Fw: Re: FOI 23/965 - PIL User Testing (Consultation) Data

MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>
Fri 23/02/2024 23:25
[redacted]

From: FOILicensing <FOILicensing@mhra.gov.uk>
Sent: 10 January 2024 17:23
To: MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>
Subject: Re: FOI 23/965 - PIL User Testing (Consultation) Data

Please see below the final response that was sent out this afternoon.

Best regards

[redacted]

From: FOILicensing
Sent: Wednesday, January 10, 2024 5:22 PM
To: [redacted]
Subject: Re: FOI 23/965 - PIL User Testing (Consultation) Data
Importance: High

Dear [redacted]

Thank you for your correspondence of 10 December 2023, where you requested the following information under the Freedom of Information Act 2000.

Your Question

I am hoping to retrieve data from the MHRA that highlights how many unique full PIL user testing reports (patient information leaflet patient consultation reports) the MHRA receives annually for medicinal products registered in the UK. Hopefully you have this data available for the last 3 years and can provide this easily. These reports are most likely to be submitted with new MAAs or Extensions perhaps, but maybe even for Type II variations. In addition to this, if you can also provide the same information for Bridging Reports too, I would very much appreciate this.

Our Response

Unfortunately, MHRA estimate that compliance with this request 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 do not keep a record of the figures that you have requested in a readily accessible form. In order to determine whether a bridging report or a full user testing report was submitted we would have to manually check for this information for each marketing authorisation that has been authorised for the last three years. We authorised over 2500 products in 2021, 2022 and 2023. Some of the marketing authorisation applications would have been assessed together and the products will share the same user testing or bridging report (e.g. for different strengths of a medicinal product); however, this still means that we would still have to check over a 1000 groups of marketing authorisations, which would take longer than the 24 working hours stipulated in the FOI Act 2000.

The Public Assessment Reports (PARs) that we publish on our website contain a section on user testing and we specify in this section whether full user testing or a bridging study was used, so you may find it useful to look at these. Please find a link to our products page below:
https://products.mhra.gov.uk/

In addition, to be able to place each marketing authorisation stated in a PAR by month and year, we publish lists of the marketing authorisations granted by month and year. A link to these is provided below:
https://www.gov.uk/government/collections/marketing-authorisations-lists-of-granted-licences

You may submit a refined request, for example, the numbers of granted marketing authorisations that have full user testing or rely on a bridging report for one specific month. However, as the information is already available in the public domain through the links we have 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 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/

Best regards

The FOI Licensing Team, MHRA

From: [redacted]>
Sent: Sunday, December 10, 2023 12:41 PM
To: MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>
Subject: FOI 23/965 - FOIA Request (Possibly) for PIL User Testing (Consultation) Data

Dear Sir or Madam

You don't often get email from [redacted] Learn why this is important

I am hoping to retrieve data from the MHRA that highlights how many unique full PIL user testing reports (patient information leaflet patient consultation reports) the MHRA receives annually for medicinal products registered in the UK. Hopefully you have this data available for the last 3 years and can provide this easily. These reports are most likely to be submitted with new MAAs or Extensions perhaps, but maybe even for Type II variations. In addition to this, if you can also provide the same information for Bridging Reports too, I would very much appreciate this.

If the information is readily available in a spreadsheet, I am happy to receive this and just review it myself rather than create a new FOIA request, however if it is not available in that format, then please treat this as a new FOIA request.

Many thanks

[redacted]