Medicines & Healthcare products Regulatory Agency

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[redacted]

Our Ref: **FOI2026/00658**

27 July 2026

Dea[redacted]

Thank you for your Freedom of Information (FoI) request received on 28 April. You wrote:

> *We've prepared a short overview below. We welcome your guidance on what would be considered in scope for a FoI.*
>
> *Devices in scope*
> *1. Cardiac implants: pacemakers, implantable cardioverter defibrillators, cardiac resynchronisation therapy devices (including relevant subtypes where applicable),...*
> *2. Neural implants: deep brain stimulation systems and spinal cord stimulation and neuromodulation systems, ...*
> *Primary request: anonymized case-level dataset*
> *We are looking for anonymized, case-level extracts from vigilance (post-market serious incident) reports for the device categories above, covering 1 January 2000 to present. If that full period is not feasible, please could you let us know what is the longest period that is feasible?*
> *Fields of interest (please could you indicate which represent data that is available):*
> • *Event date and/or date received by MORE - MHRA*
> • *Number of adverse event reports for selected AIMDs, identified by relevant GMDN codes*
> • *Device category (pacemaker / implantable cardioverter defibrillator / cardiac resynchronisation therapy device / deep brain stimulation system / spinal cord stimulation system) and device type/model fields if recorded*
> • *IMDRF annex breakdown for device problem and clinical symptoms as MHRA*
> • *Event type and seriousness*
> • *Problem / failure codes (or equivalent structured categories)*
> • *Patient sex (female/male/unknown, as recorded)*
> • *Patient age (preferably as bands)*
> • *Outcome and/or revision/explant/replacement indicator*
> • *Link to a Field Safety Corrective Action / Field Safety Notice (if recorded)*
> • *If available, any denominator/exposure proxy by sex*
> • *Any additional structured fields that are routinely available and relevant to interpreting the report*
>
> *Optional cross-tabulations (if feasible within FoI aggregation constraints)*
> • *year × device category × event type/seriousness × patient sex*
> • *if available: problem/failure code (or high-level failure mode) × device category ×*

patient sex

- *optionally: age band × device category × patient sex*
- *optionally: linkage to Field Safety Corrective Actions / Field Safety Notices*
- *Sex × device category (GMDN) × severity*
- *Sex × device issue category*
- *Sex × clinical outcome category*

Finally, a simple pragmatic question, would you be providing the information as CSV or Excel (or another machine-readable format)?

I look forward to your response and working with you to develop a FoI request that supports the progress of our research, whilst not excessively burdening your team. I hope that this work may even feed into your own internal reflection as to what data may, in the future, be made accessible through published summaries.

MHRA Response

We confirm that we hold some of the information you have requested.

Please find attached Annex 1 to 4 (in an Excel format) which contains the requested data including anonymised case data of all UK cases where the reported medical device is either a neural implant or cardiac implant, from 1 January 2000 to 10 July 2026.

For context, when a medical device report is submitted to the MHRA, the events of the incident are classified using the International Medical Device Regulatory Forum (IMDRF) adverse event terminology. It provides a uniform classification system that allows communication between regulatory authorities, manufacturers, and healthcare providers. 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 will not add up to the total number of incidents.

Additionally, medical devices are classified using the Global Medical Device Nomenclature (GMDN) which is a generic system used in the naming, classification, and categorisation of medical devices. There is a GMDN term which is in the form of a 5-digit numeric code which cross-references to a specific Term Name and Definition. Collective Terms (CT) codes are made up of a collection of similar GMDN codes with shared clinical functions, intended uses and/attributes. Table 1 and 2 below lists the GMDN and CT codes used to search our database. Please note, no search has been conducted on “neuromodulation systems” as it is a broad and non-specific term that would cover a lot of different modalities. You can to refine this search criteria should you wish to receive further information.

Table 1: A list of GDMN and CT codes used to search the MHRA database for cases where the reported medical device is a neural implant (spinal cord stimulation system and deep brain stimulation)

Spinal cord stimulation systems	Deep brain stimulation systems
64970	37307
65531	61553
62423	61552

62425	64969
65308	61554
62424	61947
61588	
44040	
66826	
67082	

Table 2: A list of GDMN and CT codes used to search database for cases where the reported medical device is a cardiac implant (implantable pacemakers, cardioverter defibrillators and cardiac resynchronisation therapy devices)

Cardiac implants pacemakers	Implantable cardioverter defibrillators	Cardiac resynchronisation therapy devices
12913	35852	47270
47264	37265	47263
47265	47940	
47266	CT258	
47267		
60789		
63188		
CT1684		
CT1685		
CT257		
CT2866		

The details of each incident including; first submission year, event classification (event type and seriousness), GMDN code/name/definition, GMDN CT code/name/definition, patient as reported IMDRF codes (annex E and F), clinical event as reported IMDRF codes (annex A), and explant dates have been displayed as a line listing as an attachment in Annex 1 (neural implants), Annex 2 (cardiac implants pacemakers), Annex 3 (implantable cardioverter defibrillators) and Annex 4 (cardiac resynchronisation therapy devices).

You asked for data regarding outcome and/or revision/explant/replacement indicator for which we have provided explant dates. Please note, this is not a mandatory field and may not always be completed by the reporter.

We have also provided aggregated tables for patient sex and age for each implant type. You proposed optional cross-tabulations, however for the majority of the tables, these can be created from data already provided to you. Age and sex data can only be provided in aggregated tables. Unfortunately, we are unable to provide any denominator/exposure proxy by sex and additional structured fields that are routinely available and relevant to interpreting the report as this is information we do not hold.

Further to your query, you can find the publicly available list to all Field Safety Corrective Action (FSCAs)/ Field Safety Notice (FSN) here: Alerts, recalls and safety information: medicines and medical devices -MHRA

I would like to take this opportunity to reiterate the importance of considering the below factors in relation to the data provided:

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

- 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 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.
- 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.
- The 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 data provided, therefore, is not a summary of known or proven adverse reactions to the device and must not be interpreted and used as such.

If you have any queries about this letter, please contact us quoting the reference number above.

Yours sincerely,

MHRA Central Freedom of Information Team
Medicines & Healthcare products Regulatory Agency

Your right to complain under the Freedom of Information Act

If you are not happy with this response you may request an internal review by e-mailing foi.request@mhra.gov.uk or by writing to: MHRA Central Freedom of Information Team, 10 South, Colonnade, Canary Wharf, London, E14 4PU

Any request for an internal review must be received by us within 40 working days of the date of this letter. Please note we are not obliged to provide a review if it is requested after more than 40 working days.

If you are not content with the outcome of the internal review, you may apply directly to the Information Commissioner's Office for a decision. Generally, the Commissioner cannot make a decision unless you have exhausted our own complaints procedure. The Information Commissioner can be contacted at: The Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire SK9 5AF.
Website: ICO FOI and EIR complaints or telephone 0303 123 1113.

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