National Guidelines for Yellow Fever Vaccination Centres and Providers



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1 Yellow Fever

Yellow fever is an acute viral haemorrhagic disease that is endemic in Sub-Saharan Africa and tropical South America, including parts of the Caribbean. The disease occurs in three transmission cycles: sylvatic (jungle), intermediate (savannah), and urban. All three forms are caused by the same virus.

Yellow fever has an incubation period of 3–6 days. Many cases are asymptomatic, but when symptoms do appear they present in two stages. The first stage includes fever, muscle pain, headache, nausea and vomiting. Approximately 12 per cent of infected patients progress to the second, toxic stage which includes bleeding, jaundice and renal failure. The case-fatality rate for the second stage can vary widely but typically ranges from 30–60 per cent.

1.1 Transmission

Yellow fever virus is a positive-single-stranded RNA arbovirus that is transmitted to humans by the bite of infected mosquitoes, primarily the *Aedes aegypti* species. Other *Aedes* and *Haemagogus* mosquito species are also able to transmit the virus.

The disease cannot be spread by contact from one person to another.

The World Organisation for Animal Health (WOAH) lists yellow fever as a zoonosis, with a range of non-human primates and a small number of neotropical mammals acting as reservoirs for the virus in areas where it is endemic. In urban areas, humans act as a reservoir for the virus.

1.2 Yellow fever in Australia

Yellow fever is a Listed Human Disease (LHD) under the *Biosecurity (Listed Human Diseases) Determination 2016* and a nationally notifiable disease under the *National Health Security (National Notifiable Disease List) Instrument 2018.* Yellow fever is on the security sensitive biological agent (SSBA) list established by the *National Health Security Act 2007.*

No locally acquired cases of yellow fever have been recorded within Australia, and much of Australia is free from yellow fever disease vectors. However, the primary vector of the disease, *Aedes aegypti*, is present in parts of north, south and central Queensland. The prevalence and distribution of this vector may be affected by climate change in the future, as set out in the National Health and Climate Strategy.

Transmission of the yellow fever virus from an infected traveller to a local mosquito population could potentially cause an outbreak of yellow fever within Australia, particularly in areas where *Aedes aegypti* is present.

2 International Obligations

2.1 International Health Regulations (2005)

Yellow fever is a disease subject to the provisions of the World Health Organization (WHO) <u>International Health Regulations 2005</u> (IHR). The purpose of the IHR is to help prevent the international spread of disease, and to do so with minimum inconvenience to international travel and trade. Australia is a State Party to the IHR.

With respect to yellow fever, the IHR:

- allows proof of vaccination to be required as a condition of entry; and
- establishes the requirements for a valid vaccination certificate.

2.2 Yellow Fever Risk Areas

Yellow fever is considered endemic in parts of sub-Saharan Africa and tropical South America, including parts of the Caribbean. Actual areas of yellow fever virus activity often exceed officially reported infected zones, and there may be risk of infection due to the presence of vectors and animal reservoirs.

WHO recommends yellow fever vaccination for persons travelling outside urban areas of countries in endemic zones, even if these countries have not officially reported the disease.

The list of yellow fever risk countries and vaccination recommendations for travellers is provided in the <u>Biosecurity (Entry Requirements) Determination 2025</u> and the Department of Health, Disability and Ageing's <u>yellow fever factsheet</u>.

2.3 International Certificate of Vaccination or Prophylaxis

Many countries require travellers who have been in a yellow fever risk area to hold a valid International Certificate of Vaccination or Prophylaxis. An example certificate is at Attachment A.

Requirements for entry into each country vary considerably. Australian entry requirements are set out in Section 2.4 below.

2.3.1 Australian Vaccination Certificate Requirements

Australian requirements for a valid International Certificate of Vaccination or Prophylaxis against yellow fever are aligned with Annex 6 of the IHR.

- 1. The vaccine or prophylaxis listed on the certificate is approved by WHO. Stamaril is the only WHO approved vaccine available in Australia.
- 2. The manufacturer and batch number of the vaccine is recorded on the certificate.
- 3. The certificate bears the official stamp of the administering centre and includes the unique state/territory identification number issued by the relevant state/territory health authority for that administering centre.
- 4. The certificate must list the date the person was vaccinated in the sequence of day, month and year, with the month written in letters.
- 5. The certificate is signed by the prescribing practitioner supervising the administration of the vaccine.

- 6. The certificate is signed by the person vaccinated.
 - a. A parent or guardian shall sign the certificate when the child is unable to write.
 - b. If the person vaccinated is unable to sign, their signature shall be their mark and the indication by another that this is the mark of the person vaccinated.
- 7. The certificate is printed and completed in English or French. It may be completed in another language, in addition to either English or French.
- 8. The certificate is an individual certificate and not a collective one. Separate certificates must be issued for each person vaccinated.
- 9. The certificate is valid for the duration of the life of the person vaccinated, beginning 10 days after the date of vaccination.*
- 10. Any amendment of the certificate, erasure, or failure to complete any part of it, may render it invalid. This includes removing or crossing out the 'valid to' dates of a certificate issued before 11 July 2016.*
- 11. An equivalent document issued by the Armed Forces to an active member of those Forces shall be accepted in place of an international certificate if:
 - a. the document embodies medical information substantially the same as that required by the international certificate; and
 - b. the document contains a statement in English or French and where appropriate in another language in addition to English or French recording the nature and date of the vaccination.

