FOI 23/501

Dear

Thank you for your email.

Please find below answers to the questions you have raised below.

Question

1. What plans does the MHRA have to improve the range and reach of registers of medical devices? Who will hold (and pay for) these registers?

Answer

In June 2023 we've published the responses to the consultation on Registration and UDI. You may find the government response to the consultation in Chapters 20 and 21 Chapter 4 - Registration and UDI - GOV.UK (www.gov.uk) helpful. It provides an outline of government plans with regards to the registration and other systems.

Please sign up for updates on our website to receiver further information once we publish it.

Question

2. In assessing and registering organisations to become Approved Bodies for the evaluation of medical devices, how will you avoid the obvious conflict of interest which has plagued Notified Bodies in the EU, namely that as Notified Bodies are paid by device manufacturers they have a vested interest in approving a device so that its manufacturer will come back to them in the future?

Answer

The Medical Device Regulations 2002 as amended set out a number of requirements to safeguard the impartiality and independence of Approved Bodies. These requirements include:

- The Approved Body must be a third party that is independent of the manufacturer and any other economic operator with an interest in the product.
- The Approved Body must be organised and operated so as to safeguard the independence, objectivity and impartiality of its activities.
- The Approved Body must have procedures in place to identify, investigate and resolve any potential conflicts of interest, including any that may result from the involvement of its staff in medical device consultancy services prior to taking up employment with the Approved Body.
- That Approved Body, its top management and the personnel responsible for carrying out the conformity assessment tasks must not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are designated and they

must not offer or provide any services that may jeopardise the confidence in their independence, impartiality or objectivity.
- The Approved Body's top level management and its assessment personnel must be impartial.
- The remuneration of the top level management and assessment personnel must not depend on the number or the results of assessments.
- The Approved Body must ensure that the activities of its subsidiaries or subcontractors, or of any associated body, do not affect its independence, impartiality or objectivity in its conformity assessment activities.

When assessing applications for designation of an Approved Body, the MHRA reviews the organisations legal status and organisation structure, including

- Legal ownership
- The organisational structure
- Individuals with influence over the organisation and/or over the conformity assessment process
- Other services provided by the organisation
- The activities of any wider organisation to which it belongs.

The MHRA also assesses the organisations processes and procedures for ensuring independence and impartiality, including:

- Documentation on structures, policies and procedures to safeguard and promote the principles of impartiality throughout the organisation, personnel and assessment activities, including ethical rules or codes of conduct
- How the applicant Approved Body ensures that the activities of subsidiaries, subcontractors and external experts do not affect its independence, impartiality or objectivity
- Documentation on the impartiality of the top-level management and personnel involved in conformity assessment activities, including their remuneration and bonuses
- Documentation on conflict of interest and resolution of potential conflicts
- Contract templates for internal and external personnel and manufacturers.

Documentation relating to independence and impartiality is further reviewed and assessed by MHRA during routine surveillance audits of designated Approved Bodies to ensure their continued compliance with the requirements of the regulations. These surveillance audits include a review of a sample of their client files to ensure that conformity assessment activity and certification decision making has been carried out in accordance with the requirements of the UK MDR 2002.

If you disagree with how we have interpreted the Freedom of Information Act 2000 with regards to your request, you can ask for the decision to be reviewed. The review will be carried out by a senior member of the Agency who was not involved with the original decision.

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

Yours sincerely

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