FOI 22/1116 - Nucleotide base sequence for "famtozinameran"

REQUEST
11 November 2022

> Please release the following documents relating to the product "Comirnaty Original/Omicron BA.4-5 (15/15 micrograms)/dose dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified)".
> 1) The full nucleotide base sequence for "famtozinameran".
> 2) The conditions attached to this Conditional Marketing Authorisation.
> 3) The Public Assessment Report for this approval.
> 4) The date and time the application was made.
> 5) The date and time the application was approved.
> Please provide the documents for 1), 2) and 3) in PDF format if possible.

MHRA RESPONSE
17 January 2023

We are pleased to be able to provide (attached) the Nucleotide base sequence for "famtozinameran".

Previous MHRA response 22 December 2022

FOI 22/1116

Thank you for your request under FOIA, we apologise for the delay.

In your request you asked the below set of questions and we have annotated responses to these questions:

1) The full nucleotide base sequence for "famtozinameran".
A. You will be aware that we have released the sequences for the earlier Pfizer/BioNTech COVID-19 vaccines. However, because the sequences differ for each vaccine, it may be that the sequence requested attracts a different level of commercial sensitivity. As such we will need to contact the third party to ascertain there perspectives on the scope for commercial harm and then we will balance these concerns, if any, against the public interest. Please accept our apologies for not taking this step sooner, we will aim to meet this aspect of the request by 4 January 2022. However, should it become necessary to conduct a public interest test we may require an extension in due course.

2) The conditions attached to this Conditional Marketing Authorisation.
This authorisation is not a Conditional Marketing Authorisation, it is a full Marketing Authorisation. However, there ‘post-authorisation measures’ that are required to be fulfilled.

This authorisation has the following post authorisation measure(s) which should be fulfilled by the date(s) shown:

1. The MAH should submit a standalone summary safety report for the Original/Omicron BA.4-5 bivalent product, with the data lock point falling 3 months after the date of approval in Great Britain.	09/02/2023
2. Within one month of approval, the MAH must submit the following concerning Post-Authorisation Vaccine Effectiveness study WI255886: a. A full updated study protocol to reflect the investigation of the Original/Omicron BA.4-5 bivalent product b. An analysis of the feasibility and power of the study to generate robust results for the Original/Omicron BA.4-5 bivalent product c. Milestones for the provision of results for the Original/Omicron BA.4-5 bivalent vaccine	09/12/2022
3. The MAH should submit the immunogenicity and safety data from study C4591044 in accordance with the schedule agreed with the European Medicines Agency.	
4. During EU variation II/0140 the MAH responded that they will assess the feasibility of studying the bivalent vaccine and future modified vaccines in studies C4591012, C4591021, and C4591036, which is not accepted. Concerning the ongoing safety studies with the initial monovalent vaccine (including booster doses) so far one or two interim reports were submitted for assessment by the EMA and subsequently limited (follow-up) safety data from the PASSs is available yet. Therefore, these safety studies should include the BA.1 bivalent vaccine as well as the BA.4/.5 bivalent vaccine in all (ongoing) PASSs or otherwise justify with methodological issues or other issues (within 3 months after approval of the bivalent vaccine).	09/02/2023
5. The MAH should provide long-term and accelerated stability data for the 1-month time point for drug substance batch GH5745.	30/11/2022
6. The MAH should provide information on the theoretical protein sizes of the mature protein and variants thereof. In addition, the MAH should update the dossier with Figure 1. BNT162 Omicron (BA.4/BA.5) Expressed Protein Size by In Vitro Translation, as provided in response to the request for supplementary information.	31/12/2022
7. The MAH should reassess and optimise the proposed specification for the RNA ratio, when a sufficient number of BNT162b2 Bivalent (Wildtype and Omicron) Drug Product batches have been manufactured.	30/06/2023

3) The Public Assessment Report for this approval.
A. The MHRA PAR for this product is the first result which populates when following the below search:
MHRA Products | Search results [please note if you right click anywhere in this document an option to save as PDF should be available].

Because this product is authorised in Great Britain via the Reliance procedure, for the scientific discussion of the quality, non-clinical and clinical assessment conducted by the EMA please see below:
Comirnaty, INN-tozinameran, tozinameran/riltozinameran (europa.eu)

4) The date and time the application was made.
A. The application was received on 7/10/2022.
5) The date and time the application was approved.
A. The application was granted 9/11/2022; 17:29

If you have a query about the information provided, please reply to this email.

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

HQA FOI Team