*Following changes to Annex 7 of the IHR that came into force on 11 July 2016, all yellow fever vaccination certificates with a 'valid until' date will continue to remain valid for the life of the person vaccinated, even if a previously documented 'valid until' date has passed.

Certificate Validity

The certificate becomes valid 10 days after vaccination and remains valid for the life of the person vaccinated. Individuals should be encouraged to protect their certificate and keep it in a safe place, such as stored with their passport.

Individuals should also be encouraged to scan or copy their certificate to record the information needed to complete a replacement certificate in the event the original is lost.

2.3.2 Re-issue of International Certificate of Vaccination or Prophylaxis

In situations where an individual has lost or damaged their certificate or changed their name, a new certificate may be issued. An accredited practitioner may issue a new or replacement certificate when they:

- are satisfied that the individual has previously received the vaccination, and
- have all relevant information, such as the date of vaccination and vaccine batch number, to complete the replacement certificate in accordance with Annex 6 of the IHR (see Section 2.3.1).

This information may be obtained from the <u>Australian Immunisation Register</u> (see <u>Section 3.5</u>) or other medical records. Without the details of the previous vaccination, an accredited provider will not be able to replace a certificate.

2.3.3 Exemptions to the International Certificate of Vaccination or Prophylaxis

Contraindications to vaccination are conditions or circumstances that increase an individual's risk of a serious adverse reaction. If the accredited practitioner is of the opinion that vaccination is contraindicated, they should inform the person of the reasons for exemption and the risks of non-vaccination.

If a person with a contraindication to vaccination intends to travel to a yellow fever risk country or area, the accredited practitioner should provide a medical exemption in the form of a dated and signed medical exemption letter on letterhead stationery from an approved Yellow Fever Vaccination Centre.

The medical exemption must clearly state that the yellow fever vaccine is contraindicated on medical grounds and display the centre's official stamp provided by the state/territory health authority. Medical exemptions should be provided for the current trip only.

2.4 Yellow Fever Vaccination Requirements for Travellers Arriving in Australia

Australia does **not** refuse entry on the grounds that a traveller has not had, or cannot prove they have had, the yellow fever vaccination.

The Australian Government recommends that travellers from a yellow fever risk country or area be vaccinated against yellow fever. Australia's list of yellow fever risk countries and areas is provided in the <u>Biosecurity (Entry Requirements) Determination 2025</u> and the department's <u>yellow fever factsheet</u>. This list is guided by the WHO list of yellow fever endemic countries and recent international surveillance data.

When entering Australia, travellers must declare if they visited a yellow fever risk country or area in the previous six days. Travellers who declare this may be asked to provide a valid International Certificate of Vaccination or Prophylaxis or a declaration as to whether they have been vaccinated at least 10 days before entering the landing place or port.

A scan or copy of the original certificate or the Australian Immunisation Register (AIR) record is not a valid International Certificate of Vaccination or Prophylaxis, but may record key information needed to re-issue a replacement (see <u>Section 2.3.2</u>).

Travellers who do not provide a yellow fever vaccination certificate, medical exemption or declaration will be referred to a Biosecurity Officer. The Biosecurity Officer will issue an action card for travellers to follow. The action card states that if the traveller develops yellow fever symptoms within six days of entering Australia, they should see a doctor.

2.4.1 Travellers Leaving Australia

It is recommended that prior to travel, travellers contact the embassy or consulate of each country they intend to visit, including those in which they will transit, as they may have different yellow fever entry requirements to Australia.

3 Yellow fever Vaccination

3.1 Yellow Fever Vaccine

Stamaril is the only WHO approved yellow fever vaccine currently available in Australia. It is supplied by Sanofi-Aventis Australia Pty Ltd (Sanofi. Only approved Yellow Fever Vaccination Centres are eligible to purchase the yellow fever vaccine, which must also be administered at the approved centre.

The yellow fever vaccine **must not** be administered by any other practitioner, or in any other place, except in rare circumstances where it may be given in a hospital (see Section 5.3).

Stamaril is a heat-stable, lyophilised, live attenuated yellow fever virus (17D strain) and protects against all yellow fever strains circulating in nature. The vaccine is propagated on avian leucosis-free chick embryos and is reconstituted for use with buffered diluent.

The vaccine must be stored at 2–80C and must not be frozen. The reconstituted vaccine must be used within one hour and be protected from light.

The vaccine is provided in a single dose kit (one ampoule of vaccine + one syringe containing 0.5 mL of diluent) and for all ages is given as a single subcutaneous or intramuscular injection.

Please refer to the Australian Immunisation Handbook for more information.

3.1.1 Vaccination Costs

Vaccination against yellow fever is **not** funded under the <u>National Immunisation Program</u>, nor by <u>states and territories</u>.

