FOI 23/108

12th March 2023

Dear

Thank you for your email.

Please find below answers to the questions you have raised below.

Any stability data that we would hold on the Pfizer vaccine would be exempt under Section 41 (information provided in confidence) and Section 43 (commercial interests) of the Freedom of Information (FOI) Act. Section 41 is an absolute exemption and no consideration of the public interest is required, except to state that we would consider the release of this information to be an actionable breach of confidence. Section 43 is a conditional exemption and requires a consideration of the public interest. We have considered the public interest and cannot see any public interest argument that outweighs the commercial harm in publishing information on the specification testing for this vaccine, which can be used by competitors in the development of their own products. This is in line with the HMA/EMA guidance on the release of information after the grant of a marketing authorisation (see page 35 of the below-linked document):
https://www.hma.eu/fileadmin/dateien/HMA_joint/02-_HMA_Strategy_Annual_Reports/07-Transparency/2012_03_HMA_EMA_Guidance_20120309_ComPersInfo.pdf

We do not hold the expiry date for the specific batch referred to in your request. It should be noted that marketing authorisation holders do not have to submit stability data or expiry dates for all batches of an authorised medicinal product.

MHRA does not hold data on the transportation and storage of medicinal products. That is the responsibility of the manufacturer and wholesaler, both of whom hold licences issued by MHRA. Licensed wholesale dealers must comply with good practice standards and pass regular Good Distribution Practice (GDP) inspections of their sites. In the UK these inspections are carried out by MHRA GDP inspectors.

GDP describes the minimum standards that a wholesale dealer must meet to ensure that the quality and integrity of medicines is maintained throughout the supply chain.

Compliance with GDP ensures, amongst other things that:

- medicines in the supply chain are authorised in accordance with UK legislation;
- medicines are stored in the right conditions at all times, including during transportation;
- contamination by or of other products is avoided;
- an adequate turnover of stored medicines takes place;
- the right products reach the right addressee within a satisfactory time period.

It is also incumbent on manufacturers and wholesalers to plan the routes the products take so that the two parties concerned should already be aware of the arrival port and subsequent mode of transport, including the conditions it was transported under, between port of arrival and the required site.

MHRA has guidance for wholesale dealers - https://www.gov.uk/government/publications/medicines-notes-for-applicants-and-holders-of-a-wholesale-dealer-licence-or-broker-registration

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 at:

Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Yours sincerely

MHRA Customer Experience Centre
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