**Travel Medicine Alliance**

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**Recommendation to Introduce Yellow Fever Vaccine Accreditation for Medical Practitioners and Practices**

Dear Minister,

We write to raise with you our concerns regarding the inadequate regulation of Yellow Fever vaccinations within [Location] and how this is both inconveniencing and risking the health of patients. We also write to recommend practical ways that our concerns can be addressed, thereby minimising the aforementioned inconvenience and health risks to patients.

Yellow Fever is a viral disease prevalent in Africa, the Caribbean, Central and South America. Yellow Fever can cause headaches, muscle pain, nausea, vomiting, weakness, visible bleeding, jaundice, kidney and liver failure, and death. Yellow Fever vaccination is almost 100 % effective in preventing Yellow Fever, if correctly administered. However, Yellow Fever vaccination can have adverse reactions, which can differ markedly between individuals. Such adverse reactions include headaches, diarrhoea, fever, nausea, weakness, abdominal and muscle pain, vomiting, arthritis, fatigue, hives, dermatitis, oedema, anaphylaxis and Yellow Fever Vaccine Associated Neurotropic Disease. The last two adverse reactions have resulted in death.

Our specific concerns are:

1. **Inadequate Yellow Fever and Yellow Fever Vaccine Specialised and Ongoing Training**

Due to the significant risks caused by administration of a Yellow Fever vaccine, a Yellow Fever vaccine should only be administered if necessary and if the benefits of vaccination outweigh the risks. Unfortunately, we are aware of many occasions when this has not occurred resulting in preventable harm to the patient. This is predominantly the result of the authorising medical practitioner having an inadequate and out-of-date understanding of destinations for which Yellow Fever vaccination is required and the risks associated with Yellow Fever vaccination, particularly of those individuals most at risk from Yellow Fever vaccination.

1. **Inadequate Ability to Treat Yellow Fever Vaccine Adverse Reactions**

Due to the significant risks caused by the administration of a Yellow Fever vaccine, the authorising medical practitioner needs to be prepared and able to treat any adverse reactions that may arise as a result of the administration of this vaccine, such as anaphylaxis that may occur within minutes following the administration of the Yellow Fever vaccine.

1. **Inadequate Retention of Patient Yellow Fever Vaccination History**

Due to the significant risks caused by administration of a Yellow Fever vaccine the authorising medical practitioner needs to maintain records, in some cases for the life of a patient, to ensure a patient does not receive unnecessary Yellow Fever vaccines.

1. **Incorrectly Completed International Yellow Fever Vaccination Certificates**

International Yellow Fever Vaccination Certificates are required to enter into various counties in Africa, the Caribbean, Central and South America and are required upon entering into other countries, such as Australia, after having been within the aforementioned regions. Unfortunately, we have observed many cases of International Yellow Fever Vaccination Certificates being incorrectly completed, which has hindered and caused stress to patients while travelling.

1. **Inappropriate Storage of Yellow Fever Vaccines**

The Yellow Fever vaccine contains the live, but attenuated, Yellow Fever virus. Therefore, the Yellow Fever vaccine must be stored continually between 2 °C to 8 °C. If this vaccine is not stored within this temperature range it loses the ability to effectively confer immunity to Yellow Fever.

Our concerns are also shared by the governments of Canada, New Zealand, Norway, South Africa and the United Kingdom. Due to these concerns the aforementioned governments now require medical practitioners to be accredited to administer Yellow Fever vaccines and medical practices to be accredited to store Yellow Fever vaccines. Based upon the accreditation requirements of the aforementioned countries and our expertise in travel medicine we recommend:

