Manufacturer Incident Report (MIR) for Serious Incidents (MDR/IVDR) and Incidents (AIMDD/MDD/IVDD)

Reporting Template Version 7.2.1

European Union Medical Devices Vigilance System

Import XML | Align form after import

Section 1: Administrative information

1.1 Corresponding competent authority

a Name of receiving national competent authority (NCA)
Agencia Española de Medicamentos y Productos Sanitarios

b EUDAMED number of NCA

c Reference number assigned by NCA for this incident
PS/JMP/61916

d Reference number assigned by EUDAMED for this incident

1.2 Date, type, and classification of incident report

a Date of submission: 2020-09-23 (e.g. 2012-10-23)

b Date of incident (e.g. 2012-10-23): 2020-08-24 to 2020-08-24

c Manufacturer awareness date: 2020-08-24 (e.g. 2012-10-23)

d Type of report
- ○ Initial
- ○ Follow up
- ○ Combined initial and final
- ◉ Final (Reportable incident)
- ○ Final (Non-reportable incident)

e In case of initial and follow-up reports, please indicate the expected date of the next report
(e.g. 2012-10-23)

f Classification of incident
- ○ Serious public health threat
- ○ Death
- ○ Unanticipated serious deterioration in state of health
- ◉ All other reportable incidents

1.3 Submitter information

1.3.1 Submitter of the report

a ○ Manufacturer ○ Authorised representative ◉ Other, please specify: Local Country Submitter

b Manufacturer's reference number for this incident
2020327840

c	If this incident involves multiple devices from the same manufacturer, please list the respective reference numbers of the other MIR forms you have submitted - NCA's local reference number - EUDAMED's reference number - Manufacturer's reference number		
d	If this incident is covered under an FSCA, please provide the relevant numbers: - NCA's local FSCA reference number - EUDAMED's FSCA reference number - Manufacturer's FSCA reference number		
e	Periodic Summary Report (PSR) ID		
f	If the incident occurred within a PMCF/PMPF investigation; please provide the Eudamed ID of that PMCF/PMPF investigation		
1.3.2	**Manufacturer information**		
a	Manufacturer organisation name Angelini Pharma Inc.		
b	Single registration number		
c	Contact's first name Jason	d	Contact's last name Oman
e	Email jason.oman@angelinipharma.com	f	Phone 229-446-3005
g	Country US - United States of America		
h	Street Wyandotte Drive	i	Street number 1231
j	Address complement	k	PO Box
l	City name Albany	m	Postal code 31705
1.3.3	**Authorised representative information**		
a	Authorised representative organisation name Angelini Pharma S.p.A.		
b	Single Registration Number		
c	Contact's first name Carlo Mario	d	Contact's last name Selvaggini
e	Email authorised.representative@angelinipharma.com	f	Phone 39071809497
g	Country IT - Italy		

h	Street Viale Amelia	i	Street number 70
j	Address complement	k	PO Box
l	City name Rome	m	Postal code 00181
1.3.4	**Submitter's details if not also manufacturer or authorised representative**		
a	Registered commercial name of company Pfizer Inc.		
b	Contact's first name Mónica	c	Contact's last name Marcano
d	Email Monica.Marcano@pfizer.com	e	Phone 34 91 490-9563
f	Country ES - Spain		
g	Street Avda. Europa	h	Street number 20 B
i	Address complement	j	PO Box
k	City name Alcobendas (Madrid)	l	Postal code 28108

Section 2: Medical device information

2.1 Unique Device Identification (UDI)

a	UDI device identifier/Eudamed ID: Unknown	b	UDI production identifier: Unknown
c	Basic UDI-DI/Eudamed-DI: Unknown	d	Unit of use UDI-DI:

2.2 Categorisation of device

a Medical device terminology

○ EMDN ○ GMDN ◉ UMDNS(ECRI) ○ GIVD/EDMS ○ Other, please specify:

b Medical device nomenclature code: 12040

2.3 Description of device and commercial information

a Medical device name (brand/trade /proprietary or common name): ThermaCare HeatWrap

b Nomenclature text/Description of the device and its intended use: Hot Packs

c	Model:	d	Catalogue/reference number:
e	Serial number:	f	Lot/batch number:
g	Software version: N/A	h	Firmware version:
i	Device manufacturing date (e.g. 2012-10-23):	j	Device expiry date (e.g. 2012-10-23):
k	Date when device was implanted (e.g. 2012-10-23): to	l	Date when device was explanted (e.g. 2012-10-23): to

m If precise implant/explant dates are unknown, provide the duration of implantation

