FOI 23/898

Dear

Thank you for your email.

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

1. Please provide the number of applications for Exceptional Use authorisation which the MHRA has received in the 3 years prior to 1 June 2023. Please include details of the number of applications which were granted

    a. 2020 – 214 received, 61 granted
    b. 2021 – 43 received, 19 granted
    c. 2022 – 84 received, 37 granted
    d. 2023 – 28 received, 6 granted

    Please note these figures cover the financial year (April 1st – March 31st)

2. Please confirm whether applications for Exceptional Use authorisation can be made by professional users who wish to put an unmarked Class I medical device into use.

    MHRA do not accept applications from professional users for Exceptional Use exemptions. Applications for exceptional use have to be submitted by the legal manufacturer or their appointed UK Responsible Person if applicable.

3. Please provide a copy of any formal document or instrument delegating to the MHRA any powers granted to the Secretary of State for Health by regulation 12(5) of the Medical Device Regulations 2002. In the absence of such documents/instruments please confirm whether the MHRA exercises the functions of the Secretary of State for Health under regulation 12(5).

    MHRA can confirm that they exercise the function for the Secretary of State under Regulations 12(5), 26(3) & 39(2) of the UK Medical Devices Regulations 2002

4. To the extent that the MHRA exercises the functions of the Secretary of State for Health under regulation 12(5) please provide details of the mechanism for making an application for authorisation.

    Details about how to apply for an exceptional use exemption can be found at this link under the heading 'How to apply to MHRA'.

    There are also details of active exemptions and recently closed exemptions that can be found here.

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: info@mhra.gov.uk

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: https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/

Yours sincerely

MHRA Customer Experience Centre
Communications and engagement team
Medicines and Healthcare products Regulatory Agency
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