchase to the public and are still prescription-only medicines until the point of provision.

12. Proposed warning statements (if applicable)

Affected vaccines will not need additional warning statements as they are not available for purchase to the public and are still prescription-only medicines until the point of provision.

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

Buccaline is an oral vaccine marketed for the prophylaxis of bacterial complications of colds. It contains four active ingredients: haemophilus influenzae type B organisms, pneumococcus organisms, staphylococcus aureus organisms, and streptococcus aglactiae organisms. The current classification of all four ingredients is prescription-only except in oral vaccines for the prophylaxis of bacterial complications of colds, where they are classified as restricted medicines. The proposed classification for the four ingredients will only affect injectable forms, therefore the classification of Buccaline will not be affected.

Part B

1. Indications and dose

– What is the medicine indicated for, and for which indication(s) is the reclassification application for?
Prophylaxis against each vaccine's indicated diseases

– What is the evidence that the proposed indication is an OTC indication ie, that the diagnosis and treatment can be understood by the consumer; that the risks of inappropriate treatment can be minimised?
Understanding of diagnosis and treatment will not be affected by reclassification of these vaccines as they cannot be purchased directly by a consumer. The vaccinator who will be able to administer these vaccines will use their professional judgement to determine whether there is an indication for the vaccine.

– What is the treatment population for the indication (age; gender etc.)?
Each vaccine has different treatment populations, which are listed in their respective product datasheets. The submission does not seek to change the indication of any vaccine.

– What is the dose and dose frequency of the medicine for this indication?
Each vaccine has different dose and dose frequencies, which are listed in their respective product datasheets. The submission does not seek to change the dose or dose frequency of any vaccine.

2. Presentation

– What is the proposed dose form and strength of the medicine to be reclassified? Is this the same for all indications?
With exceptions, this submission looks to reclassify all the dose forms and strengths of each vaccine listed in Part A, Section 1. This is the same for all indications.

The exceptions are haemophilus influenzae, pneumococcal, staphlycoccus aureus, and streptococcus beta-haemolyticus vaccines, where only injectable forms are to be reclassified.

– What disposal considerations need to be made for the medicine?
No additional disposal considerations are required. Advice on safe disposal of vaccines is available in Appendix 7 of the Immunisation Handbook 2020 [12].

– How practical and easy to use is the proposed presentation?
The presentation of the affected vaccines will not be changed.

3. Consumer benefits

The clinical efficacy of vaccines against their target diseases is well described in the Immunisation Handbook 2020 [12].

The benefits of reclassification of vaccines to allow pharmacist administration have been discussed in other MCC submissions [13] [14] [15] [16] [17]. Pharmacies are widely recognised as a trusted venue for people to receive vaccinations [18] [19] [20] and pharmacists in some other jurisdictions can administer a wider range of vaccines than pharmacists in New Zealand [2] [5].

This submission looks to discuss the strategic harms and benefits of allowing greater access to vaccines to the existing vaccinator workforce.

People can visit their provider of choice

The current legislation around vaccinators and subsequent funding arrangements forces some New Zealanders to receive vaccines from a single provider type. Most notably, all 13-64 (or 13–54-year-old Pacific Island or Māori) year old people without a qualifying health condition are unable to legally receive the flu vaccine from an authorised vaccinator without a prescription, unless there is a local vaccination program authorised by the medical officer of health. In recent years there has been movement towards funding parity between vaccines administered in general practice and pharmacy. However, there are still inconsistencies between the two settings, leading to some populations being eligible to receive a funded vaccine from one provider, but not the other.

This submission recognises the accessibility and convenience of pharmacy and the advocacy of pharmacists as health professionals. Pharmacists are one of the most often seen health professionals in New Zealand and are a trusted health service provider. Increasing the number of vaccines pharmacists can provide will allow them to promote public awareness and increase the opportunities where New Zealanders can get vaccinated. It also acknowledges the expertise of authorised vaccinators, who are trained to administer vaccines to all peoples, and this submission looks to better enable that.