1. **Accreditation of Medical Practitioners**
	1. A medical practitioner must be accredited to administer, and to authorise another qualified individual to administer on their behalf, Yellow Fever vaccines.
	2. To be accredited a medical practitioner must hold a postgraduate qualification in travel medicine, as defined by Appendix A.
	3. A medical practitioner must comply with:
		1. the immunisation standards in the most current edition of The Australian Immunisation Handbook;
		2. the guidelines regarding Yellow Fever vaccination and certification outlined in the most current edition of World Health Organization’s International Travel and Health and the Centers for Disease Control and Prevention’s Health Information for International Travel; and
		3. the guidelines regarding Yellow Fever vaccination and certification outlined in the International Health Regulations (2005), Annexes 6 and 7.3.
	4. A medical practitioner must maintain a log of:
		1. for each Yellow Fever vaccine administered to a patient:
			1. the date the vaccine was administered;
			2. the date of birth of the patient;
			3. the name of the patient;
			4. the travel destination(s) of the patient for which Yellow Fever vaccination was necessary;
			5. all reported adverse reactions associated with the administration of the vaccine;
			6. the name of the qualified individual who administered the vaccine (if not the approved medical practitioner);
			7. the trade name of the vaccine;
			8. the batch number of the vaccine;
			9. the expiry date of the vaccine; and
			10. the route and site of vaccination;
		2. all International Yellow Fever Vaccination Certificates of Exemption issued and the reason each International Yellow Fever Vaccination Certificates of Exemption was issued; and
		3. evidence of Continuing Medical Education in travel medicine education, as defined in Appendix B.
	5. A medical practitioner, or another qualified individual acting on their behalf, must only administer a Yellow Fever vaccine supplied by an accredited medical practice, as defined below.
	6. A medical practitioner’s accreditation to administer, and to authorise another qualified individual to administer on their behalf, Yellow Fever vaccines is renewable on a three-yearly basis.
	7. A medical practitioner’s accreditation must be renewed prior to the expiry of their current accreditation to ensure continuity of their accreditation.
2. **Accreditation of Medical Practices**
	1. A medical practice must be accredited to store and supply Yellow Fever vaccines.
	2. A medical practice must hold a current Cold Chain Accreditation, as defined by Appendix C.
	3. A medical practice’s accreditation to store and supply Yellow Fever vaccines is renewable on a three-yearly basis.
	4. A medical practice’s accreditation must be renewed prior to the expiry of its current accreditation to ensure continuity of its accreditation.

We therefore call upon the government of [Location] to introduce our aforementioned recommendations as soon as possible to ensure a world-class health system within [Location] and to minimise the inconvenience and health risks to patients arising from the currently inadequate regulation of Yellow Fever vaccinations within [Location]. This letter constitutes a formal and official notice of our aforementioned concerns and recommendations to address these concerns.

We appoint Dr Deborah Mills MBBS, National Medical Director of the Travel Medicine Alliance, as our representative and authorise her to communicate and act on our behalf.

In order to facilitate the government of [Location] to address our concerns and implement our recommendations, we request a meeting between [Minister] and Dr Deborah Mills as soon as possible to further clarify and discuss the issues raised within this letter.

We thank you in advance for your consideration and look forward to your response.

Yours sincerely,

[Signature]

**Appendix A**

**Definition of Postgraduate Qualification in Travel Medicine**

1. A postgraduate qualification in travel medicine includes:
	1. a postgraduate certificate or higher in travel medicine (or tropical medicine, or public health with the inclusion of at least one travel medicine paper) from James Cook University, Townsville, Australia;
	2. an International Society of Travel Medicine Certificate of Knowledge in Travel Health;
	3. a qualification equivalent to those defined in 1(A)–(B) from a recognised international university;
	4. a fellowship in infectious diseases, with postgraduate training in travel medicine (that is, at least one short course in travel medicine); or
	5. a fellowship in public health, with postgraduate training in travel medicine (that is, at least one short course in travel medicine).

If the aforementioned postgraduate qualification is more than 15 years old, the medical practitioner must submit evidence of Continuing Medical Education in travel medicine, as defined by Appendix B.

**Appendix B**

**Definition of Evidence of Continuing Medical Education in Travel Medicine**

1. To demonstrate evidence of involvement in Continuing Medical Education in travel medicine a medical practitioner must:
	1. Actively engage in surveillance for Yellow Fever and travel medicine disease outbreaks through subscription to at least one of the following approved international surveillance bulletins:
		* International Society for Infectious Diseases: ProMED-mail (http://www.promedmail.org/pls/otn/f?p=2400:1000:)
		* Worldwise weekly e-alerts (register at online@worldwise.co.nz)
		* ISTM membership and listserv (register at http://www.istm.org/)
		* Centers for Disease Control and Prevention Travel Notices (http://wwwn.cdc.gov/travel/notices.aspx)
		* WHO disease outbreak news (http://www.who.int/csr/don/en/)
		* Travax alert service (register at http://www.travax.nhs.uk/)
		* Tropimed Epidemiological News (register at www.tropimed.com)
	2. Actively participate in Continuing Medical Education in travel medicine that covers:
		1. general knowledge of (including global epidemiology and transmission of) Yellow Fever;
		2. the International Health Regulations (2005), particularly Annexes 6
		and 7;
		3. areas with risk of Yellow Fever transmission;
		4. Yellow Fever vaccine: safe use, delivery, adverse effects, contraindications and appropriate use of medical wavers;
		5. other forms of Yellow Fever prevention, such as mosquito bite prevention;
		6. access to regular outbreak alerts;
		7. risk assessment for travel; and
		8. updates to the medical practitioner’s general knowledge base and resources in the area of travel medicine in general, with the aim of ensuring the medical practitioner follows best evidence-based practice, according to internationally recognised standards, in providing pre-travel advice.

