Medicines & Healthcare products Regulatory Agency

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London
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United Kingdom
gov.uk/mhra

[redacted]

28th November 2023

FOI 23/845

Dear [redacted]

Thank you for your Freedom of Information request dated 5th November 2023 where you requested information concerning adverse incident reports received in the last five years arising from chemical incompatibility of an intravenous medication with the administration set or syringe-pump extension set being used to deliver it. Specifically, you requested the following:

- How many reports of this type we have received.
- The medications involved and the plastics they reacted with.

I can confirm that between 1st January 2018 and 27th November 2023, the MHRA has received 76 UK reports of suspected adverse incidents to an intravenous administration set, infusion pump administration set, and infusion & transfusion administration set where the following device problems have been listed: 'compatibility problem', 'material integrity problem' and 'degraded'. The GMDN CT codes used to locate these reports were as follows: CT1080, CT2391, and CT214. Please see Table 1 for a breakdown of these adverse incident reports.

However, I can also confirm that a failure description search was conducted for these 76 cases which returned **zero** cases directly referencing chemical incompatibility arising from an intravenous (IV) medication with the administration set or syringe-pump extension set being used to deliver it. It is important to note that the failure description field is a free-text field and therefore the information we receive is unstructured. Please be aware 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 associated with administration sets or syringe-pump extension sets and the relevant device problem code.

Device problem code	Device problem term	Number of incidents
A17	Compatibility Problem	2
A04	Material Integrity Problem	69
A0405	Degraded	5

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 delivery 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 AIRs and, where appropriate, dissemination of information, which could be used to prevent such repetitions, or to alleviate the consequences of such adverse events.

If you plan on sharing or publishing the data within this response more widely, please provide us with a copy beforehand so we can ensure correct interpretation.

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
Medicines and Healthcare products Regulatory Agency

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, 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
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Water Lane
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