Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom
of Information Team
10 South Colonnade
Canary Wharf
London
E14 4PU

foi.request@mhra.gov.uk.

MHRA Website

[redacted]

Our Ref: FOI2025/00110

07 March 2025

Dear [redacted],

Thank you for the correspondence sent on 10th February, where you provided clarification and requested the following information:

"*Patient deaths relating to medical devices 2020 to 2024 if possible.*

Plus, patient injuries relating to medical devices 2020 to 2024 – not sure if there is a severity scale such as life changing or recovered – I would like this data too if possible.

If there are user deaths / injuries I would like this information too.

I don't need the investigation details, but it would be interesting to help raise awareness if the device could be detailed (volumetric pump, operating table, PCA, etc)"

MHRA Response

We can confirm that the Agency holds the information you are seeking.

Request 1:

Patient deaths relating to medical devices 2020 to 2024 if possible.

The MHRA categorises adverse incident reports using one of the following four classifications: serious public health threat, death, unanticipated serious deterioration in state of health or all other reportable incidents. In this criteria an adverse incident is classified as death if the event led to the death of a patient, user, or other person.

Following a search of our database between the 1st of January 2020 and 31st December 2024, I can confirm that we have received **1,340** adverse incident reports where the incident has been classified as death. Please be aware that when interpreting this data, it is particularly important to note that causality has not been established. Healthcare professionals and members of the public are asked to report to the Yellow Card Scheme even if they have just the slightest suspicion that a medicine, vaccine or medical device may have caused the side effect.

Many suspected adverse drug reports (ADRs) and adverse incidents reported on a Yellow Card do not have any relation to the medicine, vaccine or medical device, and it is often coincidental that symptoms occurred around the same time. The reports are continually reviewed to detect possible new side effects that may require regulatory action, and to differentiate these from things that would have happened regardless for instance due to underlying or undiagnosed illness.

The MHRA codes medical devices within adverse incident reports using the Global Medical Device Nomenclature (GMDN) system. GMDN is a system of internationally agreed generic descriptors used to identify medical device products. The number of adverse incident reports classified as death broken down by GMDN CT classification is attached in Annex 1.

Request 2:

Plus, patient injuries relating to medical devices 2020 to 2024.

Following a search of our database from 1st January 2020 to 31st December 2024 I can confirm that the MHRA has received **56,517** adverse incident reports where a patient or user injury has been reported. 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 health impact, clinical signs, symptoms, and conditions of the affected patients or users concerning the medical device adverse event. The number of adverse incident reports were a patient or user injury has been reported broken down by GMDN CT and IMDRF code is also attached in Annex 2.

Request 3:

If there are user deaths / injuries I would like this information too.
The MHRA receives adverse incident reports which contain information on affected patients and users. User deaths or injuries are also included in the adverse incident data that has been provided for request 1 and 2 above.

When considering the data provided within this response, it is important to 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.

- Additionally, it is important to note that the number of reports received should not be used as a basis for determining the incidence of a reaction as neither the total number of reactions occurring, nor the number of patients using the delivery device is known.

- Global Medical Device Nomenclature (GMDN) provides a generic system to identify medical device products used to diagnose, monitor, treat and prevent disease or injury. A report can contain can contain multiple GMDN CT codes, and therefore the number provided in Annex 1 may not add up to the total number of incident reports.

- IMDRF provides standardised terms, terminology and codes for reporting adverse events related to medical devices. The codes are divided into six categories, including Annex A: problem, Annex E: clinical signs, symptoms and conditions, and Annex F: health impact. A report can contain multiple IMDRF codes, as well as this field not being compulsory when reporting an incident, therefore the total number provided in Annex 1 may not add up to the total number of incidents.

- 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 at a later date.

The MHRA routinely undertakes trending and surveillance activities, to closely monitor trends in adverse incidents and act, if required. Therefore, please continue to report adverse incidents via the Yellow Card scheme on https://yellowcard.mhra.gov.uk/ to assist our investigations. Please be reassured that we take all Yellow Card reports seriously.

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, 4-T, 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