FOI 23/644

Dear

Thank you for your request under the Freedom of Information Act. You requested:

> *Northwest Biotherapeutics recently announced that they plan to file an application for a Marketing Authorization with the MHRA in the next 30-45 days for their product DCVAX-L.*
>
> *https://www.prnewswire.com/news-releases/northwest-biotherapeutics-announces-completion-of-prerequisites-and-plans-for-submission-of-marketing-authorization-application-301912602.html*
>
> *I was just curious about a couple things:*
>
> *1. Does this mean they have completed a PIP compliance check?*
>
> *2. Does this mean that they have already had a pre-submission CHM meeting?*
>
> *3. Does this mean that the MHRA and NWBO have discussed a submission date already?*
>
> *Also: is the quickest current accelerated approval pathway 150 days? Does it typically get done in less?*

For questions 1-3, we refuse to confirm or deny whether we hold any information under Section 41 (S41) and Section 43 (S43) of the FOI Act (FOIA). S41 is an absolute exemption and no consideration of the public interest is required, except to state that we would consider the release of this information to be an actionable breach of confidence. S43 is a conditional exemption and requires a consideration of the public interest. We have considered the public interest and cannot see any public interest argument that outweighs the commercial harm in alerting competitors to whether a competitor is close to obtaining a marketing authorisation or not. You may wish to contact the company directly, as they may be willing to provide an update on their regulatory position / plans, see contact us page: Northwest Biotherapeutics Contact Us - Northwest Biotherapeutics (nwbio.com).

Regarding your supplementary question: yes, the 150-day procedure is the fastest procedure available to applicants for full national applications that are not relying on a recognition procedure. We publish information on our performance which may be of interest to you:
https://www.gov.uk/government/statistics/medicines-licensing-time-based-performance-measures

Please note that the 150-day timetable is not appropriate for every application and is determined during submission. Meeting the 150-day timetable is dependent on lots of factors, including the completeness and quality of the initial application, and the

response of the applicant to any queries or information requests which we raise; in practice this means it can take longer than 150 calendar days.

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

Yours sincerely
MHRA Customer Experience Centre
Communications and engagement team
Medicines and Healthcare products Regulatory Agency
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