Submission for medicine reclassification for consideration by the Medicines Classification Committee

Introduction

Green Cross Health appreciates the opportunity to provide a submission to the 73rd meeting of the Medicines Classification Committee (MCC). Green Cross Health encompasses the Unichem and Life Pharmacies throughout New Zealand. We aim to support the pharmacy profession by empowering our teams to take on new and exciting opportunities and deliver services for the changing needs of our communities.

Kiwis are now looking to holiday overseas more than before with the trends of departures and arrivals in New Zealand increasing every year, reaching pre-COVID levels. With the increase in travel comes the demand from individuals for advice on travel health and prophylaxis vaccinations before travelling. Currently there is a barrier to advice and administration of travel vaccines in the community, especially in certain regions where the workforce pressures are severe. These barriers can leave individuals unvaccinated and unprotected during overseas travel with the potential for them to fall extremely ill, and/or bring with them foreign diseases into New Zealand. Protection from preventable disease does not only benefit the individual but can also have economic benefit for the country, saving time and money in treating conditions, as well as reducing hospitalisations and burden on the already stretched health workforce.

We propose the reclassification of several vaccines that are indicated prior to overseas travel to permit highly trained and capable vaccinating pharmacists to consult, advise, and administer vaccines that are specific for the patient's travel purposes. For clarity, although all vaccines in this submission are referred to as travel vaccines, only typhoid, Japanese encephalitis and yellow fever vaccines have previously been considered by the MCC. The other vaccines, hepatitis A, hepatitis B and poliomyelitis vaccines can be used for other indications, however, for the purpose of this submission we will only relate to administration prior to overseas travel.

The proposed reclassification will affect vaccinators and pharmacists who have successfully completed the Vaccinator Foundation Course (or equivalent course) approved by the Ministry of Health and hold the relevant postgraduate travel medicine qualifications from an approved education facility. Where specific training is required, such is the case for certain live vaccines, the pharmacist vaccinator will also be required to complete the necessary training, set out by the Ministry of Health, before being authorised to provide the live vaccine to the public. The vaccinator will also comply with the immunisation standards of the Ministry of Health for both the storage, distribution, and administrations of the vaccines.

COVID-19 Vaccinators Working Under Supervision, Intern Pharmacist Vaccinators, Provisional Vaccinators, Provisional Pharmacist Vaccinators, and Vaccinating Health Workers are excluded from this submission.

Part A- Regulatory Context and Proposed Classification

1. International non-proprietary (INN) name of the medicine

- Hepatitis A Vaccine
- Hepatitis B Vaccine
- Japanese Encephalitis Vaccine
- Poliomyelitis Vaccine
- Typhoid Vaccine
- Yellow Fever Vaccine

2. Proprietary names (if applicable)

- **Hepatitis A Vaccine**
  - Avaxim (Sanofi)
  - Havrix (GSK)
- **Hepatitis B Vaccine**
  - Energix-B (GSK)
- **Hepatitis A and Hepatitis B**
  - Twinrix (GSK)
- **Hepatitis A and Typhoid**
  - Vivaxim (Sanofi)
- **Japanese Encephalitis Vaccine**
  - Jespect (Seqirus)
- **Poliomyelitis Vaccine**
  - IPOL (Sanofi)
- **Typhoid Vaccine**
  - Typhim Vi 25 (Sanofi)
- **Yellow Fever Vaccine**
  - Stamaril (Sanofi)

This application is from Green Cross Health, a separate company to the sponsors of these vaccinations

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

Green Cross Health Ltd, the parent company for Unichem and Life Pharmacies in New Zealand

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

This submission does not seek to change any of the vaccine's strengths, only to reclassify the vaccines that are currently available.

- **Hepatitis A Vaccine** (suspension for injection)
  - Avaxim (160 AgU/dose suspension for intramuscular injection)
  - Havrix 1440 (1440 ELISA/dose suspension for intramuscular injection)
  - Havrix 720 (720 ELISA/dose suspension for intramuscular injection)

- **Hepatitis B Vaccine** (suspension for injection)
  - Energix-B (20mcg/dose suspension for intramuscular injection)
  - Energix-B (10mcg/dose suspension for intramuscular injection)

- **Hepatitis A and Hepatitis B vaccine** (suspension for injection)
  - Twinrix Adult (720 ELISA/20mcg dose suspension for intramuscular injection)
  - Twinrix Junior (360 ELISA/10mcg dose suspension for intramuscular injection)

- **Hepatitis A and Typhoid** (solution for injection)
  - Vivaxim (160 AgU/25mcg dose suspension for intramuscular injection)

- **Japanese Encephalitis Vaccine** (suspension for injection)
  - Jespect (6 AgU/dose suspension for intramuscular injection)

- **Poliomyelitis Vaccine** (suspension for subcutaneous injection)
  - IPOL (29,7 and 26 D-antigen units of Poliovirus/dose suspension for subcutaneous injection)

- **Typhoid Vaccine** (solution for IM injection)
  - Typhim Vi 25 (25mcg/dose suspension for intramuscular injection)

- **Yellow Fever Vaccine** (suspension for IM or subcutaneous injection)
  - Stamaril (Live 17D Strain 1000IU/dose suspension for intramuscular or subcutaneous injection)

5. Pack size, storage conditions and other qualifications (if applicable)

Hepatitis A Vaccine (suspension for injection)

- **Avaxim** (160 AgU/dose suspension for injection)
  - Single dose prefilled 0.5ml syringe
  - Stored at 2° to 8°C (REFRIGERATE. DO NOT FREEZE).
  - Store protected from light.

- **Havrix** (1440 or 720 ELISA/dose suspension for injection)
  - 0.5 mL (child) or 1 mL (adult) of suspension in a pre-filled syringe (type I glass) with a plunger stopper (butyl rubber) and with a rubber tip cap.
  - OR 0.5 mL (child) or 1 mL (adult) of suspension in a vial (type I glass) with a stopper (butyl rubber).
  - Stored at 2° to 8°C (REFRIGERATE. DO NOT FREEZE).
  - Store protected from light.

Hepatitis B Vaccine (suspension for injection)

- **Energix-B** (20mcg or 10mcg dose suspension for injection)
  - 0.5 mL (child) or 1 mL (adult) of suspension in a pre-filled syringe (type I glass) with a plunger stopper (butyl rubber) and with a rubber tip cap.

- OR 0.5 mL (child) or 1 mL (adult) of suspension in a vial (type I glass) with a stopper (butyl rubber).
- Stored at 2° to 8°C (REFRIGERATE. DO NOT FREEZE).
- Store protected from light.

Hepatitis A and Hepatitis B vaccine (suspension for injection)

- **Twinrix** (720 or 360 ELISA/dose suspension for injection)
  - Single dose prefilled 0.5ml (Junior) or 1ml (Adult) syringe
  - Stored at 2° to 8°C (REFRIGERATE. DO NOT FREEZE).
  - Store protected from light.

Hepatitis A and Typhoid (solution for injection)

- **Vivaxim** (160 AgU/25 mcg dose suspension for injection)
  - Single dose prefilled 1ml syringe
  - Stored at 2° to 8°C (REFRIGERATE. DO NOT FREEZE).
  - Store protected from light.

Japanese Encephalitis Vaccine (suspension for injection)

- **Jespect** (6 AgU/ dose suspension for injection)
  - Single dose (0.5 mL) in a needle-less pre-filled glass syringe
  - Stored at 2° to 8°C (REFRIGERATE. DO NOT FREEZE).
  - Store protected from light.

Poliomyelitis Vaccine (suspension for injection)

- **IPOL** (29,7 and 26 D-antigen units of Poliovirus/dose suspension for injection)
  - Single dose (0.5 mL) in a pre-filled syringe
  - Stored at 2° to 8°C (REFRIGERATE. DO NOT FREEZE).
  - Store protected from light.

Typhoid Vaccine (solution for injection)

- **Typhim Vi 25** (25mcg/dose suspension for injection)
  - Single dose (0.5 mL) in a pre-filled syringe
  - Stored at 2° to 8°C (REFRIGERATE. DO NOT FREEZE).
  - Store protected from light.

Yellow Fever Vaccine (suspension for injection)

- **Stamaril** (Live 17D Strain 1000IU/dose suspension for injection)
  - Single dose lyophilised vaccine vial + (0.5mL) diluent syringe.
  - Stored at 2° to 8°C (REFRIGERATE. DO NOT FREEZE).
  - Store protected from light.

Pharmacies that provide a vaccination service must meet the requirements according to the National Standards for Vaccine Storage and Transportation for Immunisation Providers.