Practitioners can bill a Medicare Benefits Schedule (MBS) attendance item for consultation time spent on patient history or giving the vaccine. More detailed information on MBS billing for immunisations is available through Services Australia.

3.2 Who Should be Vaccinated

Australia's National Health and Medical Research Council (NHMRC) recommendations are published in the <u>Australian Immunisation Handbook</u>. Please note that printed copies or pdf versions may not be up to date.

A single dose of the yellow fever vaccine is sufficient to grant life-long protection for most people and is **recommended** for:

- Persons 9 months of age and older travelling to, or living in, a country or area with a high risk of yellow fever virus transmission.
 - Countries and areas Australia considers to be high risk for yellow fever transmission are listed in the <u>Biosecurity (Entry Requirements) Determination 2025</u> and the department's <u>yellow fever factsheet</u>.
- Laboratory personnel who routinely work with yellow fever virus.

The yellow fever vaccine is **not recommended** for:

- Persons travelling to an area where there is low potential for yellow fever virus exposure (that is, no reported human yellow fever cases and evidence to suggest only low levels of yellow fever virus transmission, or not included on the list of high risk countries and areas).
 - Where the authorities of a low risk country or area require yellow fever vaccination for entry, vaccination may be considered for the purpose of allowing travel.
- Pregnant women and women who are breastfeeding infants aged less than 9 months, except in situations where potential exposure to the yellow fever virus cannot be avoided or postponed.
- Persons with a contraindication to yellow fever vaccination (see <u>Section 3.3</u>).

Individuals with certain medical conditions are more likely to have a suboptimal response to vaccination. These individuals may be recommended additional doses of the yellow fever vaccine. Recommendations for revaccination should be provided by accredited practitioners and determined by clinical circumstances.

3.3 Contraindications and Precautions

More detailed information is available in the Stamaril <u>Product Information</u> and in the Australian Immunisation Handbook.

3.3.1 Specific contraindications

- Known anaphylaxis to any component of a yellow fever vaccine (including eggs and egg products).
- Anaphylaxis after a previous dose of a yellow fever vaccine.
- Severe immunocompromise due to medical condition(s) or immunosuppressive therapies.
- History of a thymus disorder.
- Infants less than 9 months (although countries experiencing an outbreak may elect to immunise infants as young as 6 months of age).

3.3.2 Precautions

- Pregnant women* and women who are breastfeeding infants aged less than 9 months, except where potential exposure to the yellow fever virus cannot be avoided or postponed (vaccine only given in exceptional circumstances).
- Adults aged 60 and over as they have a higher risk of severe adverse events.
- People who are mildly or moderately immunocompromised (vaccination can be considered on a risk-benefit assessment).
- People living with HIV (provided they are not immunocompromised or symptomatic).
- People with possible IFNAR1 deficiency should seek advice from their immunologist.
- Haematopoietic stem cell transplant recipients are recommended to receive an extra vaccine dose if they will be in an area with a risk of yellow fever virus transmission.

*Product Information states that pregnancy is a contraindication to the yellow fever vaccine. The Australian Technical Advisory Group on Immunisation recommends that pregnant women can be vaccinated where travel to an area with a risk of yellow fever virus transmission is unavoidable.

3.4 Adverse Events Following Immunisation

3.4.1 Mild adverse events

Low-grade fever, myalgia, headache and other minor symptoms in the first five days after vaccination, which can last up to two weeks.

3.4.2 Immediate hypersensitivity reactions

Although very rare, immediate hypersensitivity reactions can include anaphylaxis and occur mainly in people with anaphylactic sensitivity to eggs. There is a suggestion that anaphylactic sensitivity to gelatin (added as a stabiliser to some yellow fever vaccines) may also precipitate anaphylaxis following vaccination. Stamaril does not contain gelatin.

3.4.3 Vaccine-associated neurotropic adverse events

Yellow fever vaccine-associated neurotropic disease (YF-AND) is a severe adverse event that can be fatal in rare cases. YF-AND manifests as several distinct clinical syndromes, including meningoencephalitis (neurotropic disease), Guillain-Barre syndrome, acute disseminated encephalomyelitis and bulbar palsy. YF-AND is more likely to occur in very young infants and the elderly.

3.4.4 Vaccine-associated viscerotropic adverse events

Yellow fever vaccine-associated viscerotropic disease (YF-AVD) is a rare but severe adverse event characterised by multi-organ system failure. YF-AVD mimics naturally acquired yellow fever disease. Risk factors for YF-AVD are older age and a history of thymus disease or thymectomy.

More detailed information is available in the Stamaril <u>Product Information</u> and in the <u>Australian Immunisation Handbook</u>.

3.4.5 Reporting of Adverse Events Following Immunisation

Standard practices for reporting adverse events following immunisation (AEFI) differ for each state and territory and should be confirmed by contacting the relevant health authority. Where there are mandatory reporting requirements in place, AEFI are reported to the health authority. If there are no mandatory requirements, AEFI reporting is directed to the Therapeutic Goods Administration (TGA).

