Medicines & Healthcare products Regulatory Agency

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[redacted]

[redacted]

21 February 2024

Dear [redacted]

FOI 24/093 Swift approval program update

Thank you for your emails dated 11 January 2024, in which you requested information concerning 'the SWIFT proposal', and 25 January 2024, in which you provided the following clarification to your request:

'Here are two links to help you answer my original question.

"Accelerated approval process.

- **From 2024, the MHRA will also implement a "*swift approval process*" for the most impactful new medicines and technologies, such as "*cancer vaccines and AI therapeutics for mental health….*"**
- "We will need to wait for further detail before we know **whether the MHRA will be able to accelerate these timelines even further** and what the specific product criteria will be for this accelerated assessment route."

"The Government announced £10 million extra funding for the MHRA over the next two years to implement the above ambitions."

https://www.insideeulifesciences.com/2023/03/20/uk-mhra-to-recognize-foreign-regulatory-approvals-for-medicines-and-medical-technologies-and-promote-digital-innovation/

It's a potential program announced by Jeremy Hunt in March of 2023, partially funded by a 10 million pound infusion for matters like the swift approval process and IRP.

See additional link below:

"Accelerated approval process.
*From **2024**, the MHRA will also implement a "swift approval process" for the most impactful new medicines and technologies, such as **"cancer vaccines** and AI therapeutics for mental health."*

https://www.insideeulifesciences.com/2023/03/20/uk-mhra-to-recognize-foreign-regulatory-approvals-for-medicines-and-medical-technologies-and-promote-digital-innovation/'

Please find below, our responses to your queries:

Question 1. Could you share the tentative documents (and/or links) related to the SWIFT proposal?

We would first like to address possible misunderstanding related to news article - there is no specific programme called 'SWIFT'.

On 15 March 2023, His Majesty's Treasury announced that 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)

As such, from 1 January 2024, developers of new medicines can now submit marketing authorisation applications (MAAs) via an accelerated review procedure, the MHRA's new international recognition procedure (IRP). There are two recognition timetables for initial MAAs:

Recognition A: 60-day timetable
Recognition B: 110-day timetable

The timetables are calendar days and start once the IRP submission has been validated by MHRA.

Guidance on the new International Recognition Procedure is available via the website link below:

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

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.

Question 2. Also, are you planning or already implementing a pilot program for SWIFT before it becomes fully operational?

A pilot program was not implemented prior to the launch of the new International Recognition procedure (IRP). Rather, from 1 January 2024, the IRP replaced the European Community Decision Reliance Procedure (ECDRP). Similarly, since 01 January 2024, the Mutual Recognition/Decentralised Reliance Procedure (MRDCRP) has been incorporated under the umbrella of IRP.

Work is on-going to establish further service improvements and the final form that such improvements may take under the umbrella term of 'Swift'.

Question 3. If so, how are companies selected for that process?

Not applicable, please see response to question 2.

Details of the criteria for submission of Marketing Authorisations Applications via the IRP are available in the guidance document accessible via the electronic link:

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

We trust that you will find this information of use. 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,

Healthcare Quality and Access (HQA) FOI Team