6. Indications for which change is sought (if applicable)

- **Hepatitis A Vaccine**
  - **Avaxim**: Active immunisation against hepatitis A infection in adults and children 2 years and over at risk of infection
  - **Havrix 1440**: Active immunisation against hepatitis A infection in adults **16 years** and over at risk of infection

- **Havrix Junior**: Active immunisation against hepatitis A infection in children 1 to 15 years at risk of infection

- **Hepatitis B Vaccine**

  - **Energix-B:** (adult) Active immunisation against hepatitis B infection in adults **15 years** and over at risk of infection

  - **Energix-B:** (child) Active immunisation against hepatitis B infection in children **10 – 15 years** at risk of infection

- **Hepatitis A and Hepatitis B vaccine**

  - **Twinrix:** (adult) Active immunisation against hepatitis A and B infection in adults **16 years** and over at risk of infection

  - **Twinrix:** (child) Active immunisation against hepatitis B infection in children 1- 15 years at risk of infection

- **Hepatitis A and Typhoid**

  - **Vivaxim**: Active immunisation against typhoid fever and hepatitis A in adults **16 years** and over at risk of infection

- **Japanese Encephalitis Vaccine**

  - **Jespect**: Active immunisation against Japanese encephalitis virus in adults **18 years** and over at risk of infection

- **Poliomyelitis Vaccine**

  - **IPOL**: Active immunisation against Poliomyelitis infection in adults and children **4 years** and over at risk of infection

- **Typhoid Vaccine**

  - **Typhim Vi 25**: Active immunisation against typhoid fever caused by *Salmonella Typhi* in adults and children 2 years and over at risk of infection

- **Yellow Fever Vaccine**

  - **Stamaril**: Active immunisation against yellow fever in adults and children 9 months and over at risk of infection

Note: Vaccines of the same type have various age restrictions due to the doses and contraindications involved, the submission proposes to make the reclassification clear that the lower age limit for each type of vaccine is requested for the purpose of providing coverage for all ages groups. E.g. Hepatitis B vaccine indicated for children 10 years and above.

Further consideration for **Avaxim**, **Havrix Junior**, **Twinrix**, **Typhim Vi**, and **Yellow Fever Vaccine** to have a limit of **3 years and above** to coincide with pharmacist vaccinator's ability to administer via the intramuscular deltoid route.

7. Present classification of the medicine

- Hepatitis A Vaccine
  - Prescription-Only
- Hepatitis B Vaccine
  - Prescription-Only
- Japanese Encephalitis Vaccine
  - Prescription-Only
- Poliomyelitis Vaccine
  - Prescription-Only
- Typhoid Vaccine
  - Prescription-Only
- Yellow Fever Vaccine
  - Prescription-Only

8. Classification sought

Hepatitis A Vaccine

Prescription-Only

except *when administered by vaccinators or registered pharmacists, who have successfully completed the Vaccinator Foundation Course (or any equivalent training course approved by the Ministry of Health), hold the relevant travel medicine qualifications from an approved facility and who comply with the immunisation standards of the Ministry of Health (but excluding vaccinators who have completed the Provisional Vaccinator Foundation Course)*

Hepatitis B Vaccine

Prescription-Only

except *when administered by vaccinators or registered pharmacists, who have successfully completed the Vaccinator Foundation Course (or any equivalent training course approved by the Ministry of Health), hold the relevant travel medicine qualifications from an approved facility and who comply with the immunisation standards of the Ministry of Health (but excluding vaccinators who have completed the Provisional Vaccinator Foundation Course)*

Japanese Encephalitis Vaccine

Prescription-Only

except *when administered by vaccinators or registered pharmacists, who have successfully completed the Vaccinator Foundation Course (or any equivalent training course approved by the Ministry of Health), hold the relevant travel medicine qualifications from an approved facility and who comply with the immunisation standards of the Ministry of Health (but excluding vaccinators who have completed the Provisional Vaccinator Foundation Course)*

Poliomyelitis Vaccine

Prescription-Only

except *when administered by vaccinators or registered pharmacists, who have successfully completed the Vaccinator Foundation Course (or any equivalent training course approved by the Ministry of Health), hold the relevant travel medicine qualifications from an approved facility and who comply with the immunisation standards of the Ministry of Health (but excluding vaccinators who have completed the Provisional Vaccinator Foundation Course)*

Typhoid Vaccine

Prescription-Only

except *when administered by vaccinators or registered pharmacists, who have successfully completed the Vaccinator Foundation Course (or any equivalent training course approved by the Ministry of Health), hold the relevant travel medicine qualifications from an approved facility and who comply with the immunisation standards of the Ministry of Health (but excluding vaccinators who have completed the Provisional Vaccinator Foundation Course)*

Yellow Fever Vaccine

Prescription-Only

except *when administered by registered pharmacists who have successfully completed the Vaccinator Foundation Course (or any equivalent training course approved by the Ministry of Health), and who is authorised by the Director-General or a Medical Officer of Health in accordance with this regulation to administer, for the purposes of an approved immunisation programme, a vaccine that is a prescription medicine, may, in carrying out that immunisation programme, administer that prescription medicine otherwise than pursuant to a prescription.*[62]

9. Classification status in other countries (especially Australia, UK, USA and Canada), and any justification for harmonisation

Canada

Health Canada and the National Association of Pharmacy Regulatory Authorities (NAPRA) both have roles related to drug scheduling/classifications in Canada.[2] Medicines, including vaccines are classified into either Schedule I, Schedule II, Schedule III or Unscheduled.[3] **Schedule I drugs** require a prescription for sale and are provided to the public by the pharmacist following the diagnosis and professional intervention of a practitioner. **Schedule II drugs**, while less strictly regulated, do require professional intervention from the pharmacist at the point of sale and possibly referral to a practitioner.[3] Most vaccines will fall into either Schedule I or Schedule II.[5]

- Hepatitis A Vaccine – I
- Hepatitis B Vaccine – I
- Japanese Encephalitis Vaccine – I
- Poliomyelitis Vaccine – II
- Typhoid Vaccine – I
- Yellow Fever Vaccine – I

Prescribing authority and administering injections by pharmacists is subject to additional training and/or regulatory requirements. CPR training and application to regulatory authority is required in most cases.

An example in Ontario for a pharmacist to administer vaccines they must[64]:

- Successfully complete an OCP-approved course for pharmacist injection education
- Maintain valid certification in CPR and First Aid equivalent to St. John Ambulance or Red Cross Standard First Aid & CPR/AED Level C
- Register their training with the College

Depending on the region, pharmacists can administer vaccines upon completion of the appropriate vaccination training. The training involved in Canada is similar to the level of competencies required for New Zealand registered pharmacists to become pharmacist vaccinators. Additional training for pharmacists in British Columbia to provide travel health advice and services is available through the British Columbia Pharmacy Association. The training allows the pharmacists to meet the level of competence required to provide travel health services.[69] This training through the British Columbia Pharmacy Association is not a requirement to administer vaccines permitted for each region.

Not all provinces in Canada permit pharmacists to vaccinate, the table below shows the regions where pharmacist vaccinators can administer vaccines.[6]

PHARMACISTS' SCOPE OF PRACTICE IN CANADA

✓ Implemented in jurisdiction P Pending legislation, regulation or policy for implementation X Not implemented

		BC	AB	SK	MB	ON	QC	NB	NS	PEI	NL	YT	NWT	NU
Prescriptive Authority (Schedule 1 Drugs)	Independently, for any Schedule 1 drug	X	✓[4]	X	X	X	X	X	X	X	X	X	X	X
	In a collaborative practice setting/agreement	X	✓[4]	✓[4]	✓[4]	X	✓	✓	✓	X	X	X	X	X
Initiate[1,2]	For minor ailments/conditions	✓	✓	✓	✓[4]	✓	✓	✓	✓	✓[4]	✓	✓	X	X
	For smoking/tobacco cessation	✓	✓	✓	✓[4]	✓	✓	✓	✓	✓[4]	✓	✓	X	X
	In an emergency	✓[6]	✓	✓[6]	✓[7]	✓	✓	✓	✓	✓	✓[6]	✓[6]	X	X
Adapt/ Manage[1,3]	Make therapeutic substitution	✓	✓	✓[8]	X	X	✓	✓	✓	✓	✓	✓	X	X
	Change drug dosage, formulation, regimen, etc.	✓	✓	✓[8]	✓	✓	✓	✓	✓	✓	✓	✓	X	X
	Renew/extend prescription for continuity of care	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	X
Injection Authority (SC or IM)[1,4]	Drugs[5]	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	X	X
	Vaccines[5]	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	X	X
	Influenza vaccine	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	X	X
Labs	Order and interpret lab tests	X	✓	P[9]	✓[10]	X	✓	P	P[9]	✓[11]	X	X	X	X
Techs	Regulated pharmacy technicians	✓	✓	✓	✓[12]	✓	X	✓	✓	✓	✓	X	X	X

The table below shows what type of vaccines pharmacist vaccinators can administer in each region, when they have completed the appropriate vaccinator training.

Injection Authority and Vaccine Administration in Pharmacies Across Canada[7]

Relating to the vaccines in this submission, the table above demonstrates that Hepatitis A and Hepatitis B can be administered in a pharmacy by a pharmacist vaccinator when presented with a prescription (schedule I vaccines). Poliomyelitis vaccine is a schedule II vaccine and can be administered in several provinces by a vaccinating pharmacist without a prescription.

New Zealand could consider adopting the same method for pharmacist vaccinators to safely administer vaccines currently not included in scope when presented with a prescription, harmonising with what is allowed in Canada to increase access. The reclassification of vaccines that are of minimal risk to a prescription-with-an-exception when administered by a pharmacist can also provide the same access to the community.