Continuing Medical Education is to entail a minimum of 18 hours total (three days) over a three-yearly accreditation cycle. Within this Continuing Medical Education, one component must be Yellow Fever-specific, including a minimum of three hours total over the three-year cycle, covering the topics listed above and including an assessment component.

Medical practitioners must undertake Continuing Medical Education through an accredited or recognised Continuing Medical Education programme.

**Appendix C**

**Cold Chain Accreditation**

1. **Overview**
	1. The Yellow Fever vaccine contains the live, but attenuated, Yellow Fever virus. The Yellow Fever vaccine must be stored continually between 2 °C to 8 °C. If the Yellow Fever vaccine is not stored within this temperature range, its efficacy rapidly decreases. A Cold Chain Accreditation ensures the Yellow Fever vaccine will be stored optimally and thereby be most efficacious. Therefore, a medical practice must be Cold Chain Accredited to store and supply Yellow Fever vaccines.
2. **Accreditation**
	1. A medical practice’s Cold Chain Accreditation is renewable on a three-yearly basis.
	2. A medical practice’s Cold Chain Accreditation must be renewed prior to the expiry of its current accreditation to ensure continuity of its accreditation.

The requirements to be Cold Chain Accredited are detailed below.

1. **Cold Chain Management Policy**
	1. A medical practice that stores or supplies vaccines must have an individualised and documented Cold Chain management policy that:
		1. designates a staff member as responsible for the management of the Cold Chain;
		2. is dated and signed by the relevant staff member;
		3. is reviewed annually;
		4. details vaccine stock requirements;
		5. details vaccine ordering and storage processes;
		6. details refrigerator operation, and maintenance and management processes; and
		7. details emergency procedures for dealing with equipment and power failures.
2. **Vaccine Storage**
	1. A medical practice that stores or supplies vaccines must use a pharmaceutical refrigerator to store vaccines. This pharmaceutical refrigerator must:
		1. be of sufﬁcient size to accommodate vaccine storage requirements without exceeding the manufacturer’s recommendations for maximum storage capacity;
		2. be in a reasonably sized, well-ventilated room and not in direct sunlight or against a heat source/external wall;
		3. have sufﬁcient ventilation around the condenser of the pharmaceutical refrigerator;
		4. have an independent power point and a plug-in surge protection unit, with the plug either taped over, with a written warning against unplugging, or the pharmaceutical refrigerator wired permanently into the surge protection unit and electrical outlet;
		5. be connected to an electrical back-up generator with the capacity to power this pharmaceutical refrigerator in the event of a loss of mains power;
		6. have an electronic temperature-recording device, such as a data logger, that:
			1. measures the current temperature and the minimum and maximum temperatures reached since the device was last reset;
			2. generates a warning if the temperature of the pharmaceutical refrigerator is not within a defined temperature range; and
			3. can record and download previous data;
		7. have its temperature monitored and documented in a temperature log at the same time each working day, ideally by the same individual; and
		8. not be used to store food.
	2. A vaccine within an aforementioned pharmaceutical refrigerator must:
		1. be stored:
			1. between 2 °C and 8 °C;
			2. in its original packaging; and
			3. with the batch number and expiry date showing;
		2. not be stored:
			1. against the walls of the pharmaceutical refrigerator;
			2. closer than 25 mm to the top of a shelf within the pharmaceutical refrigerator or the pharmaceutical refrigerator itself;
			3. closer than 25 mm to the back of the pharmaceutical refrigerator; or
			4. in the bottom of the pharmaceutical refrigerator;
		3. be refrigerated immediately upon arrival from a vaccine supplier.
3. **Vaccine Deliveries**
	1. When a vaccine arrives from a vaccine supplier the recipient must take all reasonable measures to determine the vaccine has been kept at the required temperature. If the recipient has reason to believe the vaccine has not been kept at the required temperature, they should notify the vaccine supplier for advice and, if necessary, return the vaccine.
4. **Managing Cold Chain Failures**
	1. If the temperature of a pharmaceutical refrigerator being used to store vaccines is not between 2 °C to 8 °C at any time the following steps must be undertaken.
		1. The vaccines stored within the aforementioned pharmaceutical refrigerator are to be labelled “not for use” and left within pharmaceutical refrigerator. The door of the pharmaceutical refrigerator is to remain closed whenever possible.
		2. The data from the electronic temperature-recording device is to be downloaded and checked for inconsistencies and temperature fluctuations.
		3. The supplier or suppliers of any vaccines within the aforementioned pharmaceutical refrigerator are to be contacted for advice regarding what actions are to be undertaken before continuing to vaccinate or discarding these vaccines.
		4. The steps and actions taken in managing this cold chain failure are to be documented.
5. **Miscellaneous**
	1. All staff members at a Cold Chain Accredited medical practice have a responsibility to report, and if possible correct, any problems relating to cold chain storage to their employer and/or manager.