FOI 23/591

Dear

Thank you for your email that we are treating under Freedom of Information where you have asked *"I am reaching out regarding the process for decisions on regulatory approvals. When a treatment is approved/denied, is there a location on your website that would state that decision, or is it up to the company that submitted to publicly release the update?*

I am specifically referencing Northwest Biotherepeutics (DCVax-L), which I am under the impression is either in a rolling submission or already fully submitted. Is there somewhere that I can track the stage of review the treatment is in."

We publish monthly lists of new marketing authorisations granted on the MHRA website and this is available to view at the following link below: https://www.gov.uk/government/collections/marketing-authorisations-lists-of-granted-licences

We confirm that there is no marketing authorisation currently granted for DCVax-L, and regarding whether any application has been received by MHRA for a vaccine for brain tumor from Northwest Biotherapeutics, we refuse to confirm or deny 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).

There are Clinical Trial databases available where records of clinical trials that are currently in progress as well as completed trials can be searched:
https://www.clinicaltrialsregister.eu/ctr-search/search
https://www.isrctn.com/

There is also a page for this product on the NICE website that might be of interest to you: Project information | DCVax-L for treating newly diagnosed glioblastoma multiforme [ID836] | Guidance | NICE

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

Medicines and Healthcare products Regulatory Agency
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