Data from the NHS in England has shown that people are willing to receive influenza vaccines from a pharmacy as opposed a general practitioner, even if they had to pay extra [21]. In the study population, 199 people were eligible for free vaccination and 100 chose not to use the free option. The primary reason given was inconvenience of going to a general practice. Other reasons included location/hours of the pharmacy, the pharmacy environment, and vaccine availability. These results from 2012-2013 aligns with the New Zealand COVID vaccine program experience, where community pharmacies, at 30 January 2022, were administering up to 40% of COVID-19 vaccine doses every week, despite only accounting for 30% of all active providers. Contribution from community pharmacy also spiked up during the 2021-2022 Christmas and New Year period to 60%, where every other provider type recorded a decrease in numbers. This showed community pharmacy was able to continue vaccinating while other health providers closed for public holidays.

Follow-on effects of reclassification

The primary aim of reclassification is to increase the access and convenience of affected vaccines, most notably influenza and childhood routine vaccines. Increasing the number of vaccines pharmacists can administer will have further follow-on benefits. Firstly, pharmacists will be better informed to be advocates for all available immunisations. Secondly, it allows pharmacists to take part in immunisation programs previously unavailable to them, reducing the workload on the current workforce.

Community outreach

Pharmacy's ability to provide outreach to different ethnic groups has also been well documented. Of note, pharmacist Vicky Chan piloted the Community Flu Fighters programme in elderly Asian communities in Auckland in 2019 [22]. The pilot vaccinated a total of 458 individuals including 192 individuals who have never or irregularly receives the influenza vaccine. Ms Chan also organised night clinics for the Auckland Indian community in September 2021, with one clinic vaccinating over 250 individuals in one night [23]. Both events succeeded in drawing people from various cultural groups, and the ability to bring vaccinations into the community was cited as a reason for their success.

Spread the workload amongst the entire vaccinator workforce

The reclassification proposed by this submission enables consumers to select their vaccination provider of choice, which will spread the workload across the entire vaccinator workforce. Reclassification will also build resilience in the capacity of service providers as it enables them to employ vaccinators from both groups if they face increased demand.

– What are the possibilities of community harm resulting from wider use of the medicine in question (eg, the development of antibiotic resistance in bacteria or increased immunisation rates)?

Adverse events

Rates of adverse events for individual vaccines are described in their individual product datasheets and in the Immunisation Handbook 2020 [12].

Inappropriate administration of vaccines, particularly from pharmacists

Pharmacists can currently administer seven vaccines without a prescription but only two (influenza and COVID) have had widespread demand in community pharmacies. A bulk addition of vaccines and products (some with similar names) could cause medicine administration errors. If this was to occur, it'd most likely occur in the first few months after reclassification and reduce with time. This risk is minimal as pharmacists are regularly introduced to new medicines and new presentations of current medicines as part of their daily practice.

4. Contraindications and precautions

The contraindications and precautions of each vaccine are listed in their respective product datasheets and the New Zealand Formulary. Information on vaccines in the National Immunisation Schedule is also available in the Immunisation Handbook 2020 [12]. Checking

for precautions and contraindications is part of the process for safe immunisation described in the Handbook, and part of the immunisation standards for vaccinators and guidelines for organisations offering immunisation services

– Does the medicine have a low therapeutic index?
No

– What class effects need to be considered and what are the risks?
Live attenuated vaccines should not be given to immunocompromised individuals except under the direction and care of a specialist following a suitable protocol.

– What are the risks of the medicine being used in an OTC environment?
The vaccines will not be available in an OTC environment.

– What other drug interactions need to be considered? Perhaps talk about generic interaction types associated with specific technologies of vaccines. Eg live, attenuated, inactivated etc.

General interactions

Most live attenuated vaccines can be given together. If not given concurrently, wait at least 4 weeks before administering each vaccine.

Immunosuppressive therapies (including corticosteroids) may diminish the effect of vaccines. Studies on the effects of immunosuppressive drugs on the effect of various vaccines are inconsistent.

If co-administering vaccines, each vaccine should be administered in a different location.

Some vaccines may be mixed with others – information on this is available in the product datasheets and the Immunisation Handbook 2020 [12].

Cholera vaccine

Dukoral (a brand of cholera vaccine) is acid labile [24]. Food and/or drink will increase acid production in the stomach, and the effect of the vaccine may be impaired. Consequently, food and drink should be avoided 1 hour before and 1 hour after vaccination.

