Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of Information Team
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E14 4PU

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MHRA Website

[redacted]

Our Ref: **FOI2024/00813**

23rd January 2025

Dear [redacted]

Thank you for your Freedom of Information (FoI) request received on 23rd December. You wrote:

> *i want to check whether promogran prisma got any adverse effects?anyone got brain bleed and die using it?*

MHRA Response

We confirm that we hold the information you have requested.

I can confirm that up to and including 13th January 2024, we have received **1** adverse incident report concerning Promogran Prisma Matrix Wound Dressing. Please note that this data has been extracted using both a search for the Device Name/Model '*Promogran Prisma'*, a separate search of our database for the manufacturer of this device and finally a search for the below Global Medical Device Nomenclature (GMDN) Collective Term (CT) codes, which were then filtered for any that may concern the Promogran Prisma Matrix Wound Dressing.

Global Medical Device Nomenclature (GMDN) Collective Term (CT) codes:

- CT2148 Dermal dressings
- CT554 Dressings

Please note, the case identified did not report a brain haemorrhage and did not include a fatal outcome. To provide a brief overview, this case contains only the International Medical Device Regulators Forum (IMDRF) Annex A code A0101 Patient-Device Incompatibility (Problem associated with the interaction between the patient's physiology or anatomy and the device that affects the patient and/or the device). It was reported that the patient's wounds became worse. Further information on IMDRF codes can be located here.

The data must be read together with the following explanations:

- 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 device 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 adverse incident reports and, where appropriate, dissemination of information, which could be used to prevent such repetitions, or to alleviate the consequences of such adverse events.

As with all medical devices, MHRA continues to monitor their safety and performance and encourages reporting of any adverse incidents through its Yellow Card Scheme. Any emerging evidence relating to possible risks associated with these devices will be carefully reviewed and, if appropriate, regulatory action will be taken if any serious risks are confirmed.

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.