Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of Information Team
10 South Colonnade
Canary Wharf
London
E14 4PU

foi.request@mhra.gov.uk.

MHRA Website

[redacted]

Our Ref: **FOI2024/00611**

29th October 2024

Dear [redacted]

Thank you for your Freedom of Information (FoI) request received on 10 October. You wrote:

> *"For the sake of clarity, I would like to amend my FOI request dated 02.10.2024. Please replace my request of 02.10.2024 with the text below:*
>
> *This is a formal FOIA request.*
> *On 26.03.2024, under ref. FOI 24/201, MHRA released the list of organisations with an MDSO contact recorded on MHRA's database. At that time, there were 305 MDSO contacts recorded on the MHRA database. According to this list, none of the private NHS Wheelchair Service subcontractors, providing NHS community services and providing reused medical devices had an MDSO with contact recorded on MHRA's database (e.g. A J Mobility Ltd. [aka AJM Healthcare], Opcare Ltd, etc were not on MHRA's database).*
>
> *By stark contrast, according to this list all of the NHS Trusts and NHS Hospitals providing NHS Community Wheelchair Service had an MDSO in place.*
>
> *FYI, the MHRA FOI response and the said list are public and are visible on the WhatDoTheyKnow platform:*
>
> *https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.whatdotheyknow.com%2Frequest%2Fmedical_device_safety_officer_md_2%23incoming-2601733&data=05%7C02%7CAlicia.Minns%40mhra.gov.uk%7C92684acffdea4c1551c608dce9379e09%7Ce527ea5c62584cd2a27f8bd237ec4c26%7C0%7C0%7C638641672296506376%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C0%7C%7C%7C&sdata=NhryxDyZRtIupxrQwOAR2oeLK%2FRdoI2IVCt%2BUeZ4z9Q%3D&reserved=0*
>
> *According to NHS England, one of the enduring standards from past alerts that remains valid is: "Identify a medical device safety officer (MDSO) and ensure contact details are kept up to date with the MHRA's CAS team."*
>
> *https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.england.nhs.uk%2Fpatient-safety%2Fpatient-safety-insight%2Fpatient-safety-alerts%2Fenduring-standards%2Fstandards-that-remain-valid%2Fmedical-device-safety%2F&data=05%7C02%7CAlicia.Minns%40mhra.gov.uk%7C92684acffdea4c1551c*

608dce9379e09%7Ce527ea5c62584cd2a27f8bd237ec4c26%7C0%7C0%7C638641672296524297%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C0%7C%7C%7C&sdata=Lr%2Bmryx%2BlRwiZQZjOdhzy9PlELtu4tYIuLtuiQGO%2BxA%3D&reserved=0

Inexplicably, on 06.03.2024, AJM Healthcare misleadingly claimed: "AJM already has a MDSO and a has fully complied with the MHRA process.", when in fact AJM were not following the MHRA and NHS England guidances and alerts about updating MHRA regarding an MDSO.

Apparently, since this date, several private NHS WCS subcontractors have contacted MHRA to provide the contact details of their MDSO.

I would like to receive an updated list of organisations with an MDSO contact recorded on MHRA's database.

I also would like to receive the number and details of any meetings/forums/conference calls/events of the Medical Devices Safety Officer network, taking place in 2023.

How long does it take for MHRA to add a new MDSO on the MHRA database, after the MHRA CAS team receives notification of an appointment?

Do MHRA registered MDSOs file MHRA Yellow Card reports via the same channel that is available to the general public?

What support or information does MHRA provide to MDSOs to help them to improve safe and effective use and management of medical devices?

What initiatives and/or collaborative work has MHRA undertaken to encourage private subcontractors, providing NHS community services, to appoint and notify MHRA about MDSOs - thereby ensuring equal standards and effective risk management compared to NHS Trusts who all systematically appoint MDSOs and rapidly notify MHRA of the appointment?

Does MHRA intend to put a reminder in the next version of the Managing Medical Devices guidance about the importance of appointing an MDSO and notifying MHRA of their contact details?
Comment: it might be helpful if MHRA published in the above guidance the up-to-date email address of the MHRA CAS team where notification of appointment of an MDSO should be sent, together with a link to the MDSO Contact Form (Appendix F, p22/25), as was published in the 2014 directive.
https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.england.nhs.uk%2Fwp-content%2Fuploads%2F2019%2F12%2Fpsa-med-dev-0414.pdf&data=05%7C02%7CAlicia.Minns%40mhra.gov.uk%7C92684acffdea4c1551c608dce9379e09%7Ce527ea5c62584cd2a27f8bd237ec4c26%7C0%7C0%7C638641672296537454%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C0%7C%7C%7C&sdata=Kt6qJhOaf51aactcoRJ%2Fi8PwXzaMfSVkgU0k2sTB01A%3D&reserved=0

I would greatly appreciate a response in PDF format on the WhatDoTheyKnow website.

Many thanks in advance.
Yours faithfully,
[redacted]"

MHRA Response

We confirm that we hold the information you have requested and is below.

1. ***I would like to receive an updated list of organisations with an MDSO contact recorded on MHRA's database.***

   As of 16 October 2024, there are 220 organisations with a Medical Device Safety Officer (MDSO) recorded on our database, please see the accompanying PDF for a complete listing of those organisations (Annex A).

