

ADRS Case Number: 386482 - 19/04/2016 - Posted

ADR Number: 386482
 Status: Posted
 Withdrawal/Rejection Reason:
 Sequence No: 1

Case Date: 19/04/2016
 Duplicates: Single

Previous No:

Next No:

Patient Details

Patient ID: [REDACTED]

Date of Birth:

Age: 47Y

Ethnicity:

Gender: Male
 Female
 Unknown

Weight: 0 kg

State:

Medicare Number:

Reaction Coding

Onset Date: 11/11/2015

Reaction Outcome: * Unknown U

Outcome Date:

Severity Details: Caused or prolonged inpatient hospitalisation H

Adverse Reaction Description :

DUPLICATE OF 377658

Case Description: Information had been received on 18-APR-2016 from lawyer regarding a case in litigation. It was alleged in litigation that on or about 11-NOV-2015, a 47 year old male underwent surgery in relation to a check-up for bilateral hip pain. On or about 11-NOV-2015 at an unknown time after attending the surgery, patient attended a second surgery where he was administered two betamethasone acetate (+) betamethasone sodium phosphate (CELESTONE CHRONODOSE) injections that consisted of one injection to each of his left and right hips. On or about 11:53 am on 27-JAN-2016, patient again attended surgery where he was administered a further two betamethasone acetate (+) betamethasone sodium phosphate (CELESTONE CHRONODOSE) injections in the same manner as previously received. On or about 29-JAN-2016, patient began limping at work and suffered severe pain in his left hip. After about four days after this treatment, patient began to experience further pain to his right and left hip. Patient saw physician and underwent magnetic resonance imaging (MRI) which revealed fluid build-up in his hip. Although patient was unable to remember to exact date, he attended an appointment with a physician where he was administered one cortisone (unspecified) injection to his left hip. On or about 09-MAR-2016, patient awoke with severe pain to his left and right hips and could not walk. Patient was transported by ambulance to the hospital where he has remained until this current date. Since being admitted, patient underwent four operations to his hips to date. Patient was uncertain of the dates of these operations. Patient reported that prior to being treated by physician on the first occasion, he had never sustained an injury and/or pain or discomfort to his left and right hips. The operating surgeon informed the patient that the infection was caused by a fungus that could only occur by piercing of the skin. Patient noted that the only piercing of the skin was a result of the injections he received. Patient noted the contaminated betamethasone acetate (+) betamethasone sodium phosphate (CELESTONE CHRONODOSE) administered to him by injection was a necessary condition to him suffering the injury. Patient claimed that he suffered severe pain from the scedosporium prolificans (fungal infection) that resulted in hip replacement surgery. No further information expected.

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Treatment:
Hospitalisation:*

Lowest Level Term	Adverse Reaction Description
Fungal infection	N/A
Hypokinesia	N/A
Arthralgia	N/A
Gait disturbance	N/A
Product contamination microbial	N/A
Abasia	N/A
Fatigue	N/A
Scar	N/A
Laceration	N/A
Joint effusion	N/A

Medicine Coding

* Medicine Name:
Dose:
Frequency:
Form:
Route:
Begun Date:
Halted Date:
Reason for Use:

Medicine Coding

* Medicine Trade Name:
ARTG Product:
* Suspect Code: Other drug O
Action taken with medicine:
Rechallenge:

Reason for Use:
Dosage Start Code:
Dosage Halt Code:
Batch:
First/Single Indicator: N
Previously Used: N

Medicine Name/Trade Name	Drug Begun Date	Drug Halt Date	Withdrawal Code	Reason for Use	Suspect Code
Celestone Chronodose	11/11/2015	N/A	N/A	Hip pain	Suspected

Laboratory Coding

Investigation Type
No Entries

Supporting Documents

Title	Type	Location
19 April 2016 Referred to Medicine Problem AUS/16/0843 01 Jun 2016 Follow-up 1 CIOMS submission AUS/16/0843 19 Apr 2016 Initial CIOMS submission	Attachment Attachment Attachment	Emailed Emailed Emailed

Correspondence

Type	Mode	Author	Date
Company Acknowledgement - Single	Not Sent	ADRS New Case	19/04/2016

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Company Acknowledgement - Single	Emailed on 19/04/2016 12:35:27 PM	Agent: [REDACTED]	19/04/2016
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Comments

Title	Comments	Author	Date
Initial Comment	MSD reporter: [REDACTED]	Merck Sharp Dohme	19/04/2016

Additional Coding

* Causality: Causality unclear 04
 * Drug Status: General marketing GM
 Include/Exclude: General List Report ie Causality unclear G
 WHO Extract Date:
 WHO Report:
 Other Factors:
 Possible Interaction:
 Additional Information:

Reporter Details

Name:	Merck Sharp Dohme	Type:	Drug Company
Address:	Merck Sharp and Dohme (MSD) Building A 26 Talavera Road		
Suburb:	Macquarie Park	Phone:	[REDACTED]
State/Region:	NSW	Fax:	[REDACTED]
Postcode:	2113	Email:	[REDACTED]
Country:	AUS		

Case History 