Number of years: Number of months: Number of days:

n	Implant facility:	o	Explant facility:

p

	Notified body (NB) ID number(s) (if applicable)	Notified body (NB) certificate number(s) of device (if applicable)
1	1639	BE18/819943306
2		

q Please indicate the date of one of the following:

○ First declaration of conformity
○ The device first CE marked
○ First placed on the market
○ First put into service
○ If software, date first made available

Year: Month:

2.4 Risk class of device when placed on market

a

◯ This device has been placed on the market before the implementation of the MDD/AIMDD/IVDD

b

MDD/AIMDD

- ◯ active implant
- ◯ class III
- ◯ class IIb
- ◉ class IIa
- ◯ class I
- ◯ class Is
- ◯ class Im
- ◯ class Ism
- ◯ custom-made

IVDD

- ◯ IVD Annex II List A
- ◯ IVD Annex II List B
- ◯ IVD devices for self-testing
- ◯ IVD general

c

MDR

- ◯ class III
- ◯ class IIb
- ◯ class IIa
- ◯ class I

Type (Multiple choice)

- ☐ implantable
- ☐ active device
- ☐ intended to administer and/or remove a medicinal product
- ☐ sterile conditions
- ☐ measuring function
- ☐ reusable surgical instruments
- ☐ software
- ☐ systems
- ☐ procedure packs
- ☐ custom-made
- ☐ non-medical purpose

IVDR

- ◯ class D
- ◯ class C
- ◯ class B
- ◯ class A

Type (Multiple choice)

- ☐ self-testing
- ☐ near-patient testing
- ☐ professional testing
- ☐ companion diagnostic
- ☐ reagent
- ☐ software
- ☐ instrument
- ☐ sterile conditions

2.5 Market distribution of device (region/country)

(according to the best knowledge of the manufacturer)

a

☐ All EEA, Switzerland and Turkey

☒ AT	☒ BE	☐ BG	☒ CH	☐ CY	☒ CZ	☒ DE	☒ DK	☐ EE	☒ ES	☒ FI	☒ FR	☒ GB
☐ GR	☐ HR	☒ HU	☒ IE	☐ IS	☒ IT	☐ LI	☐ LT	☒ LU	☐ LV	☒ MT	☒ NL	☒ NO
☒ PL	☒ PT	☒ RO	☒ SE	☐ SI	☒ SK	☒ TR						

Others:

2.6 Use of accessories, associated devices or other devices

a Relevant accessories used with the device being reported on (please list with corresponding Manufacturer if different from device being reported on)

N/A

b Relevant associated devices used with the device being reported on (please list with corresponding Manufacturer if different from device being reported on)

N/A

Section 3: Incident information derived from healthcare professional/facility/patient/lay user/other

3.1	Nature of incident
a	Provide a comprehensive description of the incident, including (1) what went wrong with the device (if applicable) and (2) a description of the health effects (if applicable), i.e. clinical signs, symptoms, conditions as well as the overall health impact (i.e. Death; life-threatening; hospitalization – initial or prolonged; required intervention to prevent permanent damage; disability or permanent damage; congenital anomaly/Birth defects; indirect harm; no serious outcome)

This is a spontaneous report received from a contactable consumer. A female patient of unknown age exposed to ThermaCare heatwrap (THERMACARE HEATWRAP) on unknown date for unknown indication. Medical history and concomitant medications were not reported. The reporter had lumbago, the patient (physiotherapist) could not massage the reporter with the thermacare patches, reporter had to take it off otherwise it will remain on her hands reporter didn't know what, her hands remained very bad reporter didn't know why. The Physiotherapist tells that when she massages someone who uses Thermacare patches, something remains in her hands and it affects her hands. The action taken in response to the events of the product was unknown. The outcome of the events was unknown. Product investigation results are as follows: Conclusion: The root cause category is non-assignable (complaint not confirmed as a quality defect). There was limited device specific information provided, no batch number or return sample was available for evaluation. Without a batch reference number, a manufacturing and technical evaluation cannot be completed for the wrap involved in this case. There is not a product quality related trend identified for the subclass Adverse Event Safety Request for Investigation. The manufacturing operations employ quality control procedures which include in process testing, thermal testing and visual inspection, to ensure the quality of the product being packaged. Reasonably Suggest Device Malfunction: No. Severity of Harm: N/A. A return sample has not been received at the site for evaluation as of 26-Aug-2020.

Additional information has been requested and will be provided as it becomes available.

Follow-up (11Sep2020): New information obtained from CITI includes: product investigation results.

Follow-up (18Sep2020): This is a follow-up report obtained from CITI.