Studies showed when pharmacies in Canada adopted the travel health services, there were key benefits for patients and pharmacists, with a major reason being the ease of access it provided, and the limitation presenting as a lack of prescribing authority pharmacist vaccinators had.[8]

United Kingdom

The Medicines and Healthcare products Regulatory Agency (MHRA) regulates medicines, including vaccines, supplied in the UK. The MHRA decides whether medicines should be granted licences (also known as Marketing Authorisations) and whether licenses can be varied as information about the medicines develops. These decisions are based on safety, quality and effectiveness data submitted.[19]

All vaccines are classified as Prescription Only Medicines (POM) under the legislation (HMR 2012). As such they cannot be supplied and/or administered unless there is a valid prescription/patient specific direction (PSD) or appropriate legal mechanism available.[20] The vaccination training involved in the UK encompass the level of competencies required for New Zealand registered pharmacists to become pharmacist vaccinators, with the addition of specific procedures relating to the country e.g. Patient Specific Direction (PSD) and Patient Group Direction (PGD) competencies. There are also requirements for pharmacist vaccinators in the UK to know correct techniques for intradermal, intranasal, and oral administration of vaccines.[21]

Immunisation training for registered health practitioners is available locally or there is the option to qualify through an experienced training provider that meets the National Minimum Standard and Core Curriculum for Immunisation Training, which pharmacists can complete.[21]

A summary of the different legal mechanisms available below, where a pharmacist vaccinator can administer vaccines without a prescription once they have completed the vaccinator training:

- Option 1: National Protocol
- Option 2: National Patient Group Direction (PGD)
- Option 3: Patient Specific Directions (PSDs)

COVID-19 vaccine administration in the UK currently uses the National Protocol and PDG pathway, and it is possible to use the same pathway for travel vaccines if needed, however, this is not currently practiced on a national level.[22] The PGD is similar to a standing order in New Zealand, where a standing order could provide a pathway for the vaccines in this submission to be delivered improving access for travellers.

Some pharmacies in the UK in certain regions currently provide travel clinic consultations and vaccine administrations (on PGD or PSD) through pharmacy.[23,24] To become a specialist travel health pharmacist in the UK, there are additional training requirements to ensure that the level of practice and expertise should always be the same across all professions to ensure competence.[70] The Royal College of Physicians and Surgeons of Glasgow (RCPSG) advise that all practitioners who practice travel medicine should cover the below standard in their training[70]:

- An overview of Travel Medicine
- How services are organised including NHS/private provisions
- Standards for practice
- What a consultation should aim to achieve
- Travel Medicine Resources available and how to use them
- The importance of risk assessment in a pre-travel consultation and how a consultation should be structured
- Tools to support practice
- Risk of vaccine and non-vaccine preventable diseases abroad
- Challenges that you could experience in practice

This submission proposes that pharmacist vaccinators in New Zealand will be required to complete additional specialist training through an approved education facility to meet appropriate competency standards and administer travel vaccines.

Australia

The Therapeutic Goods Administration (TGA) is responsible for assessing vaccines and other medicines before they can be used in Australia. The TGA only register a vaccine for use in Australia if its benefits are much greater than its risks.[9] There are 10 schedules in Australia, for the purpose of this submission only Schedules 2, 3 and 4 are of relevance. Schedule 2 medicines are pharmacy-only, schedule 3 medicines are pharmacist-only and schedule 4 medicines are classed as prescription-only medicines or prescription animal remedy.[10,11] All vaccines in this submission are classed as schedule 4 medicines.

- Hepatitis A Vaccine – S4
- Hepatitis B Vaccine – S4
- Japanese Encephalitis Vaccine – S4
- Meningococcal Vaccine – S4
- Poliomyelitis Vaccine – S4
- Typhoid Vaccine – S4
- Yellow Fever Vaccine – S4

For a pharmacist to become a vaccinator they must complete a training course that complies with the Australian Pharmacy Council 'Standards for the Accreditation of Programs to Support Pharmacist Administration of Vaccines'. The pharmacist vaccinator must hold this certificate confirming competency to vaccinate following completion of an accredited training program for all authorised vaccines that they intend to administer. They must also hold a cardio-pulmonary resuscitation (CPR) certificate issued within the last 12 months. If the pharmacist is administering vaccines to people aged less than 14 years of age, the CPR certificate must include paediatric CPR training.[16] The training involved in Australia is very similar to the competencies required for New Zealand registered pharmacists to become pharmacist vaccinator.

A pharmacist vaccinator can administer certain vaccines without a prescription under the Medicines, Poisons and Therapeutic Goods Regulation 2008.[12] A pharmacist vaccinator in Australia may vaccinate adults and children 5 years and above against conditions listed in Table 1 – Approved Vaccines (below) of the ACT Pharmacist Vaccination Standards (Vaccination Standards) provided they comply with all aspects of the Vaccination Standards. For the vaccines related to this submission Hepatitis A, Hepatitis B, Poliomyelitis and Typhoid vaccines are part of the National Immunisation Programme (NIP) and can be administered by pharmacists across Australia without a prescription.[14]

An intern pharmacist may also vaccinate against these conditions provided they do so in accordance with the Vaccination Standards and under the supervision of a pharmacist who is authorised to administer the vaccine.[13]

Additional training for pharmacists in Victoria to provide travel health advice and services is available through the Pharmaceutical Society of Australia. The training allows the pharmacists to meet the level of competence required to provide travel health services. [68]

Table 1: Approved Vaccines[14]

Column 1 Approved Substance	Column 2 Person age
SARS-COV-2 (COVID-19) vaccine	5 years and older
Diphtheria toxoid	5 years and older
Tetanus toxoid	5 years and older
Pertussis antigen	5 years and older
Haemophilus influenzae vaccine	5 years and older
Hepatitis A (Hep A) vaccine	5 years and older
Hepatitis B (Hep B) vaccine	5 years and older
Human papillomavirus (HPV) vaccine	10 years and older
Influenza vaccine	5 years and older
Measles vaccine	5 years and older
Mumps vaccine	5 years and older
Rubella vaccine	5 years and older
Meningococcal vaccine (ACWY) (quadrivalent) conjugate vaccine	5 years and older
Meningococcal B vaccine	5 years and older
Meningococcal C vaccine	5 years and older
Inactivated poliomyelitis vaccine	5 years and older
Respiratory syncytial virus (RSV) vaccine †	60 years and older
Typhoid vaccine	5 years and older
Varicella vaccine	5 years and older
Zoster vaccine Recombinant Varicella zoster virus glycoprotein e antigen vaccine (Shingrix recombinant vaccine brand only)	50 years and older

Pharmacist vaccinators in New South Wales (with additional training), Queensland, South Australia, and Victoria, can also administer Japanese encephalitis vaccine from the list related to this submission without a prescription.[15,16,17,18]

New Zealand could consider adopting the same method for pharmacist vaccinators to safety administer a wider range of vaccines by expanding what is in the New Zealand national schedule, harmonising with the Australian approved vaccine list.

United States of America

All U.S. states permit pharmacist vaccinators to administer vaccines, however, state laws differ on the details of this authorisation. The Public Readiness and Emergency Preparedness (PREP) Act authorisations have precedence over state regulations during times of public emergency, which included the COVID-19 pandemic. Pharmacist vaccinators in community pharmacy can vaccinate their communities based on each states age regulations for influenza and COVID-19.[25]

Vaccinator training requires pharmacists to complete a practical program of at least 20 hours that is approved by the Accreditation Council for Pharmacy Education (ACPE). This training program must include hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines.[26]

Prescription requirements and administration authority for routine vaccinations in adults also differ among states. Seventeen states allow pharmacists to prescribe vaccines, and 32 states allow administration via a prescriber-approved protocol or non–patient-specific order. Some states have specific requirements for certain vaccines.[25]

Pharmacists in Arizona, Iowa and Maryland can administer vaccines recommended by CDC Health Information for International Travel without a prescription. Administration authority excludes other vaccines.[27]

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

Sales volume for each of the vaccines in this submission are unavailable due to restrictions. The vaccines in the submission are also outside the National Immunisation Schedule (NIS) and access to this information for private vaccines are not readily available to the public. An OIA request was submitted through Health New Zealand to the Aotearoa Immunisation Register (AIR). At the time of submission, this information was not received.

However, it is evident that overseas travel habits for Kiwis are returning to pre-COVID levels, meaning there is an increasing need for access for travel advice, prophylaxis treatment and vaccinations. We expect as the number of departures and arrivals into New Zealand are increasing (evident with the local data in the next section), the sales number for all travel vaccines are also increasing.

