Medicines & Healthcare products
Regulatory Agency

[redacted]

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom
**gov.uk/mhra**

[redacted]

15 December 2023

Dear [redacted]

[redacted] **MHRA ref FOI 23.890**

Thank you for your Freedom of Information request dated 17 November 2023 [redacted] concerning this medical device (the Device):

| | |
|---|---|
| **Manufacturing details:** | RRR Manufacturing Pty Limited |
| **MHRA Reference number:** | 18636 |
| **Device:** | Non-rechargeable public automated external defibrillator |
| **GMDN Code:** | 48047 |

You asked for:

1 The total number of representations and communications reporting issues or concerns with the Device since 1 January 2022 (Communications);

2 The identity of those involved in such Communications (where disclosure would not be exempt under section 40(2) FOIA);

3 To the extent that it would be feasible within the cost limit, the content of the Communications themselves;

4 To the extent that (3) is not feasible, please provide the content of Communications, from or with, including phone calls or meetings with UK providers of defibrillator products, brand manufacturers and suppliers of such products;

5 As regards those parties raising concerns or making representations to MHRA, other than those set out in (4), the nature of any Communications made by them;

6 The responses of MHRA to such Communications; and

7 The overall number of complaints, if any, received regarding external defibrillator products since January 2022 (excluding complaints relating to the Device).

**Response**

In respect of questions 1, 2, 3, 4, 5 and 6 of your request, we can neither confirm nor deny whether we hold the information you have requested under sections 43(3), 41(2) and 40(5) of the Freedom of Information Act.

The decision to issue a 'neither confirm nor deny' response is not affected by whether we do or do not hold the information but relates to the consequences of confirming or denying the information is held. We have considered the consequences of confirming or denying that a particular type of information is held. The decision to neither confirm nor deny is separate from a decision not to disclose.

When the Agency responds to a request under FOIA, it is a disclosure to the world at large rather than to a private requestor. This is something the Agency must consider when determining whether the information is held and when determining if other exemptions apply.

On basis of the general principle that disclosure is to the world at large, when considering an exemption with an associated prejudice test, that test should focus on the consequences of disclosing the information to the wider public.

Here what the Agency must consider is whether there is a real and significant chance that a member of the wider public will use the information in a way that would prejudice the interests protected by the exemption and whether the information is likely to be used if the information is released into the public domain. Given that the request is about complaints about a product, this is more than likely to be the case and the information is therefore withheld.

Section 43(3) FOIA commercial interests

Section 43(3) provides an exemption from the duty to confirm or deny whether you hold information, if doing so would, or would be likely to, prejudice the interests protected by section 43(2). Whether we hold or do not hold the information pertaining to the complaints about a medical device would be likely to prejudice the manufacturer's commercial interests If held – the type of information you have requested is generally considered to be commercially confidential; in the circumstances of your request, this supports the use of these specific exemptions to neither confirm nor deny that the information is held.

Section 41(2) Information provided in confidence

In this case, the type of information you have requested would fall under the class of information that the section 41(2) exemption is designed to protect, because it would be obtained by the public authority from a third party, and confirmation or denial that the information is held would itself constitute an actionable breach of confidence by that or any

other person. The requested information would be of a type that would have the necessary quality of confidence, as it would not be trivial or otherwise available in the public domain, and it would be provided to the public authority in circumstances which give rise to a duty of confidence, the breach of which (through confirmation or denial that the information is held) would cause detriment to any third party. In this case, any confirmation or denial would itself place a detail about any third party into the public domain that itself may constitute an actionable breach.

S40(5) FOIA personal information

The Agency is not obliged to confirm or deny if you hold another person's personal data if:

- It would breach the UK GDPR data protection principles;
- It would contravene an objection to processing; or
- The information would be exempt from a subject access request.

There is no public interest in this case as any breach would breach the principles of the data protection principles.

The DPA defines personal data as any information relating to an identified or identifiable living individual. If an individual cannot be directly identified from the information, it may still be possible to identify them. You need to consider all the means reasonably likely to be used to identify an individual. There may be circumstances in which simply confirming whether or not you hold the personal data could itself reveal something about that individual.

In relation to question 7, I can confirm that the MHRA has received a total of 640 UK spontaneous suspect adverse incident reports concerning external defibrillators, from 01/01/2022 to present. To note, this data was extracted from our database using the corresponding GMDN CT code 'CT269', which is used to group external defibrillators. 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.

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.

**Appeal rights**

If you disagree with how we have interpreted the Freedom of Information Act 2000 in answering your request, you can ask for an internal review. Please reply to this email, within two months of this reply, specifying that you would like an Internal Review to be carried out.

If you are dissatisfied with the outcome of the internal review, you have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review the handling of a request unless the public authority has first been asked to conduct an internal review.

The Information Commissioner can be contacted online via an electronic form:
https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/

Or by writing to:

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

Yours sincerely,

Kind regards

**MHRA Customer Experience Centre**
Communications and engagement team
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