Medicines & Healthcare products Regulatory Agency

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Canary Wharf
London
E14 4PU
United Kingdom
www.gov.uk/mhra

[redacted]

21st November 2023

Dear [redacted]

FOI 23/825 - MRI Safety: heart valves, annuloplasty rings and cardiac occluders

Thank you for your Freedom of Information (FOI) request dated 29th October 2023 where you asked:

- **If there have been any adverse incidents reported to the MHRA in relation to these devices (heart valves, annuloplasty rings and cardiac occluders) and MRI?**

The MHRA codes medical devices within adverse incident reports using the Global Medical Device Nomenclature (GMDN). GMDN is a system of internationally agreed generic descriptors used to identify medical device products. In response to your request, we have widened our search criteria to cover all adverse incidents reported to the MHRA containing the GMDN CTs heart valve, heart valve bioprostheses, heart valve prostheses, mechanical heart valve prostheses, transcatheter heart valve bioprostheses, annuloplasty rings, cardiac occluders or cardiovascular occluders and magnetic resonance imaging (MRI) systems. This is demonstrated in table 1 below which shows the number of adverse incidents submitted in relation to the above criteria as of the 31st of October 2023 inclusive. The table includes reports received from manufacturers, healthcare professionals and members of the public.

We should advise that these figures need to be interpreted with caution as they are not the same as complication rates.

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Table 1: The number of adverse incident reports for the device types listed above and MRI systems up to and including 31st October 2023.

Device type	GMDN CT Codes	Number of incidents on the MHRA database
1. Heart valve (including heart valve bioprostheses, heart valve prostheses, mechanical heart valve prostheses and transcatheter heart valve bioprostheses) AND magnetic resonance imaging (MRI) systems	CT1178, CT1169, CT2267 and CT2365	None reported.
2. Annuloplasty rings AND magnetic resonance imaging (MRI) systems	CT1170	None reported.
3. Cardiac occluders (and its variation 'cardiovascular occluders') AND magnetic resonance imaging (MRI) systems	CT2977	1

Please also note the following considerations in relation to the data provided in the table above:

- This information is accurate at the time we conduct the search on our database, changes in the number of adverse events can occur following receipt of additional information.
- The database search encompassed the querying of the failure description, a mandatory free-text field that may not always be fully completed. Therefore, the outcome may vary depending on the availability, and accuracy of the entered text.
- The number of reports received should not be used as a basis for determining the incidence of a health/clinical effect as neither the total number of effects occurring, nor the number of patients using the device is known.
- The inclusion of a report on the MHRA adverse incident database does not necessarily mean that the events described were caused by the device.

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 on https://yellowcard.mhra.gov.uk/. 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,

Medicines & Healthcare products Regulatory Agency

FOI Team,
Safety and Surveillance
Medicines and Healthcare products Regulatory Agency

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The Information Commissioner's Office
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Water Lane
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Cheshire
SK9 5AF