Medicines & Healthcare products Regulatory Agency

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[redacted]

Our Ref: **FOI2026/00861**

21 August 2026

Dear [redacted]

Thank you for your Freedom of Information (FoI) request received on 4 August. You wrote:

I am making a request under the Freedom of Information Act 2000 concerning adverse incident reports involving Nevro spinal cord stimulation systems in the United Kingdom.

Please provide information held by the MHRA for the period 1 January 2020 to the date of this request concerning medical-device adverse incident reports relating to:

- *Nevro HFX*
- *Nevro Senza*
- *Senza II*
- *Senza Omnia / Omnia*
- *Nevro implantable pulse generators (IPGs), particularly model NIPG2500*

I would specifically like to know:

1. *The total number of UK adverse incident reports received concerning these devices, broken down by calendar year where possible.*
2. *Where recorded, the number of reports involving any of the following:*

- *electric shock or electric-shock-like sensations*
- *unintended or abnormal stimulation*
- *overstimulation*
- *muscle spasms, contractions or involuntary movements*
- *burning sensations*
- *heating or abnormal warmth around the implanted IPG*
- *pain at or around the IPG/battery pocket*
- *pain along the lead or IPG-to-lead pathway*
- *battery or IPG malfunction*
- *charging problems*
- *abnormal electrode/contact impedance*
- *lead or connector malfunction*
- *device or IPG migration*

1. *Where recorded, the number of incidents in which symptoms were reported to stop, substantially improve or otherwise change when stimulation was switched OFF.*

2. The number of reported incidents resulting in:

- *revision surgery*
- *replacement of the IPG/generator*
- *replacement of leads*
- *complete explantation of the spinal cord stimulation system*
- *serious injury*
- *death*

1. Specifically for the Nevro NIPG2500, please provide the number of adverse incident reports involving this model and, where possible, the reported event/problem categories and outcomes.
2. Where disclosure is permitted, please provide anonymised incident narratives or summaries for reports involving electric-shock sensations, abnormal stimulation, muscle spasms/contractions, burning/heating or pain associated with the IPG.

I am not requesting any patient-identifiable information.

If providing individual incident narratives would engage an exemption or cause this request to exceed the appropriate cost limit, please provide the requested numerical/aggregated information and event categories instead.

If any part of this request is considered too broad to process within the statutory cost limit, I would be grateful if you could provide advice and assistance under Section 16 of the Freedom of Information Act as to how I might narrow the request while retaining information specifically concerning NIPG2500/HFX adverse incidents.

I would prefer the information electronically, ideally in spreadsheet or CSV format if the data are held in a structured database.

MHRA Response

We confirm that we hold the information you have requested.

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.

We have conducted a search of our database and can confirm that from 1 January 2020 up to and including 4 August 2026, the MHRA has received 46 medical device adverse incident reports associated with Nevro HFX, Nevro Senza, Senza II, Senza Omnia/Omnia and Nevro implantable pulse generators (IPGs), including the NIPG2500 model. The information requested is provided in the tables below.

We use International Medical Device Regulators Forum (IMDRF) codes to classify adverse event terminology, including medical device problems, patient and user outcomes, and other relevant adverse event information. Annex E codes are used to classify medical device problems, while Annex F codes are used to classify the associated health impact on patients or users. Where appropriate, the information presented below is derived from adverse event and health impact data recorded using IMDRF coding terminology.

Please note that a single adverse incident report may contain multiple adverse event terms, device problem codes and health impact codes. As such, the figures presented in different categories are not mutually exclusive and should not be summed.

With regard to your request, "*Where disclosure is permitted, please provide anonymised incident narratives or summaries for reports involving electric-shock sensations, abnormal stimulation, muscle spasms/contractions, burning/heating or pain associated with the IPG*", the MHRA is withholding the requested case narratives under Section 40(2) of the Freedom of Information Act 2000.

The requested adverse incident case narratives contain personal data relating to identifiable living individuals. Although direct identifiers could be removed, the detailed clinical information contained within individual case narratives, including demographic information, clinical history, adverse event details, treatment information and other case-specific circumstances, could reasonably enable identification of individuals when combined with other information available to the requester or in the public domain.