PR ID (Inv): 5166612; PR ID (CR): 5166501; (Parent) Brand/Trade-Name: THERMACARE HEAT WRAP
TOPICAL; (Parent) Complaint Class: External Cause Investigation; (Parent) Complaint Sub-Class: Adverse Event Safety Request For Investigation; Device or Combo?: Yes.

CITI PR ID#5166612; Site: DCHU; Record Type: CITI / Summary Investigation; Status: Closed.

(Parent) Complaint Class:External Cause Investigation
(Parent) Complaint Sub-Class:Adverse Event Safety Request For Investigation
(Parent) Brand/Trade-Name: THERMACARE HEAT WRAP TOPICAL
(Parent) Product Family-API: THERMACARE
Product-Description: THERMACARE LOWER BACK/HIP HEATWRAP 8 HR
Product-Category:TOPICAL
(Parent) Product-Type: OTC
(Parent) Combination-Product: No
(Parent) Combination-Product-Type: N/A
(Parent) Sterile-Product: No
(Parent) Medical-Device:Yes
(Parent) UDI-(if appl): N/A
Lot#Unknown; Expiration Date: Not provided
Description of Complaint: Product Complaint Exchange: [ThermaCare HeatWrap/ Injury to hand NOS]
patient has lumbago, the physio could not massage him while using the thermacare patches. The Physio tells that when she massages someone who uses Thermacare patches, something remains in her hands and it affects her hands.
Brief Complaint Description: This is a spontaneous report received from a contactable consumer. A female patient of unknown age exposed to ThermaCare heatwrap (THERMACARE HEATWRAP) on unknown date for unknown indicaion. Medical history and concomitant medications were not reported. The reporter had lumbago, the patient (physiotherapist) could not massage the reporter with the thermacare patches, reporter had to take it off otherwise it will remain on her hands reporter didn't know what, her hands remained very bad reporter didn't know why. The action taken in response to the events of the product was unknown. The outcome of the events was unknown. Additional information has been requested and will be provided as it becomes available.
Reasonably Suggest Device Malfunction: Yes
Severity of Harm: S3
Failure Mode: Device Defective-Remains on Skin
IDC - Level 1: Quality
IDC - Level 2: Product Complaint
IDC - Level 3: Complaint - Function / Therapeutic Properties
Investigation Decision: Repeat Investigation?: No
Was CAPA Previously Identif'd?: No
Full Investigation Required?:No
QA Review & Rationale:DCHU reviewed the classification, sub-classification, priority, product information and justification. Site Assignment Grid was reviewed and is accurate and appropriate. An investigation will be performed. A full investigation was not performed the DCHU as providing the batch record information is the manufacturing site's requirement; therefore, a summary investigation was performed. The field for device malfunction in CITI is required to conditionally populate the severity ranking.

Reportability Determination: The complaint for patient communicates that her physio has told her that she will not be able to give her a massage with the Thermacare patches since "it remains on her hands I don't know what", her hands remain very bad, she does not know why for ThermaCare HeatWrap is 30-day reportable in the US; if it were to recur it would be likely to cause or contribute to death or serious injury. This event is 15-day reportable for ROW as this could lead to death or serious deterioration in state of health if it were to recur. This is a reportable malfunction. This product was used for treatment. Case Reportability Determination: Argus AER # 2020327840 CL #3, CL#5; DCHU Peer Reviewer Reportability Determination: Agreed.
Investigation Findings:Summary of Investigation:This investigation was conducted for an unknown lot Number Lower Back/Hip (LBH) 8-hour product. Based on the complaint narrative/Reportability Determination: The complaint for patient communicates; that her physio has told her that she will not be able to give her a massage with the Thermacare patches on since "it remains on her hands I don't know what", her hands remain very bad, she does not know why ThermaCare HeatWrap causes this. This event is 30-day reportable in the US; if it were to recur it would be likely to cause or contribute to death or serious injury. This event is 15-day reportable for ROW as this could lead to death or serious deterioration in state of health if it were to recur. This is a reportable malfunction. This product was used for treatment. There was limited device specific information provided, no batch number was available for evaluation. Without a batch reference number, a manufacturing and technical evaluation cannot be completed for the wrap involved in this case. There is not a product quality related trend identified for the subclass Adverse Event Safety Request for Investigation.
Root Cause / CAPA:Process Related?: N/A; Vendor Related?:No; Final Confirmation Status:Not Confirmed; Root Cause Category (Tier 1): Non-assignable (Complaint Not Confirmed);Root Cause Category (Tier 2): Non-assignable (Complaint Not Confirmed); Root Cause Category (Tier 3): N/A.
Conclusion & Approvals: Additional Approval(s) Req'd?: No; Product Quality Impact: No;
Market / Clinical Impact: No; Stability Impact: No; SQRT Review Required?: No; AQRT Review Req'd?: No
Reserve Sample Evaluation:Rsrv. Sample Evaluation Reqd?:No Source Value;Rsrv. Sample Eval. Rationale: Not performed by DCHU; Confirmed Reserve Defect?:No.
Trend/Complaint History: Lot-Specific Trend Identified?: No;
Expedite Trends:Expedite Trend Identified?: No; Exped Trend Assmt. & Rationale:N/A
Complaint Sample Evaluation:(Parent) Sample_Status: Sample Availability Unknown;
Site Sample Status: Not Received.
Confirmed Compl Sample Defect?: N/A - Not Received

