

Norbrook® Laboratories Limited

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Urgent: Action Needed Within Forty Eight Hours (48) of Receipt

23rd February, 2017

CLASS 2 ANIMAL DRUG ALERT PRODUCT RECALL

Our Ref: MDR 01-02/17

Drug Name: Propofol Emulsion for Injection 1%w/v

Brand Name: Please refer to Table 1 below:

To whom it may concern;

Norbrook Laboratories Ltd is voluntarily recalling the product **Propofol Emulsion for Injection 1.0%w/v** and all brand names listed below as a precautionary measure. Norbrook has verified that an issue of coring, i.e. the shearing off of a portion of the 20mm bromobutyl bung, as the vial is pierced to withdraw finished product has been observed in a small number of vials. This may result in particles from the bung entering the product and potentially being drawn up into the syringe upon extraction of the product from the vial. It may also result in the bung not resealing fully after use. Norbrook thus request your action **within forty eight hours (48)** of receipt of this letter. Your company is requested to **immediately quarantine** any remaining stock within your inventory. Only the products listed below are affected by this notice.

In consultation with the Veterinary Medicines Directorate, we request that all remaining vials of the products listed below be returned to your wholesale distributor. Please check your remaining stock to determine whether you have any of the specified products indicated below. If yes, as previously requested, ensure you quarantine all vials of this product and contact your wholesale distributor.

Table 1

Brand Name	Licence No	Market
Repose	58506	Australia

Norbrook Laboratories Ltd is committed to supplying you with quality products and we sincerely regret any inconvenience this issue may cause. Thank you in advance for your assistance. Should you have any questions,

Our Vision

Our Values

please contact Mrs Deborah Curran (+4428 30264435) or alternatively by email to deborah.curran@norbrook.co.uk

Sincerely

Ms. Deborah Curran

QMS & Ops Compliance Manager

Mr. Ken Allen

Qualified Person and Quality Advisor