Date of consent to distribute, located on individual datasheets:[1,4,32,34,48,49,50,51,52,53]

- Hepatitis A Vaccine
  - Avaxim - 1/3/2001
  - Havrix 1440 - 24/2/1994
  - Havrix Junior - 12/9/1996
- Hepatitis B Vaccine
  - Energix-B (adult/child) - 24/3/1988
- Hepatitis A and Hepatitis B vaccine
  - Twinrix: (adult/child) – 15/10/1998
- Hepatitis A and Typhoid
  - Vivaxim – 5/8/2004
- Japanese Encephalitis Vaccine
  - Jespect – 18/10/2012
- Poliomyelitis Vaccine
  - IPOL – 17/7/1997
- Typhoid Vaccine

    - Typhim Vi 25 – 17/11/1994
- Yellow Fever Vaccine
    - Stamaril – 6/11/1997

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

The vaccinating workforce in New Zealand is quite diverse, consisting of[71]:

- Regulated healthcare professionals
- Non-regulated healthcare professionals
- COVID-19 vaccinators

Pharmacists in New Zealand sit under the banner of regulated healthcare workers and must complete an approved vaccinator training programme through the Immunisation Advisory Centre (IMAC), complying with the immunisation standards of the Ministry of Health to administer a range of specified vaccines.[72] Pharmacist vaccinators can currently administer age-restricted Influenza, COVID-19, Meningococcal B, Meningococcal ACWY, Human papillomavirus, Varicella zoster, Tdap and the live MMR vaccine without a prescription. [72]

Pharmacist vaccinators must maintain all documentation and evidence that demonstrates their conformance with the Ministry's Immunisation Standards for Vaccinators, as outlined in the Immunisation Handbook. This includes evidence of their clinical assessment, current APC, CPR and all training courses, including biennial Vaccinator Update Course.[65] Training involved, and competency standards required before a pharmacist can become a vaccinator is similar to the requirements for pharmacists in Canada, UK, Australia and the U.S.

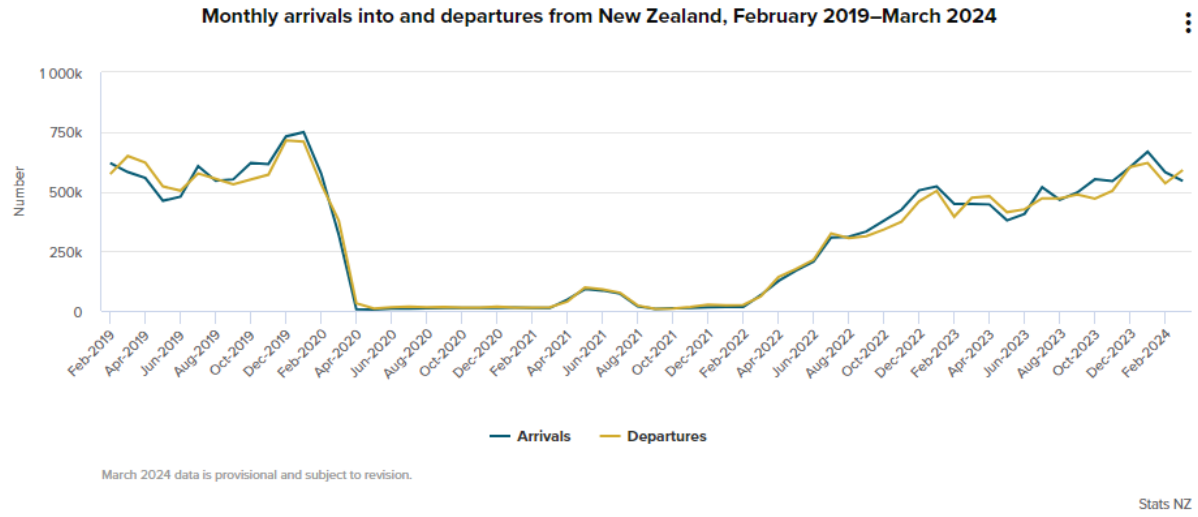
Intern pharmacists can complete a vaccinator training course through IMAC, however restrictions through the Medicines Regulations 1984 does not allow them to administer the full range of vaccines that pharmacist vaccinators can administer without a prescription. Intern pharmacists can administer age restricted Influenza, COVID-19, Human papillomavirus, and the live MMR vaccine.[72]

New Zealand pharmacist vaccinators now have the option to extend their skills and become a fully authorised vaccinator upon completion of additional training and clinical assessment through IMAC, increasing pharmacist vaccinators scope to deliver vaccines on the National Immunisation Schedule for all age groups.[73]

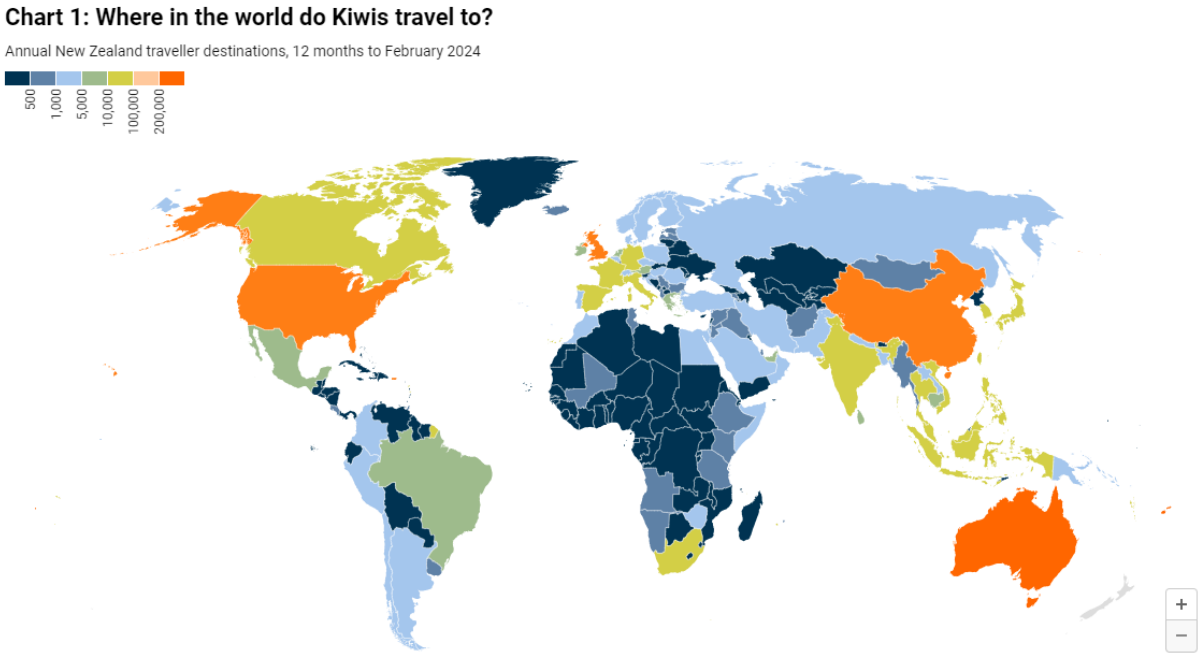
Healthpoint lists 536 locations across New Zealand that offer travel services, including facilities that offer travel consultations without vaccinations, potentially over representing the access the public have for travel vaccines.[28] Many of the sites (471) are located in the North Island, with the rest (65) in the South Island. There is added pressure on the already stretched workforce in the South Island and could potentially leave individuals unvaccinated against diseases that they will be exposed to during overseas travel.

The below table shows the increase in travel trends for Kiwis over the last few years, showing that travel habits have almost returned to pre-pandemic rates. The Ministry of Business Innovation & Employment (MBIE) predict that tourism is set to return at pace.[29]

Monthly arrival into and departure from New Zealand[30]



The image below shows which countries Kiwis prefer to travel to[31]



Vaccines in this submission have been include by considering the travel habits of Kiwis and their likelihood of being exposed to specific diseases in various countries.

12. Labelling or draft labelling for the proposed new presentation(s) (if applicable)

The vaccines in this submission will not need to be relabelled as they are not available for purchase to the public. They will continue to be classified as a prescription-only medicine until the point of provision by the pharmacist vaccinator.

13. Proposed warning statements (if applicable)

The current warning statements for injectable vaccines included in this submission are detailed below, there is no need for additional warning statements as the vaccines are not available to the public for purchase.

Warning statements that will continue for all injectable vaccines in this submission include:

- Appropriate medical treatment and supervision should always be readily available in case of a rare anaphylactic event following the administration of the vaccine.
- Caution should be exercised when the vaccine is administered to subjects with hypersensitivity to active ingredients and excipients in the vaccine bearing in mind contact with any other component involved in the administration (e.g., latex gloves)
- Syncope (fainting) can occur following, or even before, any vaccination as a psychogenic response to the needle injection. It is important that procedures are in place to avoid injury from faints.[32]
- Live vaccines such as the Yellow Fever Vaccine are contraindicated in pregnant women, people with anaphylaxis to a previous dose of the vaccine or vaccine ingredient, and some people with immune system dysfunction.[33]
- Most of vaccines in this submission are administered intramuscularly, these vaccines must be administered with caution to individuals with thrombocytopenia or bleeding disorders since bleeding may occur following an administration to these individuals.[34]
- Under no circumstances should any of the vaccines in this submission be administered intravenously

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

All products included in this submission listed are only indicated and available as vaccines for administration, therefore will not affect any other products available.

