FOI 23/392

Dear

I've now looked into the delay to your request. In terms of the FOIA, an internal review concerning a delayed request focuses on the handling aspects and the provisions of the FOIA that are relevant to that point – in this case, whether the statutory time frame was met. Our response to your request has exceeded the statutory deadline set out in section 10(1) of the legislation, and I apologise for this.

I should explain that we have experienced a backlog of requests from the earlier part of 2023, and we are currently working to complete these as a priority. I am sorry that your request is one of those that has been delayed.

I mentioned in my previous email that I would also make enquiries with colleagues to see if the response to your request could be completed, and I am providing this response below.

Your request asked for:

> *"In his opening comments at a recent MHRA Board meeting, Stephen Lightfoot stated that the MHRA board is "...responsible for agreeing the strategic direction of the Agency...". He did, however make the point that "...regulatory decisions themselves are made by Ministers in the Department of Health and Social Care, on the recommendations of the MHRA officials...".*
>
> *It has also been stated by Dame June Raine that the MHRA is now operating not as a safety 'watchdog' but as an 'enabler ' to ensure healthcare products can be quickly made available for public use.*
>
> *I would like to understand whether the change in approach, that Dame June outlines, was a 'top-down' instruction from the DHSC or a 'bottom-up' initiative from the MHRA.*
>
> *If it was 'top-down', I would be grateful if you would provide me with a copy of the letter / communication that instructed this change. If it was 'bottom-up', I would be grateful if you would provide me with the minutes of the meeting where this was discussed and agreed (plus any supporting information that was used to inform that decision), along with any correspondence from the DHSC agreeing to and/or sanctioning this new approach."*

The quote you have mentioned in your request refers to one of the MHRA's strategic priorities, the MHRA Delivery Plan 2021-2023:

> *"A new and ambitious Delivery Plan centred on putting patients first, has been published today by the Medicines and Healthcare products Regulatory Agency (MHRA).*
>
> *"Putting patients first: A new era for our agency", ensures the agency keeps a constant focus on delivering meaningful outcomes for patients, protecting*

public health through excellence in regulation and science and becoming a truly world-leading, enabling regulator.

At the core of the plan is how the MHRA will draw together its scientific and regulatory expertise to help facilitate the UK life sciences sector and health service; develop new regulatory frameworks; quickly realise the benefits of new therapies and innovative technologies such as artificial intelligence (AI), to improve outcomes for patients; and ensure the continued safety, quality and efficacy of medicines and medical devices.

https://www.gov.uk/government/news/mhra-puts-delivering-for-patients-at-the-heart-of-its-delivery-plan-2021-2023

The Delivery Plan is available here:

https://www.gov.uk/government/publications/the-medicines-and-healthcare-products-regulatory-agency-delivery-plan-2021-2023

Also available on this link is "*Delivery Plan 2021-2023 Updates for year two*".

The rationale for the Delivery Plan, and the development and approval for this, can be found in the published MHRA Board Meeting minutes. Under section 21 of the FOIA, I confirm that we hold the information requested and I provide links to these minutes below:

https://assets.publishing.service.gov.uk/media/6013c3428fa8f53fc149bc05/Agenda_and_Board_Papers_-_19_January_2021.pdf
https://assets.publishing.service.gov.uk/media/603dfd528fa8f577c95c147c/MHRA_Board_Meeting_Papers_-_16_February_2021.pdf

The draft Delivery Plan was presented as a paper to the Board in April 2021. Both the Minutes and the paper are here:

https://assets.publishing.service.gov.uk/media/60911e6ee90e076aab2a05f7/MHRA_Board_Meeting_Pack_-_April_2021.pdf

You may also be interested in the discussion in this public Board meeting, which is available here:
https://youtu.be/0QUV3AtgWyQ

The discussion begins at 33 minutes and 10 seconds.

The approval of the Delivery Plan by the Board is available in the Board Meeting minutes for May 2021:

https://assets.publishing.service.gov.uk/media/60ba10c2e90e0743a8ed35a4/MHRA_Board_Meeting_Pack_-_18_May_2021.pdf

To see more about the respective roles of the MHRA Chair and Chief Executive Officer, and reporting to the DHSC, you may also be interested in the "*Framework*

Agreement Between the Department of Health and the Medicines and Healthcare products Regulatory Agency":

https://assets.publishing.service.gov.uk/media/5a80b1d9e5274a2e8ab51a2c/DH_and_MHRA_Framework_Agreement_A.pdf

To assist, and for further background information, I have also included links to the Government's Life Sciences Vision:
https://www.gov.uk/government/publications/life-sciences-vision

https://assets.publishing.service.gov.uk/media/612763b4e90e0705437230c3/life-sciences-vision-2021.pdf

And the response to it:

https://www.gov.uk/government/news/bold-new-life-sciences-vision-sets-path-for-uk-to-build-on-pandemic-response-and-deliver-life-changing-innovations-to-patients

I hope this response is useful for you. I apologise again for our delay in responding to your request.

Yours sincerely

Lou Lander

Freedom of Information Manager
MHRA Customer Experience Centre
Communications and engagement team
Medicines and Healthcare products Regulatory Agency

Appeal rights
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
If you remain dissatisfied with the outcome of the internal review, you have the right to apply directly to the Information Commissioner for a decision.
The Information Commissioner can be contacted at: Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF. Or online at: https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/