Medicines & Healthcare products
Regulatory Agency

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

[redacted]

31 May 2024

MHRA reference FOI2024/00110

Dear [redacted],

Thank you for your information request, which we received on 14 May. You asked the below questions and we have included our responses beneath each of these.

1. *The date from which MHRA has had a backlog of national marketing authorisation applications which have exceeded the statutory period for assessment (210 days)?*

2. *The number of complaints MHRA has received in relation to the backlog of national marketing authorisation applications from the date stated in (1), or if this date is not known, since 1 January 2022.*

3. *MHRA's procedure / process for prioritising national marketing authorisation applications.*

4. *How many national marketing authorisation applications have been transferred to the IRP procedure as of today's date, and how many of these have been approved under the IRP?*

5. *The steps MHRA has taken to ensure that marketing authorisation applications that are not eligible for the International Recognition Procedure, are assessed within the statutory period of 210 days, since the date stated in (1), or this this date is not known, since 1 January 2022.*

6. *The steps MHRA has taken to ensure that the application for illuccix™ (PL 57676/0001) is assessed within the statutory period of 210 days. As Telix is the applicant, we confirm that we do not consider this information to be confidential and this information should therefore not be exempted from disclosure under the FOIA.*

7. *How many national marketing authorisation applications were ahead illuccix™ (PL 57676/0001) in the queue for assessment:*
   a. At the time of the application (31 March 2023)
   b. 6 months after the application (30 September 2023)
   c. As of the present date?"

We have dealt with your request under the Freedom of Information Act 2000 (FOIA).

We confirm that we hold some of the information you have asked for; however, we consider that the information is exempt from disclosure because Section 12 of the FOIA applies.

Section 12 allows public authorities to refuse requests where the cost of dealing with them would exceed the "appropriate limit" in the FOIA; for central government departments this is set at £600. This represents the estimated cost of one person spending 24 working hours to determine if the requested information is held, and then to locate, retrieve and extract it.

We will explain how compliance with your request would exceed the appropriate limit and why Section 12 applies in this case.

Question 2 of your request is asking for the *"number of complaints MHRA has received in relation to the backlog of national marketing authorisation applications from the date stated in (1), or if this date is not known, since 1 January 2022."* The word complaint is a very broad term that can cover correspondence that has been received by a number of MHRA email mailboxes since 1 January 2022. These mailboxes would include those for individual MHRA assessors, support staff, line managers and senior MHRA managers (such as heads of divisions and Executive Board members), as well as shared mailboxes (such as the Customer Experience Centre). We calculate that to search each mailbox for any correspondence that matches your request would take approximately one hour per mailbox. Therefore, we would only be able to search 24 mailboxes before we reach the limit in the FOIA beyond which Section 12 applies on Question 2 alone. It should also be noted that complaints to MHRA can also come to us by other means than email, such as physical letters or discussions in meetings or telephone conversations.

Advice and Assistance

When Section 12 of the FOIA applies, we also provide advice to assist you in making a new, narrowed request for a smaller amount of information. In this case, we advise that you could narrow your request by asking for the number of complaints received to a specific mailbox, for example the info@mhra.gov.uk mailbox that we specify on our website:

Complaints procedure - Medicines and Healthcare products Regulatory Agency - GOV.UK (www.gov.uk)

It should be noted that other sections of the FOIA could also apply to any refined request submitted. For example, Question 6 and Question 7 concern specific information for an application that is currently pending at MHRA. You have stated *"as Telix is the applicant, we confirm that we do not consider this information to be confidential and this information should therefore not be exempted from disclosure under the FOIA."* However, the FOIA is 'applicant blind.' This means that in providing a response to one person, we are expressing a willingness to provide the same response to anyone. In other words, the release of information under the FOIA is not the release of information to an individual, but a release of information into the public domain in general. This is exemplified by our proactive publishing of responses by MHRA to FOI requests received, please see the link below:
https://www.gov.uk/government/publications/mhra-requests-under-the-freedom-of-information-act-foia

In view of the above, any refined request for information concerning specific applications that are currently pending with MHRA would likely be exempt from disclosure under Section 41 (information provided in confidence) and Section 43 (commercial interests) of the FOIA. For further information specific to applications that you have with MHRA, we advise that you contact the Regulatory Information Service at MHRA at ris.na@mhra.gov.uk.

We would also like to bring to your attention that MHRA currently publishes information on its performance with regards to national marketing authorisation applications in our annual reports and accounts, and our performance metrics for the assessment of clinical trials and established medicines.

Links to the annual report and accounts for the business years 2021/22, and 2022/23 are provided below:
https://www.gov.uk/government/publications/medicines-and-healthcare-products-regulatory-agency-annual-report-and-accounts-2021-to-2022
https://www.gov.uk/government/publications/medicines-and-healthcare-products-regulatory-agency-annual-report-and-accounts-2022-to-2023

A link to the performance metrics for the assessment of clinical trials and established medicines by MHRA from April 2022 is provided below:
https://www.gov.uk/government/publications/mhra-performance-data-for-assessment-of-clinical-trials-and-established-medicines

This concludes our response to your request.

If you have a query about this response, please contact us at foi.request@mhra.gov.uk

Please remember to quote the reference number at the top of this letter in any future communications. Details of your appeal rights are below.

Yours sincerely,

Healthcare, Quality and Access Group
Medicines and Healthcare products Regulatory Agency

Appeal rights

If you are dissatisfied with the handling of your request, you can ask us to conduct an internal review. Internal review requests should be submitted within two months of the date you receive this response and addressed to: foi.request@mhra.gov.uk

If you remain dissatisfied with the outcome of the internal review, you 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 a request unless the requester has first asked us to conduct an internal review.

The Information Commissioner can be contacted through their online webform at: https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/

Or in writing to: Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF

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https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/

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