Medicines & Healthcare products Regulatory Agency

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom
gov.uk/mhra

01 February 2024

Dear [redacted]

FOI 24/022

Thank you for your email of 5 January 2024 where you requested the following:
I have a few questions about the approval process for MAAs submitted to the MHRA, specifically regarding a recent submission made by sponsor [redacted] *for DCVAX-L.*

Please find our responses to each of your questions below.

1. Is there a difference between MAA submission and validation? Do/can they occur simultaneously? The sponsor let us know that the MAA was submitted on December 20th 2023, can we assume that the MAA was validated or that it still needed to be?

MAA submission is the process by which the applicant submits their application to the MHRA via the MHRA submission portal. Validation does not occur simultaneously. It is a process by which the application is checked to ensure that all the correct documentation, specific to the type of application, has been submitted.

Regarding your question about a specific application for DCVAX-L made by [redacted] 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 for DCVAX-L 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.

2. Once an application is validated, does the assessment timetable start from the day it was originally submitted, or from the day that it was validated (assuming they don't occur simultaneously).

The assessment timetable for new active substances and biosimilar products or existing active substances will begin after validation of the application.

3. In the submission PR the sponsor noted that they requested the 150 day accelerated assessment. Is this something that the MHRA can inform the public on? Was that request granted? As long as the application was "high quality" is it likely that the 150 day assessment will be used?

For general guidance on the 150-day assessment process, please refer to the link below:
https://www.gov.uk/guidance/guidance-on-150-day-assessment-for-national-applications-for-medicines#validation

Regarding your question about a specific application for DCVAX-L made by [redacted] 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. Please refer to Q1 above.

4. The sponsor submitted the MAA prior to the December 25 deadline that corresponds with CHM meeting dates in March. Is it possible for the CHM meeting to occur at an earlier date?

Regarding your question about a specific application for DCVAX-L made by [redacted] 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. Please refer to Q1 above.

5. Does the MHRA prohibit/discourage sponsors from updating shareholders on the status of the MAA? Example: the sponsor has informed us that the MAA was submitted, assuming validation occurs sometime after this, could the sponsor also inform us that it was validated?

Applicants are not prohibited or discouraged from sharing information about their Marketing Authorisation application by the MHRA.

We now consider this response closed. 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