

REQUEST FOI 23/153

21 February 2023 09:02

Pfizer-BioNTech mRNA COVID-19 Vaccine Post-thaw Expiry Dates Extension

In early January 2022 The MHRA, NHS England and NHS Improvement told pharmacy led vaccination sites that Pfizer-BioNTech mRNA COVID-19 Vaccines post-thaw expiry dates could be safely extended from 31 to 45 days.

Please can you confirm what evidence was used to support the safety of this change to vaccine storage, handling and delivery protocol? Particular in relation to unfolding/unlocking spike proteins.

In addition, please can you confirm the following batches were affected by this policy change: FK9712, FN5254, FL9994, FM3802, FN3543, FK0112, FK9706, FH3220, FN1664, FF8288, FM3092, FH4751, FK9707, FK0596, FG3712, FK9413, FN4817, FH0114, FF3319, FL1939?

MHRA RESPONSE

9 March 2023

The changing of storage conditions would have been based on stability data submitted to the agency to show that the vaccine was still in compliance with the shelf-life specifications. Unfortunately, this information is exempt from disclosure under Section 41 and Section 43 (S41/S43) of the FOI Act.

Comirnaty vaccine is in the form of mRNA encapsulated in lipid nanoparticles, rather than being stored in the form of a protein. The drug product is therefore mRNA and not protein. 'Unfolding/unlocking of the spike proteins' is therefore not being tested in the drug product. The mRNA is translated into protein once it has been administered to an individual.

Whilst stability data is exempt from disclosure under S41/S43 of the FOIA, please be reassured that any proposal to change/extend the finished product shelf-life or post-thaw handling shelf-life would have been supported by the relevant stability data (long-term or under stressed conditions) to ensure that the vaccine was still in compliance with the shelf-life specifications and still met the required standard of quality.

However, we do not hold specific information against the aforementioned batches when they are not identified as the primary quality batches or stability batches submitted for evaluation. Therefore, we would not be able to confirm if these batches had an extended post-thaw duration.

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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