The TGA monitors AEFI as an important component of its strategy for adverse events safety, information and education. The TGA manages the Australian Adverse Events Management System that houses all adverse reaction reports related to medicines and vaccines.

Health professionals and consumers can report AEFI to the TGA or to their relevant state or territory health authority. Information on how to report is available on the TGA website.

Further information regarding AEFI and contact details for state and territory health authorities are available on the <u>department's website</u>.

3.5 The Australian Immunisation Register

In addition to the International Certificate of Vaccination or Prophylaxis, it is important that administration of a yellow fever vaccination is reported to the <u>Australian Immunisation</u> <u>Register</u> (AIR), including the vaccine batch number. The AIR allows for a permanent and accessible record of vaccination.

As best practice, prescribing practitioners should report yellow fever vaccination to the AIR at the time of vaccination. Individuals may also request their vaccine information is reported to the AIR.

Batch numbers are reported to the AIR by selecting the Batch Number field under the Vaccine/Brand field when recording or updating an immunisation encounter. Batch numbers do **not** appear on printed or downloaded AIR Immunisation History Statements. Instead, they can be viewed online by a recognised vaccination provider in the AIR immunisation history section or by viewing details of immunisation encounters.

For more information on how to use the AIR, please access the <u>AIR education module</u> available on the Services Australia website.

4 Roles and Responsibilities

4.1 Department of Health, Disability and Ageing

Under the *Biosecurity Act 2015*, the Minister for Health and the department have statutory responsibility for preventing the entry, emergence, spread and establishment of LHDs, including yellow fever.

The department is responsible for:

- Implementing Australia's obligations as a State Party to the IHR.
- Liaising with WHO and Australian Government partner agencies on yellow fever issues.
- Establishing the yellow fever vaccination requirements for travellers arriving in Australia.
- Establishing and maintaining National Guidelines that comply with WHO requirements.
- Facilitating an online Yellow Fever Vaccination Learning and Accreditation Course.
- Maintaining a national list of individual practitioners who have completed the course.
- Sharing a list of practitioners who have completed the course with State and Territory Health Authorities.

4.2 State and Territory Health Authorities

Under funding agreements with the states and territories, the relevant state or territory health authority is responsible for the approval of Yellow Fever Vaccination Centres and accredited practitioners within its jurisdiction.

The role of the state or territory health authority includes:

- Assessing, approving and monitoring Yellow Fever Vaccination Centres in accordance with these guidelines.
- Withdrawing approval for Yellow Fever Vaccination Centres that are not acting in accordance with these guidelines.
- Confirming that individual practitioners have met accreditation requirements.
- Issuing Yellow Fever Vaccination Centres with a unique provider/identification number and stamp.
- Advising Sanofi of the Yellow Fever Vaccination Centres authorised, or no longer authorised, to purchase the vaccine within 7 days of the change in authorisation status.
- Maintaining a publicly available list of approved vaccination centres within the jurisdiction.
- Where necessary, informing the department of non-compliance cases involving Yellow Fever Vaccination Centres or accredited practitioners.
- Under extenuating circumstances authorising an exception to allow the yellow fever vaccine to be administered in a hospital (see <u>Section 5.3</u>).
- Reporting adverse events following vaccination to the TGA (see <u>Section 3.4.1</u>).

4.3 Approved Yellow Fever Vaccination Centres

A primary care practice can apply to their state or territory health authority to become an approved Yellow Fever Vaccination Centre, eligible to provide the yellow fever vaccine.

The role of a Yellow Fever Vaccination Centre includes:

- Meeting a set of minimum requirements to obtain accreditation for administering the yellow fever vaccine, including appropriate cold chain management of Stamaril vaccines delivered to the centre (see <u>Section 5.3.1</u>).
- Maintaining minimum requirements in accordance with these guidelines and advising the relevant state/territory health authority within 7 days if these requirements are no longer met.
- Providing details of all accredited practitioners practicing at the vaccination centre to the relevant state/territory health authority.
- Updating the state/territory health authority of significant changes within 7 days. These include
 - when practitioners join or leave the centre
 - o changes of address/location including website or contact details.
- Ensuring yellow fever vaccination is recorded in the AIR, including the vaccine batch number (see <u>Section 3.5</u>).
- Reporting adverse events following immunisation to the relevant State or Territory health authority or the TGA (see <u>Section 3.4.1</u>).
- Retaining an accurate record of yellow fever vaccination history, including all the information required to issue a replacement certificate (see Section 2.3.2).
- Ordering International Certificate of Vaccination or Prophylaxis through the <u>WHO order</u> form.
- Ordering the yellow fever vaccine, Stamaril, through Sanofi.
- Destroying provider stamps in accordance with state/territory health authority requirements once the vaccination centre is no longer approved.

4.4 Yellow Fever Vaccine Suppliers

Stamaril is the only WHO approved yellow fever vaccine currently available in Australia. Stamaril is supplied by Sanofi.