Conclusion: Based on the complaint narrative/Reportability Determination: The complaint for patient communicates; that her physio has told her that she will not be able to give her a massage with the Thermacare patches on since "it remains on her hands I don't know what", her hands remain very bad, she does not know why ThermaCare HeatWrap causes this. This event is 30-day reportable in the US; if it were to recur it would be likely to cause or contribute to death or serious injury. This event is 15-day reportable for ROW as this could lead to death or serious deterioration in state of health if it were to recur. This is a reportable malfunction. This product was used for treatment.
The root cause category is non-assignable (complaint not confirmed as a quality defect). There was limited device specific information provided, no batch number or return sample was available for evaluation. Without a batch reference number, a manufacturing and technical evaluation cannot be completed for the wrap involved in this case. There is not a product quality related trend identified for the subclass Adverse Event Safety Request for Investigation. The manufacturing operations employ quality control procedures which include in process testing, thermal testing and visual inspection, to ensure the quality of the product being packaged.
This event is 30-day reportable in the US; if it were to recur it would be likely to cause or contribute to death or serious injury. This event is 15-day reportable for ROW as this could lead to death or serious deterioration in state of health if it were to recur. This is a reportable malfunction. This product was used for treatment. This investigation is concluded. If additional information becomes available, it will be assessed at that time.

3.2 Medical device problem information

a IMDRF Medical device problem codes (Annex A)

Coding with IMDRF terms is a mandatory requirement.

	Choice 1 *(most relevant)*	Choice 2	Choice 3	Choice 4	Choice 5	Choice 6
IMDRF 'Medical device problem codes'	Code: A24	Code	Code	Code	Code	Code

If you think the incident is unique and a suitable IMDRF term is missing, briefly explain:

b	Number of patients involved 1
c	What is the current location of the device? ◯ Healthcare facility/carer ◯ Distributor ◯ Patient/user ◯ Discarded ◯ In transit to manufacturer ◯ Remains implanted ◯ Manufacturer ◉ Unknown ◯ Other:
d	Operator of device at the time of the incident ◯ Healthcare professional ◉ Patient/lay user ◯ Other, please describe
e	Usage of device (as intended) ◉ Initial use ◯ Reuse of a single use medical device ◯ Reuse of a reusable medical device ◯ Re-serviced/refurbished/fully refurbished ◯ Problem noted prior use ◯ Other:
f	Remedial actions taken by healthcare facility, patient or user subsequent to the incident

3.3 Patient information

a IMDRF 'Health Effect' terms and codes (Annex E, F)
Coding with IMDRF terms is a mandatory requirement.

	Choice 1 *(most relevant)*	Choice 2	Choice 3	Choice 4	Choice 5	Choice 6
IMDRF 'Clinical signs, symptoms, and conditions codes' (Annex E)	Code E2402	Code	Code	Code	Code	Code
IMDRF 'Health impact' codes (Annex F)	Code F25	Code	Code	Code	Code	Code

If you think the incident is unique and a suitable IMDRF term is missing, briefly explain:

No appropriate term or code available suggest to consider addition of limb discomfort.

b Age of patient at the time of the incident
years ____ months ____ days ____

c Gender ◉ Female ○ Male ○ Unknown ○ Not applicable

d Body weight (kg)

e List any of the patient's prior health condition or medication that may be relevant to this incident

3.4 Initial reporter (can be healthcare professional of facility, patient, lay user)

a Role of initial reporter
○ Healthcare professional ◉ Patient ○ Lay user ○ Other, please specify

b Name of healthcare facility where incident occurred

c Healthcare facility report number (if applicable)

d	Contact's first name	**e**	Contact's last name
f	Email	**g**	Phone
h	Country: ES - Spain		
i	Street	**j**	Street number
k	Address complement	**l**	PO Box
m	City name	**n**	Postal code

Section 4: Manufacturer analysis

4.1 Manufacturer's preliminary comments

a	For **initial** and **follow-up** reports: preliminary results and conclusions of manufacturer's investigation

b	Initial actions (corrective and/or preventive) implemented by the manufacturer

c	What further investigations do you intend in view of reaching final conclusions?