2. ***I also would like to receive the number and details of any meetings/forums/conference calls/events of the Medical Devices Safety Officer network, taking place in 2023.***

   There are monthly meetings that MDSO Network members are invited to attend on the first Wednesday of every month (excluding August and January; due to a number of members being on annual leave). These meetings provide an opportunity to share updates from the MDSO Network, MHRA, NHS England (NHSE) Patient Safety Team and National Association of Medical Device Educators & Trainers (NAMDET). Usually, a guest speaker also presents on a topic agreed by the MDSO Editorial Board. The meeting draws to a close with an open mic discussion providing members with the opportunity to ask questions and discuss issues with the wider network.

   Once a year, there is also an annual MDSO Network and Medication Safety Officer (MSO) Network joint virtual conference organised by MHRA and NHSE.

   In addition to these meetings, the MDSO Editorial Board meet monthly.

   The MDSO Network also have access to a dedicated Microsoft Teams channel where resources are stored, and within this there is an “MDSO Discussion” sub-channel where members can ask each other questions.

3. ***How long does it take for MHRA to add a new MDSO on the MHRA database, after the MHRA CAS team receives notification of an appointment?***

   Once a notification is received to the safetyalerts@mhra.gov.uk email address of a new MDSO (or an update to an existing organisational MDSO), this will be made within 18 working days, if not before.

4. ***Do MHRA registered MDSOs file MHRA Yellow Card reports via the same channel that is available to the general public?***

   Yes, they submit Yellow Card reports via the main website.

5. ***What support or information does MHRA provide to MDSOs to help them to improve safe and effective use and management of medical devices?***

   The MDSO Network is jointly supported by MHRA and NHSE.

   The MHRA provides administrative resources to support operation of the network. For example, maintaining the MDSO contact list, MDSO Network Microsoft Teams channel and organising meetings. These forums enable the MHRA to regularly update members about

latest news and guidance. For instance, during the monthly MDSO Network meetings there is a standing agenda item covering updates from the MHRA, NHSE Patient Safety Team and NAMDET. Content from the meetings is made available on the Microsoft Teams channel for members to watch back later if they are unavailable on the day.

The MHRA also works closely with and supports the MDSO Editorial Board. For example, the MDSO Editorial Board are currently working on releasing an updated version of the MDSO Handbook which MHRA are collaborating with them on.

Additionally, the MHRA issue safety alerts for healthcare professionals, such as National Patient Safety Alerts, Device Safety Information and supporting guidance: Alerts, recalls and safety information: drugs and medical devices emails - GOV.UK (www.gov.uk).

We also publish weekly summaries of Field Safety Notices (FSNs) issued by manufacturers of medical devices. We know that MDSOs review these summaries frequently and use them as a helpful tool to stay up to date.

Furthermore, the MHRA maintain an updated MDSO contact list on the Manufacturers Online Reporting Environment (MORE) to ensure there is an effective system in place for manufacturers to cascade FSNs to MDSOs.

To support manufacturers of medical devices to effectively communicate FSNs, MHRA has previously published guidance that highlights the importance of utilising the MDSO Network: Effective field safety notices (FSNs): guidance for manufacturers of medical devices - GOV.UK

6. ***What initiatives and/or collaborative work has MHRA undertaken to encourage private subcontractors, providing NHS community services, to appoint and notify MHRA about MDSOs - thereby ensuring equal standards and effective risk management compared to NHS Trusts who all systematically appoint MDSOs and rapidly notify MHRA of the appointment?***

   We recognise that not all organisations have appointed an MDSO despite the 2014 Patient Safet Alert. This requirement has now been reiterated in the latest version of NHS Standard Contract - NHS England » 2023/24 NHS Standard Contract. However, MHRA will continue to work with NHSE to consider additional ways to raise awareness of the need to appoint an MDSO within large healthcare providers, including those in the independent sector.

7. ***Does MHRA intend to put a reminder in the next version of the Managing Medical Devices guidance about the importance of appointing an MDSO and notifying MHRA of their contact details?***

   The review of the Managing Medical Devices guidance document is ongoing. The revised guidance is being strengthened to emphasise the importance of MDSOs and their role in supporting patient safety through collaboration with the MHRA.

   The current version states that: *"Healthcare organisations should appoint Medical Device Safety Officers (MDSO). Part of the MDSO role is to report adverse incidents to the MHRA and other official agencies. The lines of accountability should include reference to the appointment of such safety officers".*

If you have any queries about this letter, please contact us quoting the reference number above.

Yours sincerely,

Your right to complain under the Freedom of Information Act

If you are not happy with this response you may request an internal review by e-mailing foi.request@mhra.gov.uk or by writing to: MHRA Central Freedom of Information Team, 10 South, Colonnade, Canary Wharf, London, E14 4PU

Any request for an internal review must be received by us within 40 working days of the date of this letter. Please note we are not obliged to provide a review if it is requested after more than 40 working days.

If you are not content with the outcome of the internal review, you may apply directly to the Information Commissioner's Office for a decision. Generally, the Commissioner cannot make a decision unless you have exhausted our own complaints procedure. The Information Commissioner can be contacted at: The Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire SK9 5AF.
Website: ICO FOI and EIR complaints or telephone 0303 123 1113.

Re-use of our information
The MHRA information supplied in response to your request is subject to Crown copyright. Information created by the MHRA which is disclosed under the Freedom of Information Act is made available for re-use under the Open Government Licence (OGL) v3.0, except where this is otherwise stated. There are some restrictions on re-use under the OGL and these can be viewed here:
https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/