Medicines & Healthcare products Regulatory Agency

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[redacted]

10 August 2023

FOI 23/548

Dear [redacted]

Thank you for your Freedom of Information request dated 27th July 2023, where you asked for "information on adverse incidents relating to devices that deliver drugs to the brain". Including the following GMDN codes: 32568, 45170, 61100, 61964, 62753 and 62990.

Further to your request, please see Table 1 which includes the number of UK, spontaneous adverse incident reports associated with the above mentioned GMDN codes. We have also included the respective reported medical device problem(s) and reported clinical effect(s) as requested. It is important to note that a singular report can contain more than one device problem and associated clinical effect.

Please be aware that where less than 5 reports have been received the number has not been included within the table. This is in compliance with data protection laws and to protect patient/reporter confidentiality.

Please note that 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. In addition, details of the reports may have changed since the report was submitted.

Table 1. The number of adverse incidents reported in association with the respective drug delivery system GMDN code, including reported medical device problem and clinical effect.

Device Type	GMDN Code	Reported Medical Device Problem(s)	Number of Reports	Reported Clinical Effect(s)

Neurological stereotactic surgery system	32568	Appropriate term not available.	<5	None Reported.
		Off-label use.	<5	None Reported.
Stereotactic surgery system probe, single-use	45170	-	0	-
Neurosurgical probe	61100	-	0	-
Intracerebral cannula, implantable	61964	No apparent adverse event.	<5	None reported.
Intracerebral cannula, non-implantable, single-use	62753	-	0	-
Neurosurgical retraction cannula	62990	-	0	-

The data must be read together with the following explanations:

- 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 after the use of the 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.
- When interpreting the above data 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 dermal filler is known.
- 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.
- Adverse incident reports by members of the public are voluntary but play a substantial part in the successful operation of the vigilance system. All reports received via Yellow Card are sent to the relevant manufacturer (if known and anonymised as appropriate) to feed into the vigilance system.
- Adverse incident reports include mandatory reporting by manufacturers to MHRA for certain types of incidents that occurred in the UK as part of the regulatory post market surveillance ‘vigilance’ system. The principal purpose of this system is to improve the

protection of health and safety of patients. This is to be achieved by the evaluation of reported AIRs and, where appropriate, dissemination of information, which could be used to prevent such repetitions, or to alleviate the consequences of such adverse events.

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If you have a query about the information provided, please reply to this email.

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 you receive this response and addressed to: info@mhra.gov.uk

Please remember to quote the reference number above in any future communications.

If you were to remain dissatisfied with the outcome of the internal review, you would have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of your request unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted at:

Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Yours sincerely,

FOI Team,
Safety and Surveillance group