



Medicines & Healthcare products  
Regulatory Agency

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London  
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United Kingdom  
[gov.uk/mhra](https://www.gov.uk/mhra)

[REDACTED]

03/05/2024

MHRA reference: FOI2024/00026

Dear [REDACTED],

Thank you for your information request, which we received on 03/05/2024. You asked for:

*"1. How many EAMS step I PIM designation applications has the MHRA received between April 2014 to March 2024?"*

*2. Is this data available by financial year? If so, I would be grateful for the number of applications for each of the following financial years 2014/15, 2015/16, 2016/17, 2017/18, 2018/19, 2019/20, 2020/21, 2021/22, 2022/23, 2023/24?"*

*3. How many EAMS step II applications has the MHRA received between April 2014 to March 2024?"*

*4. Is this data available by financial year? If so, I would be grateful for the number of applications for each of the following financial years 2014/15, 2015/16, 2016/17, 2017/18, 2018/19, 2019/20, 2020/21, 2021/22, 2022/23, 2023/24?"*

*5. How many pre-submission meetings MHRA have held with interested parties wishing to discuss their full EAMS application between April 2014 to March 2024?"*

*6. Is this data available by financial year? If so, I would be grateful for the number for each of the following financial years 2014/15, 2015/16, 2016/17, 2017/18, 2018/19, 2019/20, 2020/21, 2021/22, 2022/23, 2023/24?"*

*7. How many of the current and expired scientific opinions were completed within the 75 day procedure?"*



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8. *Is this data available by financial year? If so, I would be grateful for the number for each of the following financial years 2014/15, 2015/16, 2016/17, 2017/18, 2018/19, 2019/20, 2020/21, 2021/22, 2022/23, 2023/24?*

9. *How many of the current and expired scientific opinions were completed within the 90 day procedure?*

10. *Is this data available by financial year? If so, I would be grateful for the number for each of the following financial years 2014/15, 2015/16, 2016/17, 2017/18, 2018/19, 2019/20, 2020/21, 2021/22, 2022/23, 2023/24?*

11. *How many of the current and expired scientific opinions were completed with an additional 30 days in addition to the 90 day procedure?*

12. *Is this data available by financial year? If so, I would be grateful for the number for each of the following financial years 2014/15, 2015/16, 2016/17, 2017/18, 2018/19, 2019/20, 2020/21, 2021/22, 2022/23, 2023/24?"*

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

We confirm that we hold 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.

There have been 171 applications received for EAMs between April 2014 and November 2023. In order to comply with your request in its entirety, we would need to look at each application and ascertain how many applications would be relevant to each of your questions. In addition, we would need to look at each application individually to see how many applications, for example, were completed within the procedure timelines you have stipulated. This would take approximately 30-45 minutes per application. For this reason, we calculate that this would take us over the 24 working hours stipulated in the FOIA.



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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 focussing on a smaller subset of applications received that you would like specific information for. Please note that other sections of the FOIA may also apply to future requests, for example, Section 22 may apply to some data for EAMs applications received from November 2023 to April 2024, as these will be published in future updates to the EAMs information on the MHRA website and future Annual Reports.

Some information on the numbers of EAMS Step 1 applications received and Scientific Opinions from April 2014 to November 2023 is available on the MHRA website, please see the link below:

<https://www.gov.uk/government/statistics/early-access-to-medicines-scheme-applications-pending-refused-granted>

Some information on EAMs broken down by year can be obtained from the MHRA Annual Report and Accounts for each year. These can be obtained through a search of the government website. A link to this search is provided below:

<https://www.gov.uk/search/all?keywords=MHRA+Annual+Report&order=relevance>

This concludes our response to your request.

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

Health Quality and Access Division  
**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](mailto: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/>



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

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