FW: FOI 23/973

FOILicensing <FOILicensing@mhra.gov.uk>
Mon 15/01/2024 15:05
To:MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>; [redacted]
Cc [redacted] FOILicensing <FOILicensing@mhra.gov.uk>

1 attachments (129 KB)
FOI 23_973.pdf;

Hi all,

This one has been sent out.

Many thanks,
[redacted]

From: FOILicensing <FOILicensing@mhra.gov.uk>
Sent: Monday, January 15, 2024 3:03 PM
To: [redacted]
Subject: FOI 23/973

Dear [redacted]

Thank you for your correspondence of 12 December 2023, where you requested the following information under the Freedom of Information Act 2000.

Your Question

Under this FOI request could you, please let me know how many submissions in the last 10 years has the MHRA received and approved for licensing requests of new medicine (not repurposed medicine), where animal experiments were not used as part of the development and submission. Additionally, numbers of received and approved licensing requests of new medicines that did include animal experiment data?

Our Response

Unfortunately, MHRA estimate that compliance with this request would exceed the appropriate limit under Section 12 Freedom of Information (FOI) Act 2000, which is set at 24 working hours per request. Public authorities are not obliged to work past the appropriate limit under Section 12(1) of the FOI Act 2000 and we are, therefore, refusing your request.

MHRA do not keep a record of the figures that you have requested in a readily accessible form. In order to determine whether animal studies were submitted as part of the application, we would have to manually check for this information for each marketing authorisation that has been granted for a new active substance, for the last ten years. MHRA authorised over 200 products containing new active substances in this time period. We would have to manually open the case folder for each application and review the non-clinical assessment or submitted non-clinical data to establish if animal studies were used, which would take longer than the 24 working hours stipulated in the FOI Act 2000.

Please find a list of granted applications for new active substances attached.

The Public Assessment Reports (PARs) that we publish on our website contain a non-clinical section where we provide information about studies that were submitted as part of the

application. The published Summaries of Product Characteristics (SmPCs) also contain a section on pre-clinical safety. Please find a link to our products page below: https://products.mhra.gov.uk/

You may submit a refined request, for example, for the numbers of granted marketing authorisations for new active substances that included animal studies for one specific month. However, as the information is largely already available in the public domain through the information provided above, this information may be exempted under other sections of the FOI Act 2000 – such as Section 21 (information accessible by other means, for PARs and SmPCs that have been published by MHRA) and Section 22 (information intended for future publication, for PARs that are not yet published).

We now consider this request closed. If you do submit a refined request, this will be a new request and the 20 working days statutory time limit will begin from the date your refined request is received.

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,
FOI Team