Part B- Clinical Context and Implications

15. Indications and dose

- **What is the medicine indicated for, and for which indication(s) is the reclassification application for?**

All the vaccines in this submission are currently classified as prescription only medicine/vaccine indicated to stimulate the development of immunity toward a specific infectious agent.

The reclassification of the listed vaccines will propose the same indication for active immunity against a specific infection, in a situation where the individual is travelling to a country where the risk is high, with restrictions on age, based on the type of vaccine.

- **What is the evidence that the proposed indication is an OTC indication i.e., that the diagnosis and treatment can be understood by the consumer; that the risks of inappropriate treatment can be minimised?**

The intention of this submission is to reclassify the vaccines from prescription-only to a prescription only medicine, except under specific circumstances, be provided by a vaccinator or registered pharmacist who has completed the appropriate trainings. The understanding of diagnosis and treatment will not be affected by the reclassification as these vaccines cannot be purchased directly by the public.

- **What is the treatment population for the indication (age, gender etc.)?**

The treatment populations will include all people who are travelling to countries where there is susceptibility to specific infection, excluding those that are contraindicated for the specific vaccine whether it be due to age (minimum of 3 years and above) or other existing conditions.

- **What is the dose and dose frequency of the medicine for this indication?**

Each vaccines' dose is available as a proprietary product in the appropriate dosing for an adult and in some instances, for a child. In this submission, all vaccines involved are related to dosing specified by the manufacturer for the appropriate age groups.

Where the dosing schedule is for travelling purposes, the datasheet outlines the number of doses and frequency required. When there is a need to reconstitute and adjust doses, this will be outlined in the packaging provided.

- Hepatitis A Vaccine (suspension for injection)
  - **Avaxim** (160 AgU/dose suspension for IM injection)
    - Single dose of 0.5ml for adults and children
  - **Havrix** (1440 or 720 ELISA/dose suspension for IM injection)
    - Single dose of 0.5 mL (child) or 1 mL (adult) of suspension

- Hepatitis B Vaccine (suspension for injection)
  - **Energix-B** (20mcg dose suspension for IM injection)
    - 3 doses of 1 mL (adult) suspension used as scheduled below, when in areas of high risk:
    - 1st dose: At elected date
    - 2nd dose: 1 month later
    - 3rd dose: 2 months from the date of the first dose.

- Hepatitis A and Hepatitis B vaccine (suspension for injection)
  - **Twinrix** (720 ELISA/dose suspension for IM injection)
  - 1ml (Adult) single dose for adults 16 and above as rapid schedule for travellers.
    - 1st dose: At elected date
    - 2nd dose: 7 days later
    - 3rd dose: 21 days later

- Hepatitis A and Typhoid (solution for IM injection)
  - **Vivaxim** (160 AgU/25 mcg dose suspension for injection)
    - Single dose of 1 mL for adults 14 days prior to travel

- Japanese Encephalitis Vaccine (suspension for IM injection)
  - **Jespect** (6 AgU/ dose suspension for injection)
    - 2 doses 0.5 mL given 28 days apart

- Poliomyelitis Vaccine (suspension for subcutaneous injection)
  - **IPOL** (29,7 and 26 D-antigen units of Poliovirus/dose suspension for subcutaneous injection)
    - Single dose (0.5 mL) given if 10 years have elapsed since the last dose and exposure is possible.

- Typhoid Vaccine (solution for IM injection)
  - **Typhim Vi 25** (25mcg/dose suspension for IM injection)
    - Single dose of 0.5 ml in adults and children

- Yellow Fever Vaccine (suspension for IM or subcutaneous injection)
  - **Stamaril** (Live 17D Strain 1000IU/dose suspension for IM or subcutaneous injection)
    - Single dose of 0.5 ml in adults and children

16. Presentation

- **What is the proposed dose form and strength of the medicine to be reclassified? Is this the same for all indications?**

All the vaccines are readily available in their dosage forms, with some needing to be reconstituted before administration. There is only one indication for the purpose of this submission for each of the vaccines, which is to develop immunity against the infectious agent for individuals that are at risk due to overseas travel.

Below are the listed dose forms, and strengths of each vaccine:

- Hepatitis A Vaccine (suspension for injection)
  - Avaxim (160 AgU/dose suspension for injection)
  - Havrix (1440 or 720 ELISA/dose suspension for injection)

- Hepatitis B Vaccine (suspension for injection)
  - Energix-B (20mcg/dose suspension for injection)

- Hepatitis A and Hepatitis B vaccine (suspension for injection)
  - Twinrix (720 ELISA/dose suspension for injection)

- Hepatitis A and Typhoid (solution for injection)
  - Vivaxim (160 AgU/25 mcg dose suspension for injection)

- Japanese Encephalitis Vaccine
  - Jespect (6 AgU/dose suspension for injection)

- Poliomyelitis Vaccine
  - IPOL (29,7 and 26 D-antigen units of Poliovirus/dose suspension for injection)

- Typhoid Vaccine
  - Typhim Vi 25 (25mcg/dose suspension for injection)

- Yellow Fever Vaccine
  - Stamaril (Live 17D Strain 1000IU/dose suspension for injection)

- **What disposal considerations need to be made for the medicine?**

All vaccines are required to be disposed via a sharps container according to the guidelines set out in the Immunisation Handbook 2024 [page 633]. Vaccinating pharmacists are familiar with this practice and have the appropriate processes for dealing with disposal of vaccines. No additional considerations for disposal are required.

- **How practical and easy to use is the proposed presentation?**

There will be no change to the presentation of the vaccines upon approval of this submission.

17. Consumer benefits

- **What is the history of this medicine's use for the proposed indication(s) i.e., number of users; number of countries used in?**

The World Health Organisation (WHO) state that certain vaccines are recommended to provide protection against diseases endemic to the country of origin or of destination.[35] The Immunisation Handbook also recommends those that are travelling, including students entering the country for study, have their vaccines administered appropriate for the country.[36] Travel vaccines are extensively used

throughout the world to decrease the spread of infections. Some countries require proof of vaccination from travellers, protecting and preventing the incidence of diseases into their country. The first proof of immunisation to travel dates back to 1769 developed for smallpox.[37]

Hepatitis A vaccine for example is one of the most used vaccines in preventing disease in travellers. The number of imported cases in developed countries decreased substantially over the last two decades, partially due to integration of the vaccine into childhood immunisation programmes, improvement of sanitation and access to clean water in many areas. However, the decrease was mainly attributed to the vaccination of travellers against hepatitis A.[37]

- **To what extent is this medicine used for the proposed indication(s) i.e., duration of use; frequency of use?**

Travel vaccinations are recommended by the World Health Organisation (WHO), and most vaccines are straightforward to administer with a consultation, whereas others required more clinical involvement and education. Although some vaccines in this submission have other indications, when required for an individual that is travelling, the need is easily determined, and vaccines are scheduled accordingly. Certain vaccines in this submission are solely indicated for individuals travelling to high-risk countries.

- **What is the evidence that improved access is beneficial for the individual?**

In light of the COVID-19 pandemic, there is increased awareness of the importance of protection through immunisation.

Pharmacists are widely acknowledged to be an underused resource in the health care system. A report from the United Nations showed that 8% of travellers needed medical care during their trips or after returning home, much of which was preventable through prophylactic use of medicines and/or vaccines.[38]

Having appropriate access to travel vaccines provides immunity for the individual from acquiring infections, preventing hospital visits while overseas or death from diseases that are preventable.[63] It also allows the vaccinated individual to enjoy their trip overseas without the risk of health complications.

Depending on the vaccine, the individual is immune against the disease, not only for course of the trip, but for many years after. Clinical trials have shown that immunisation against hepatitis A after the second dose gives protection that lasts for 17 years, possibly up to 30-40 years in some cases.[41] For an avid traveller, the ease of access through community pharmacy will give them the opportunity to access the additional doses, allowing protection in various countries for multiple trips.

- **What is the evidence of improved consumer involvement in their health?**

Pharmacists can already provide oral vaccines such as the Cholera (as Dukoral) and Haemophilus influenzae (as Buccaline) without requiring any additional training. These oral vaccines are classified as prescription only except when provided by a pharmacist for specific indications. Reclassification of the travel vaccines in this submission is proposed in a similar way, but with additional training. Community pharmacies in New Zealand have the benefit of offering travel vaccines on top of the advice and treatments already available through pharmacists as done in other countries. Encouraging additional training for pharmacists in the travel clinic space has the potential to facilitate discussion on overall preparedness for overseas travel for consumers through an accessible convenient environment.

A 2011 study at a U.S-based university travel health clinic demonstrated that pharmacists with appropriate training provided superior evidence-informed clinical recommendations prescribing individuals antibiotics for travellers' diarrhoea when indicated 96% of the time. Furthermore, patients seen by the pharmacist travel specialist received their medications 75% of the time when prescribed antibiotics for their travellers' diarrhoea compared to 63% with other care groups.[38]

- **What are the benefits from a consumer viewpoint?**

The reclassification of the listed vaccines has the potential to increase the opportunities for the public to access several travel vaccines, decreasing wait times and missed opportunities as travel vaccine appointments need to be booked at least 8 weeks in advance before due travel.[40]

A survey of 53 community pharmacists in Alberta, Canada, in 2012 found that 1 in 4 respondents reported counselling a patient on a travel-related topic at least once per week, increasing to 69% of respondents doing so at least monthly. As international travel rates continue to grow, so too will opportunities for pharmacists to interact with individuals who are planning travel.[74]

Greater access to travel consultations and vaccinations through community pharmacy will increase patient awareness regarding the need for pre-travel health advice and immunity, impacting not only protection against vaccine preventable diseases, but also preparing travellers on for the broader risks they may encounter. Anti-diarrhoea medicines, water purification tablets and oral rehydration therapy are readily available in community pharmacy, combined with the benefit of a travel consultation clinic in pharmacy, presents the option of timely convenience for the individual. Nine studies done across the U.S., Canada and the UK showed that consumers had high levels of satisfaction (94-100%) with the pharmacist-managed travel health services.[67]

A travel consultation can also offer the patient critical advice on prevention of infections where a vaccine is currently unavailable, such as malaria, dengue, Zika and other diseases. Referral will be a key element to ensure that travellers receive prophylaxis as necessary by working with GP colleagues, achieving collaborative care for the patient.

18. Contraindications and precautions

General considerations for vaccines in this submission

- **What are the contraindications for the medicine and how easy are they to identify and prevent?**

Contraindications for a particular vaccine are generally uncovered during a consultation with the individual, and pharmacist vaccinators are well trained in navigating resources and datasheets for the required vaccine(s) to identify when its administration is not suitable for the individual.

The Immunisation Handbook 2024 [page 624] outlines the process to identify contraindication and precautions for each vaccine and provide this for each disease condition.

In addition to this, pharmacist vaccinators will be trained through the appropriate postgraduate travel medicine programme, having the knowledge of red flags, contraindications and precautions for each vaccine to allow them to provide the appropriate advice, consultation and administration of the vaccines safely.[42]

As with any vaccine, there is a risk of anaphylaxis. It is mandatory that pharmacies that provide a vaccination service, hold adrenaline and other emergency equipment used in the treatment of anaphylaxis and acute reactions and pharmacist vaccinators are trained and complete regular two yearly first aid and emergency management updates.[43]

- **What are the precautions for this medicine and how easy are these to understand?**

Specific precautions for individual vaccines are available in the Immunisation Handbook 2024, in addition to the relevant datasheets. In individuals with thrombocytopenia or a bleeding disorder, a vaccine should be administered by subcutaneous route since bleeding may occur

following an intramuscular administration to these individuals.

If co-administration with other vaccines is indicated, injections should be given into separate limbs, and this information is outlined on each datasheet where applicable.

- **Does the medicine have a low therapeutic index?**

Vaccines do not have a low therapeutic index, however, will need to be administered with caution in patients that are taking other medications with a low therapeutic index due to potential reduction in the activity of specific CYPs following vaccination.[44]

- **What class effects need to be considered and what are the risks?**

Yellow Fever vaccine is classed as a live strain vaccine and should not be given to those who are contraindicated to receive live vaccines, i.e. immunocompromised and pregnant women.[45,46]

Immunisation of special groups will always need to be considered prior to vaccination, and these include immunocompromised and pregnant women as stated above, and those with specific conditions outlined in Chapter 4 of the Immunisation Handbook 2024.[66]

Most of the vaccines in the submission are administered intramuscularly. There are vaccines in this submission where subcutaneous administration may be required. Pharmacist vaccinators are trained to administer vaccines via the subcutaneous route safely.

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

In general, there are several reasons to avoid excess alcohol consumption after a vaccination. Excess alcohol consumption can potentially mask the side effects of the vaccine and make it difficult to determine which side effects are attributable to the vaccine or alcohol.[47]

Excessive alcohol consumption on a regular basis may also affect the immune system. Research has shown that alcohol intake of 15 or more drinks per week for men and 8 or more drinks per week for women may suppress the immune system along with other factors such as smoking, a lack of sleep and a poor diet.[47]

- **Are there any other restrictions when taking the medicine i.e., driving restrictions or operating machinery?**

Although vaccines do not normally interfere with an individual's ability to drive a car or operate machinery, it is advisable to understand how each vaccine affects the individual, as in some, vaccinations can cause dizziness or lightheadedness.[48]

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

Chapter 4 of the Immunisation Handbook 2024 discusses special populations and the additional steps to be taken to administer vaccines safely.[66]

The relevant datasheets will determine the excipients of each vaccine brand, and pharmacist vaccinators are trained to determine what is of concern for the individual if exposed to the ingredient and advise accordingly. The pharmacist vaccinator will exercise their professional judgement to ascertain whether the vaccine is indicated for the individual. All vaccines should be postponed in individuals suffering from acute severe febrile illness.

Specified considerations for vaccines in this submission, in addition to the above.

Hepatitis A Vaccine

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

Administration of this vaccine during pregnancy is not recommended. The vaccine should be given to pregnant women only if clearly needed and following an assessment of the risks and benefit.

No data on the use of Vivaxim in children and adolescents aged below 16 years is available. Immunogenicity and clinical experience with Vivaxim in the elderly is limited.[49]

Hepatitis B Vaccine

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

Patients with chronic liver disease e.g. alcoholic liver disease, chronic biliary cirrhosis, chronic active hepatitis, etc., should not be precluded from vaccination against hepatitis B. In these patients, hepatitis B vaccination should be considered on a case-by-case basis.

Adequate human data on the use during pregnancy and adequate animal reproduction studies are not available. Adequate human data on the use during lactation and adequate animal reproduction studies are not available. The vaccinator should discuss the possible risks and benefits before administering TWINRIX during pregnancy.[50]

Japanese Encephalitis Vaccine

- **What other drug interactions need to be considered?**

In individuals receiving immunosuppressive therapy or individuals with immunodeficiency, an adequate immune response may be diminished.[51]

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

There are limited data from the use of JESPECT in pregnant women. The vaccine should be used during pregnancy only when clearly needed and the possible advantages outweigh the possible risks for the fetus.[51]

It is not known whether vaccine antigens or antibodies induced by the vaccine are excreted in human milk. Therefore, caution should be exercised when JESPECT is administered to a nursing woman.[51]

Poliomyelitis Vaccine

- **What other drug interactions need to be considered?**

As each dose may contain undetectable traces of neomycin, streptomycin sulfate and polymixin B sulfate which are used during vaccine production, caution should be exercised when the vaccine is administered to subjects with hypersensitivity to these antibiotics (and other antibiotics of the same classes). As with other injectable vaccines, appropriate medical treatment and supervision should always be available in case of anaphylactic reactions.

The immunogenicity of IPOL could be reduced by immunosuppressive treatment or immunodeficiency.[52]

Typhoid Vaccine

- **What other drug interactions need to be considered?**

No data on the use of Vivaxim in children and adolescents aged below 16 years are available. Immunogenicity and clinical experience with Vivaxim in the elderly is limited.[49] Data concerning use with other vaccines are limited. However, no interaction is anticipated when vaccines are given at separate sites using separate syringes.

The immunogenicity of Typhim Vi could be reduced by immunosuppressive treatment or immunodeficiency. Vaccination of individuals with chronic immunodeficiency, such as HIV infection, is recommended even if the antibody response might be limited.[34]

Yellow Fever Vaccine

- **What other drug interactions need to be considered?**

To avoid reduction in serological responses, another live vaccine, if not given concurrently with Stamaril, should be given after four weeks have elapsed

Stamaril should not be administered to individuals with a congenital or acquired immune deficiency that impairs cellular immunity.[53] This includes individuals receiving immunosuppressive therapies, such as chemotherapy or high doses of systemic corticosteroids or any other medicinal products including biologicals with known immunosuppressive or immunomodulating properties.

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

Stamaril should not be administered to children less than 6 months of age due to the risk of encephalitis.[53]

Stamaril should not be administered to symptomatic HIV-infected individuals.[53]

Stamaril should not be administered to HIV-infected individuals who are asymptomatic when accompanied by evidence of impaired immune function.[53]

Stamaril should not be administered to individuals with a history of thymus dysfunction (including myasthenia gravis, thymoma or thymectomy (for any reasons).[53]

Thymectomy and thymus disease have been identified as potentially influencing the development of yellow fever vaccine-associated viscerotropic disease. Healthcare providers are advised to ask for a history of thymus dysfunction prior to administering yellow fever vaccine. Alternative means of prevention for such individuals are to be considered. Individuals with rare hereditary problems of fructose intolerance should not take this vaccine.[53]

For individuals following an immunosuppressive treatment, it is recommended to delay the vaccination until the immune function has recovered. In individuals taking high doses of systemic corticosteroids, it is advisable to wait for at least one month. Individuals following other immunosuppressive treatments should seek advice from a specialist.[53]

Individuals aged 60 years and older may have an increased risk of serious adverse events (systemic or neurological reactions persisting more than 48 hours), including YEL-AVD and YEL-AND, compared to other age groups.[53]

Stamaril must not be administered to individuals with symptomatic HIV infection or with asymptomatic HIV infection when accompanied by evidence of impaired immune function.[53]

In individuals with thrombocytopenia or a bleeding disorder, the vaccine should be administered by subcutaneous route since bleeding may occur following an intramuscular administration to these individuals.[53]

Stamaril should not be used in pregnant and breast-feeding women, unless when clearly needed, and following an assessment of the risks and benefits.[53]

Before considering administration of yellow fever vaccine, care should be taken to identify individuals who might be at increased risk of adverse reactions following vaccination.[53]

19. Undesirable effects

Immunisation Handbook 2024 [page 31] outlines general adverse events experienced through vaccine administration below[54]:

- Injection-site reactions
- Well-recognised events, such as headaches, dizziness, muscle aches, mild fever and tiredness
- Mild allergic reactions, such as mild rashes and itching
- Rare but serious allergic reactions, called anaphylaxis, which can occur in response to any medicine or vaccine and some foods – health care professionals giving vaccines are trained to recognise the symptoms of serious allergic reactions and promptly treat them
- Immunisation stress-related responses due to fear or anticipation of the needle injection (e.g., fainting or hyperventilation)
- Coincidental medical conditions
- New adverse events (i.e., those not already listed in the prescribing information [datasheet]).

Hepatitis A Vaccine, Hepatitis B Vaccine, Japanese Encephalitis Vaccine and Typhoid Vaccine
Undesirable effects of the vaccines and its frequencies are listed in the datasheet for each individual product and in the New Zealand Formulary (NZF). The information includes the consequences of these effects and risks for the patient.

Poliomyelitis Vaccine
Undesirable effects of the vaccines and its frequencies are listed in the datasheet for each individual product and in the New Zealand Formulary (NZF). The information includes the consequences of these effects for the patient.
Potential safety concerns for the vaccine include:

- Blood and lymphatic system disorders
- Nervous system disorders
- Psychiatric Disorders

Although no causal relationship between IPOL and Guillain-Barre Syndrome (GBS) has been established, GBS has been temporally related to administration of another inactivated Poliomyelitis vaccine (IPV).

Yellow Fever Vaccine
Undesirable effects of the vaccines and its frequencies are listed in the datasheet for each individual product and in the New Zealand Formulary (NZF). The information includes the consequences of these effects for the patient.
Potential safety concerns for the vaccine include:

- Blood and lymphatic system disorders
- Nervous system disorders
- Infections and infestations

20. Overdose

Hepatitis A Vaccine
Cases of administration of more than the recommended dose (overdose) have been reported with Avaxim. Adverse events reported following overdosage were similar to those reported with normal vaccine administration

Hepatitis B Vaccine
Cases of overdose have been reported during post-marketing surveillance. Adverse events reported following overdosage were similar to those reported with normal vaccine administration

Yellow Fever Vaccine
Cases of administration of more than the recommended dose (overdose) have been reported with Stamaril. When adverse reactions were reported, the information was consistent with the known safety profile of Stamaril.

There is no data or cases of overdosage reported for the following vaccines:

- Japanese Encephalitis Vaccine
- Poliomyelitis Vaccine
- Typhoid Vaccine

Vaccines do not have a low therapeutic index and are pre-packaged into the appropriate dosing units; the possibility of an overdose is generally very small. There are situations where additional administration may occur due to programmatic error, there is little data available on the safety of and extra dose of a vaccine.[55]

With the introduction of the AIR, a vaccinator is required to establish the individual's vaccination history/status prior to administration of any vaccine, minimising the possibility of unnecessary additional doses.

21. Medication errors and abuse/ misuse potential

Undesirable effects and vaccine overdose are the main issues of concern in post-market findings. The majority of vaccines have a wide therapeutic range, and in addition to this, many of them are available in their appropriate dosage forms and quantities making the likelihood of an overdose generally very small.[55]

Most vaccines will be supplied ready to be administered, others may need to have needles attached or the vaccine reconstituted. Handling needles always carries a risk of needle-stick injuries for both the patient and the pharmacist vaccinator. Pharmacies providing a vaccination service and pharmacist vaccinators are already well-versed in managing adverse events and incidents. They are also familiar with the standard operating procedures for immunisations and the cold chain, and they meet the minimum staffing and equipment requirements outlined in the Immunisation handbook 2024 [page 615].

Increasing access to the listed vaccines in this submission through reclassification will still be authorised and administered by a healthcare professional who has completed the appropriate postgraduate travel studies, not compromising the level of safety that currently exists. The potential of risk and abuse will be heavily mitigated by the direct involvement that they have.

22. Communal harm and/or benefit

- **What are the possibilities of community benefit resulting from wider use of the medicine in question (e.g., greater herd immunity as a result of improved access to a communicable disease vaccine)?**

Benefits

The study, led by the World Health Organisation (WHO), shows that immunisation is the single greatest contribution of any health intervention. The study published by 'The Lancet' reveals that global immunisation efforts have saved an estimated 154 million lives – or the equivalent of 6 lives every minute of the year.[56]

The increased access to the travel vaccines is expected to do the same, where having more people immunised will directly reduce the spread of infection from person to person. In some instances, diseases can be eradicated through administration of vaccines, such was seen in the large-scale vaccination which eradicated the wild poliovirus type 2 in 1999 and wild poliovirus type 3 in 2020.[57]

By protecting individuals, vaccination can also protect the wider community, being known as herd immunity. Herd immunity occurs when the vaccine coverage is high, meaning an infectious case is unlikely to encounter susceptible contacts, so transmission stops.[58,59]

Community pharmacies are easily accessible and used by most of the population, healthy and unwell, and all ages. Increasing access to travel advice and administration of travel vaccines in regions where workforce pressures are the most severe will certainly lighten the burden that these areas currently face. For individuals located in rural areas, especially in the South Island, scheduling multiple doses of vaccines at least 8 weeks in advance can be difficult. Allowing community pharmacies to provide travel health services will improve the equity of access, awareness for individuals and overall protection for the community.

Pharmacists already supply non-prescription anti-diarrhoea medicines, water purification tablets and oral rehydration therapy to prospective travellers. Cholera and Haemophilus influenzae vaccines are already available through a pharmacist in New Zealand, and with the addition of travel vaccination through trained pharmacist vaccinators, will provide the community with another healthcare professional group actively involved in immunisation and advocating for its use. U.S. experience indicates pharmacists can provide advocacy and accessibility that increase vaccinations. Increased advocacy plus convenience/accessibility provides a strong reason to reclassify these vaccines.

Administration of travel vaccines by trained pharmacist vaccinators provides public health benefits and potential benefits to the taxpayer by decreasing health sector burden when foreign diseases are prevented from entering the country. Population growth, an aging population and developments in healthcare put an increasing demand on health services in a constrained fiscal environment. This requires better use of the existing health workforce, including extending existing roles, and preventive care. Increasing the pool of vaccinators to administer travel vaccines helps to meet the population's needs now and in the future.

- **What are the possibilities of community harm resulting from wider use of the medicine in question (e.g., the development of antibiotic resistance in bacteria or increased immunisation rates)?**

Harm

There are situations where additional administration may occur due to programmatic error, but there is little data available on the safety of and extra dose of a vaccine.[55]

Increase in access to travel vaccines or vaccines in general will proportionally increase the amount of negative post-market finding, including injuries, inadvertent administrations of the incorrect vaccines and reporting of side effects. In terms of health promotion, there is little risk as with more people being vaccinated, there is greater control in the spread of preventable diseases.

The risks with Yellow Fever vaccines are a little more complex than other vaccines listed in this submission, due to number of contraindications that need to be explored. There is the possibility of harm to the individual if the contraindications are not thoroughly investigated.

There is potential that for those in communities that do not believe in the benefits of vaccination to further harbour and push back on the progression of access to vaccines more readily in the community. This can potentially marginalise those that are pro-vaccination, against those that are not.[61]

23. Integrated benefit-risk statement

The reclassification of vaccines proposed in this submission will fundamentally improve access to travellers, allowing for a boost in immunity against preventable diseases not just for individuals but for their communities upon return. The cascading list of benefits are outlined below:

- Increases the travel vaccinator workforce
- Decreases wait times, and travellers missing full schedule of vaccines for maximum effectiveness
- Increases awareness/education of the importance of travel vaccination (as pharmacy provides an educational hub to their communities)
- Increases individual immunity
- Decreases hospital visits and deaths while overseas
- Decreases burden on the healthcare sector for preventable diseases
- Averts the cost to treat illnesses related to preventable diseases brought into the country
- Potential to eradicate certain diseases

With the authority of determining the appropriateness and safety lying with a postgraduate level trained and regulated pharmacist, the risk of harm is greatly reduced, however some that could still exit are listed below:

- Unintentional overdose with multiple administrations
- Incomplete consultation leading to administration of the vaccine for whom it is contraindicated in.
- Incorrect dose administered, or incorrect route (intramuscular instead of subcutaneous)
- Needle-stick injuries
- Increase incidence of adverse effects from the vaccines

As trends in New Zealand show that the rate of travel continues to increase year on year since the pandemic, so does the demand for travel vaccines. With the current workforce pressures the health sector is facing, the benefit of reclassifying these travel vaccines provides a distribution of that workload and improves access to our communities.