The role of the vaccine supplier includes:

- Manufacturing Stamaril.
- Supplying Stamaril to approved Yellow Fever Vaccination Centres.
- Advising wholesalers of approved Yellow Fever Vaccination Centres.
- Checking the list of approved Yellow Fever Vaccination Centres before vaccine distribution, to confirm a centre is still approved.
- Advising the department of significant supply chain issues, including major delays, shortages or problems in distribution.
- Reporting adverse events following immunisation to the TGA (see Section 3.4.1).

4.5 Accredited Practitioners

Medical practitioners and nurse practitioners can apply to their state or territory health authority to become accredited to prescribe and administer the yellow fever vaccine.

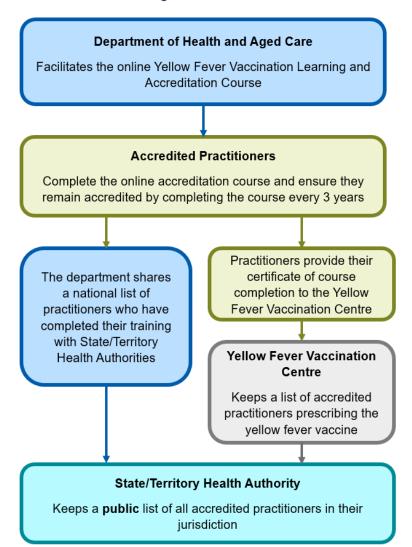
The role of the individual practitioner includes:

- Completing the online Yellow Fever Vaccination Learning and Accreditation Course.
- Downloading a completion certificate and providing it to the Yellow Fever Vaccination Centre in which they intend to practise.
- Renewing their accreditation every three years by completing the course again.
- Advising travellers on their need for yellow fever vaccination, considering factors such as medical history and travel itinerary.
- Prescribing and administering the yellow fever vaccine to people who should be vaccinated.*
- Only administering the vaccine at an approved Yellow Fever Vaccination Centre, except in rare circumstances where it may be given in a hospital (see <u>Section 5.3</u>).
- Issuing people with a valid International Certificate of Vaccination or Prophylaxis (see Section 2.3).
- Providing a formal medical exemption if vaccination is contraindicated (see <u>Section 2.3.3</u>).
- Reporting yellow fever vaccination to the AIR, including the vaccine batch number (see Section 3.5).
- Reporting adverse events following immunisation to the TGA (see <u>Section 3.4.1</u>).

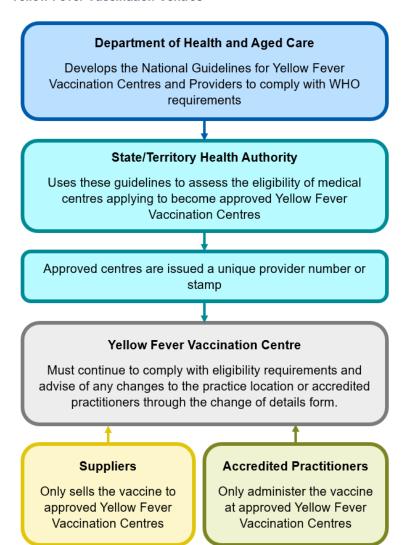
^{*}The prescribing practitioner may delegate the administration of the yellow fever vaccine to a health professional on the premises who is not accredited to prescribe the yellow fever vaccine, but is authorised to administer vaccinations. The prescribing practitioner must still be onsite when this vaccine is administered.

4.6 Responsibility Flowcharts

Yellow Fever Vaccination Learning and Accreditation Course



Yellow Fever Vaccination Centres



5 Approval Procedures for Yellow Fever Vaccination Centres and Practitioners

5.1 Yellow Fever Vaccination Learning and Accreditation Course

Individual practitioners responsible for prescribing and administering the vaccine at approved Yellow Fever Vaccination Centres are accredited to do so through successful completion of the online Yellow Fever Vaccination Learning and Accreditation Course. The course can be found on the department's website.

This course highlights safe and appropriate prescribing information for medical practitioners or nurse practitioners seeking to be eligible to prescribe the yellow fever vaccine. Yellow fever vaccine providers are encouraged to undertake further education in travel medicine.

5.2 Accredited practitioners

5.2.1 Medical Practitioners

A medical practitioner seeking to prescribe and administer the yellow fever vaccine at a Yellow Fever Vaccination Centre is required to successfully complete the online Yellow Fever Vaccination Learning and Accreditation Course and obtain a completion certificate.

The completion certificate is to be provided to the Yellow Fever Vaccination Centre where the practitioner intends to practise. An accredited practitioner may only prescribe and administer the vaccine at an approved Yellow Fever Vaccination Centre, except in rare circumstances where it may be given in a hospital (see Section 5.3).

5.2.2 Nurse Practitioners

Nurse practitioners are eligible to seek accreditation to prescribe the vaccine, provided that yellow fever vaccination is included on their prescribing formulary.

A nurse practitioner seeking to prescribe the yellow fever vaccine at a Yellow Fever Vaccination Centre is required to successfully complete the online Yellow Fever Vaccination Learning and Accreditation Course and obtain a completion certificate.

