Chief Health Officer Advisory

10 February 2015 Status: Active

Temporary change to Rabies immunoglobulin (RIg) access

Status: Active

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Issued by: Dr Rosemary Lester, Chief Health Officer, Victoria

Issued to: Medical Practitioners and Emergency Departments

Key messages

- There is a shortage of Rabies immunoglobulin (RIg) in Australia.
- Imogam, the usual RIg used in Australia, is temporarily unavailable and will not be available until further notice.
- KamRAB will be the alternative RIg.
- There are temporary changes to the ordering process as KamRAB is not registered in Australia.

What is the issue?

RIg is one component of the post-exposure prophylaxis for people who may have been exposed to rabies virus or other lyssaviruses. RIg is in short supply globally and Australia has exhausted its supply of the registered human RIg product, Imogam.

An alternative human RIg product, KamRAB has been sourced. This is not registered for use in Australia. It is being made available under category A of the Special Access Scheme (SAS) via the Immunisation Program at the Department of Health & Human Services.

As KamRAB is a blood product, the Therapeutic Goods Administration (TGA) requires patients or their parent/guardian to provide informed consent before KamRAB is administered.

What action is required?

- Medical Practitioners are required to complete an alternative form for the period that KamRAB is replacing Imogam. This form is available from the website and includes the product order section, the SAS category A section, blood product patient consent section and a consumer information fact sheet. Completed forms must be sent to the Immunisation Program at the Department of Health by fax 1300 768 088 or email immunisation@health.vic.gov.au.
- Medical Practitioners are asked to report any adverse event to the TGA and SAEFVIC, and to note which human RIg product was administered (KamRAB or Imogam).

Why is KamRAB not registered in Australia?

Australia has previously had sufficient access to other Rabies immunoglobulin product. Timeframes around the depletion of stock and access to an alternative product were not sufficient to undertake the necessary steps for licencing KamRAB with the TGA.

As KamRAB is not registered for use in Australia the product has not yet undergone a full assessment of safety and efficacy by the TGA in Australia. KamRAB is produced under Good Manufacturing Practices (GMP) as certified by the government of the country of origin. In addition, the product is currently undergoing clinical trials to allow registration in the United States.

Information about the residual risk of blood borne infections in the Australian context (which may differ from the US from where KamRAB is sourced) is available from the Australian Red Cross Blood Service website (see www.transfusion.com.au/adverse_events/risks/estimates for further details). In the Australian context, the residual risk of acquiring a blood borne infection from blood products is described as negligible (<1:1,000,000).[i] The American Red Cross quotes the risk of transfusion-transmission of HIV is approximately 1 in 2,000,000.[ii]

Human RIg produced under GMP is not expected to cause serious adverse reactions.[iii] Further detail is provided in the KamRAB product information.

Reporting adverse events

Adverse events should be reported by you to the TGA and SAEFVIC noting whether it was KamRAB or Imogam that was administered to a patient. In addition, the patient can report any adverse event directly to the TGA and SAEFVIC.

Information on reporting adverse events is available from the TGA website (http://www.tga.gov.au/safety/problem.htm#medicine) and the SAEFVIC website (https://www.saefvic.org.au)

More information

Clinical information

Further information about indications and methods of administration of RIg is available from The Australian Immunisation Handbook; 10th edition, 2013 (Part 4.15), on the Department of Health's website - http://www.health.gov.au/internet/immunise/publishing.nsf/Content/Handbook-home

Information provided by the TGA regarding the Special Access Scheme can be viewed on the TGA website - http://www.tga.gov.au/hp/access-sas.htm

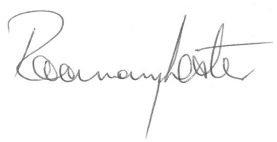
Consumer information

A consumer information fact sheet is included with the product order form. Alternatively, you can download the consumer information sheet.

Contacts

Immunisation Program, Department of Health & Human Services, Victoria. Phone: 1300 651 160.
Email: immunisation@health.vic.gov.au, Fax: 1300 768 088.

Yours sincerely



Dr Rosemary Lester PSM
Chief Health Officer

Authorised by the Victorian Government, 1 Treasury Place Melbourne.

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i Australian Red Cross Blood Service 2013, Residual risk estimates for transfusion-transmissible infections, accessed 11 December 2013, http://www.transfusion.com.au/node/115

ii Stramer S. Current Risks of Transfusion-Transmitted Agents Arch Pathol Lab Med—Vol 131, May 2007

iii WHO Expert Consultation on rabies. World Health Organ Tech Rep Ser. 2005;931:1