Medicines & Healthcare products
Regulatory Agency

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[redacted]

17th November 2023

Dear [redacted]

FOI 23/854

Thank you for your follow-up correspondence dated 8th November, where you provided a list of GMDN codes that you would like to receive the information below for. Please accept our apologies for any inconvenience caused previously.

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- *How many ophthalmic medical device manufacturers have withdrawn their MHRA registrations over the last 5 years?*

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 the GMDN codes below[1]. I can confirm that the MHRA has received **94** UK adverse incident reports associated with these GMDN codes submitted as of 1st January 2018 to 13th November 2023 inclusive.

[1]10575, 10828, 11290, 12036, 12726, 13481, 13488, 13489, 13704, 14147, 17899, 32312, 22754, 32758, 32764, 32766, 32772, 33678, 35010, 35287, 35314, 35349, 35527, 35559, 35787, 37896, 38168, 39610, 44796, 45918, 46705, 47007, 47240, 47871, 61489, 62469, 62620, 62674, 63391, 63398, 63399, 63409, 63416, 63479, 63485, 63486, 63522, 63553,63787,63788,64251

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 how many of these incidents have resulted in permanent harm to patients, we have conducted a search on the following IMDRF Annex F codes- F12 Serious Injury/Illness/Impairment and F02 Death reported alongside the GMDN codes above[1]. I can confirm that of the 94 adverse incident reports received for these GMDN codes, we have not received any reports that also code the IMDRF code of serious injury/illness/impairment or death.

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

We have not received any reports of serious injury/illness/impairment or death for the GMDN codes specified in your request therefore we are unable to comment on how many of these harms were caused directly by the surgical instrument.

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 7 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?**

I can confirm that the MHRA holds the information that you have requested. However, we have also determined that the information is exempt under Section 12 of the Freedom of Information (FOI) Act, and we cannot process your request any further. Section 12 of the Act allows public authorities to 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.

Although we hold information on devices which have been registered with the MHRA, this information is not easily extractable. An individual would need to liaise with our internal IT colleagues to locate the records from 2018 to 2023, as per your request. Following this, the individual will have to manually open each record associated with a GMDN code. Checking each record for your requested GMDN codes, would take a minimum of 120 seconds and in some instances longer. In addition to this, due to the volume of GMDN codes that fall in the scope of this request, the data included within the response would require review by more than one colleague to ensure the information provided was accurate. Following manually checking each record, multiple colleagues would then have to input into the draft response. Completing the process outlined above would mean an individual would spend over 24

hours locating, retrieving, and extracting the information for your request, therefore exceeding the time limit defined under the FOI act. However, all publicly available information on registered devices can be found on our Public Access Registration Database, please utilise this site for your research.

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.

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