ADR Number: 377658
Status: Posted
Withdrawal/Rejection Reason:
Sequence No: 1

Case Date: 18/03/2016
Duplicates: Single
Previous No:
Next No:

Patient Details

Patient ID: [redacted]
Date of Birth: [redacted]
Age:

Ethnicity:
Gender: ● Male ○ Female ○ Unknown
Weight: 0 kg

State: QLD
Medicare Number:

Reaction Coding

Onset Date: 12/02/2016
Reaction Outcome: ★ Not yet recovered F
Outcome Date:
Severity Details: Caused or prolonged inpatient hospitalisation H
Adverse Reaction Description: Bilateral hip joint septic arthritis with Scedosporium prolificans (fungus)
Concerned that celestone may have been contaminated with fungus
Treatment: Multiple hip washouts; Treatment with voriconazole and terbinafine; Problem ongoing as of 18/3/2016 (still in hospital)

fURTHER INFORMATION:
17/02/2016 Scedosporium (inflatum) prolificans left hip
31/05/2016 Scedosporium (inflatum) prolificans right hip

Please note also that in a addition to receiving intra-articular Celestone, the patients received intra-articular radiological contrast at the same time.
The product used was Celestone (Merck). No batch numbers were recorded.

Hospitalisation: ★

Lowest Level Term	Adverse Reaction Description
Scedosporium prolificans infection	N/A
Septic joint	N/A
Product quality issue	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	09/02/2016	N/A	N/A	Osteoarthritis of hips	Suspected
Chronodose	N/A	N/A	N/A	N/A	Suspected
Contrast Medium Nos	N/A	N/A	N/A	N/A	Suspected
Saline					

Laboratory Coding

Investigation Type
Albumin

Supporting Documents

Title	Type	Location
FI-01	Other	Emailed

Correspondence

Type	Mode	Author	Date
Acknowledgement - General	Not Sent	ADRS New Case	18/03/2016
Acknowledgement - General	Not Sent	Agent	22/03/2016
General request for information on a report	Emailed on 22/03/2016 12:04:35 PM	[redacted]	22/03/2016

Comments

Title	Comments	Author	Date
Follow-up information	Additional information obtained on 01/07/16 from radiologist and ID specialist - see trim container 2016/011586:	[redacted]	08/11/2016
Initial Comment	Procedure undertaken for this case and case 390962 by same radiologist. Concomitantly administered saline, contrast and local anaesthetic. Awaiting further information from radiologist regarding brand names and batch numbers and technique for injection. CT used for guidance rather than USS. Intraarticular injections given in a a private radiology practice. Details should be available through: [redacted] Queensland Diagnostic Imaging 2 Lake Street Varsity Lakes Qld 4227 Tel: [redacted]		18/03/2016

Additional Coding

☆	Causality:	Causality possible	03
☆	Drug Status:	General marketing	GM
	Include/Exclude:	Report Included	I
	WHO Extract Date:	13/12/2016	13/12/2016
	WHO Report:	Successful	

Other Factors:
Possible Interaction:
Additional Information:

Reporter Details

Name:	[redacted]	Type:	Specialist
Address:	Gold Coast University Hospital		
Suburb:	Southport	Phone:	[redacted]
State/Region:	QLD	Fax:	
Postcode:	4215	Email:	[redacted]
Country:	AUS		

Case History

CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

AUS/16/0843

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH Day	Month	Year	2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET Day	Month	Year
PRIVACY	AUSTRALIA		PRIVACY		47 Years	Male	Unk	11	NOV	2015

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)
Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas)

Other Serious Criteria: Medically Significant
scedosporium prolificans (fungal infection) resulting in three surgeries to remove infection and hip replacement surgery [Scedosporium infection]
restricted movement/confined to bed/using a walking aide to facilitate movement [Hypokinesia]
severe pain in left hip/further pain to right and left hip [Arthralgia]
limping [Gait disturbance]
Celestone Chronodose was contaminated [Product contamination microbial]
could not walk [Abasia]
exhaustion [Fatigue]

(Continued on Additional Information Page)

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALISATION
- ☒ INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY
- ☐ LIFE THREATENING
- ☐ CONGENITAL ANOMALY
- ☐ OTHER

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)
#1) CELESTONE CHRONODOSE (betamethasone acetate (+) betamethasone sodium phosphate) Injection
(Continued on Additional Information Page)

20. DID REACTION ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☒ NA

15. DAILY DOSE(S)
#1) UNK, Unknown

16. ROUTE(S) OF ADMINISTRATION
#1) Unknown

17. INDICATION(S) FOR USE
#1) hip pain (Arthralgia)

21. DID REACTION REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☒ NA

18. THERAPY DATES (from/to)
#1) 11-NOV-2015 / Unknown

19. THERAPY DURATION
#1) Unknown

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)

23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)

From/To Dates	Type of History / Notes	Description
Unknown	Current Condition bilateral	Pain in hip (Arthralgia)
11-NOV-2015 to Unknown	Historical Condition x 2	Hip surgery (Hip surgery)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER
MSD
MSD Australia, MSD North Ryde Post Business Centre, Locked Bag 2234
North Ryde, NSW 1670 AUSTRALIA
Phone: [redacted]

26. REMARKS
Medically Confirmed: No

24b. MFR CONTROL NO.
1604AUS011123

25b. NAME AND ADDRESS OF REPORTER
NAME AND ADDRESS WITHHELD.
NAME AND ADDRESS WITHHELD.
NAME AND ADDRESS WITHHELD.

