Medicines & Healthcare products Regulatory Agency

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

FOI 24/201

26 March 2024

Dear

Thank you for your request of 28 February 2024 under the Freedom of Information Act. You requested:

- 1. What is the current number of Medical Device Safety Officers in the MHRA CAS team database?
- 2. Kindly release the full list of all organisations which currently have an MDSO in place, and have sent their contact details to MHRA's CAS team.
- 3. In a previous FOI request, MHRA responded that care homes are represented in the MDSO network, so how many care homes are currently represented and which care homes are represented?
- 4. How many MDSOs are currently in the MHRA's CAS team's database, to represent outsourced NHS Community Wheelchair Services (e.g. AJM Healthcare and Opcare Ltd.)?
- 5. How many MDSOs are currently in the MHRA's CAS team's database, to represent ICBs, Trusts, Hospitals (please give a breakdown)?
- 6. If AJM Healthcare and Opcare Ltd. currently have a MDSO in place, when did these organisations notify the MHRA's CAS team about the MDSO's appointment?

We will provide answers to each of these questions below. Please note that as we are reliant on MDSOs making themselves known to us, the true number of MDSOs and the organisations they represent may vary from the data provided below. The information we hold can also change over time as new MDSOs and their respective organisations join the network, or when outdated contacts are deleted. These questions have been answered to the best of our knowledge using information that has been shared with us by the MDSOs themselves. When MDSOs provide their contact details, they are asked to record the 'Name of Trust or organisation' and 'Type of Trust or sector (e.g. Acute, Mental Health, Community etc)'. However, these are free text fields that consequently do not always fit neatly into categories when filtering data.

The original Stage Three Directive Patient Safety Alert calling for the establishment of the MDSO network can be found here: <u>NHS/PSA/D/2014/006</u>. This document details the scope of the alert and the organisations that are required to nominate a MDSO. It is important to note that although the alert instructs organisations to contact the MHRA CAS team, the contact details of MDSOs are not held within CAS but on a separate MHRA database.

1. What is the current number of Medical Device Safety Officers in the MHRA CAS team database?

There are currently 305 MDSO contacts recorded on our database. Please note that this figure includes a number of additional contacts who support the lead MDSO with their duties and/or form part of a team within the same organisation.

2. Kindly release the full list of all organisations which currently have an MDSO in place, and have sent their contact details to MHRA's CAS team.

There are currently 200 organisations with an MDSO contact currently recorded on our database, please see the accompanying PDF for a complete listing (Annex A).

3. In a previous FOI request, MHRA responded that care homes are represented in the MDSO network, so how many care homes are currently represented and which care homes are represented?

We do not currently hold records of any organisations that have identified themselves specifically as a 'Care Home', although there are a total of eight organisations that have recorded themselves as a 'Hospice':

- 1. St Peter's Hospice
- 2. St Wilfrid's Hospice
- 3. St Barnabas Hospice
- 4. Rennie Grove Peace Hospice
- 5. Peace Hospice Care
- 6. Mountbatten Hospice
- 7. Hospice UK
- 8. Heart of Kent Hospice

We previously held one record for an organisation called 'Care UK', which is why we responded "Yes" to FOI 23/840 when asked: "Are care homes represented in the Medical Device Safety Officer (MDSO) Network, with whom MHRA work closely?". However, since then, the contact details for this organisation have been removed in more recent updates to our active contacts.

4. How many MDSOs are currently in the MHRA's CAS team's database, to represent outsourced NHS Community Wheelchair Services (e.g. AJM Healthcare and Opcare Ltd.)?

We do not currently have any organisations in our records who have identified themselves as being an outsourced NHS Community Wheelchair Service.

5. How many MDSOs are currently in the MHRA's CAS team's database, to represent ICBs, Trusts, Hospitals (please give a breakdown)?

On our systems, there are 251 MDSOs spread across 161 organisations that have identified themselves as belonging to either a ICB or Trust, and the breakdown for that is as follows:

- 15 MDSOs across 8 ICBs; and
- 236 MDSOs across 153 Trusts (including ambulance, combined, acute, community health, specialist, mental health, learning disability and children's).

We are unable to provide an accurate figure for the number of hospitals represented on our system as some healthcare organisations may contain multiple sites within a single organisation. For example, an MDSO is usually associated to a larger healthcare provider such as a Trust and therefore the same MDSO could cover a number of hospital sites.

6. If AJM Healthcare and Opcare Ltd. currently have a MDSO in place, when did these organisations notify the MHRA's CAS team about the MDSO's appointment? We do not hold this information.

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 you receive this response and addressed to: <u>info@mhra.gov.uk</u>

Please remember to quote the reference number above in any future communications.

If you were to remain dissatisfied with the outcome of the internal review, you would 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 our handling of your request unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted at:

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

Or online via <u>https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/</u>

Yours sincerely

MHRA Customer Experience Centre

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