

From: [REDACTED]
To: [REDACTED]
Cc: [REDACTED]
Subject: RE: Celestone Chronodose ADR report due to possible product contamination [SEC=UNCLASSIFIED]
Date: Friday, 15 July 2016 1:29:54 PM
Attachments: [image001.png](#)
[image002.png](#)
[image003.png](#)
[image004.jpg](#)

Dear [REDACTED]
I have forwarded on your request for a Public Case Detail summary for this case as per your email earlier in the week. You should receive the PCD by early next week at the latest. Batch details are not available at present for this case. I will ensure that communication is directed to [REDACTED] whilst you are leave.

Please let me know if you have any questions.

Kind regards,

[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: Thursday, 14 July 2016 8:21 PM

To: [REDACTED]

Cc: [REDACTED]

Subject: RE: Celestone Chronodose ADR report due to possible product contamination
[SEC=UNCLASSIFIED]

Proprietary

Dear [REDACTED]

I am writing in follow up to your email earlier this week to enquire whether you have further information regarding this case that you can share with MSD.

As I will be out of the office on leave next week (**returning 25Jul2016**), can I ask that you please direct all correspondence relating to this case to [REDACTED] (PV Associate), with cc to our pharmacovigilance mailbox [REDACTED] so that your enquiry is handled in a timely manner?

With warm regards

[REDACTED]
Global Safety Lead Australia & New Zealand

MSD Pharmacovigilance Department-Merck Global Safety

Merck Sharp & Dohme (Australia) Pty Limited

Postal Address: MSD North Ryde Post Business Centre, Locked Bag 2234 North Ryde NSW 1670

e-mail: [REDACTED]

Direct Telephone: [REDACTED]

Mobile: [REDACTED]

Department Telephone: [REDACTED]

Department Fax: [REDACTED]
Department email: [REDACTED]
www.msd-australia.c



From: [REDACTED]
Sent: Monday, 11 July 2016 5:51 PM
To: [REDACTED]
Cc: [REDACTED]
Subject: Celestone Chronodose ADR report due to possible product contamination
[SEC=UNCLASSIFIED]

Dear [REDACTED]

I refer to the adverse event report of fungal joint infection following Celestone Chronodose intra-articular injection (ADR 386482, your reference AUS/16/0843) submitted to the TGA on the 19th of April 2016. Please be aware that the TGA has recently received a second report of fungal joint infection with *S. prolificans* after intra-articular injection with Celestone Chronodose in a different patient.

We are investigating further and will be in touch if we require any information.

Kind regards,

**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

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