Australian Government
Department of Health, Disability and Ageing

AUSTRALIAN TECHNICAL ADVISORY GROUP ON IMMUNISATION (ATAGI)

STATEMENT

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COUNTERFEIT RABIES VACCINES AND RABIES IMMUNOGLOBULIN: GUIDANCE FOR TRAVELLERS AND HEALTHCARE PROVIDERS

Reports of counterfeit vaccines overseas arise periodically. This ATAGI statement provides principles-based guidance for assessing the validity of vaccination courses received overseas and managing doses suspected to be invalid. It does not provide incident-specific response advice.

Overview

- Rabies is a fatal disease once symptoms develop but can be prevented through timely and appropriate post-exposure prophylaxis. Depending on the circumstances and local availability, rabies post-exposure prophylaxis may include rabies vaccine together with rabies immunoglobulin (RIG) or a rabies monoclonal antibody product.
- Counterfeit (fake) rabies vaccines and have been reported overseas, recently in India and the Philippines[1].
- The fake products may differ from the genuine vaccine and RIG in formulation, packaging, labelling, and/or manufacturing.
- In addition to fake products, storage or transport problems may affect the quality of rabies vaccines and RIG. Travellers should obtain these products from reputable healthcare providers wherever possible.
- People who received fake vaccine may not be fully protected against rabies and are advised to get replacement doses to ensure they are adequately protected.
- The probability that an Australian traveller who received rabies vaccine and or RIG overseas will be adversely affected is low. However, a precautionary approach is being taken due to the potentially high severity of impact associated with inadequate rabies post-exposure prophylaxis.

Who may be affected?

- Travellers may be affected if they:
  - received rabies vaccine and/or RIG overseas, and
  - were administered one or more doses of rabies vaccine and/or RIG suspected or confirmed to be fake.

Recommended actions

For people who have returned to Australia from overseas

- Because it is difficult to confirm whether a genuine or fake product was used, concerned travellers should consult a healthcare provider, who can help them identify invalid doses with the checks below and complete a valid course
- Any dose of suspected fake rabies vaccine should be considered invalid and replaced with a rabies vaccine registered in Australia
- A dose of suspected fake RIG should be considered invalid. However, this should not be replaced, unless still within 7 days of receiving the1st dose of vaccine

[1] Pattnaik et al. (2026). Counterfeit anti-rabies vaccine as a neglected issue: a manufacturers' perspective. Available at https://www.ovid.com/jnls/ijsoncology/fulltext/10.1097/ij9.0000000000000150~counterfeit-anti-rabies-vaccine-as-a-neglected-issue-a. *DOI:* 10.1097/IJ9.0000000000000150.Accessed 13 October 2026.

For healthcare providers

- Rabies vaccines received overseas are considered valid if they are:
  - A World Health Organization (WHO)-prequalified rabies vaccine, or
  - Another cell culture-derived rabies vaccine that contains at least 2.5 IU of rabies virus per dose, with scientific literature or product information demonstrating an acceptable post-exposure antibody response (rabies virus neutralising antibody ≥0.5 IU per mL).

- Providers should document any vaccines received overseas in the Australian Immunisation Register (AIR) once a traveller has returned to Australia.

- The WHO publishes alerts of any suspected or confirmed fake prequalified rabies vaccine as WHO Medical Product Alerts.

- If the traveller has photographs of the vaccine, packaging or product information leaflet, indicators that it may be fake include[2]:
  - poor quality packaging, spelling mistakes or grammatical errors
  - discrepancies between manufacturing or expiry dates on the outer and inner packaging
  - vaccine appearance that is inconsistent with the product information, including discolouration or evidence of degradation

- Revaccination with rabies vaccine in Australia is recommended when:
  - the vaccine administered is suspected to be fake based on the indicators outlined above
  - the vaccine administered was a nervous tissue rabies vaccine
  - the vaccine administered was a veterinary vaccine intended for use in animals
  - the vaccine potency and/or rabies antibody response cannot be verified through scientific literature or the product information
  - the batch number or vaccine administered was unknown or is implicated in a product alert from the WHO, other regulatory bodies or the manufacturer
  - it is unclear which rabies post-exposure prophylaxis product was administered – vaccine, rabies immunoglobulin or monoclonal antibody

- Serological testing can be considered on a case-by-case basis in travellers who completed post-exposure prophylaxis overseas where there is some uncertainty about the adequacy of treatment. Where undertaken, serological testing should be performed at least 2 weeks after completion of the post-exposure schedule. If there is significant concern about the reliability of the post-exposure prophylaxis received, restarting post-exposure vaccination is likely to be the most appropriate course of action. Serological testing with a level of ≥0.5 IU per mL is considered protective.

- Where a vaccine is suspected to be fake or invalid, replace any dose(s) with dose(s) of a valid rabies vaccine registered in Australia (Rabipur® or Verorab®). See **Table 1** for further detail.

Table 1: Rabies vaccine scenarios and recommended provider actions*

Scenario	Recommended Action
All doses received are considered invalid	Restart full post-exposure prophylaxis course with an Australian registered vaccine (Rabipur® or Verorab®)
Some doses received are considered invalid	Ignore invalid doses; count valid doses^ and resume schedule from last valid dose with a registered vaccine (Rabipur® or Verorab®)

*Note that rabies immunoglobulin (RIG) should not be replaced, unless still within 7 days of receiving the1st dose of vaccine. ^Rabies vaccine doses are considered valid if the vaccine used was either a World Health Organization prequalified rabies vaccine or a cell culture–derived rabies vaccine for human use containing at least 2.5 IU of rabies virus per dose, with scientific literature or documentation in the product information demonstrating an acceptable post-exposure antibody response (rabies virus neutralising antibody ≥0.5 IU per mL), and the batch is not suspected to be a fake product.

[2] World Health Organization (WHO). 9/12/2019. Substandard and falsified medical products: Advice to patients and consumers. Available at: https://www.who.int/news-room/questions-and-answers/item/substandard-and-falsified-medical-products-advice-to-patients-and-consumers - Accessed 16 October 2026

For people travelling overseas

- Avoid contact with animals and bats when travelling to countries where rabies occurs.
- Consider getting vaccinated against rabies before travelling to areas where rabies occurs. This makes treatment simpler if you are exposed to rabies during your trip.
- If you are scratched, bitten or exposed to the saliva of an animal you should:
    - thoroughly wash the wound with soap and water for at least 15 minutes, apply a topical disinfectant (e.g. Betadine) and seek urgent medical care
    - where possible, obtain rabies post-exposure prophylaxis at a clinic with appropriate local accreditation or inspection
    - where possible, request a World Health Organization prequalified rabies vaccine or ask the provider if the Traceability and Verification System (TRVST) can be used
    - keep detailed records of any rabies treatment received outside of Australia, including dates, type of vaccine, product names, batch numbers and expiry dates
    - where possible, take photos of the vaccine packaging (outer and inner packaging), label, batch-number stickers, the vaccine vial (if possible) and medical records
    - ask the person providing treatment if you can take the packaging and product information leaflet
    - ask the person providing the vaccine if there have been any concerns in the region regarding fake rabies vaccines of the brand you are receiving.
- Upon returning to Australia, follow up with your healthcare provider to discuss if any additional doses are required.

Additional information on rabies pre- and post-exposure rabies immunisation, including vaccines available in Australia and acceptable rabies vaccines can be viewed in the Australian Immunisation Handbook Chapter on rabies and other lyssaviruses.