The completion certificate is to be provided to the Yellow Fever Vaccination Centre where the nurse practitioner intends to practise. An accredited nurse practitioner may only administer the vaccine at an accredited Yellow Fever Vaccination Centre, except in rare circumstances where it may be given in a hospital (see <u>Section 5.3</u>).

5.2.3 Maintenance of Accreditation

Accreditation is valid for three years, after which the course must be completed again.

Accreditation of an individual practitioner may be revoked at the discretion of the relevant state or territory health authority. The individual and the Yellow Fever Vaccination Centre will be notified in writing of the date on which the practitioner must cease to prescribe the vaccine.

5.3 Yellow Fever Vaccination Centres

5.3.1 Application for Approval

Only primary care practices are eligible to become approved Yellow Fever Vaccination Centres.

Applications for approval as a Yellow Fever Vaccination Centre are made to the relevant state or territory health authority. A model application form is at Attachment B. A responsible person must be nominated as a point of contact for administrative requirements.

Applications are assessed against the criteria in <u>Section 5.3.1</u>. Once approved, the practice must sign the form acknowledging the conditions that apply to a Yellow Fever Vaccination Centre (see <u>Attachment C</u>).

On receipt of the signed form, the state or territory health authority issues the practice with a unique provider/identification number or stamp and advises Sanofi of the eligibility of this practice to purchase the yellow fever vaccine.

Approval as a Yellow Fever Vaccination Centre is not transferrable but is retained if the practice changes location, once the relevant health authority is notified. There is no restriction to the number of practices that may be approved in each state or territory.

5.3.2 Withdrawn Approval & Non-compliance

A state or territory health authority may withdraw its approval of a practice as a Yellow Fever Vaccination Centre if any of the conditions of appointment at Attachment C are not met.

If there are no accredited practitioners available at the clinic to prescribe the vaccine and complete the relevant paperwork, approval is automatically suspended until such time as an accredited practitioner is available. An accredited practitioner must be onsite when the vaccine is administered.

Serious breaches of patient safety or unethical conduct may result in the immediate withdrawal of approval as a yellow fever vaccination centre. When approval is withdrawn, the state or territory health authority must notify the practice in writing that it is no longer eligible to provide yellow fever vaccinations. The practice must cease to do so from the date stipulated in the notification.

The state or territory health authority must advise Sanofi that the practice in question is no longer eligible to purchase the vaccine.

For other instances of non-compliance, the relevant health authority may elect to impose a probationary period in which the practice must provide evidence of its suitability to continue as a Yellow Fever Vaccination Centre.

5.3.3 Hospital administration

The yellow fever vaccine should only be administered at an approved Yellow Fever Vaccination Centre. Under exceptional circumstances, such as where a patient under supervision in a hospital requires the vaccine, an exception may be made by the relevant state/territory health authority.

When the vaccine is administered in a hospital setting, it must still be acquired through a Yellow Fever Vaccination Centre and the hospital must have facilities in place to manage cold chain storage and immediate adverse events, including anaphylaxis.

Yellow fever vaccines administered at hospitals must be under the supervision of an accredited practitioner who has completed the online Yellow Fever Vaccination Learning and Accreditation Course.

5.3.4 Criteria for Assessing Vaccination Centres

The following criteria are used to assess the application for a primary care practice to become an approved Yellow Fever Vaccination Centre:

- The practice has at least one practitioner accredited to prescribe and administer the vaccine.
- 2. The practice's cold chain management strategies are in line with the <u>National Vaccine Storage Guidelines Strive for 5</u>. Evidence of this could be through practice accreditation, provision of the centre's vaccine management protocol or another mechanism approved by the state or territory health authority.
- 3. The practice can identify early signs of adverse events following immunisation and treat immediate hypersensitivity reactions, including anaphylaxis.
- 4. The practice records evidence of valid informed consent.
- 5. The practice has access to up-to-date travel advisory and travel health information for practitioners to provide travellers advice on mosquito protection and safe travel practices:
 - a. Yellow Fever Fact Sheet
 - b. State and Territory websites
 - c. healthdirect Travel Health Advice
 - d. Smartraveller
 - e. <u>Yellow Fever</u> and <u>Protection against Mosquitoes, Ticks & Other Arthropods</u> from the United States of America Centers for Disease Control and Prevention's Yellow Book
- 6. The practice can retain an accurate record of yellow fever vaccination history. Ensuring yellow fever vaccination is reported to the AIR, including the vaccine batch number (see Section 3.5).

Resources

<u>Australian Immunisation Handbook.</u> Australian Technical Advisory Group on Immunisation (ATAGI). Australian Government Department of Health, Disability and Ageing.

Australian Immunisation Register. Services Australia.

Australian Immunisation Register - eLearning. Services Australia.

Biosecurity Act 2015. Commonwealth of Australia.

Biosecurity (Entry Requirements) Determination 2025. Commonwealth of Australia.

