

From: [REDACTED]
To: [REDACTED]
Subject: RE: FW: Further information request for cases of fungal septic arthritis post intra-articular steroid injection [SEC=UNCLASSIFIED]
Date: Thursday, 2 March 2017 1:28:21 PM

Hi [REDACTED]

Yes I agree with your response – it would not be appropriate for the TGA to comment on this.

[REDACTED]

[REDACTED]

Signal Investigation Unit
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, 2 March 2017 12:54 PM
To: [REDACTED]
Subject: FW: FW: Further information request for cases of fungal septic arthritis post intra-articular steroid injection [SEC=UNCLASSIFIED]

Hi [REDACTED]

I've received the below email from an interventional radiologist who has contacted me previously regarding two patients of his that developed *scedosporium prolificans* joint infection after intra-articular injection with Celestone Chronodose. He is writing to inform me that he may have found an environmental contaminant and has asked me whether I think this could be the source (see email below). The completed safety filter for this issue concluded that there was inadequate evidence to support contamination of Celestone Chronodose.

I am proposing to respond with the following response. Given the legal sensitivities around this case, would you mind having a quick look at my proposed response before I send it out?

Thank you!

[REDACTED]

"Dear [REDACTED]

Thank you for your email. I am unable to comment on whether the air conditioning unit in your facility is likely to be a source of Scedosporium prolificans. I suggest that you liaise internally with your infection control representative and as discussed previously, with your local public health unit.

Kind regards,"

[REDACTED]
Medical Officer
Signal Investigation Unit
Pharmacovigilance and Special Access Branch

Phone: [REDACTED]
Email: [REDACTED]

Therapeutic Goods Administration

Department of Health
PO Box 100
Woden ACT 2606 Australia
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I acknowledge the traditional custodians of the lands and waters where we live and work, and pay my respects to elders past, present and future.

From: [REDACTED]
Sent: Wednesday, 1 March 2017 7:18 PM
To: [REDACTED]
Subject: Re: FW: Further information request for cases of fungal septic arthritis post intra-articular steroid injection [SEC=UNCLASSIFIED]

Hi [REDACTED] we may have found an environmental source (as you alluded to months ago) for the rare infections to 2 patients while undergoing a CT guided injection. There is an airconditioning unit which blows directly onto the CT table where I carry out the procedures. Since installation no one to our knowledge has cleaned the filters until today when my lead radiographer noticed the aircon looking particularly dirty and called maintenance to clean. Attached are the photos taken which are quite gross and show fungus against the white plastic backing. Do you think this is the source? It would certainly explain a lot of things.
regards
[REDACTED]

[REDACTED]

On 13 September 2016 at 12:56, [REDACTED] wrote:
Dear [REDACTED]

Apologies for missing your call on Friday – I have been on leave. I returned your call this morning but was told that you are on leave for the next few weeks. Please let me know when you are back from leave and I will return your call then.

In the meantime, if you are able to provide the additional information we requested (see below), that would be greatly appreciated.

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

I acknowledge the traditional custodians of the lands and waters where we live and work, and pay my respects to elders past, present and future.

From: [REDACTED]
Sent: Friday, 1 July 2016 11:24 AM
To: [REDACTED]
Subject: Further information request for cases of fungal septic arthritis post intra-articular steroid injection [SEC=UNCLASSIFIED]

Dear [REDACTED]

Thank you again for your time on the phone this morning. As discussed we are collecting additional information for the two cases of septic arthritis with *Scedosporium Prolificans* following an intra-articular steroid injection at your imaging practice. Below is the list of additional information we are collecting. I have included questions on patient risk factors and adverse event in case you have this information available to you.

Procedure Details (if more than one procedure, please provide details for each injection)

- Date and time of procedure:
- Anatomical site of injection:
- Indication for injection:
- Facility location:
- Room type (e.g. procedure room/outpatient setting):
- Number of procedure list:
- Number of patients on the same list who were injected with Celestone on the same day:

Medication Details (if more than one procedure, please provide details for each injection)

- Brand name of steroid injected:
- Batch (if available):
- Expiry (if available):
- Dose:
- Other medications injected? If yes, please provide details for these medications if available:
 - Brand name:
 - Dose/volume:
 - Batch number (if available):
 - Expiry date (if available):
 - How were the other medications mixed with the steroid:

Procedure Technique (if more than one procedure, please provide details for each injection)

- Preparation used to clean the skin prior to injection (e.g. alcohol swab / chlorhexidine / betadine), brand name and batch (if available):
- Details of aseptic technique (e.g. were sterile gloves, mask, gown, and/or sterile drape/towel used):
- Was the needle changed between drawing up the steroid and injecting the steroid:
- Description of technique for drawing up medications and administration:

Patient Risk Factors:

- Did the patient have any of the following risk factors for septic arthritis:
 - *Previous joint surgery*
 - *Presence of prosthetic material in the joint*
 - *Diabetes mellitus*
 - *Immunosuppressive medication*
 - *Pre-existing joint disease (e.g. rheumatoid arthritis)*

Adverse Event Details

- Onset date:
- Clinical details:
- Outcome:

Please feel free to provide any other information that you think may be of use.

Thank you very much for your time and assistance in providing this additional information. Please feel free to contact me if you think of any additional information.

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
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