

From: [REDACTED]
To: [REDACTED]
Subject: Re: Further info [SEC=UNCLASSIFIED]
Date: Friday, 8 July 2016 10:36:32 AM

Hi [REDACTED] some quick answers...

- Was ultrasound gel used for guidance during the procedures? If so, was the gel sterile? Please provide the brand name, batch number and expiry date of the gel used and the management procedures for ultrasound gel within your facility. If ultrasound guidance was used, was a sterile cover used on the probe?

These 2 cases were performed under CT guidance and thus Ultrasound was not used and so no gel used either.

- What are the brand names and batch numbers (if available) of the syringes and needles used in the procedures?

Brand names I'll get for you soon, but I have a feeling these details are not recorded when used, but I will recheck.

- How was the Celestone Chronodose medication drawn up from the ampoule? If the rubber stopper was pierced, was the top of the rubber stopper wiped prior to drawing up the medication and if so, what was the stopper wiped with?

The ampules are in a break open glass container, single use only.

- Were multiple doses taken from the same ampoule?

Single use only.

Hope this helps.

[REDACTED]

On 8 July 2016 at 10:26, [REDACTED] wrote:

Dear [REDACTED]

Thank you for your email regarding your progress with the initial request for further information. We have some additional questions to assist in our assessment of these two cases which I would be grateful if you could provide. These additional questions are listed below.

- Was ultrasound gel used for guidance during the procedures? If so, was the gel sterile? Please provide the brand name, batch number and expiry date of the gel used and the management procedures for ultrasound gel within your facility. If ultrasound guidance was used, was a sterile cover used on the probe?
- What are the brand names and batch numbers (if available) of the syringes and needles used in the procedures?
- How was the Celestone Chronodose medication drawn up from the ampoule? If the rubber stopper was pierced, was the top of the rubber stopper wiped prior to drawing up the medication and if so, what was the stopper wiped with?

- Were multiple doses taken from the same ampoule?

Thank you again for your assistance.

Kind regards,

[REDACTED]

[REDACTED]

Medical Officer
Adverse Event Monitoring and Vaccine Safety
Pharmacovigilance and Special Access Branch

Phone: [REDACTED]

Email: [REDACTED]

Therapeutic Goods Administration

Department of Health
PO Box 100
Woden ACT 2606 Australia
www.tga.gov.au

From: [REDACTED]

Sent: Monday, 4 July 2016 8:45 AM

To: [REDACTED]

Subject: Further info

Hi [REDACTED] still putting together the answers to your questions and should have it to you by end of today.

regards

[REDACTED]

[REDACTED]

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