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Attachment A: International Certificate of Vaccination or Prophylaxis

MODEL INTERNATIONAL CERTIFICATE OF VACCINATION OR PROPHYLAXIS

This is to certify that [name], date of birth, sex,								
nationality, national identification document, if applicable								
whose signature	whose signature follows							
has on the date i	has on the date indicated been vaccinated or received prophylaxis against:							
(name of disease or condition)								
in accordance with the International Health Regulations.								
Vaccine or prophylaxis	Date	Signature and professional status of supervising clinician	Manufacturer and batch No. of vaccine or prophylaxis	Certificate valid from	Official stamp of administering centre			
	Date	professional status of	batch No. of vaccine or	valid from				
prophylaxis	Date	professional status of	batch No. of vaccine or	valid from				
prophylaxis	Date	professional status of	batch No. of vaccine or	valid from				

This certificate is valid only if the vaccine or prophylaxis used has been approved by the World Health Organization.

This certificate must be signed in the hand of the clinician, who shall be a medical practitioner or other authorized health worker, supervising the administration of the vaccine or prophylaxis. The certificate must also bear the official stamp of the administering centre; however, this shall not be an accepted substitute for the signature.

Any amendment of this certificate, or erasure, or failure to complete any part of it, may render it invalid.

The validity of this certificate shall extend until the date indicated for the particular vaccination or prophylaxis. The certificate shall be fully completed in English or in French. The certificate may also be completed in another language on the same document, in addition to either English or French.

Attachment B: Application for a Primary Care Practice to become an Approved Yellow Fever Vaccination Centre

This application is made in the name of the primary care practice and signed by the practitioner who takes responsibility for the practice continuing to meet WHO and Australian requirements for yellow fever vaccination.

(a) Practice Details				
Name of Practice:				
Address:				
Vaccine Delivery Address				
(if different to the address above	e):			
Telephone:				
Email:				
Website (if applicable):				
Fax number:				
Name of Contact for Administrative Requirements relating to Yellow Fever Vaccination (practice manager or other):				
(b) Practitioners who will administer the yellow fever vaccine				
Note: A Yellow Fever Vaccination Centre must have at least one practitioner accredited to administer the yellow fever vaccine. Accreditation is achieved through successful completion of the Yellow Fever Vaccination Learning and Accreditation Course.				
1	Name:			
	Ahpra Number: Course completion certificate attached: □			
2	Name: Ahpra Number: Course completion certificate attached: □			
3	Name: Ahpra Number: Course completion certificate attached: □			
4	Name: Ahpra Number: Course completion certificate attached: □			

(c) Cold Chain Management				
Does this practice have a vaccine management protocol?	Υ	N		
If yes, please attach a copy to this form.				
Does this practice have a purpose-built vaccine refrigerator with a thermometer or temperature indicator?	Υ	N		
Brand name, model and litre capacity of fridge:				
Is the refrigerator regularly serviced and continuously monitored?	Υ	N		
If yes, please provide details:				
During the last five years, has this practice experienced any significant cold chain breaches?	Υ	N		
If yes to any cold chain breaches, have procedures been remedied and is cold chain storage now consistent with the National Vaccine Storage Guidelines, Strive for Five 2005 (Vaccine Storage Guidelines) and any state/territory requirements? Please detail any breaches and remedies:	Y	N		
Does this practice have an easily accessible copy of the <i>Vaccine Storage Guidelines</i> , and any state/territory requirements, to manage cold chain breaches?	Υ	N		
Are cold chain management strategies in line with the <i>Vaccine Storage Guidelines?</i> Evidence of this could be through practice accreditation or another mechanism approved the state or territory health authority.	Y	N		
(d) Consent				
Does this practice have formal procedures in place for recording valid consent for yellow fever vaccination? If yes, please attach copies of consent forms.	Υ	N		
If no, please advise how verbal consent is evidenced:				
(e) Procedures to address indications and contraindications				
Does this practice have formal procedures in place to prevent inadvertent administration of live vaccines to people with contraindications?	Υ	N		
Please provide details:				

(f) Referrals from Other Practices					
Will all practitioners covered by this application refer people back to their usual GP once yellow fever vaccination is complete?	Υ	N			
(g) Dealing with Adverse Reactions					
Does this practice have all the equipment, drugs and procedures in place to deal with an immediate severe adverse event following immunisation, including anaphylaxis?	Υ	N			
(h) Travel Health Advice					
Do all practitioners listed in (b) have access to up-to-date travel advisory and travel health information?	Υ	N			
Please specify sources used in this practice:					
Does the practice have membership of any Travel Medicine Associations?	Υ	N			
If yes, please list:					
(g) General Practice Accreditation					
Does the practice hold General Practice Accreditation? If yes, please attach a copy of certification to this form.	Υ	N			
Name of Applicant:					
Applicant must be a practitioner accredited to administer the yellow fever vaccine					
Signature					
Date:					
lease submit completed form to [address/email address of state/territory health authority].					

