Medicines & Healthcare products Regulatory Agency

[redacted]
By email: [redacted]

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

[redacted]

19 January 2024

Dear [redacted]

Re: FOI 24/011 CellAED

Thank you for your email of 19 December 2023 which is being handled as a Freedom of Information request under the Freedom of Information Act (FOIA). In our acknowledgment of 11 January 2024, we explained that this is because the questions we have identified below are requests for recorded information and meet the criteria for a valid FOI request that is set out in section 8 of the FOIA.

Our acknowledgement also explained that this meant that the next steps would be to consider whether the information you have asked for is held by the MHRA and whether any exemptions may apply.

Your email of 19 December 2023 asked for:

1. *"…provide copies of any peer reviewed papers relating to the efficacy and safety of the CellAED?"*
2. *"I ask for the release of clinical data to support both the efficacy and safety of this product."*
3. *"The CEO of CellAED and also their medical director have stated publicly that the CellAED is "equal or better than every other defibrillator on the market" – please provide clinical evidence for this."*

4. *"What evidence of safety relates to the use of the CellAED on neonates when every other defibrillator in the public domain specifically excludes the use in this category?"*
5. *"The CellAED has an experimental dual exponential waveform that lacks open peer reviewed evidence – please provide evidence that the low energy double 'monophasic' exponential curves have any clinical impact."*
6. *"What evidence does MHRA have that in a real world clinical setting, the shock profile has any significant impact in SCA?"*
7. *"Please supply evid3ence that this power energy is effective in achieving RoSC in anything other than small patients with low TTI."*
8. *"Can you provide evidence that the battery is sufficient to perform as presented?"*
9. *"Please provide evidence that the pads adhesion is sufficient to deliver the required shock energy"*
10. *"Can MHRA guarantee that the energy is sufficient to deliver a shock after 6, 9 or 12 months?"*
11. *"Clinical data for the hospital resuscitation teams – please advise how this data is being provided to the resus teams in hospitals?"*

Response

We should first explain here that when a written request for recorded information is received by a public authority, which is recognised as meeting the section 8 criteria for a valid request, then the public authority must cite the relevant provisions of the FOIA if it is the case that the request should be refused. A valid request under section 8 can only be refused by utilising the appropriate FOIA exemptions.

Before setting out the decision in this case, there are two points that we would like to explain, as these both have relevance for your request.

The first is that any response under the FOIA is considered to be provided to 'the world'; a response issued under the FOIA is a public one rather than a private disclosure to a single requester. This means that when we are considering the decision on any FOIA request, our considerations must be based on the presumption that any response will be publicly available to 'everyone'.

The second is that when we consider a request under the FOIA, the identity and motives of the individual requester cannot be taken into account – any decision made needs to be based on the assumption that the response will be available to 'the world'.

Further guidance on these points is available on the Information Commissioner's website:

https://ico.org.uk/for-organisations/foi-eir-and-access-to-information/freedom-of-information-and-environmental-information-regulations/consideration-of-the-applicant-s-identity-or-motives/

In this case, the request concerns a medical device – the CellAED defibrillator – which has been registered for use in the UK. In considering this aspect of your request, we should first explain the role of the MHRA in the regulation of medical devices and begin by explaining that the MHRA does not approve medical devices or issues licences for their sale or use in the UK. This occurs only in exceptional circumstances, where there is an unmet clinical need

and no suitable UKCA or CE marked product available; in such circumstances an exceptional use application can be made to the MHRA.

Rather, the MHRA designates the task of assessing devices and issuing UKCA certificates to UK Approved Bodies (AB) who ensure that the requirements set out in the Medical Devices Regulations 2002 (as amended) are met by manufacturers. CE certificates issued for devices by EU notified bodies (NBs) are also currently accepted in the UK.

The MHRA is responsible for regulating the UK medical devices market, performs market surveillance of medical devices on the UK market and is able to take decisions over the marketing and supply of devices in the UK. MHRA is the designated authority that administers and enforces the law on medical devices in the UK and is responsible for the designation and monitoring of Approved Bodies.

This means that the MHRA may hold information about a medical device in respect of the various different activities that we undertake.

In the context of the MHRA's role in the regulation of medical devices, and bearing in mind the points set out above, that an FOIA response is 'to the world' and available to all, we would further explain that the ICO's guidance advises that there may be cases when confirming or denying information is held can – in itself – disclose information which would be exempt, or which could prejudice the interest an exemption is there to safeguard.