Diphtheria, tetanus and pertussis (acellular, component) vaccine

When considered necessary, Boostrix (a brand of Tdap vaccine) can be administered simultaneously with other vaccines or immunoglobulins [25].

Haemophilus influenzae vaccine

As with other vaccines it may be expected that in patients receiving immunosuppressive therapy or patients with immunodeficiency, an adequate response may not be achieved [26].

Hepatitis A vaccine

Havrix (a brand of hepatitis A vaccine) is an inactivated vaccine its concomitant use with other inactivated vaccines is unlikely to result in interference with the immune responses [27].

Human papillomavirus vaccine

Immunosuppressive therapies, including irradiation, antimetabolites, alkylating agents, cytotoxic drugs, and corticosteroids (used in greater than physiologic doses), may reduce the immune responses to vaccines [28].

Japanese encephalitis vaccine

In patients receiving immunosuppressive therapy or patients with immunodeficiency an adequate immune response may be diminished [29].

Measles, mumps, and rubella vaccines

If tuberculin testing has to be done it should be carried out before or simultaneously with vaccination since it has been reported that live measles (and possibly mumps) vaccine may cause a temporary depression of tuberculin skin sensitivity [30]. This anergy may last for 4-6 weeks and tuberculin testing should not be performed within that period after vaccination to avoid false negative results.

If Priorix (brand of MMR vaccine) cannot be given at the same time as other live attenuated viral vaccines, an interval of at least one month should be left between both vaccinations.

In subjects who have received human gammaglobulins or a blood transfusion, vaccination should be delayed for at least three months because of the likelihood of vaccine failure due to passively acquired mumps, measles and rubella antibodies.

Pneumococcal vaccine

Pneumovax 23 (brand of pneumococcal vaccine) and Zostavax (brand of varicella zoster vaccine) should not be given concurrently because concomitant use in a clinical trial resulted in reduced immunogenicity of Zostavax [31]. In this trial, the immunogenicity of Pneumovax 23 was not affected by Zostavax. The two vaccines should be administered at least 4 weeks apart.

Rabies vaccine

Immunosuppressive treatments, including long-term systemic corticosteroid therapy, may interfere with antibody production and cause the failure of the vaccination [32]. It is therefore advisable to perform serological test (RVNA) level using a Rapid Fluorescent Focus Inhibition Test (RFFIT) 2 to 4 weeks after the last injection.

As rabies immunoglobulin interferes with development of immune response to the vaccine, the recommendation of administration of rabies immunoglobulin must be strictly followed.

Varicella Zoster vaccine

Pneumovax 23 and Zostavax should not be given concurrently because concomitant use in a clinical trial resulted in reduced immunogenicity of Zostavax [31]. In this trial, the immunogenicity of Pneumovax 23 was not affected by Zostavax. The two vaccines should be administered at least 4 weeks apart.

Varicella (chickenpox) vaccine

Vaccination should be deferred for at least 5 months following blood or plasma transfusions, or administration of immune globulin or varicella-zoster immune globulin (VZIG) [33]. Following administration of Varivax (a brand of Varicella (chickenpox) vaccine), any immune globulin including VZIG should not be given for 2 months thereafter unless its use outweighs the benefits of vaccination.

Vaccine recipients should avoid use of salicylates for 6 weeks after vaccination with Varivax as Reye syndrome has been reported following the use of salicylates during wildtype varicella infection.

Recombinant varicella zoster virus glycoprotein E antigen

Shingrix (a brand of recombinant varicella zoster virus glycoprotein E antigen) can be given concomitantly with unadjuvanted seasonal influenza vaccine, 23- valent pneumococcal polysaccharide vaccine (PPV23) or reduced antigen diphtheria tetanus-acellular pertussis vaccine [34].

– What food and/or drink interactions need to be considered?

Dukoral is acid labile. Food and/or drink will increase acid production in the stomach, and the effect of the vaccine may be impaired. Consequently, food and drink should be avoided 1 hour before and 1 hour after vaccination.

– Are there any other restrictions when taking the medicine ie, driving restrictions or operating machinery?