24c. DATE RECEIVED BY MANUFACTURER
18-APR-2016

24d. REPORT SOURCE
☐ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL ☒ OTHER: Spontaneous

DATE OF THIS REPORT
18-APR-2016

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: 1604AUS011123

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

scarring [Scar]
two large lacerations [Laceration]
fluid build up in hip [Joint effusion]

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. Patient reported that the betamethasone acetate (+) betamethasone sodium phosphate (CELESTONE CHRONODOSE) that was injected into his left and right hips was contaminated and resulted in the injury he sustained. Patient noted that the pain from the scedosporium prolificans (fungal infection) and consequential hip replacement surgery and scarring should have been foreseen. Patient reported he underwent surgery on three occasions to left and right hips to remove infection that resulted in two large lacerations. Patient claimed that he sustained a disability resulting form restricted movement, being confined to bed and using a walking aide to facilitate mobility. Patient noted he was currently only able to walk 25 meters at a time before being confined to bed due to pain and exhaustion. Since the date of the incident, patient reported he had not been able to work, drive a motor vehicle, perform home duties or participate in social events with his family and friends.

Restricted movement/confined to bed/using a walking aide to facilitate movement was considered to be disabling.

Upon internal review, scedosporium prolificans (fungal infection) resulting in three surgeries to remove infection and hip replacement surgery was considered to be medically significant.

Additional information is not expected.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	02-FEB-2016	Nuclear magnetic resonance imaging	fluid build-up in hip	

14-19. SUSPECT DRUG(S) continued

14. SUSPECT DRUG(S) (include generic name)	15. DAILY DOSE(S); 16. ROUTE(S) OF ADMIN	17. INDICATION(S) FOR USE	18. THERAPY DATES (from/to); 19. THERAPY DURATION
#1) CELESTONE CHRONODOSE (betamethasone acetate (+) betamethasone sodium phosphate) Injection; Regimen #2	UNK, Unknown; Unknown	hip pain (Arthralgia)	27-JAN-2016 / Unknown; Unknown

MSD reporter: [redacted]
AUS/16/0843
19Apr2016

CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		Day	Month	Year				Day	Month	Year	
PRIVACY	AUSTRALIA		PRIVACY		47 Years	Male	Unk	11	NOV	2015	☐ PATIENT DIED

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)
Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas)

Other Serious Criteria: Medically Significant
Scedosporium prolificans (fungal infection) resulting in three surgeries to remove infection and hip replacement surgery [Scedosporium infection]
Restricted movement/confined to bed/using a walking aide to facilitate movement [Hypokinesia]
Severe pain in left hip/further pain to right and left hip [Arthralgia]
Limping [Gait disturbance]
Celestone Chronodose was contaminated [Product contamination microbial]
Could not walk [Abasia]
Exhaustion [Fatigue]

(Continued on Additional Information Page)

- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALISATION
- ☒ INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY
- ☐ LIFE THREATENING
- ☐ CONGENITAL ANOMALY
- ☐ OTHER

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)
#1) CELESTONE CHRONODOSE (betamethasone acetate (+) betamethasone sodium phosphate) Injection
(Continued on Additional Information Page)

20. DID REACTION ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☒ NA

15. DAILY DOSE(S)
#1) UNK, Unknown

16. ROUTE(S) OF ADMINISTRATION
#1) Unknown

17. INDICATION(S) FOR USE
#1) hip pain (Arthralgia)

21. DID REACTION REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☒ NA

18. THERAPY DATES (from/to)
#1) 11-NOV-2015 / Unknown

19. THERAPY DURATION
#1) Unknown

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)

23. OTHER RELEVANT HISTORY, (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)

From/To Dates	Type of History / Notes	Description
Unknown	Current Condition Bilateral	Pain in hip (Arthralgia)
11-NOV-2015 to Unknown	Historical Condition x 2	Hip surgery (Hip surgery)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER
MSD
MSD Australia, MSD North Ryde Post Business Centre, Locked Bag 2234
North Ryde, NSW 1670 AUSTRALIA
Phone: [redacted]

26. REMARKS
Medically Confirmed: No
World Wide #: AU-009507513-1604AUS011123

24b. MFR CONTROL NO.
1604AUS011123

24c. DATE RECEIVED BY MANUFACTURER
26-MAY-2016

24d. REPORT SOURCE
☐ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL ☒ OTHER: Spontaneous

DATE OF THIS REPORT
30-MAY-2016

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

25b. NAME AND ADDRESS OF REPORTER
NAME AND ADDRESS WITHHELD.
NAME AND ADDRESS WITHHELD.
NAME AND ADDRESS WITHHELD.
NAME AND ADDRESS WITHHELD.
NAME AND ADDRESS WITHHELD.