4.2 Cause investigation and conclusion

a	**For Final (Reportable incident):** Description of the manufacturer's evaluation concerning possible root causes/causative factors and conclusion

Conclusion: The root cause category is non-assignable (complaint not confirmed as a quality defect). There was limited device specific information provided, no batch number or return sample was available for evaluation. Without a batch reference number, a manufacturing and technical evaluation cannot be completed for the wrap involved in this case. There is not a product quality related trend identified for the subclass Adverse Event Safety Request for Investigation. The manufacturing operations employ quality control procedures which include in process testing, thermal testing and visual inspection, to ensure the quality of the product being packaged. Reasonably Suggest Device Malfunction: No. Severity of Harm: N/A. A return sample has not been received at the site for evaluation as of 26-Aug-2020.

b	**For Final (Non-reportable incident):** Fill out rationale for why this is considered not reportable

c	Is root cause confirmed? ○ Yes ◉ No
d	Has the risk assessment been reviewed? ◉ Yes ○ No If 'No', rationale for no review required:

	If the risk assessment has been reviewed, is it still adequate? ◉ Yes ○ No Results of the assessment:

According to RPT – 38832 Hazard Analysis, effective date: 01-Sep-2020, No Severity is required when a device malfunction has not been identified in the complaint investigation narrative.

e IMDRF 'Cause Investigation' terms and codes (Annex B, C, D)

Coding with IMDRF terms is a mandatory requirement.	Choice 1 *(most relevant)*	Choice 2	Choice 3	Choice 4	Choice 5	Choice 6	Choice 7	Choice 8
IMDRF Cause investigation: Type of investigation (Annex B)	Code B17	Code B12	Code	Code	Code	Code	Code	Code

IMDRF Cause investigation: Investigation findings (Annex C)	Code C19	Code	Code	Code	Code	Code

IMDRF Cause investigation: Investigation conclusion (Annex D)	Code D14	Code	Code	Code	Code	Code

If you think the incident is unique and a suitable IMDRF term is missing, briefly explain:

f IMDRF Component codes (Annex G)

Coding with IMDRF terms is a mandatory requirement.

	Choice 1 *(most relevant)*	Choice 2	Choice 3	Choice 4	Choice 5	Choice 6
IMDRF 'Component' codes (Annex G)	Code	Code	Code	Code	Code	Code

If you think the incident is unique and a suitable IMDRF term is missing, briefly explain:

g Description of remedial action/corrective action/preventive action/field safety corrective action (FSCA)

(For a FSCA, fill in the FSCA form)

N/A

h Time schedule for the implementation of the identified actions

N/A

i Final comments from the manufacturer on cause investigation and conclusion

Based on the information provided, the events accidental exposure to product and limb discomfort as described in this case is considered a malfunction, assessed as associated with the use of the device. This case meets Final 15-day EU and 30-day FDA reportability. There was limited device specific information provided, no batch number or return sample was available for evaluation. Without a batch reference number and/or return sample a manufacturing and technical evaluation cannot be completed for the wrap involved in this case. Product effect varies with each individual. There is not a complaint trend for any class(es) associated to the suggested key product complaints database terms. No Remedial action/corrective action/Field Safety Corrective Action is suggested at this time.

4.3 Similar incidents (for Final (Reportable incident))

4.3.1 Use of IMDRF terms and codes for identifying similar incidents

a Identification of similar incidents using IMDRF Adverse Event Reporting terms and codes

Tick-mark which code or combination of codes were used for identifying similar incidents.

	Choice 1
IMDRF code relating to most relevant 'Medical device problem' (Annex A)	☐
IMDRF code relating to most relevant 'Investigation finding' (Annex C, 'Cause investigation')	☐

☒ Other – enter description of what similar incidents are based on and the rationale why the above IMDRF codes were not used

PT Accidental exposure to product (10073317) and Limb discomfort (10061224)
MedDRA codes were used instead of the IMDRF codes at this time to be able to fully identify previous reports of similar incidents until the IMDRF codes will be available for retrieval of the information for identification of previous similar incidents".

4.3.2 Use of in-house terms/codes for identifying similar incidents (only for transition period)

a If similar incident were not identified by IMDRF codes but by in-house codes, please provide the codes and terms below.

