Medicines & Healthcare products Regulatory Agency

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Canary Wharf
London
E14 4PU
United Kingdom
gov.uk/mhra

[redacted]

[redacted]

02 February 2024

Dear [redacted]

FOI 24/029

Thank you for your FOI request, dated 08 January 2024, asking the following questions:

> "At whose instigation was Batch EJ0553 of BNT162b2 introduced on 27/28 November 2020 for consideration for MHRA authorisation – e.g., was it at BioNTech's instigation or the MHRA (or any other UK government party such as CHM?) and what was the reason provided for why this was introduced?
>
> Were BioNTech BNT162b2 batches EJ0724 and EJ1688 ever supplied to the United Kingdom for use on the UK population and if so when were they supplied?"

MHRA response
Please note, batches of vaccine that meet the specifications in the approval are certificated, allowing the manufacturer to market them in the UK for use.

We have checked our records and confirm that we hold the information for the first part of your first question: on 27 November 2020, Pfizer/BioNTech confirmed that the first BNT162b2 batch to be distributed to the UK was to be batch EJ0553. It is not the MHRA's role or that of the Commission on Human Medicines (CHM) to instigate the release of specific batches to the UK. For the second part of your first question, we can advise that, it is usually for the Marketing Authorisation Holder to decide which vaccine batches are released to the different markets where the product is approved; for this part of your question, we hold no further information.

In response to your second question, the MHRA issued letters to BioNTech permitting the release of batch EJ0724 on 08 December 2020, and permitting the release of batch EJ1688 on 09 December 2020. However, the MHRA does not hold the requested information on

where the vaccines were supplied or when, as deployment of the vaccine once batches are released is outside the MHRA's remit.

You may wish to contact the UK Health Security Agency (UKHSA) for further information via the below details:

enquiries@ukhsa.gov.uk

To make information access requests including Freedom of Information (FOI) requests, Environmental Information Regulations (EIR) requests and data subject access requests (SAR) to UKHSA, please email:

InformationRights@UKHSA.gov.uk

The supply of licensed covid vaccines to UK hospitals and vaccine centres is also partly a matter for NHS England and the healthcare systems in the devolved governments (Scotland, Northern Ireland and Wales). You may wish to redirect your enquiry to NHS England and the devolved governments via the links below:

NHS England: www.nhs.uk and www.england.nhs.uk/contact-us/foi/
NHS Northern Ireland: www.hscni.net
NHS Scotland: www.scot.nhs.uk and www.nhsinform.scot/freedom-of-information-foi/
NHS Wales: www.nhs.wales

The "House of Commons Committee of Public Accounts The rollout of the COVID-19 vaccine programme in England Eleventh Report of Session 2022–23":

https://committees.parliament.uk/publications/23019/documents/168825/default/

clarifies the role of the different organisations in England.

We trust that you will find this information of use. However, if you disagree with how we have interpreted the Freedom of Information Act 2000 in answering your request, you can ask us to review our actions and decisions by writing to: info@mhra.gov.uk, and requesting an internal review.

Please note that your internal review request must be in a recordable format (email, letter, audio tape etc.), and that you have 40 working days upon receipt of this letter to ask for a review. We aim to provide a full response to your review request within 20 working days of its receipt. Please quote the reference number above in any future communications.

If you are not content 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 in writing to:

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

Yours sincerely,

HQA FOI Team