No

– Are there any special populations where exposure to the medicine needs to be restricted?

The indicated populations of each individual vaccine are listed in their respective product datasheets and in the Immunisation Handbook 2020 [12]. The vaccinator will exercise their professional judgement to ascertain whether the vaccine is indicated for the consumer. Reclassification of the listed vaccines does not enable unsupervised access.

5. Undesirable effects

The adverse events of each vaccine are listed in their respective product datasheets, the New Zealand Formulary, and the Immunisation Handbook 2020 [12].

There are no notable, specific adverse events attributable to a singular vaccine or type of vaccine.

Current vaccinators are well-equipped and trained to advise and treat adverse events from vaccines. The subject is also well covered in the vaccinator foundation training course.

6. Overdose

The potential for overdose is very small as most vaccines are packaged in unit doses. The use of a national immunisation register will minimize the risk of a person receiving a vaccine at the wrong time.

7. Medication errors and abuse/misuse potential

– Would reclassification affect the risk of unnecessary use?
Very unlikely. Reclassification could possibly increase the chance of a person receiving the same vaccine twice (for example, a dose of the influenza vaccine at their GP, and another at their workplace). However, a vaccination is usually a memorable event, and the use of a national immunisation register will provide the vaccinator with an up-to-date vaccination history to minimize the risk of a double dose.

– Is the medicine be provided with necessary tools to allow correct dosing eg, liquids supplied with a measuring device?
Some products come with pre-attached needles, some do not. Vaccinators are expected to keep necessary supplies on hand if required.

– What are the reported medication errors post-market?
Data on post-market medication errors is available on each vaccine's product datasheet, and in the Immunisation Handbook 2020 [12].

– How would reclassification affect import considerations?
The vaccines still hold the prescription-only classification until point of administration. As such, there are no changes in requirements around import or distribution.

– What is the addiction potential of the medicine?
The vaccines in this submission do not have addictive potential.

8. Communal harm and / or benefit

– What are the possibilities of community benefit resulting from wider use of the medicine in question (eg, greater herd immunity as a result of improved access to a communicable disease vaccine)?
Vaccination has greatly reduced the burden of infectious diseases. The WHO calls immunisation "a global health and development success story, saving millions of lives every year [35]. Vaccines reduces the risks of getting a disease by working with the body's natural defences to build protection."

The section below from the Immunisation Handbook 2020 [12] succinctly describes the communal benefits of immunising individuals.

> *By protecting individuals, vaccination can also protect the wider community. This herd immunity occurs when the vaccine coverage is high, meaning an infectious case is unlikely to encounter susceptible contacts, so transmission stops.*
>
> *The whole population benefits when a vaccine prevents carriage and transmission of a human-only pathogen, such as polio virus, measles virus or Streptococcus pneumoniae, and circulation of these pathogens can be reduced and even eliminated. This phenomenon, called herd or community immunity, can prevent infections spreading and therefore protect vulnerable members of the population, such as the very young, the very old, or those with underlying conditions that increase their risk from infectious diseases (ie, the immunocompromised). These individuals may not themselves be able to receive some vaccines (eg, live vaccines) or may not mount a sufficiently effective immune response to other vaccines.*
>
> *The population benefits depend on the disease itself, the nature of the vaccine and the proportion or target group of the population needed to be immunised to prevent the disease from spreading.*
>
> *Immunisation Handbook 2020*

9. Integrated benefit-risk statement

– A summary of the reclassification benefits

Reclassification of the vaccines in this submission will allow consumers to access vaccinations from a larger pool of vaccinators. It will also spread the workload more evenly amongst authorised and pharmacist vaccinators to relieve pressures across primary care sectors.

Pharmacists have been providing influenza vaccines since 2013 and the COVID-19 experience has shown that New Zealanders find community pharmacies to be a trusted provider for vaccinations.

Authorised vaccinators have traditionally been the primary provider of scheduled and funded vaccines. Reclassification will allow consumers to receive unscheduled or unfunded vaccinations from authorised vaccinators without obtaining a prescription first.

– A summary of the reclassification risk of harm

The potential of harm arising from the proposed reclassifications is minimal.

