

Seqirus  
63 Poplar Road  
Parkville Victoria 3052

10 January 2017

**Safety Alert**  
**Important information regarding**  
**Stonefish Antivenom 2000U Injection Vial**  
**Lot 056007501, expiry November 2017**  
**AUST R: 74892**  
**TGA Reference: RC-2017-RN-00020-01**

Dear Healthcare Professional,

This letter is to highlight important information regarding Seqirus' Stonefish Antivenom (AV), Lot 056007501, expiry November 2017.

Stonefish AV is indicated for the treatment of patients who, following envenoming by a stonefish, have systemic manifestations or severe oedema and pain which do not respond to first aid measures. It is available as a vial containing 2,000 units in aqueous solution. The product volume is potency-dependent; thus it varies from batch to batch and the volume in each vial is printed on the carton.

**This is to notify you that the Stonefish AV Lot 056007501 has 2.52 mL printed on the carton as product volume, instead of the volume of 2.29 mL.** This notification applies only to Lot 056007501.

There is no risk of suboptimal response as the vials from this lot each contain 2000 units, as per the label claim. However, we recommend that the extracted (nominal) volume of 2.29mL is used when calculating the (1:10) volume for dilution for Intravenous (I.V.) administration.

**No stock is required to be returned.**

Please refer to the Stonefish AV Product Information, contained in the Stonefish AV carton and also available at [www.seqirus.com.au/PI](http://www.seqirus.com.au/PI) before prescribing or administering.

For further information or to report an adverse event, please contact Seqirus' Medical Information on 1800 642 865 (within Australia) / +613 9389 1932 (outside Australia) or [medinfo.aust@csl.com.au](mailto:medinfo.aust@csl.com.au).

This safety alert has been undertaken following consultation with the Therapeutic Goods Administration (TGA).

Please complete the attached acknowledgement form and return it by email [customer.service.NSW.AU@seqirus.com](mailto:customer.service.NSW.AU@seqirus.com), even if you do not have any of the affected product that is the subject of this safety alert, as we require this information to reconcile the process.

Seqirus would like to apologise for any inconvenience caused by this labelling error.

Yours faithfully,



Dr. Jane Leong  
**Head of Medical Affairs, Asia Pacific**