Attachment C: Conditions Applying to an Approved Yellow Fever Vaccination Centre

In the conditions appearing below:

- i. 'Appointment' means appointment as an approved Yellow Fever Vaccination Centre.
- ii. 'Practice' means a primary care practice appointed by the relevant state/territory health authority as a Yellow Fever Vaccination Centre.
- iii. 'Applicant' means the medical practitioner or nurse practitioner applying to have the primary care practice approved as a Yellow Fever Vaccination Centre and who takes responsibility for the practice continuing to meet WHO and Australian requirements for yellow fever vaccination.
- iv. 'Accredited practitioner' means a medical practitioner or nurse practitioner who has achieved accreditation through successful completion of the online Yellow Fever Vaccination Learning and Accreditation Course.
- 1. The Applicant acknowledges that the [insert state/territory] Government is not liable for any costs incurred by the practice as a result of provision of yellow fever vaccination.
- 2. All practitioners at the practice who administer or supervise administration of the yellow fever vaccine are accredited.
- 3. The practice will issue an International Certificate of Vaccination or Prophylaxis against yellow fever in line with Australian and WHO requirements. Please see <u>Section 2.3.1</u> of the <u>National Guidelines for Yellow Fever Vaccination Centres and Providers</u> for a list of Australian requirements.
- 4. People referred to the practice for yellow fever vaccination will only be provided with relevant travel advice. Other non-urgent medical problems or their complications identified during the consultation will be managed only with the consent of the referring doctor or will be returned to the referring doctor for treatment.
- 5. Changes relating to the particulars of the practice, including any change of name or address, shall be notified to the relevant state/territory health authority within 7 days. At the discretion of the relevant state/territory health authority, the appointment may be transferred to a new address without any requirement to reapply.
- 6. If the person nominated as point of contact for yellow fever vaccination administrative requirements leaves the practice, the state/territory health authority must be informed of another person to take their place within 7 days.
- 7. If the Applicant leaves the practice, another medical practitioner or nurse practitioner must agree to take responsibility for the practice continuing to meet clinical standards for yellow fever vaccination by completing the relevant form and forwarding to the relevant state/territory health authority within 7 days.
- 8. The practice will notify the relevant state/territory health authority if it intends to cease provision of yellow fever vaccinations or if circumstances change which will alter its capability to adhere to the requirements in this document within 7 days.
- 9. The practice will notify the state/territory health authority of all medical practitioners and nurse practitioners accredited to administer the yellow fever vaccine, and if they leave the practice, within 7 days.

- 10. The practice will participate in periodic surveys distributed by the relevant state/territory health authority related to yellow fever vaccine provision.
- 11. Details of the practice, such as the name of the practice, address and telephone number, will be included in lists of Yellow Fever Vaccination Centres on the relevant state/territory health authority website.
- 12. The practice will, from time to time, allow a person or persons authorised in writing by the relevant state/territory health authority, to enter premises used by the practice for the purposes of conducting yellow fever vaccinations in order to ensure compliance with all specified conditions. The practice will provide all records relating to yellow fever vaccinations to that person or persons upon request, with an adequate timeframe given by the state/territory health authority to allow for the accessing of records.
- 13. A breach of any of the above conditions by the practice may, at the discretion of the relevant state/territory health authority, may result in
 - i. a probationary period, subject to the conditions set by [insert state/territory]
 Government, or
 - ii. withdrawal of the appointment.
- 14. The appointment may be immediately withdrawn in the case of a breach of patient safety, evidence-based practice or medical ethics.
- 15. On being notified in writing by the relevant state/territory health authority that the appointment to provide yellow fever vaccinations has been withdrawn, the practice shall cease to conduct vaccinations on the date stipulated in the notification.
- 16. If the primary care practice, of which I am an approved representative, is appointed as a Yellow Fever Vaccination Centre, I hereby agree to the above conditions.

Name of Applicant:

	•	,	
Signature			
Date:			
Please submit con	npleted form to [address/email	address of state/territo	ry health authority].

Applicant must be a practitioner accredited to administer the vellow fever vaccine

Attachment D: Change of Details Form

(a) Practice Details						
Nam	Name of Practice:					
Address:						
(b) C	Changes to Practice Details					
□С	hange of Practice Name	New Practice Name	:			
□С	hange of Practice Address	New Practice Addres	s:			
□С	hange of Telephone number	New Telephone num	ber:			
□С	hange of Website Address	New Website addres	s:			
□С	hange of Email	New Email:				
For A	hange of Contact Person Administrative Requirements relating to by Fever Vaccination (practice ager or other)	New Contact Persor	า:			
□ 0	□ Other					
(c) Changes to Practitioners who are prescribing the yellow fever vaccine						
			Add	Remove		
1	Name: Ahpra Number: Course completion certificate attache	d: □				
2	Name: Ahpra Number: Course completion certificate attache	d: □				
3	Name: Ahpra Number: Course completion certificate attache	d: □				
			Add	Remove		
4	Name: Ahpra Number: Course completion certificate attache	d: □				

(c) Changes to Practitioners who are prescribing the yellow fever vaccine					
5	Name: Ahpra Number: Course completion certificate attached: □				
6	Name: Ahpra Number: Course completion certificate attached: □				
(d) Other comments:					
Please outline any other changes to Practice Details:					
Name:					
Signature					
Date:	Date:				

Please submit completed form to [address/email address of state/territory health authority].