Medicines & Healthcare products
Regulatory Agency

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[redacted]

12 February 2024

Dear [redacted]

FOI 24/094 - SWIFT Approval Process - 2024 A

Thank you for your request for information dated Monday, January 15, 2024 where you asked the below questions. We have numbered your questions and annotated our responses below each.

1. I was curious if there has been an updated guidance on the SWIFT Approval Process that is mentioned in the report below:

"The MHRA will also have a fully operational swift approval process in place from 2024 for the most impactful new medicines and technologies - such as cancer vaccines and AI therapeutics for mental health".

https://www.biopharma-reporter.com/Article/2023/03/16/mhra-gets-10m-boost-from-uk-government

Our response to Q.1:

We would first like to address some of the misconstrued text / misunderstanding related to news article and the purposes of funding allocated to MHRA, see below:

- “The Medicines and Healthcare products Regulatory Agency (MHRA) will receive £10 million extra funding over two years to maximise its use of Brexit freedoms and accelerate patient access to treatments. This will allow, from 2024, the MHRA to introduce new, swift approvals systems, speeding up access to treatments already approved by trusted international partners and ground-breaking technologies such as cancer vaccines and AI therapeutics for mental health.”

Source: Chancellor unveils a Budget for growth - GOV.UK (www.gov.uk)

The term ‘swift approvals systems’ does *not* relate to a specific singular new procedure type, rather the term is applied in the general sense. The MHRA press release on this subject is available for your information below:

MHRA to receive £10m from HM Treasury to fast-track patient access to cutting-edge medical products - GOV.UK (www.gov.uk)

A key action of the MHRA corporate plan is to deliver predictable and reliable operational performance having defined our priority improvements for our core services to ensure swift and robust decisions on medical products, safety signals and compliance. We are currently identifying service improvements across all priority areas with robust plans for implementation and effective change management to be in place by end Q4, as outlined in our 2023-2024 business plan. The 2024/2025 business plan will include further objectives relating to operational performance. Please also note, from 1 January 2024, developers of new medicines can now submit marketing authorisation applications (MAAs) via the MHRA’s new International Recognition Procedure. We aim to review national MAAs within 210 days.

In line with the explanation above, we hold no information on updated guidance on the SWIFT Approval Process. However, we can direct you to the webpage below related to the international recognition procedure which makes up a part of the initiatives related to the funding.

https://www.gov.uk/government/publications/international-recognition-procedure/international-recognition-procedure

2. Is this program operational?

Our response to Q.2:

As described above the international recognition procedure is operational, but work is on-going to establish further service improvements and the final form that such improvements may take under the umbrella term of ‘Swift’.

3. Are there currently any marketing authorisation applications that are utilizing this approval process?

Our response to Q.3:

Because all improvements are not yet known and/or finalised we do not hold information related to this question. However, we can confirm that we hold x no. of applications submitted under the International Recognition Procedure.

4. Northwest Biotherapeutics has recently submitted a MAA for its drug DCVAX-L which is a cancer vaccine, is there any chance it would be approved under the SWIFT process?"

Our response to Q.4:

We note that in FOI 24/022 we neither confirmed nor denied that an application was held for DC-Vax-L, however, it has since come to our attention that the company have made their application public knowledge on their website. Therefore, we are now in a position to confirm that an MAA is held for DC-Vax-L. However, unfortunately we cannot comment further on the status of the application. As the press release correctly mentions "The application also requests to be considered under the MHRA's rapid 150-day review pathway, which the agency has established for new medicines for serious unmet medical needs […] the review process will be a period of intensive and extensive further work involving responding to questions and requests for further information by the regulatory authority".

https://nwbio.com/northwest-biotherapeutics-announces-marketing-authorization-applications-submitted-uk-mhra-dcvax-l-glioblastoma/

We understand that this market authorisation application applies for this product to be used in a serious condition that is often associated with poor prognosis. However, the benefits and risks still need to be carefully weighed and considered. Please be assured that our assessment teams will endeavour to complete their reviews and assessments as soon as is reasonably possible without compromising on safety considerations.

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,

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