

From: [REDACTED]
To: [REDACTED]
Subject: FW: Further information request for cases of fungal septic arthritis post intra-articular steroid injection [SEC=UNCLASSIFIED]
Date: Tuesday, 13 September 2016 12:56:11 PM

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]
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 Signature]

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

Phone: [Redacted]

Email: [Redacted]

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