Medicines & Healthcare products
Regulatory Agency

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Mr [redacted]
[redacted]

23rd April 2023

FOI 24/289

Dear [redacted]

Thank you for your Freedom of Information request dated March 22nd 2024. Within your request, you asked for:

- *Patient deaths reported by both Edwards Lifesciences LLC (ref 13105) and Medtronic Corevalve LLC (ref 12980) relating to their "Aortic transcatheter heart valve bioprosthesis, stent-like framework devices" GMDN code 60245, Class III in the most recent 12-month period.*

Please note that the release of information related to specific manufacturers is exempt as its disclosure is prohibited by other legislation. In this case, section 237 of the Enterprise Act 2002 prohibits a public authority from releasing information which came to it in connection with the exercise of its functions, and which relates to the affairs of an individual or business.

The MHRA is satisfied that the information you have requested:

- constitutes information which came to us in connection with the exercise of the Agency's functions. The MHRA has a duty of consumer protection under the Consumer Protection Act 1987 which is listed as a specified function under Schedule 14 of the Enterprise Act 2002, and receives information while exercising consumer protection functions in its role as the regulator of medicines and healthcare products.
- relates to the affairs of Edwards Lifesciences LLC and Medtronic Corevalve LLC, businesses which continue to exist. On that basis we are satisfied that section 44 of FOI Act applies and the information is exempt from release.

However to be helpful, further to your request we have widened the search criteria for any adverse incidents reported for this device type which specify a fatality, including those from patients, healthcare professionals and manufacturers. I can confirm that between 1st January 2023 and 12th April 2024, the MHRA has received **16** UK fatal reports of suspected adverse incidents concerning Aortic transcatheter heart valve bioprosthesis, stent-like framework

devices (GMDN code 60245). The International Medical Device Regulators Forum (IMDRF) Annex F code used to locate these reports was F02 (Death). The IMDRF Annex F terms are used to describe the health impact that the event caused. You can find further information on IMDRF codes and corresponding terms here. Please see Table 1 below for a breakdown of these adverse incident reports, including the respective IMDRF Annex E codes reported, which describe clinical signs and symptoms for your reference.

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 fatal adverse incident reports relating to Aortic transcatheter heart valve bioprosthesis, stent-like framework devices (GMDN code 60245) since 01/01/2023, respective to reported IMDRF Annex E codes.

First Submission Year	IMDRF Annex E Code	IMDRF Annex E Term
2023	E060110	Ventricular Fibrillation
2023	E0515	Vascular Dissection
2023	E0602	Cardiac Arrest
2023	E0133	Stroke/CVA
	E0602	Cardiac Arrest
2023	E0501	Aneurysm
	E0515	Vascular Dissection
	E2342	Multiple Organ Dysfunction Syndrome
2023	E0602	Cardiac Arrest
2023	E0602	Cardiac Arrest
	E2321	Low Blood Pressure/ Hypotension
2023	E2401	Insufficient Information
2023	E2401	Insufficient Information
2023	E0515	Vascular Dissection
	E2342	Multiple Organ Dysfunction Syndrome
2023	E0619	Pericardial Effusion
	E0621	Valvular Insufficiency/ Regurgitation
	E2013	Rupture
2023	E0515	Vascular Dissection
	E0602	Cardiac Arrest
	E2321	Low Blood Pressure/ Hypotension
2023	E0515	Vascular Dissection
	E2342	Multiple Organ Dysfunction Syndrome
2024	E0602	Cardiac Arrest
	E2007	Fall
2024	E1906	Unspecified Infection
2024	E0133	Stroke/CVA
	E0503	Embolism/Embolus

	E0602	Cardiac Arrest
	E0621	Valvular Insufficiency/ Regurgitation
	E062101	Aortic Valve Insufficiency/ Regurgitation
	E2321	Low Blood Pressure/ Hypotension

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 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 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.

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,

FOI Team,

Safety and Surveillance
Medicines and Healthcare products Regulatory Agency

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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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