FOI 23/974 - Tepkinly

Dear

Thank you for your request for information dated 21 October and we apologise for the delay.

In your request you asked:

> ***"Subject: New bi-specific antibody therapy Tepkinly***
>
> *I refer to the above subject and attach MHRA press release dated 20 October 2023. I have noted the content and am alarmed to learn that the most common side effect of this new medicine is "cytokine release syndrome". I would therefore be pleased to receive further more detailed information. Is this an experimental "black triangle" medicine? Can you please provide a hyperlink to the* ***Public Assessment Report [PAR]*** *for* ***Tepkinly*** *published by MHRA"*

Due to an oversight this has not been responded to and we apologise as we haven't met the statutory deadline. We are now treating this under FOI and the reference for your request is **FOI 23/974**

Please see below our response to your request.

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.

Please also note, the Patient Information Leaflet (PIL) is available to patients and the public and the summary of product characteristics (SmPC), although, primarily intended for healthcare professionals is also available for the public to view. The SmPC, among other important information, describes the key safety and efficacy data which supported the grant of the marketing authorisation of this medicine.

We trust that you will understand the need for this approach at this time. 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,

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