Gmail

Derek Lamb <liquidgands@gmail.com>

Initial Letter with User Report MHRA Ref: 2019/010/022/401/011

1 message

grace.smith@mhra.gov.uk <grace.smith@mhra.gov.uk> 28 January 2020 at 15:36
Reply-To: aic@mhra.gov.uk
To: derek.lamb@viamed.co.uk

28/01/2020

(See attached file: IncidentReport-2019-010-022-401-011.pdf)(See attached file: Resend report email.pdf)

Use the 'paperclip' icon to view attachments within the PDF

MHRA Ref: 2019/010/022/401/011 quote this in any reply

We have received the attached adverse incident report from RMCH concerning the following device:

Device: Intense Pulse Light Source, Item: Eye Protection, Model: Eyemax 2 premmie, Reporting Organisation's Reference Number: 2093734

What you need to do now
If you have already sent a vigilance report for this incident, email us as soon as possible on aic@mhra.gov.uk to tell us the MHRA reference number that we assigned to the incident.

If you are about to send a vigilance report for this incident make sure you quote this number: 2019/010/022/401/011 on your report.

You are responsible for investigating this incident.

We need your final report within 30 days.

In box number 12 of the form / comments field on MORE add the following information:

- risk assessment
- number of devices you supplied in the UK, EU and world-wide (Select and specify the most suitable time period for these data, e.g. within last 12 months, or since first sold)
- date when device was first supplied in the UK.

If you are carrying out a field safety corrective action (FSCA), fill in this form (Field Safety Corrective Action, Medical Devices Vigilance System, MEDDEV 2.12/1 rev 7) and provide extra information in box 7 of the form / Description of the FSCA tab on MORE as detailed in the annex below.

If you don't have all the information immediately available, you can send us a follow-up report but tell us when you expect to send us the final report. This reduces the number of reminders we send you.

Contact the reporter if you need more details of the incident and to obtain the device(s). Please do not use or share the reporter's details for any purpose beyond investigating the incident.
Once you've finished your investigation, we will forward your device analysis results, remedial/corrective action and final comments (contained in box 11) to the reporter.

If this incident happened in: Scotland, Northern Ireland, Wales, the devolved administration of that country may contact you. We've contacted you because we've decided to open our own, parallel investigation. MHRA work with the UK devolved administrations, which operate their own reporting and investigation systems for medical device incidents. You should co-operate with both investigations.

Provide us with an electronic copy of the Instructions for Use for the device involved. If it is a large document please send relevant sections.

Yours sincerely
Patient Safety Communications Team
Devices Information and Operations Group, MHRA

Note: from 01 January 2020 you can only report to us via our Manufacturer's On-line Reporting Environment (MORE) which you can access through our reporting page or on the new Manufacturer's Incident Report (MIR) form. Guidance is available on the EC website under Guidance MEDDEVs 2.12 Post-Market Surveillance.

Use this email address aic@mhra.gov.uk to contact us. We check it regularly.

You can access the Medical Device Safety Officer (MDSO) contact list via MORE in order to copy them in on communications regarding Field Safety Notices (FSNs). This can help you ensure appropriate targeting and prompt action of the FSN within the MDSO's organisation.

We would advise you to familiarise yourself with the new EU Medical Devices Regulation 2017/745 (MDR) and the *in vitro* Diagnostic Medical Devices Regulation 2017/746 (IVDR) as they will fully apply in the UK from the 26 May 2020 and 26 May 2022 respectively. The Regulations introduce extensive changes, which you can read about in our guidance. These changes will affect manufacturers, importers, distributors, authorised representatives, as well as health institutions.

Annex: Extra information we need in section 7 of your FSCA report

1. **Risk assessment for the FSCA including:**

1.1. how many incidents have you received related to this FSCA?

1.2. what is the hazard presented by using the device with this issue? Send us a copy of the Health Hazard Evaluation (HHE) or Clinical risk assessment report?

1.3. if this is a batch issue, why it is restricted to these batches only?

1.4. do you know if this issue affects other CE-marked devices? (eg own-brand labelled products)

1.5. provide update on root cause investigation / conclusions of tests and other investigations on suspect or other samples

1.6. Please provide details of long term corrective actions

2. **Where the FSCA applies to the UK**:

2.1. what is the FSN distribution list (named contacts and locations)? Include any additional people who will be sent the letter (chief executives, Medical Device Safety

Officers (MDSOs), medical directors, community pharmacists etc). You can send us this as a separate document .

2.2. how will you contact the end user if affected customers include distributors. Send us a copy of the list of distributors. Confirm who will be managing the FSCA and compiling reconciliation data for these end users.

2.3. how many sites are affected in the UK? How many devices/tests did each site receive? You can send us this as a separate document.

2.4. when was the affected product distributed/installed?

2.5. how will you monitor the extent to which the FSN message has been received? (eg fax-back form / telephone follow-up). What are your key dates for actions?

2.6. how many UK sites have confirmed receipt of your FSN?

2.7. how many UK sites have confirmed that they have successfully undertaken the action(s) specified in your FSN?

2.8. what is the expected date of completion of the field safety corrective action?

3. **Provide regular updates on points 2.6 and 2.7**

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2 attachments

IncidentReport-2019-010-022-401-011.pdf
22K

Resend report email.pdf
40K