FOI 24/137 - Freedom of Information request

MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>

Wed 06/03/2024 09:14

To [redacted]

FOI 24/137

Dear [redacted]

Regarding your Freedom of Information (FOI) request of 09 February 2024, please see below our responses to each of your questions:

1. Between 1 January 2014 and 31 December 2023, how many licensing applications were submitted to MHRA for: • All medicines • Medicines for rare diseases? • MHRA timeframes

Between 1 January 2014 and 31 December 2023, 14877 marketing authorisation applications were received by MHRA.

Unfortunately, we do not collect the numbers of applications received for medicines for rare diseases by year and our applications are not categorised in such a way that we can obtain that number easily from our databases. In order to calculate this number, we would need to open every application received between 1 January 2014 and 31 December 2023, and determine whether each application was for a medicine for a rare disease. This would exceed the appropriate limit under Section12 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.

To assist, we can advise that lists of granted medicinal products, by month and year, are available on the MHRA website, which you can look through to determine how many medicines for a rare disease were authorised. A link to these is provided below: https://www.gov.uk/government/collections/marketing-authorisations-lists-of-granted-licences

We do not understand what is meant by "Between 1 January 2014 and 31 December 2023, how many licensing applications were submitted to MHRA for MHRA timeframes." Perhaps you can provide clarification on what this part of your request means and we can log this as a new request.

2. What was the mean average waiting time for completed licensing decisions for a) all medicines and b) medicines for rare diseases, broken down by the following years:

- 1 January 2014 to 31 December 2014
- 1 January 2015 to 31 December 2015
- 1 January 2016 to 31 December 2016
- 1 January 2017 to 31 December 2017
- 1 January 2018 to 31 December 2018
- 1 January 2019 to 31 December 2019
- 1 January 2020 to 31 December 2020

- 1 January 2021 to 31 December 2021
- 1 January 2022 to 31 December 2022
- 1 January 2023 to 31 December 2023?

Information on MHRA targets and our performance against these targets for all medicines is provided in our annual reports. Links to these for each business year from 2014 are provided below:
https://www.gov.uk/government/publications/medicines-and-healthcare-products-regulatory-agency-annual-report-and-accounts-2013-to-2014
https://www.gov.uk/government/publications/medicines-and-healthcare-products-regulatory-agency-annual-report-and-accounts-2014-to-2015
https://www.gov.uk/government/publications/medicines-and-healthcare-products-regulatory-agency-annual-report-and-accounts-2015-to-2016
https://www.gov.uk/government/publications/medicines-and-healthcare-products-regulatory-agency-annual-report-and-accounts-2016-to-2017
https://www.gov.uk/government/publications/medicines-and-healthcare-products-regulatory-agency-annual-report-and-accounts-2017-to-2018
https://www.gov.uk/government/publications/medicines-and-healthcare-products-regulatory-agency-annual-report-and-accounts-2018-to-2019
https://www.gov.uk/government/publications/medicines-and-healthcare-products-regulatory-agency-annual-report-and-accounts-2019-to-2020
https://www.gov.uk/government/publications/medicines-and-healthcare-products-regulatory-agency-annual-report-and-accounts-2020-to-2021
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

Unfortunately, we do not collect the mean average waiting time for completed licensing decisions for medicines for rare diseases by year and our applications are not categorised in such a way that we can obtain that number easily from our databases. In order to calculate this number, we would need to open every application received between 1 January 2014 and 31 December 2023, and determine whether each application was for a medicine for a rare disease then calculate the time taken to complete that application. This would exceed the appropriate limit under Section12 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 early access schemes

3. Between 7 April 2014 and 31 December 2023, how many applications did MHRA receive for the Early Access to Medicines Scheme for:

- All medicines
- Medicines for rare diseases?

We publish information on Early Access to Medicines Scheme (EAMs) applications received for all medicines, Promising Innovative Medicine (PIM) designations and positive Scientific Opinions (POs). A link to further information on our EAMs, including metrics, is provided below:
https://www.gov.uk/guidance/apply-for-the-early-access-to-medicines-scheme-eams

Unfortunately, we do not collect information on EAMs applications specific for medicines for rare diseases and our applications are not categorised in such a way that we can obtain that number easily from our databases. In order to calculate this number, we would need to open every EAMs application received between 1 January 2014 and 31 December 2023, and determine whether each application was for a medicine for a rare disease. This would exceed the appropriate limit under Section12 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.

4. Between 7 April 2014 and 31 December 2023, how many Early Access to Medicines Scheme applications for a) all medicines, and b) medicines for rare diseases were:

- Approved for a Promising Innovative Medicine (PIM) designation
- Not approved for a PIM designation
- Withdrawn before PIM designation decision?

Please see our response to Q3 above.

5. Between 7 April 2014 and 31 December 2023, how many Early Access to Medicines Scheme applications for a) all medicines, and b) medicines for rare diseases:

- Received a positive Scientific Opinion
- Did not receive a positive Scientific Opinion
- Were withdrawn before a Scientific Opinion?

Please see our response to Q3 above.

6. Between 7 April 2014 and 31 December 2023, how many completed Early Access to Medicines Scheme applications that received a PIM and positive Scientific Opinion for a) all medicines, and b) medicines for rare diseases were:

- Commissioned by NHS England
- Not commissioned by NHS England
- Withdrawn before commissioning by NHS England?

We do not hold any information on subsequent commissioning of medicines that received a PIM designation and SO by NHS England.

7. Between 1 January 2021 and 31 December 2023, how many Innovative Licensing and Access Pathway applications, broken down by a) all medicines, and b) medicines for rare diseases:

- Were received in total
- Were awarded an Innovation Passport
- Were not awarded an Innovation Passport
- Are still in process
- Were withdrawn?

We publish information on the Innovative Licensing and Access Pathway (ILAP) applications received for all medicines, including metrics. A link to this is provided below:
https://www.gov.uk/guidance/innovative-licensing-and-access-pathway

Unfortunately, we do not collect information on ILAP applications specific for medicines for rare diseases and our applications are not categorised in such a way that we can obtain that number easily from our databases. In order to calculate this number, we would need to open every ILAP application received and determine whether each application was for a medicine for a rare disease. This would exceed the appropriate limit under Section12 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.

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,

MHRA Customer Experience Centre
Communications and engagement team
Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU

From: [redacted]
Sent: Thursday, February 8, 2024 7:04 PM
To: MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>
Subject: FOI 24/137 Freedom of Information request