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: **FOI2025/00196**

31 March 2025

Dear [redacted],

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

> *I'd like to know the following please :*
> *How many spinal cord stimulators products have been given MHRA clearance? This includes all equipment related to SCS and DRG and related frequence products ? eg includes insertion needles, tunnelling tools etc,*
> *How many intrathecal pain pumps and associated equipment to perform a procedure?*
> *How many products have been given clearance for radiofrequency nerve ablation ?*
> *How many manufacturers supply the above, please provide companies' names?*
> *How much income is device by the MHRA from companies that supply spinal cord stim devices ?*
> *How much income does the MHRA receive from medical device companies in total*
> *As a percentage of income ? compared to Pharmaceuticals.*
> *Please advise on how you communicate with other bodies such as the TGA or FDA ? Ie in what form?*

MHRA Response

We can confirm that the Agency holds some of the information you are requesting. Of the information we hold, some of the information is exempt for disclosure. We will set out a response to each request below.

How many spinal cord stimulators products have been given MHRA clearance? This includes all equipment related to SCS and DRG and related frequence products ? eg includes insertion needles, tunnelling tools etc,

We can confirm we do not hold this information, the MHRA does not carry out assessments or approve medical devices placed on the UK market. Registration of medical devices with the MHRA (the UK Competent Authority) does not represent any form of clearance, accreditation, certification, approval or endorsement by the MHRA. The manufacturer holds the legal responsibility for obtaining the necessary certification and registering their devices with the agency. Higher risk medical devices such as spinal cord stimulators require approval by UK Approved Bodies for the GB or Notified Bodies for the EU market.

How many intrathecal pain pumps and associated equipment to perform a procedure?

We can confirm we do not hold this information, the MHRA does not develop or enforce procedural standards or protocols for clinician's use of medical devices. It is the responsibility of individual NHS Trusts to establish these guidelines and ensure adherence to best practices for patient care and procedural protocols for clinician's use of medical devices. We continue to recommend medical devices to be used within their manufacturer's guidance.

How many products have been given clearance for radiofrequency nerve ablation ?
How many manufacturers supply the above, please provide companies' names?

We can confirm we do not hold this information, the MHRA does not carry out assessments or approve medical devices placed on the UK market. Registration of medical devices with the MHRA (the UK Competent Authority) does not represent any form of clearance, accreditation, certification, approval or endorsement by the MHRA. The manufacturer holds the legal responsibility for meeting certification requirements and registering their medical devices with the agency. We can confirm that the Agency holds this information. However, the information is exempt under Section 21(1) of the Freedom of Information Act because the information is reasonably accessible to you, as it is already in the public domain. However, to be helpful you can find the information you seek at on the Public Access Registration Database PARD. You can use the Advance Search in PARD to search by Global Medical Device Nomenclature (GMDN®) Term in the Medical Device Type field. Specific GMDN® Terms can be identified by searching on keywords e.g. 'Spinal Cord', 'intrathecal', 'pump', 'ablation' etc.

How much income is device by the MHRA from companies that supply spinal cord stim devices ?
How much income does the MHRA receive from medical device companies in total?
As a percentage of income ? compared to Pharmaceuticals?

We can conform we hold this information. However, the information is exempt under Section 21(1) of the Freedom of Information Act because the information is reasonably accessible to you, as it is already in the public domain.

However, to be helpful you can find the information you seek with the latest publishes Annual Report of Accounts. We are only able to direct you to figures for 2023/24 as the current financial years report has not been finalised, we expect this to be done later in the year.

Please advise on how you communicate with other bodies such as the TGA or FDA ?
Ie in what form?

We can confirm we hold this information, the MHRA maintains strong relationships with international regulators, including the TGA and FDA. The agency regularly engages with its international counterparts to ensure patient safety, share information, and participate in international forums for engagement and discussing regulation policy.

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
The MHRA information supplied in response to your request is subject to Crown copyright. Information created by the MHRA which is disclosed under the Freedom of Information Act is made available for re-use under the Open Government Licence (OGL) v3.0, except where this is otherwise stated. There are some restrictions on re-use under the OGL and these can be viewed here:
https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/