There could be an increased risk of inappropriate administration or double dosing of vaccines as there will be more providers providing vaccination services. This is discussed in Part B, Section 10.

– A summary of the need for the medicine at the classification proposed

The current regulatory framework for vaccinators creates inequities in access for New Zealanders.

Community pharmacies have proven to be an accepted venue for consumers to receive their vaccines.

Authorised vaccinators are restricted in what vaccines they can provide and who they can provide to based on funding agreements, rather than clinical capability.

Both groups of vaccinators are required to go through the same clinical training but have markedly different restrictions in their practice.

– Precedent – how are other medicines in the same class classified?

No vaccines currently hold the same classification as proposed in this submission. However, the COVID-19, diphtheria, tetanus and pertussis combination vaccine, HPV, influenza, measles, meningococcal, mumps, rubella, and varicella vaccines have the "prescription-only except when" classification which specifies conditions in which pharmacist vaccinators can administer vaccines.

10. Risk mitigating strategies

Incomplete and decentralised database of vaccinators

There is currently no national register of active vaccinators in New Zealand. Authorised vaccinators apply to their local medical of health for authorisation. Pharmacists are encouraged to notify the Pharmaceutical Society of New Zealand and the Pharmacy Defence Association when they have completed their vaccinator training, but there is no requirement to do so.

If this submission is successful, authorised vaccinators will no longer need to apply for authorisation from their local medical officer of health. Te Whatu Ora is exploring the development of a national register in this situation to fill this gap.

"Vaccinator" is not a defined role

The classification statements proposed in this submission specify a "vaccinator" who is providing the vaccine. A vaccinator is not a defined role in the Medicines Act or Regulations and therefore anyone can potentially claim to be one. However, the statements also specify the requirement to follow immunisation standards of the Ministry of Health, which sets out the required characteristics of the vaccinator[7].

[7] https://www.health.govt.nz/our-work/immunisation-handbook-2020/appendix-3-immunisation-standards-vaccinators-and-guidelines-organisations-offering-immunisation

Inappropriate/double dosing of vaccines

Reclassification of vaccines in this submission will allow more providers to administer vaccines, which will increase the chance of a vaccine being administered at an inappropriate time. A workplace provider could for example, administer the same vaccine to someone who has recently received the same vaccine at their general practice. The National Immunisation Solution minimises this risk as it's available to all vaccination providers, not just traditional health services such as general practice and pharmacy.

Vaccines with new routes of administration

The proposed reclassification statements for most of the vaccines in this submission are silent on the route of administration. There could be a potential classification issue should there be a product containing vaccines in this submission that is appropriate for provision to the public without a vaccinator, for example an oral tablet for mass inoculation against a pandemic. However, this is unlikely as there are no vaccines of this description approved by the FDA, or Medsafe. In the event a rapid change in classification is required to allow the provision of a vaccine without a vaccinator, section 106 of the Medicines Act 1981 allows a temporary reclassification of a medicine by the Minister of Health by notice in the Gazette.

References

[1] "National Drug Schedules," [Online]. Available: https://www.napra.ca/national-drug-schedules. [Accessed 1 July 2022].

[2] Canadian Pharmacists Association, "Scope of Practice Immunisation English," 20 June 2022. [Online]. Available: https://www.pharmacists.ca/cpha-ca/function/utilities/pdf-server.cfm?thefile=/cpha-on-the-issues/Immunization_Authority_Chart.pdf. [Accessed 4 July 2022].

[3] "Australian Register of Therapeutic Goods search," [Online]. Available: https://tga-search.clients.funnelback.com/s/search.html?query=&collection=tga-artg. [Accessed 1 July 2022].

[4] National Centre for Immunisation Research and Surveillance, "Administration of vaccines – Scope of practice for healthcare professionals," 3 February 2022. [Online]. Available: https://www.ncirs.org.au/sites/default/files/2022-02/NCIRS%20Administration%20of%20vaccines%20-%20Scope%20of%20practice%20for%20healthcare%20%20professionals_3_02_2022_Final.pdf. [Accessed 1 July 2022].

