Medicines & Healthcare products
Regulatory Agency

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[redacted]

7th November 2023

Dear [redacted]

FOI 23/752 - Information request

Thank you for your request dated 10 October 2023 where you asked for the following information under the FOIA:

- *How many incidents have been reported on ophthalmic surgical devices over the last 5 years?*
- *How many of these incidents have resulted in permanent harm to the patient (e.g., loss of an eye) or death?*
- *How many of these harms were caused directly by the surgical instrument?*
- *How many ophthalmic medical devices have been removed from the UK market by manufacturers over the last 5 years?*
- *How many ophthalmic medical device manufacturers have withdrawn their MHRA registrations over the last 5 years?*

I can confirm that we hold the some of the data you have requested, details of which are below.

1. ***How many incidents have been reported on ophthalmic surgical devices over the last 5 years?***

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 incident reports containing GMDN CT [1]Codes that reflect the data you have requested. I can confirm that the MHRA has received **1540** UK adverse incident

[1] CT1106-Corrective contact lenses, CT1108-Soft contact lenses, CT1109-Rigid contact lenses, CT1110-Contact lens solutions, CT1136-Ophthalmic laser systems, CT1183-Spectacle lenses, CT1184-Ophthalmoscopes, CT1187-Intraocular lenses, CT132-Contact lenses and associated devices, CT1324-Lensmeters, CT1753-Phacoemulsification/vitrectomy systems, CT2135-Intraocular lens injectors, CT230-Ophthalmic devices, CT2658-Ophthalmic solutions, CT640-Phacoemulsification/vitrectomy systems and associated devices, CT126-Spectacles/Spectacle lenses and associated devices, CT1888-Optical coherence tomography systems, or CT975-Optical coherence tomography systems and associated devices

reports associated with these ophthalmic devices submitted as of 1st January 2018 to 6th November 2023 inclusive.

2. **How many of these incidents have resulted in permanent harm to the patient (e.g., loss of an eye) or death?**

The MHRA codes adverse events within adverse incident reports using the International Medical Device Forum (IMDRF) terminology. IMDRF terminology is a system of internationally agreed codes used to describe the clinical signs, symptoms, and conditions of the affected patient concerning the medical device adverse event. As per your request concerning permanent harm to patients, we have conducted a search on the following IMDRF Annex F codes- F12 Serious Injury/Illness/Impairment and F02 Death.

Further to this, I can confirm that of the 1540 adverse incident reports received for ophthalmic devices, 66 reports included Serious Injury/Illness/Impairment and 1 reported Death. It is important to note that it not always possible to determine how many of these adverse incidents resulted in *permanent* damage as we do not collect final outcomes.

3. **How many of these harms were caused directly by the surgical instrument?**

We do hold this information. However, we have encountered a technical issue which has impacted our ability to extract this data from our system. We hope to have this rectified as soon as possible. We will aim to be in touch within the next 10 working days.

4. **How many ophthalmic medical devices have been removed from the UK market by manufacturers over the last 5 years?**

We do not hold data on the numbers of ophthalmic devices removed from the UK market by manufacturers for non-safety related reasons. However, we do hold information on safety related removals such as Field Safety Notices (FSNs). I can confirm the MHRA has received 10 UK Field Safety Notices for products within our search criteria where the manufacturer has recalled their device from the UK market. Further information can be found here.

5. **How many ophthalmic medical device manufacturers have withdrawn their MHRA registrations over the last 5 years?**

We do not hold information on manufacturers who have withdrawn their MHRA registrations. The unregistering of a manufacturer with the MHRA does not automatically mean that the manufacturer has withdrawn their registration with us. Information about registrations is available via our Public Access Registration Database.

We do hold information on devices which have been registered with the MHRA, this process is described on our website. If you wish to make a new request regarding registrations then we recommend that you provide us with details of specific manufacturer, device, or product a GMDN code of interest. We will consider your new request under the FOIA.

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.

- The figures provided above are not the same as complication rates.

- 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.

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.

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: Information Commissioner’s Office Wycliffe House Water Lane Wilmslow Cheshire SK9 5AF.

Yours sincerely,

FOI Team
Safety and Surveillance
Medicines and Healthcare products Regulatory Agency