Disclosure under the Freedom of Information Act is considered disclosure to the world at large. Release of this information would therefore constitute unfair and unlawful processing of personal data and would contravene the data protection principles set out in Article 5(1)(a) of the UK General Data Protection Regulation (UK GDPR). Accordingly, the information is exempt from disclosure under Section 40(2) of the Freedom of Information Act 2000.

1. Total number of UK adverse incident reports received

Table 1: Displays the number of adverse incident reports associated with Nevro HFX, Nevro Senza, Senza II, Senza Omnia/Omnia and Nevro implantable pulse generators (IPGs), including model NIPG2500, received by the MHRA between 1 January 2020 and 4 August 2026, broken down by calendar year.

Year	Cases Received
2020	9
2021	3
2022	8
2023	9
2024	12
2025	2
2026	3
Total	**46**

2. Reports involving the specified event categories

Table 2: Displays the number of adverse incident reports in which the specified event categories were identified. Reports may contain more than one event category and therefore may be counted in more than one category.

Event Category	Number of Reports
Electric shock or electric-shock-like sensations	8
Unintended or abnormal stimulation	4
Overstimulation	0
Muscle spasms, contractions or involuntary movements	1
Burning sensations	1
Heating or abnormal warmth around the implanted IPG	1
Pain at or around the IPG/battery pocket	4
Pain along the lead or IPG-to-lead pathway	0
Battery or IPG malfunction	2
Charging problems	0
Abnormal electrode/contact impedance	0
Lead or connector malfunction	4
Device or IPG migration	1

3. Reports where symptoms changed when stimulation was switched off

A search of the available incident information identified 5 reports in which symptoms were reported to stop, substantially improve, or otherwise change when stimulation was switched off.

4. Reported outcomes

Table 3: Displays the number of reports where the specified outcomes were identified.

Outcome	Number of Reports
Revision surgery	4
Replacement of the IPG/generator	3
Replacement of leads	2
Complete explantation of the spinal cord stimulation system	Not determinable from the reports provided*
Serious injury	2
Death	3

* *The reports reviewed describe device removal or explantation. However, they do not consistently specify whether removal involved the complete spinal cord stimulation system (IPG, leads and associated components). Consequently, the number of incidents resulting in complete explantation of the spinal cord stimulation system cannot be reliably determined from the information held.*

5. Adverse incident reports involving the Nevro NIPG2500 model

A total of 9 adverse incident reports involving the Nevro NIPG2500 model were identified. The information held regarding these reports is summarised below. Reports may contain more than one event category or outcome and may therefore be included in more than one category.

Table 4: NIPG2500 event categories

Event Category	Number of reports
Infection (including pocket-site and bacterial infections)	5
Pain/discomfort (including pocket pain and shocking sensations)	3
Itching/swelling	1
Burning sensation with heat/shock sensations	1

Table 5. NIPG2500 reported outcomes

Outcome	Number of reports
Medication required	5
Hospitalisation	3
Device explantation/removal reported	5
Device replacement/revision reported	1

The identified adverse incident reports primarily related to infection, pain/discomfort and skin reactions. Reported outcomes included medication treatment, hospitalisation, device explantation/removal and device replacement/revision. No deaths were identified among the reports provided for this model.

When reviewing adverse incident data, please note:

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 individual patients, as individuals may submit multiple reports relating to the same issue at any time after the event occurred. Where possible, multiple reports relating to the same event are linked. However, as reporters are not required to complete all fields, we cannot always be certain enough to identify and link every duplicate report.

It should also be noted that this information may include a range of recognised complications associated with this type of procedure and does not necessarily indicate a fault with any particular device. In addition, the figures provided may include reports where the incident information has been obtained from published literature.

The figures are accurate at the time they were extracted from our database. Minor changes may occur where additional information is subsequently received from the reporter. The inclusion of a report on the MHRA adverse incident database does not necessarily mean that the events described were caused by the device. Such events may be attributable to other

factors, including underlying patient conditions, user factors or procedural complications. The data provided should not therefore be regarded as a summary of known or proven adverse reactions and must not be interpreted 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.

Re-use of our information
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