[5] National Centre for Immunisation Research and Surveillance, "Vaccines from community pharmacy - at a glance," 9 June 2022. [Online]. Available: https://www.ncirs.org.au/sites/default/files/2022-06/NCIRS%20Information%20Sheet-%20Vaccines%20from%20community%20pharmacy_9%20June%202022-Final.pdf. [Accessed 27 June 2022].

[6] NATIONAL COVID-19 VACCINATION PROGRAMME, "Legal mechanisms for administration of the COVID-19 Vaccine(s)," 10 December 2020. [Online]. Available: https://www.england.nhs.uk/coronavirus/wp-content/uploads/sites/52/2020/12/C0923-legal-mechanisms-for-adminstration-of-the-covid-19-vaccines-v2-10-december-2020.pdf. [Accessed 5 July 2022].

[7] C. Schmit and A. Reddick, "Pharmacist Vaccination Laws," The Policy Surveillance Program, 1 January 2016. [Online]. Available: https://lawatlas.org/datasets/pharmacist-vaccination. [Accessed 5 July 2022].

[8] Ministry of Health, "National and DHB immunisation data," 29 April 2022. [Online]. Available: https://www.health.govt.nz/our-work/preventative-health-wellness/immunisation/immunisation-coverage/national-and-dhb-immunisation-data. [Accessed 9 July 2022].

[9] Ministry of Health, "COVID-19: Vaccine data," 17 July 2022. [Online]. Available: https://www.health.govt.nz/covid-19-novel-coronavirus/covid-19-data-and-statistics/covid-19-vaccine-data. [Accessed 19 July 2022].

[10] Ministry of Health, "How is my DHB performing?," 22 June 2022. [Online]. Available: https://www.health.govt.nz/new-zealand-health-system/health-targets/how-my-dhb-performing. [Accessed 9 July 2022].

[11] Health Quality & Safety Commission, "Health System Indicators framework," 15 June 2022. [Online]. Available: https://reports.hqsc.govt.nz/HSI/#!/. [Accessed 9 July 2022].

[12] Ministry of Health, "Immunisation Handbook 2020," 19 May 2022. [Online]. Available: https://www.health.govt.nz/publication/immunisation-handbook-2020. [Accessed 30 June 2022].

[13] "Submission for Reclassification of Dukoral®," Medsafe, July 2011. [Online]. Available: https://www.medsafe.govt.nz/profs/class/Agendas/agen46Vibrio-Cholera.pdf. [Accessed 6 July 2022].

[14] "Submission for Reclassification of Influenza Vaccination," January 2012. [Online]. Available: https://www.medsafe.govt.nz/profs/class/Agendas/agen47Influenza.pdf. [Accessed 6 July 2022].

[15] "Submission for Reclassification of the Combined Diphtheria-TetanusAcellular Pertussis Vaccine for use in Adults," July 2012. [Online]. Available: https://www.medsafe.govt.nz/profs/class/Agendas/agen48Diphteria.pdf. [Accessed 6 July 2022].

[16] "Submission for Reclassification of the Meningococcal Vaccine for use in Adults," January 2013. [Online]. Available: https://www.medsafe.govt.nz/profs/class/Agendas/Agen49Meningococcal.pdf. [Accessed 6 July 2022].

[17] "Submission for Reclassification of the Zoster Vaccine for use in Adults," July 2013. [Online]. Available: https://www.medsafe.govt.nz/profs/class/mccAgenNov2013/6.8-MCC-Zoster-Vaccine-Submission.pdf. [Accessed 6 July 2022].

[18] J. Isenor, T. Alia, J. Killen, B. Billard, B. Halperin, K. Slayer, S. McNeil, D. MacDougall and S. Bowles, "Impact of pharmacists as immunizers on influenza vaccination coverage in Nova Scotia, Canada," *Hum Vaccin Immunother,* vol. 12, no. 5, pp. 1225-8, 2016.

[19] W. Richardson, "A Review of the Pharmacist as Vaccinator," *Innovations in pharmacy,* vol. 10, no. 3, 2019.

[20] J. Grabenstein, H. Guess, A. Hartzema, G. Koch and T. Konrad, "Effect of vaccination by community pharmacists among adult prescription recipients," *Med Care,* vol. 39, no. 4, pp. 340-8, 2001.