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

Trained pharmacist vaccinators can administer a range of vaccines classified as a prescription medicine and have been doing this for many years. Although many vaccines are classified as prescription only, some can be administered by a pharmacist vaccinator who has successfully completed a Vaccinator Foundation Course (or equivalent approved by the Ministry of Health) and complies with the immunisation standards. In New Zealand, vaccines that pharmacist vaccinators can administer without a prescription include Influenza, COVID-19, Meningococcal B, Meningococcal ACWY, Human papillomavirus, Varicella zoster, Tdap and the live MMR vaccines

In countries such as USA, Canada, UK and Australia selected vaccines are classified as prescription only, however, under certain conditions, can be administered by a trained pharmacist vaccinator, including some of the travel vaccines in this submission. This has increased the travel health workforce for these countries and reduced the burden on the broader healthcare system by increasing accessibility and convenience for individuals. The submission proposes that the potential risks are mitigated by requiring vaccinating pharmacists in New Zealand to complete additional postgraduate travel health studies through an approved educator, providing a further step to ensure that the vaccinating pharmacist is competent to carry out a full consultation on travel health and administration of travel vaccines.

For a vaccinating pharmacist wanting to deliver basic travel health consultation for non-complex travellers, with the provision of advice and treatment with medicines currently within their scope, they can complete the Introduction to Travel Health training course available through IMAC. For pharmacists that would like to further their education, and understand the complexities of travel medicine, there are currently three options available through the University of Otago:

- Postgraduate Certificate in Travel Medicine (PGCertTravMed)
- Postgraduate Diploma in Travel Medicine (PGDipTravMed)
- Master of Travel Medicine (MTravMed)

The length of the study is determined by which course the pharmacist chooses, ranging from 1-4 years, including whether they choose to study full-time or part-time. Both the postgraduate certificate and the diploma are available through distance learning where pharmacist vaccinators can study while continuing to work.

This submission proposes that at least one of the above qualifications be completed by the pharmacist vaccinator to ensure that the appropriate knowledge is acquired before administering travel vaccines. The postgraduate certificate which can be completed over an academic year covers the two papers, GENA713 and GENA714. The topics involved are similar, if not, are more comprehensive than the requirements needed for pharmacist vaccinators in the UK to deliver travel vaccines through the PGD or PSD pathway.

GENA713 Travel Medicine 1[77]
- Overview of travel medicine
- Travel medicine resources
- Preparing the intending traveller
- Covid-19 and Travel
- Travel vaccines: the basics
- Routine vaccines and travel
- Recommended travel vaccines
- Required travel vaccines

GENA714 Travel Medicine 2[78]
- Fitness to fly
- Prevention of food- and water-borne disease
- Prevention of vector-borne disease
- Sexually transmitted infections and travel
- Travel-related dermatology

- Tuberculosis and the traveller
- The Returning traveller
- Injury prevention in traveller

For vaccines with higher risk, such as the Yellow Fever vaccine, additional training and authorisation as per requirements through Health New Zealand will need to be completed before beginning to administer this vaccine.[62]

A study published in the *Journal of the American Pharmacists Association* highlighted that in the USA, pharmacist-administered vaccinations have led to increased immunisation rates, particularly for travel-related vaccines.[39] This model can be harmonised in New Zealand, where pharmacists are already well-equipped to handle vaccine administration, as evidenced by their role in the COVID-19 vaccination rollout. Furthermore, requiring additional postgraduate training through the University of Otago ensures that pharmacists are adequately prepared to manage the unique aspects of travel medicine.

The benefits of this reclassification include:

- **Increased Accessibility**: Community pharmacies are more accessible to the public than other healthcare settings, which can lead to higher vaccination rates.
- **Reduced Healthcare Burden**: By decentralising vaccination services, the strain on general practitioners and hospitals can be alleviated, allowing these resources to be used more efficiently elsewhere.
- **Economic Benefits**: Increased vaccination rates can prevent the importation of diseases, reducing the overall healthcare costs associated with treating preventable diseases.

24. Risk mitigating strategies

- **Are there any risk mitigation strategies required? If so, what risk mitigation strategies are required e.g., healthcare professional education; integration of care; consumer information to be provided etc.?**

Existing Processes and Collaboration
Establishing appropriate persons to vaccinate will be straight-forward for pharmacists as this is a process pharmacists are familiar with currently. A pre-vaccination checklist and consent form will be used by the pharmacist vaccinator, as a reference guide and to record each consultation.

Cold Chain
Appropriate storage and handling of the travel vaccines is important for the viability of vaccinations. Pharmacies that currently offer a vaccination service manage the storage and supply of cold chain products, including vaccines, and have robust and efficient cold chain Standard Operating Procedures (SOPs) to manage this. The importance of appropriate cold chain systems and potential resulting issues with temperature breaches are covered within the assessment of a pharmacist vaccinator. During this assessment, the pharmacy's cold chain SOPs are reviewed together with contingency plans in the event of a cold chain failure. Vaccine refrigerator temperatures are monitored within a community pharmacy and the vaccination service must meet all the requirements of the National Standards for Vaccine Storage and Transportation for Immunisation Providers, as well as being subject to regular Medsafe audit process.

Compliance with standards
Pharmacists will comply with immunisation standards of the Ministry of Health. Pharmacists will be well-informed by the Pharmacy Guild of New Zealand, the Pharmaceutical Society of New Zealand, Green Cross Health and from articles about a reclassification that will be published in Pharmacy Today, so chances of inadvertent administration by a pharmacist who is not accredited is highly unlikely.

Aotearoa Immunisation Register (AIR)
The national register for vaccines has been established and involves a centralised platform to view individuals' vaccination status, mitigating the risk of inadvertently administering an additional dose of the same vaccine when not scheduled. With the introduction of the AIR, pharmacist vaccinators are required to have access and establish an individual's vaccination history/status prior to the administration of any vaccine, minimising the possibility of additional or contraindicated doses.

Vaccines Record Card
A physical patient resource is available through health care professionals which guides individuals on what vaccines are needed for their destination(s) and holds a physical record for reference of the vaccines they have received.

Additional Training and Collaborative work
Pharmacist vaccinators will be encouraged to complete existing courses such as the one available through IMAC. Although this training is comprehensive it is only indicated for non-complex patients. It will be mandatory requirement for pharmacist vaccinators to complete a postgraduate study in travel medicine before administering travel vaccines in this submission. For vaccines with higher risk, such as the Yellow Fever vaccine, additional training and authorisation as per requirements through Health New Zealand will need to be completed before beginning to administer this vaccine.[62] During a travel consultation with a pharmacist, referral will be a key element to ensure that travellers receive appropriate prophylaxis, when necessary, by working with GP colleagues, achieving collaborative care for the patient.

Dosages and information needed to safely administer the vaccines are provided in the packaging they are received in. Existing knowledge regarding vaccines in addition to the postgraduate qualification, where a pharmacist is required to complete a postgraduate travel vaccine certification, will enable the pharmacist to diagnose and manage disease conditions relating to each vaccine, adding another layer of expertise and safety when providing these travel vaccines without a prescription.

- **What post-market surveillance activities would be carried out?**

Post-marketing surveillance is already carried out when the vaccine is delivered. Reclassification will allow travel vaccines to be available through community pharmacies by trained pharmacist vaccinators providing an increase in data for collection for post-market surveillance.

- **Is the proposed reclassification supported by professional bodies?**

Professional bodies have been consulted and notified of this submission. The Pharmacy Guild of New Zealand has been consulted several times during the process of writing the proposal and support the reclassification of the travel vaccines in this submission.

Conclusion

Reclassifying the vaccines included in this submission for administration by trained pharmacist vaccinators is a crucial step in improving access to essential travel health services. As overseas travel increases, it is important that individuals have timely access to expert advice and necessary vaccinations to ensure that they are protected abroad. This also helps safeguard public health upon their return, reducing healthcare costs associated with treating preventable diseases.

Allowing pharmacist vaccinators to administer these vaccines aligns with practices in Australia, Canada and the UK where pharmacist led vaccination and travel health services have been successful in improving accessibility and public health outcomes. In these countries, pharmacists undergo comprehensive vaccinator training programmes, with additional specialised travel health training available in certain regions for pharmacists to be able to provide travel health services. In the US, certain states permit pharmacist vaccinators to administer vaccines without a prescription, further improving accessibility to travel health services.

In New Zealand, this submission seeks to harmonise these international best practices by requiring pharmacist vaccinators to undergo postgraduate training to maintain the highest standards before administering any travel vaccines. Additionally, they should complete the necessary authorisation requirements before administering the Yellow Fever vaccine.

Pharmacists already supply non-prescription anti-diarrhoeal medicines, water purification tablets and oral rehydration therapy to prospective travellers. Additionally, pharmacist vaccinators, have been administering vaccines to the public for many years. With their knowledge and expertise, they work collaboratively with other health care professionals and are well suited to provide travel health services tailored to the needs of their communities. By expanding the role of pharmacist vaccinators in travel health, they can play a key part in improving equity of access ensuring that more people receive essential health support before travelling.

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