	Choice 1	
Code/term for most relevant medical device problem	Code	
	Term	
Code/term for most relevant root cause evaluation	Code	
	Term	

☐ Other – enter description of what similar incidents are based on and the rationale why the above codes were not used

4.3.3 Number of similar incidents and devices on the market

a Indicate on which basis similar incidents were identified regarding the device or device variant:

○ Model ○ Software ○ Lot/Batch ○ Product platform ◉ Other variant

Details of the selection made above

Thermacare Lower Back/Hip Heatwrap 8 Hr
Similar search terms used: hand, accidental exposure to product, limb discomfort

b Indicate to what criteria the number of devices on the market (also known as denominator data) is based on (tick the most appropriate):

- ○ Devices placed on the market or put into service
- ○ Units distributed within each time period
- ○ Number of tests performed
- ○ Number of episodes of use (for reusable devices)
- ○ Active installed base
- ○ Units distributed from the date of declaration of conformity/CE mark approval to the end date of each time period
- ○ Number of devices implanted
- ◉ Other -describe

Thermacare Lower Back/Hip Heatwrap 8 Hr

c Enter the number of similar incidents and devices on the market for the indicated time periods

You must use yearly time periods unless:

A: a different time period has been specified by the European vigilance Working Group

B: the device has not been on the European market for more than three years

	Time period (N) Year to date = incident year (e.g. 2012-10-23)		Time period (N-1) calendar year one year before incident (e.g. 2012-10-23)		Time period (N-2) calendar year two years before incident (e.g. 2012-10-23)		Time period (N-3) calendar year three years before incident (e.g. 2012-10-23)	
Start date	2020-01-01		2019-01-01		2018-01-01		2017-01-01	
End date	2020-07-31		2019-12-31		2018-12-31		2017-12-31	
	Number of similar incidents	Number of devices on market	Number of similar incidents	Number of devices on market	Number of similar incidents	Number of devices on market	Number of similar incidents	Number of devices on market
Country of incident	1	757,368	0	1,069,248	0	1,224,816	0	559,728
EEA + CH + TR	1	6,382,956	0	14,063,676	0	15,406,944	0	13,576,560
World	1	11,151,048	0	25,489,308	0	29,004,729	0	24,712,164

d Comments on how similar incidents and associated number of devices on the market were determined

Actual figures for country of incident may be lower. Figures are approximate due to shared distribution in the region. US05 is not included in the distribution search. The time period for the end date in the year to date in the incident year is populated only twice a year.

Section 5: General comments

Coded summary of report (will be auto populated from previous selections)

Medical device name

ThermaCare HeatWrap

Basic UDI-DI	Unknown		
UDI device identifier	Unknown	UDI production identifier	Unknown

IMDRF adverse event reporting terms and codes

IMDRF=International Medical Device Regulators Forum. Coding with IMDRF terms is a mandatory requirement.

IMDRF clinical signs, symptoms, conditions codes	E2402							
IMDRF health impact codes	F25							
IMDRF Medical device problem codes	A24							
IMDRF Component codes								
IMDRF Cause investigation: Type of investigation	B17	B12						
IMDRF Cause investigation: Investigation findings.	C19							
IMDRF Cause investigation: Investigation conclusion.	D14							

Submission of this report does not represent a conclusion by the manufacturer and / or authorised representative or the national competent authority that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.

I affirm that the information given above is correct to the best of my knowledge.

Before signing and submitting

Check the form | Save as PDF

Date

Signature/Digital Signature

Yasmin Kassis

Digitally signed by Yasmin Kassis
DN: cn=Yasmin Kassis, o=Pfizer, ou=Spain Drug Safety Unit, email=yasmin.kassisperela@pfizer.com, c=ES
Date: 2020.09.24 07:38:05 +02'00'

Send as XML file — Submit XML by Email

Send as PDF file — Submit PDF by Email

3.1 a - Provide a comprehensive description of the incident

This is a spontaneous report received from a contactable consumer. A female patient of unknown age exposed to ThermaCare heatwrap (THERMACARE HEATWRAP) on unknown date for unknown indication. Medical history and concomitant medications were not reported. The reporter had lumbago, the patient (physiotherapist) could not massage the reporter with the thermacare patches, reporter had to take it off otherwise it will remain on her hands reporter didn't know what, her hands remained very bad reporter didn't know why. The Physiotherapist tells that when she massages someone who uses Thermacare patches, something remains in her hands and it affects her hands. The action taken in response to the events of the product was unknown. The outcome of the events was unknown. Product investigation results are as follows: Conclusion: The root cause category is non-assignable (complaint not confirmed as a quality defect). There was limited device specific information provided, no batch number or return sample was available for evaluation. Without a batch reference number, a manufacturing and technical evaluation cannot be completed for the wrap involved in this case. There is not a product quality related trend identified for the subclass Adverse Event Safety Request for Investigation. The manufacturing operations employ quality control procedures which include in process testing, thermal testing and visual inspection, to ensure the quality of the product being packaged. Reasonably Suggest Device Malfunction: No. Severity of Harm: N/A. A return sample has not been received at the site for evaluation as of 26-Aug-2020.

