FOI 23/321

Dear

Thank you for your request under the Freedom of Information Act; please accept our apologies for the long delay in this reply. You requested:

> I would like to submit an FOI request to know the following:
>
> ❶ Meta-data request - The dates when issues covering “Specials” Drug Importation were on the agenda of the governing body of the MHRA in the last 5 years.
>
> ❷ If so please provide the text of the agenda item(s)
>
> ❸ Did the MHRA Corporate Plan(April 2021 - March 2024) make any reference or discuss Drug Specials Importation strategy/policy
>
> ❹ Meta-data - Dates in 2021 to 2023 when the Unlicensed Imports Team discussed Drug Specials Importation with the MHRA’s generic drugs regulatory approval team.

Your first two requests relate to The Board. By way of background, The Board is responsible for advising and agreeing the strategic direction of the Agency, endorsing the Agency’s recommendations to Ministers on key financial and performance targets, and advising on and monitoring plans to ensure those targets are met.

The Board supports the Chief Executive Officer in the effective delivery of services and overall performance by providing leadership, developing strategy, advising on the delivery of policies, maintaining high standards of corporate governance, scrutinising performance and ensuring that controls are in place to manage risk. The Board and its Non-Executive Directors have no involvement in any regulatory decisions affecting medicines, medical devices or any other products or services delivered by the Agency. These decisions are the responsibility of the Chief Executive Officer, supported by the Executive Committee.

Further information about The Board including agendas from previous meetings are available on our website at this link: https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency/about/our-governance

Your third request asked about our Corporate Plan, which is a publicly available document. The current version can be found on our website at the first link below, which runs from 2023 to 2026. However, your request straddles the current plan and the previous plan which ran from 2018 to 2023. The previous plan is available at the second link below:

https://www.gov.uk/government/publications/mhra-corporate-plan-2023-to-2026

https://www.gov.uk/government/publications/mhra-corporate-plan-2018-to-2023

For your fourth request, we receive in the region of 80-100,000 notifications of intentions to import unlicensed medicines per year. Notifications are received on a daily basis and there are frequent interactions between the team which handle these notifications and the assessment teams that are involved in the licensing of generic medicines. These interactions can take the form of messages via platforms such as Microsoft Teams or Skype / Instant messenger (which was previously used), or via the telephone or email and are very much a part of standard agency day to day operations. We do not hold details of every discussion which may have taken place over this timeframe and as such it is not possible for us to provide a breakdown of such discussions. If there is a specific medicine that is of interest to you then we would be happy to search our records for anything we do hold.

We apologise once more for the long delay in this reply.

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

Or online via: https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/

Yours sincerely

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