Mfr. Control Number: 1604AUS011123

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Scarring [Scar]
Two large lacerations [Laceration]
Fluid build up in hip [Joint effusion]

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. Patient reported that the betamethasone acetate (+) betamethasone sodium phosphate (CELESTONE CHRONODOSE) that was injected into his left and right hips was contaminated and resulted in the injury he sustained. Patient noted that the pain from the scedosporium prolificans (fungal infection) and consequential hip replacement surgery and scarring should have been foreseen. Patient reported he underwent surgery on three occasions to left and right hips to remove infection that resulted in two large lacerations. Patient claimed that he sustained a disability resulting form restricted movement, being confined to bed and using a walking aide to facilitate mobility. Patient noted he was currently only able to walk 25 meters at a time before being confined to bed due to pain and exhaustion. Since the date of the incident, patient reported he had not been able to work, drive a motor vehicle, perform home duties or participate in social events with his family and friends.

An AE QIR has been requested by quality for this case. While there is no lot number associated with this case, an AE QIR is being performed for lots on the subject market.

Information received on 26-MAY-2016 reported that all in-process quality checks for the lot number(s) in question were satisfactory. The results indicated that the lot number(s), for this product and other reported products, as applicable, were manufactured in accordance with manufacturing site standard operating procedures. The lot(s) met the requirements for market release.

Restricted movement/confined to bed/using a walking aide to facilitate movement was considered to be disabling.

Upon internal review, scedosporium prolificans (fungal infection) resulting in three surgeries to remove infection and hip replacement surgery was considered to be medically significant.

Additional information is not expected.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	02-FEB-2016	Nuclear magnetic resonance imaging	Fluid build-up in hip N/A	

14-19. SUSPECT DRUG(S) continued

14. SUSPECT DRUG(S) (include generic name)	15. DAILY DOSE(S); 16. ROUTE(S) OF ADMIN	17. INDICATION(S) FOR USE	18. THERAPY DATES (from/to); 19. THERAPY DURATION
#1) CELESTONE CHRONODOSE (betamethasone acetate (+) betamethasone sodium phosphate) Injection; Regimen #2	UNK, Unknown; Unknown	hip pain (Arthralgia)	27-JAN-2016 / Unknown; Unknown

ADR Number: 377658 Case Date: 18/03/2016

Fields marked ★ are mandatory

★ Title: FI-01
Description:
★ Delivery Method: Emailed
Attachment(s):

From: [redacted]
Sent: Thursday, 30 June 2016 8:38 PM
To: ADR Reports
Subject: FW: Scedosporium prolificans infection associated with corticosteroid intra-articular injections

Please note also that in a addition to receiving intra-articular Celestone, the patients received intra-articular radiological contrast at the same time.

The product used was Celestone (Merck).
No batch numbers were recorded.
The radiologist involved may be able to help further:
[redacted]

From: [redacted]
Sent: Thursday, 30 June 2016 5:38 PM
To: ADR Reports
Subject: FW: Scedosporium prolificans infection associated with corticosteroid intra-articular injections

The product used was Celestone (Merck).
No batch numbers were recorded.
The radiologist involved may be able to help further:
[redacted]

From: [redacted]
Sent: Thursday, 30 June 2016 11:10 AM
To: [redacted]
Subject: Scedosporium prolificans infection associated with corticosteroid intra-articular injections

Patient 1
[redacted]
Tel: [redacted]
17/02/2016 *Scedosporium* (*inflatum*) *prolificans* left hip (Gold Coast University Hospital 1300 744 284)
31/05/2016 *Scedosporium* (*inflatum*) *prolificans* right hip (Gold Coast University Hospital)

Radiologist: [redacted]

Queensland Diagnostic Imaging
[redacted]
Both hips injected with corticosteroid [redacted]

Patient 2
[redacted]
Tel: [redacted] Mobile: [redacted]
[redacted]
Currently (30/3/16) an inpatient in Ward 8 Gold Coast Private Hospital

Right knee injected with corticosteroid in [redacted] at
Queensland Diagnostic Imaging
[redacted] Tel: [redacted]

[redacted] *Scedosporium (inflatum) prolificans* right knee (Sullivan and
Nicolaides Pathology [redacted]
08/04/2016 No growth from right knee fluid
04/07/16 Further debridement with culture planned

[redacted]
Director of Infectious Diseases and Immunology
Gold Coast University Hospital

1 Hospital Boulevard
Southport QLD 4215

Tel: [redacted]

Web: www.goldcoast.health.qld.gov.au
Intranet: gchweb.sth.health.qld.gov.au

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