Additional information has been requested and will be provided as it becomes available.

Follow-up (11Sep2020): New information obtained from CITI includes: product investigation results.

Follow-up (18Sep2020): This is a follow-up report obtained from CITI.

PR ID (Inv): 5166612; PR ID (CR): 5166501; (Parent) Brand/Trade-Name: THERMACARE HEAT WRAP TOPICAL; (Parent) Complaint Class: External Cause Investigation; (Parent) Complaint Sub-Class: Adverse Event Safety Request For Investigation; Device or Combo?: Yes.

CITI PR ID#5166612; Site: DCHU; Record Type: CITI / Summary Investigation; Status: Closed.

(Parent) Complaint Class:External Cause Investigation
(Parent) Complaint Sub-Class:Adverse Event Safety Request For Investigation
(Parent) Brand/Trade-Name: THERMACARE HEAT WRAP TOPICAL
(Parent) Product Family-API: THERMACARE
Product-Description: THERMACARE LOWER BACK/HIP HEATWRAP 8 HR
Product-Category:TOPICAL
(Parent) Product-Type: OTC
(Parent) Combination-Product: No
(Parent) Combination-Product-Type: N/A
(Parent) Sterile-Product: No
(Parent) Medical-Device:Yes
(Parent) UDI-(if appl): N/A
Lot#Unknown; Expiration Date: Not provided
Description of Complaint: Product Complaint Exchange: [ThermaCare HeatWrap/ Injury to hand NOS]
patient has lumbago, the physio could not massage him while using the thermacare patches. The Physio tells that when she massages someone who uses Thermacare patches, something remains in her hands and it affects her hands.
Brief Complaint Description: This is a spontaneous report received from a contactable consumer. A female patient of unknown age exposed to ThermaCare heatwrap (THERMACARE HEATWRAP) on unknown date for unknown indicaion. Medical history and concomitant medications were not reported. The reporter had lumbago, the patient (physiotherapist) could not massage the reporter with the thermacare patches, reporter had to take it off otherwise it will remain on her hands reporter didn't know what, her hands remained very bad reporter didn't know why. The action taken in response to the events of the product was unknown. The outcome of the events was unknown. Additional information has been requested and will be provided as it becomes available.
Reasonably Suggest Device Malfunction: Yes
Severity of Harm: S3
Failure Mode: Device Defective-Remains on Skin
IDC - Level 1: Quality
IDC - Level 2: Product Complaint
IDC - Level 3: Complaint - Function / Therapeutic Properties
Investigation Decision: Repeat Investigation?: No
Was CAPA Previously Identif'd?: No
Full Investigation Required?:No
QA Review & Rationale:DCHU reviewed the classification, sub-classification, priority, product information and justification. Site Assignment Grid was reviewed and is accurate and appropriate. An investigation will be performed. A full investigation was not performed the DCHU as providing the batch record information is the manufacturing site's requirement; therefore, a summary investigation was performed. The field for device malfunction in CITI is required to conditionally populate the severity ranking.
Reportability Determination: The complaint for patient communicates that her physio has told her that she will not be able to give her a massage with the Thermacare patches since "it remains on her hands I don't know what", her hands remain very bad, she does not know why for ThermaCare HeatWrap is 30-day reportable in the US; if it were to recur it would be likely to cause or contribute

to death or serious injury. This event is 15-day reportable for ROW as this could lead to death or serious deterioration in state of health if it were to recur. This is a reportable malfunction. This product was used for treatment. Case Reportability Determination: Argus AER # 2020327840 CL #3, CL#5; DCHU Peer Reviewer Reportability Determination: Agreed.
Investigation Findings:Summary of Investigation:This investigation was conducted for an unknown lot Number Lower Back/Hip (LBH) 8-hour product. Based on the complaint narrative/Reportability Determination: The complaint for patient communicates; that her physio has told her that she will not be able to give her a massage with the Thermacare patches on since "it remains on her hands I don't know what", her hands remain very bad, she does not know why ThermaCare HeatWrap causes this. This event is 30-day reportable in the US; if it were to recur it would be likely to cause or contribute to death or serious injury. This event is 15-day reportable for ROW as this could lead to death or serious deterioration in state of health if it were to recur. This is a reportable malfunction. This product was used for treatment. There was limited device specific information provided, no batch number was available for evaluation. Without a batch reference number, a manufacturing and technical evaluation cannot be completed for the wrap involved in this case. There is not a product quality related trend identified for the subclass Adverse Event Safety Request for Investigation.
Root Cause / CAPA:Process Related?: N/A; Vendor Related?:No; Final Confirmation Status:Not Confirmed; Root Cause Category (Tier 1):Non-assignable (Complaint Not Confirmed);Root Cause Category (Tier 2): Non-assignable (Complaint Not Confirmed); Root Cause Category (Tier 3): N/A.
Conclusion & Approvals: Additional Approval(s) Req'd?: No; Product Quality Impact: No;
Market / Clinical Impact: No; Stability Impact: No; SQRT Review Required?: No; AQRT Review Req'd?: No
Reserve Sample Evaluation:Rsrv. Sample Evaluation Reqd?:No Source Value;Rsrv. Sample Eval. Rationale: Not performed by DCHU; Confirmed Reserve Defect?:No.
Trend/Complaint History: Lot-Specific Trend Identified?: No;
Expedite Trends:Expedite Trend Identified?: No; Exped Trend Assmt. & Rationale:N/A
Complaint Sample Evaluation:(Parent) Sample_Status: Sample Availability Unknown;
Site Sample Status: Not Received.
Confirmed Compl Sample Defect?: N/A - Not Received