In these circumstances, the FOIA allows a public authority to give a 'neither confirm nor deny' ('NCND') response. This means that the public authority can respond by refusing to inform the requester whether or not they hold any information.

The ICO's guidance explains:

> *What is the purpose of a 'neither confirm nor deny' ('NCND') response?*
>
> *In most cases, you should be able to say whether you hold information relevant to the request. However, there are also cases when confirming or denying information is held can – in itself – disclose information which is exempt or which could prejudice the interest an exemption is there to safeguard.*
>
> *In these circumstances, the right under section 1(1)(a) is disapplied and FOIA allows you to give a so-called 'neither confirm nor deny' ('NCND') response. This means that you can respond by refusing to inform the applicant whether or not you hold any information.*
>
> *The aim of an NCND response is to leave entirely open the position about whether you hold the requested information so that no inferences can be drawn from an acknowledgement of the fact that information is held or not held.*

When the MHRA receives a request for information which asks for specific details of information which may be held as any part of our role in regulating medical devices, we apply the principles set out in this guidance.

Following this guidance, in respect of questions 1-11 above, MHRA therefore neither confirms nor denies whether we hold the requested information under sections 41(2) and 43(3) of the FOIA.

Section 41 provides:

> ***41 Information provided in confidence.***
>
> *(1)Information is exempt information if—*
>
> *(a)it was obtained by the public authority from any other person (including another public authority), and*
>
> *(b)the disclosure of the information to the public (otherwise than under this Act) by the public authority holding it would constitute a breach of confidence actionable by that or any other person.*
>
> ***(2)The duty to confirm or deny does not arise if, or to the extent that, the confirmation or denial that would have to be given to comply with section 1(1)(a) would (apart from this Act) constitute an actionable breach of confidence.***

Section 41(2) disapplies the duty to confirm or deny under section 1(1)(a) of the FOI Act, as revealing whether or not the requested information is held would constitute an actionable breach of confidence.

Section 43 provides:

> ***43 Commercial interests.***
>
> *(1)Information is exempt information if it constitutes a trade secret.*
>
> *(2)Information is exempt information if its disclosure under this Act would, or would be likely to, prejudice the commercial interests of any person (including the public authority holding it).*
>
> ***(3)The duty to confirm or deny does not arise if, or to the extent that, compliance with section 1(1)(a) would, or would be likely to, prejudice the interests mentioned in subsection (2).***

Section 43(3) of the FOI act sets aside the duty to confirm or deny if this would itself prejudice the commercial interests of the public authority or a third party.

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 – if held – 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 the third party.

S43(3) FOIA is a qualified exemption and requires a consideration of the public interest in neither confirming nor denying that the requested information is held. In favour of confirming or denying, we consider that there is a general public benefit where confirmation or denial demonstrates openness and transparency, and where this could inform the public and contribute to public scrutiny and debate.

In favour of maintaining the exemption to neither confirm nor deny, there is a greater public interest in ensuring that commercial entities are able to communicate and work with the MHRA in their regulatory role without fear that, if they do so, the existence of any confidential commercial discussions may be revealed through confirmation or denial that information is held in response to a request. Doing so could also harm relations with commercial businesses and, particularly, impact on the openness of third parties in their discussions with the MHRA.

Therefore, MHRA have concluded that in all the circumstances of this case, we neither confirm nor deny that the requested information is held.

We appreciate that this will not be the response that you were hoping for, however we hope the explanation above will be of assistance in explaining the approach the MHRA takes to requests for the type of information you are seeking.

As general advice, we would advise that anyone wishing to report a non-compliance with the regulations can do so here https://www.gov.uk/government/publications/report-a-non-compliant-medical-device-enforcement-process/report-a-non-compliant-or-suspected-counterfeit-medical-device

We also encourage the reporting of suspected side effects to medicines, vaccines, e-cigarettes, medical device incidents, defective or falsified (fake) products to our Yellow Card scheme here:

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

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,

MHRA Customer Experience Centre
Communications and engagement team
Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU

MHRA are now publishing FOIA responses on our Disclosure Log; these are redacted to remove the requester's personal details. Our published responses to date can be found on our website at the following link:

Transparency and freedom of information releases - GOV.UK (www.gov.uk)