Medicines & Healthcare products
Regulatory Agency

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United Kingdom
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[redacted]
By email: [redacted]

03 April 2024

FOI 24/214

Dear [redacted]

Thank you for your information request, dated 28 February 2024, where you asked 4 questions. I have stated each question in full and the answer is below each question.

1. Please tell me how many complaints or concerns have been raised in respect of "Universal" slings since MHRA started looking into medical devices.

As per your request, the MHRA have conducted a search for all adverse incident reports we have received concerning ‘universal slings' based upon a free text search for ‘universal sling’ within the following fields within a device adverse incident report; failure description, device trademark name brand, manufacturer name, device model number and clinical event patient remedial action.

I can confirm we have received **42** UK device adverse incident reports to date.

2. Please tell me how many complaints or concerns have been raised in respect of **any** type of slings since MHRA started looking into medical devices.

The MHRA codes medical devices within adverse incident reports using the Global Medical Device Nomenclature (GMDN). GMDN is a system of internationally agreed generic descriptors used to identify medical device products. As per your request we have conducted a search for all adverse incident reports containing the following GMDN Codes:
12330- Mobile patient lifting system, electrically-powered
30021-Freestanding patient lifting system, electrically-powered
33476-Patient lifting system divided leg sling
36773-Fixed patient lifting system, electrically-powered
37480-General-purpose patient lifting system sling/harness
38129-Overhead track patient lifting/transfer system
38869-Patient lifting system hammock sling
40536-Patient lifting system stretcher

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45675-Fixed patient lifting system, manual
46149- Freestanding patient lifting system, manual
47986- Female stress urinary incontinence surgical mesh-sling synthetic polymer
60844-Female faecal incontinence surgical mesh-sling, synthetic polymer.

I can confirm that the MHRA has received **442** UK adverse incident reports associated with slings to date. Table 1 (below) displays further information.

Table 1 - Details of adverse incident reports concerning slings

GMDN Code	GMDN Name	Number of Reports
12330	Mobile patient lifting system, electrically-powered	93
30021	Freestanding patient lifting system, electrically-powered	1
33476	Patient lifting system divided leg sling	3
36773	Fixed patient lifting system, electrically-powered	14
37480	General-purpose patient lifting system sling/harness	8
38129	Overhead track patient lifting/transfer system	152
38869	Patient lifting system hammock sling	1
40536	Patient lifting system stretcher	1
45675	Fixed patient lifting system, manual	1
46149	Freestanding patient lifting system, manual	1
47986	Female stress urinary incontinence surgical mesh-sling, synthetic polymer	164
60844	Female faecal incontinence surgical mesh-sling, synthetic polymer	3

When considering the data provided within this response, please consider the below information:

- Inclusion of a report on our adverse incident database does not necessarily mean the events described were caused by that device but could be due to unrelated patient/user factors.

- The majority of reports indicate an issue experienced by a single user. However, some cases may represent the same user experiencing further issues or multiple events in the same report.

- Reports do not necessarily represent an individual patient. Individuals may report an incident at any time after the event and people can make multiple reports at any time after the use of device and on the same issue.

- Where possible, multiple reports for the same event are linked. However, as reporters are not required to complete all fields, we cannot always be sure enough to link every duplicate.

- It should be noted that this information may include a range of recognised complications related to this type of procedure and does not necessarily indicate a fault with any particular device.

- The numbers may include reports where the incident has been taken from published literature or the report may be about notification of a safety communication.

- These numbers of reports are accurate at the time they are extracted from our database and minor changes in the numbers can occur if the reporter of the incident gives us more details later.

Please note in addition to searching structured data fields it is also possible to search the database using free text searches. Free text searches however require manual review of each individual incident to confirm whether the report is relevant to your request. A free text search for ‘sling’ was conducted on our database which returned 1105 results. It would take an assessor approximately 3 minutes to review each of these results, meaning that they would be required to spend 55.25 hours on this request. Therefore, this information is exempt from disclosure under Section 12 of the FOI act as it would take in excess of 24 hours to complete.

Section 12 of the FOI Act specifies that a public authority may refuse requests where the cost of dealing with them would exceed the appropriate limit, which for central government is set at £600. This represents the estimated cost of one person spending 24 working hours in determining whether the department holds the information, locating, retrieving, and extracting the information.

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3. Please tell me what advice you have given in respect of the use of "Universal" slings, and do you currently endorse the use of "Universal" slings and in what respect?

The MHRA has not produced any advice which is specific to the use of "Universal" slings, however, the MHRA has issued advice involving all hoists and slings. In 2007 the MHRA issued a Medical Device Alert (ref MDA/2007/031), and in 2015 NHS England issued a Patient Safety Alert (ref NHS/PSA/W/2015/010) jointly with the MHRA.

The MHRA does not endorse medical devices, and therefore does not endorse "Universal" slings.

4. Did you ever investigate my specific concerns about Sidhil Universal slings being used with a hoist that was not specifically a Sidhil bedhead hoist?

The MHRA has investigated your concerns and provided you with the outcome of our investigation. Your concerns were first raised with the MHRA in August 2007. The MHRA investigated, and you were subsequently sent the closure report upon conclusion of the investigation in June 2008. In July 2008, you requested copies of all communication between the MHRA, Sidhil, LIKA, LBB and LGO, which was provided in July 2008. It was also provided when requested in September 2011.

If you have a query about the information provided, please reply to this email.

If you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date you receive this response and addressed to: info@mhra.gov.uk

Please remember to quote the reference number above in any future communications.

If you were to remain dissatisfied with the outcome of the internal review, you would have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of your request unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted at:

Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

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Yours sincerely,

FOI Team
Safety & Surveillance