Conclusion: Based on the complaint narrative/Reportability Determination: The complaint for patient communicates; that her physio has told her that she will not be able to give her a massage with the Thermacare patches on since "it remains on her hands I don't know what", her hands remain very bad, she does not know why ThermaCare HeatWrap causes this. This event is 30-day reportable in the US; if it were to recur it would be likely to cause or contribute to death or serious injury. This event is 15-day reportable for ROW as this could lead to death or serious deterioration in state of health if it were to recur. This is a reportable malfunction. This product was used for treatment.
The root cause category is non-assignable (complaint not confirmed as a quality defect). There was limited device specific information provided, no batch number or return sample was available for evaluation. Without a batch reference number, a manufacturing and technical evaluation cannot be completed for the wrap involved in this case. There is not a product quality related trend identified for the subclass Adverse Event Safety Request for Investigation. The manufacturing operations employ quality control procedures which include in process testing, thermal testing and visual inspection, to ensure the quality of the product being packaged.
This event is 30-day reportable in the US; if it were to recur it would be likely to cause or contribute to death or serious injury. This event is 15-day reportable for ROW as this could lead to death or serious deterioration in state of health if it were to recur. This is a reportable malfunction. This product was used for treatment. This investigation is concluded. If additional information becomes available, it will be assessed at that time.

4.2 a - Description of the manufacturer's evaluation concerning possible root causes/causative factors and conclusion

Conclusion: The root cause category is non-assignable (complaint not confirmed as a quality defect). There was limited device specific information provided, no batch number or return sample was available for evaluation. Without a batch reference number, a manufacturing and technical evaluation cannot be completed for the wrap involved in this case. There is not a product quality related trend identified for the subclass Adverse Event Safety Request for Investigation. The manufacturing operations employ quality control procedures which include in process testing, thermal testing and visual inspection, to ensure the quality of the product being packaged. Reasonably Suggest Device Malfunction: No. Severity of Harm: N/A. A return sample has not been received at the site for evaluation as of 26-Aug-2020.

4.2 d - Results of the assessment:

According to RPT – 38832 Hazard Analysis, effective date: 01-Sep-2020, No Severity is required when a device malfunction has not been identified in the complaint investigation narrative.

4.2 i - Final comments from the manufacturer on cause investigation and conclusion

Based on the information provided, the events accidental exposure to product and limb discomfort as described in this case is considered a malfunction, assessed as associated with the use of the device. This case meets Final 15-day EU and 30-day FDA reportability. There was limited device specific information provided, no batch number or return sample was available for evaluation. Without a batch reference number and/or return sample a manufacturing and technical evaluation cannot be completed for the wrap involved in this case. Product effect varies with each individual. There is not a complaint trend for any class (es) associated to the suggested key product complaints database terms. No Remedial action/corrective action/Field Safety Corrective Action is suggested at this time.

4.3.1 - Other

PT Accidental exposure to product (10073317) and Limb discomfort (10061224)
MedDRA codes were used instead of the IMDRF codes at this time to be able to fully identify previous reports of similar incidents until the IMDRF codes will be available for retrieval of the information for identification of previous similar incidents".

4.3.3 a - Details of the selection made above

Thermacare Lower Back/Hip Heatwrap 8 Hr
Similar search terms used: hand, accidental exposure to product, limb discomfort

4.3.3 d - Comments on how similar incidents and associated number of devices on the market were determined

Actual figures for country of incident may be lower. Figures are approximate due to shared distribution in the region. US05 is not included in the distribution search. The time period for the end date in the year to date in the incident year is populated only twice a year.