RE: FOI 24/318 CEC-179891 Inquiry - Overview of IRP applications lodged with the MHRA with the FDA as Reference Regulator (RR)

FOILicensing <FOILicensing@mhra.gov.uk>
Thu 04/04/2024 13:27
To [redacted]
Cc [redacted] MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>;FOILicensing <FOILicensing@mhra.gov.uk>

Reference number: FOI 24/318

Dear [redacted]

Thank you for your request for information dated, 5 March 2024, which we have treated as a Freedom of Information Request where you asked:

> "We are contacting you with an inquiry concerning the applications for marketing authorisation made under the International Recognition Procedure (IRP).
>
> Since we were not able to find the information on your website, we wanted to request if you could provide us with a list of all the applications that have already been received under this procedure and in particular those where the FDA constitutes the Reference Regulator (RR). Many thanks in advance for your assistance."

Our response:

We do not publish a list of IRP applications we have received. However, the IRP applications received will include a combination of granted IRPs and pending IRPs, and this is reflected in the different form of the responses given below.

Granted IRPs
We have granted 4 authorisations applied for through IRP. Public Assessment Reports will be produced for products granted through IRP and these reports will be published on the MHRA website. Once published the reports will be located on the following website: https://products.mhra.gov.uk/.

Timelines to PAR publication for IRPs.
For IRP PARs produced for new active substances 30 days from date of grant; for established medicines, 60 days from date of grant.

As the requested information will be published, in accordance with our publication schedule, we are exempting release under Section 22 of the Freedom of Information (FOI) Act.

Section 22
(1) Information is exempt information if—
(a) the information is held by the public authority with a view to its publication, by the authority or any other person, at some future date (whether determined or not),
(b) the information was already held with a view to such publication at the time when the request for information was made, and
(c) it is reasonable in all the circumstances that the information should be withheld from disclosure until the date referred to in paragraph (a).
Each of the three criteria must be met for section 22(1) to be engaged. The assessment reports are held by the MHRA with the settled expectation that this PAR will be published at a future date; in this case, this expectation is based on the section 64 of the Human Medicines Regulations 2012, which sets out the duties of the MHRA for the publication of PARs:

Duties of licensing authority in connection with determination
(6) The licensing authority must—
(b) make the assessment report publicly available (with the omission of information of a commercially confidential nature) as soon as is reasonably practicable after it has been prepared or revised; and
(c) include in the assessment report a summary, written in a manner that is understandable to the public, that contains, in particular, a section relating to the conditions of use of the medicinal product.

As stated in section 22(1)(a), it is not necessary for the date of publication to be determined for section 22(1) to apply.
We take a consistent approach to support the scheduled publication of PARs for wider public benefit. We believe it is reasonable in all the circumstances, fair, and in line with accepted practices, to withhold the information requested ahead of the wider schedule of publication. In this case, there is a settled intent to publish the PAR at a future date, and it is reasonable to maintain the schedule for this planned publication.

Public interest
We have considered the public interest within the process of engaging Section 22. A factor in favour is the general principle in transparency, to provide for earlier release of this particular information. We also understand there is a public interest in making the information available for public scrutiny. However, responding to individual requests on an ad hoc basis while the information requested forms part of the scheduled approach to wider publication, creates an additional burden for staff and disrupts the existing approach to the process. This factor strongly favours maintaining the exemption.

We therefore consider that section 22(1) applies to the requested information at this time."

Pending IRPs
We neither confirm nor deny we hold information relevant to your request. Section 41(2) and Section 43(3) of the Freedom of Information Act (FOIA) absolves us from the requirement to say whether or not we hold information:

41.
—(2) The duty to confirm or deny does not arise if, or to the extent that, the confirmation or denial that would have to be given to comply with section 1(1)(a) would (apart from this Act) constitute an actionable breach of confidence.

43.
(1)Information is exempt information if it constitutes a trade secret.
(2)Information is exempt information if its disclosure under this Act would, or would be likely to, prejudice the commercial interests of any person (including the public authority holding it).
(3)The duty to confirm or deny does not arise if, or to the extent that, compliance with section 1(1)(a) would, or would be likely to, prejudice the interests mentioned in subsection (2).

Public interest test
Section 17(3) of the Act requires us to conduct a Public Interest Test (PIT) when considering the neither confirm nor deny provision of a qualified exemption. In applying this exemption, we are required to consider whether, in all the circumstances of the case, the public interest in neither confirming nor denying that the information is held outweighs the public interest in confirming or denying whether the MHRA holds the information you have requested. The 'public interest' is not the same as what interests the public. In carrying out a PIT, we consider the greater good or benefit to the community as a whole in saying whether information is held or not. The 'right to know' must be balanced against the need to enable effective procedural governance and to serve the best interests of the public. The FOI Act is 'applicant blind'. This means that we cannot, and do not, ask about the motives of anyone who asks for information. In providing a response to one person, we are expressing a willingness to provide the same response to anyone.

Considerations in favour of confirming whether or not we hold the information
To confirm or deny whether or not an application has been received by MHRA would be of interest to patient groups and healthcare professionals in knowing and understanding whether a relevant treatment could soon be available to patients. It would also be of benefit in general to show transparency in MHRA's day-to-day work for the public to see what applications are currently being considered by MHRA.

Considerations in favour of neither confirming nor denying whether we hold the information
To confirm or deny whether we are currently considering an application for a particular medicine would be of great interest to rival companies who are marketing or looking to market their own products. Knowledge of whether an application is being considered by MHRA can be used as market intelligence in order to gauge when a new product is likely to come onto the market so strategies can be employed to prevent that product getting a foothold in the market. Further, to confirm or deny that we may hold any information on applications that are not yet authorised in the UK can create a chilling effect, with companies reluctant or unwilling to submit applications for their products to the UK. This would result in fewer medicines being available for patients.

We trust that you will understand this position and the response. However, If you disagree with how we have interpreted the Freedom of Information Act 2000 in answering your request, you can ask us to review our actions and decisions by writing to: info@mhra.gov.uk, and requesting an internal review.

Please note that your internal review request must be in a recordable format (email, letter, audio tape etc.), and that you have 40 working days upon receipt of this letter to ask for a review. We aim to provide a full response to your review request within 20 working days of its receipt. Please quote the reference number above in any future communications.

If you are not content 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 online via an electronic form: 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

Yours sincerely,

HQA FOI Team