Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

[redacted]

MHRA

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

www.gov.uk/mhra

23rd May 2024

Dear [redacted]

FOI 2024/0011

Thank you for your email dated 26th April 2024, where you asked for information on the following:

> "*I wish to understand if there have been any further reports to MHRA regarding the following needles becoming detached from their hub during administration?*
>
> *Smiths Medical Jelco Hypodermic needle - Pro Needle with Needle protection Device.*
>
> *There appears there could be a problem with the needles.*
>
> *These are supplied within Zypadhera injection product but are also available to purchase through NHS contract and so are also stocked on our wards.*
>
> *Our hospital have had 3 instances reported since January 2024 surrounding 'faulty Zypadhera injection' and a fourth instance occurred yesterday.*
>
> *This is unprecedented in such a short space of time and involves 4 experienced staff nurses administering the product across 3 different patients and has seriously undermined professionals' and patient confidence in the product.*
>
> *Pharmacy have requested that all nursing professionals involved have reported to MHRA via Yellow card.*"

Further to your request I can confirm the MHRA do hold this information. I can confirm that the MHRA has not received any UK spontaneous suspected Adverse Drug Reaction (ADR) reports relating to the medicinal product Zypadhera and needle issues.

Separate to this, since January 2024, the Defective Medicines Report Centre (DMRC) at the MHRA have received two reports relating to the medicinal product Zypadhera and needle issues. We note that one of these reports was provided by a healthcare professional from the Midlands Partnership University NHS Foundation Trust and no definitive root cause was identified due to the unavailability of the sample for testing. Currently, the DMRC do not consider the product defective and we have no

current signals that suggest a widespread issue, as such and we will not be considering any further market action at this stage, based on the current evidence. DMRC acts on issues that may affect public health. Individual complaints regarding quality defects are managed by the company in accordance with the requirements of the Rules and Guidance for Pharmaceutical Manufacturers and Distributors. The MHRA license and inspect all UK manufacturers, wholesale dealers and importers of medicines to ensure these requirements are met.

With regard to Smiths Medical Jelco Hypodermic needles specifically, unfortunately we cannot share information about specific manufacturers, makes or models of devices, or who has reported problems to us. This is because there are confidentiality clauses in the legislation that we work under and the agreements under which information is provided to us which limit disclosure in some circumstances. This type of information is exempt from disclosure under section 43 of the Freedom of Information Act (FOIA) as disclosure may prejudice the commercial interests of a third party.

Considering the above however, it would be very helpful if you could confirm the reference numbers of any Yellow Cards submitted relating to these incidents. Please may I also ask that any incidents with Zypadhera where no patient harm has occurred are submitted as defective medicines Yellow Cards in order to ensure they are processed by the appropriate MHRA unit. 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.

I hope the information provided is helpful, but 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 of this response; and can be addressed to this email address.

Yours sincerely,

FOI Team,
Safety and Surveillance

If you have a query about this email, please contact us. If you are unhappy with our decision, you may ask for it to be reviewed. That review will be undertaken by a senior member of the Agency who has not previously been involved in your request. If you wish to pursue that option please write to the Communications Directorate, 4-T, Medicines and Healthcare products Regulatory Agency, (via this email address). After that, if you remain dissatisfied, you may ask the Information Commissioner at:

The Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire

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