Medicines & Healthcare products Regulatory Agency

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom
www.gov.uk/mhra

[redacted]

7th December 2023

Dear [redacted]

FOI 23/916 - Request for information: Adverse incidents reported to the MHRA relating to mesh for pelvic organ prolapse and stress urinary leakage for the years 2020, 2021 and 2022.

Thank you for your Freedom of Information (FOI) request dated 6th July 2023. Please accept my sincerest apologies for the delay in providing you with a response to your FOI.

In your email request you asked for:

- **Information regarding the number of adverse incidents from prolapse and incontinence mesh reported to the MHRA for the years 2020, 2021 and 2022.**

In response to your request, we have widened our search criteria to cover all adverse incidents reported to the MHRA in relation to vaginal mesh, focussing on the indications stress urinary incontinence, pelvic organ prolapse and unknown indication from January 2020 to December 2022 inclusive. Please see tables 1a, 1b and 1c below respective to the reported indication of the vaginal mesh. Please note that the data in the tables are categorised by 'Professional users', 'Members of Public' and 'Other'.

We should advise that these figures need to be interpreted with caution as they are not the same as complication rates.

Table 1a: The number of adverse incident reports received for 'stress urinary incontinence'.

Year	Professional users	Member of Public	Other*
2020	186	30	16
2021	124	31	37
2022	8	0	94

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Table 1b: The number of adverse incident reports received for 'pelvic organ prolapse'.

Year	Professional users	Member of Public	Other*
2020	58	13	12
2021	33	6	20
2022	5	1	22

Table 1c: The number of adverse incident reports received for 'unknown indication'.

Year	Professional users	Member of Public	Other*
2020	49	15	22
2021	28	14	23
2022	6	6	41

*This includes reports where the captured reporter origin includes the manufacturer, submitter, devolved administration, authorised representative, other, or where the field has been left empty.

Please also note the following considerations in relation to the data provided in the tables above:

- This information is accurate at the time we conduct the search on our database, changes in the number of adverse events can occur following receipt of additional information.
- Use of our Yellow Card scheme by the healthcare sector and members of the public is voluntary and it does not provide absolute adverse incident figures.
- The adverse incident figure is for all reports received within the time period specified.
- Individuals may report an incident at any time after the event and people can make multiple reports at any time after the mesh has been implanted 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.
- Some reports do not include the necessary information to determine the indication of use of the surgical mesh, but we have included them to give you the data we hold on these devices since 2020 to 2022. These are identified as 'unknown indication'.
- It should be noted that this information may include a range of recognised complications related to this type of surgical procedure and do not necessarily indicate a fault with any particular device.
- Adverse incident data includes surgical mesh for surgical mesh-slings, pelvic organ prolapse surgical meshes or extra-gynaecological surgical meshes by different surgical approaches (e.g., transvaginal, retropubic and abdominal). We are unable to break this down as this is not a mandatory field in Yellow Card and may be unknown to the reporter.
- The number of reports received should not be used as a basis for determining the incidence of a health/clinical effect as neither the total number of effects occurring, nor the number of patients using the device is known.
- The inclusion of a report on the MHRA adverse incident database does not necessarily mean that the events described were caused by the device.

Should you wish to share this information as part of the national report on mesh complications, please ensure to include the accompanying considerations alongside the data to prevent misinterpretation.

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As with all medical devices, MHRA continues to monitor their safety and performance and encourages reporting of any adverse incidents through its Yellow Card scheme on https://yellowcard.mhra.gov.uk/. Any emerging evidence relating to possible risks associated with these devices will be carefully reviewed and, if appropriate, regulatory action will be taken if any serious risks are confirmed.

I hope the information provided is helpful, but 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 of this response; and can be addressed to this email address.

Yours sincerely,

FOI Team,
Safety and Surveillance
Medicines and Healthcare products Regulatory Agency

If you have a query about this email, please contact us. If you are unhappy with our decision, you may ask for it to be reviewed. That review will be undertaken by a senior member of the Agency who has not previously been involved in your request. If you wish to pursue that option please write to the Communications Directorate, Medicines and Healthcare products Regulatory Agency, (via this email address). After that, if you remain dissatisfied, you may ask the Information Commissioner at:

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