[21] C. Anderson and T. Thornley, " "It's easier in pharmacy": why some patients prefer to pay for flu jabs rather than use the National Health Service," *BMC Health Serv Res,* vol. 14, no. 35, 2014.

[22] V. Chan, "Community Flu Fighters in Asian communities - some insights and learnings to share," 2019. [Online]. Available: https://www.immune.org.nz/sites/default/files/pdf/12Community%20Flu%20Fighters%20Vicky%20Chan.pdf. [Accessed 7 July 2022].

[23] Scoop News, "Supporting vaccine programme and ethnic communities," 7 September 2021. [Online]. Available: https://www.scoop.co.nz/stories/GE2109/S00046/supporting-vaccine-programme-and-ethnic-communities.htm. [Accessed 7 July 2022].

[24] Seqirus (NZ) Ltd, "Dukoral New Zealand Datasheet," 8 April 2022. [Online]. Available: https://www.medsafe.govt.nz/profs/Datasheet/d/Dukoralsusp.pdf. [Accessed 14 July 2022].

[25] GlaxoSmithKline NZ Limited, "Boostrix New Zealand Datasheet," 25 June 2020. [Online]. Available: https://www.medsafe.govt.nz/profs/Datasheet/b/Boostrixinj.pdf. [Accessed 14 July 2022].

[26] GlaxoSmithKline NZ Ltd, "Hiberix New Zealand Datasheet," 20 August 2019. [Online]. Available: https://www.medsafe.govt.nz/profs/Datasheet/h/hiberixinj.pdf. [Accessed 14 July 2022].

[27] GlaxoSmithKline NZ Ltd, "Havrix New Zealand Datasheet," 21 January 2019. [Online]. Available: https://www.medsafe.govt.nz/profs/Datasheet/h/Havrixinj.pdf. [Accessed 14 July 2022].

[28] Merck Sharp & Dohme (NZ) Limited, "Gardasil 9 New Zealand Datasheet," 4 March 2020. [Online]. Available: https://www.medsafe.govt.nz/profs/Datasheet/g/gardasil9inj.pdf. [Accessed 14 July 2022].

[29] Seqirus (NZ) Ltd, "Jespect New Zealand Datasheet," 9 February 2021. [Online]. Available: https://www.medsafe.govt.nz/profs/Datasheet/j/jespectinj.pdf. [Accessed 14 July 2022].

[30] GlaxoSmithKline NZ Limited, "Priorix New Zealand Datasheet," 9 November 2021. [Online]. Available: https://www.medsafe.govt.nz/profs/Datasheet/p/Priorixvac.pdf. [Accessed 14 July 2022].

[31] Merck Sharp & Dohme (NZ) Limited, "Pneumovax 23 New Zealand Datasheet," 19 May 2017. [Online]. Available: https://www.medsafe.govt.nz/profs/Datasheet/p/Pneumovax23inj.pdf. [Accessed 14 July 2022].

[32] Sanofi-Aventis New Zealand Limited, "Merieux New Zealand Datasheet," 21 August 2020. [Online]. Available: https://www.medsafe.govt.nz/profs/Datasheet/m/merieuxinj.pdf. [Accessed 14 July 2022].

[33] Merck Sharp & Dohme (NZ) Limited, "Varivax New Zealand Datasheet," 19 April 2022. [Online]. Available: https://www.medsafe.govt.nz/profs/Datasheet/v/Varivaxinj.pdf. [Accessed 14 July 2022].

[34] GlaxoSmithKline NZ Limited, "Shingrix New Zealand Datasheet," 21 June 2021. [Online]. Available: https://www.medsafe.govt.nz/profs/Datasheet/s/shingrixinj.pdf. [Accessed 14 July 2022].

[35] World Health Organisation, "Vaccines and immunisation," [Online]. Available: https://www.who.int/health-topics/vaccines-and-immunization#tab=tab_1. [Accessed 9 July 2022].

[36] J. Fonseca, J. Pearson Sharpe, S. Houle and N. Waite, "Time for harmonization: Pharmacists as immunizers across Canadian jurisdictions," *Can Pharm J (Ott),* vol. 152, no. 6, pp. 395-400, 2019.