FOI 23/639

Dear

Thank you for your request for information dated 24 August 2023, where you asked:

> *"I refer to the above subject and to my request for information - dated 22 August 2023 - addressed to the Freedom of Information Team at the Department of Health and Social Care following guidance published by the DHSC 21 August 2023.*
>
> *I have received a prompt reply from the DHSC confirming that they do not hold the information requested. A copy of their letter - dated 24 August 2023 - is attached hereto together with their guidance on the subject, updated 21 August 2023. The content of the letter should be self-explanatory.*
>
> *I would be grateful if you could arrange to provide me, from MHRA records, with a copy of the "**scientific information**" that extending the shelf life of this product will not affect its safety profile or how well it works."*

Our Response

We confirm under Section 1(1)(a), that we hold the requested information i.e. scientific information to support the shelf life of the product. Please note, stability data/information is used as a guide to infer product quality throughout the shelf life or a shelf life extension. While these regulatory requirements are very reassuring of stability, they cannot *be used to state that an extension 'will not affect a product's safety profile or how well it works'.* There is always a potential for incalculable or unknown variables and limitations.

We consider the information is exempt as s41(1) and 43(2) apply. This is in line with the Heads of Medicines Agencies (HMA)/European Medicines Agency (EMA) guidance on transparency – see page 35 of the below-linked document, where it states that Section 3.2.P.8 (which concerns stability) is commercially confidential information (CCI):

https://www.ema.europa.eu/en/documents/other/heads-medicines-agencies/european-medicines-agency-guidance-document-identification-commercially-confidential-information_en.pdf"

In a [ic-167627-x2z0.pdf%20(ico.org.uk)] decision notice, ICO have made the following view in regard to the HMA transparency guideline:

"31. The HMA/EMA (Heads of Medicines Agency/European Medicines Agency) guidance referred to earlier is intended to assist bodies dealing with information requests on medicinal products, ultimately the decisions are the public authorities to make but it is clear this document is used to provided consistency and guidance."

Section 41(1)

Information provided to us in confidence, with the expectation that it will not be released, is exempt from disclosure under the FOI Act. Information will be covered by Section 41 if: it was obtained by the authority from any other person; its disclosure would constitute a breach of confidence; a person or organisation could bring a court action for that breach of confidence; and that court action would be likely to succeed.

Section 43(2)
Information where disclosure would be likely to prejudice the commercial interests of any person, including third parties or the public authority that holds the information. Section 43 is a qualified exemption, which means that we have considered whether the public interest in releasing the information is outweighed by the public interest in not giving the information. In favour of disclosure, we consider that there is a general public benefit from understanding the scientific rationale for extending the shelf life of a product used in COVID-19.

However, we consider that the public interest will be better served by not releasing the information as release of the information would be likely enable the competitors to overcome regulatory hurdles in the research and development of their own products. The company/commercial enterprise could suffer as a result of the information being released. Releasing the information would also prejudice the Agency's commercial interests in this case and in future. As a market regulator, it is vital that the Agency can freely engage in dialogue with organisations about commercial activities. In this case we have not identified any issues which would benefit the public as a whole by being brought to their attention.

If you disagree with how we have interpreted the Freedom of Information Act 2000 in answering your request, you can ask for an internal review. Please reply to this email, within two months of this reply, specifying that you would like an Internal Review to be carried out.

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 online via an electronic form: https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/
Or
by writing to:
Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Yours sincerely

MHRA Customer Experience Centre
Communications and engagement team
Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU