Medicines & Healthcare products Regulatory Agency

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London
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United Kingdom
**gov.uk/mhra**

[redacted]

1 December 2023

Dear [redacted]

**FOI 23/421**

Thank you for your request for information dated 15 June 2023, please accept our sincere apologies for the delay. In your request you asked the following questions and we have provided our responses below each question.

1. A copy of the November 17th 2020, letter from the DHSC to the MHRA requesting authorisation, on a temporary basis, of its proposed supply of a vaccine manufactured by Pfizer/BioNTech collaboration, named "COVID-19 mRNA Vaccine BNT162b2", under Regulation 174 of the Human Medicines Regulations 2012, ("the Regulations").

Our response:
*Please find attached copy of the DHSC letter sent to the MHRA requesting the temporary authorisation of BNT162b2 vaccine under Regulation 174.*

2. The batch number of BNT162b2 the MHRA granted the TUA for.

Our response:
*The first batch temporary authorisation under Regulation 174 was provided for was batch EJ0553.*

*This information is held however, Section 21(1) of the Freedom of Information Act 2000 applies as this information is publicly available on the gov.uk website. Please see link below.*

https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19/conditions-of-authorisation-for-pfizerbiontech-covid-19-vaccine

3. Which of the two processes BioNTech said in its clinical trials protocols it was using to manufacture BNT162b2 was used to manufacture the specific batch of BNT162b2 that MHRA granted a TUA for? 'Process 1' which was used for small scale manufacturing of product for the clinical trials or process 2 which was used for mass manufacture?

Our response:
*In terms of the clinical trial protocol vaccines manufactured by both processes were administered, the majority of participants received vaccines manufactured by Process 1. In terms of the temporary approval under Reg. 174, all batches distributed for use in the UK were manufactured by Process 2. This information is held however, Section 21(1) of the Freedom of Information Act 2000 applies as this information is publicly available, see clinical trial protocol and excerpt below.*

The initial BNT162b2 was manufactured using "Process 1"; however, "Process 2" was developed to support an increased scale of manufacture. In the study, each lot of "Process 2"-manufactured BNT162b2 will be administered to approximately 250 participants 16 to 55 years of age. The safety and immunogenicity of prophylactic BNT162b2 in

https://www.nejm.org/doi/suppl/10.1056/NEJMoa2034577/suppl_file/nejmoa2034577_protocol.pdf

4. It was specified in BioNTech trial protocol that an analysis comparing the reactogenicity and safety of process 1 and process 2 batches (eg comparing the numbers of serious adverse events and deaths) would be conducted. Please provide a copy of the analysis or report produced, received, reviewed or evaluated by MHRA comparing the safety data of the two products.

Our response:
*Under section 1(1)(a), we confirm that the below;*

*"To describe the safety and immunogenicity of prophylactic BNT162b2 in individuals 16 to 55 years of age vaccinated with study intervention produced by manufacturing "process 1" or Process 2", is not information held.*
*In October 2020 an exploratory objective was added in the C4591001 study to describe safety and immunogenicity of vaccines produced by manufacturing "Process 1" or "Process 2" in participants 16 to 55 years of age. This exploratory objective was removed and documented in protocol amendment 20 in September 2022 due to the extensive usage and consequently vaccine surveillance of vaccines manufactured via "Process 2.*

5. Copies of any written advice given by Vaccine BR EWG to the Commission of Human Medicines (CHM) on 11th September 2020, 8th October 2020, 27th October 2020, 28th November 2020 and 30th November 2020, regarding the requirements for authorisation for the temporary supply of COVID-19 mRNA Vaccine BNT162b2.

Our response:
*We have identified the following sets of minutes regarding this Expert Working Group (EWG):*

| Meeting dates | Status in relation to your request |
|---|---|
| 11th September 2020 | *BNT162b2 was not discussed at CHM or EWG and is therefore considered out of scope of this request.* |
| 8th October 2020 | As above. |
| 27th October 2020 | As above, however, *EWG discussed BNT162b2 on 28th October.* |
| 28th October 2020 | *EWG minutes provided* |
| 28th November 2020 | *EWG minutes provided* |
| 30th November 2020 | *CHM minutes which are published on GOV.UK website:* Commission on Human Medicines (CHM) and Expert Advisory Group (EAG) Final Summary Minutes \| Powered by Box |

*In line with the table above, we are providing minutes of the Vaccine BR EWG meetings of 28th November 2020 and 28th October 2020. Redactions have been made under Sections 40 and 43(2) of the FOIA.*

*Section 40(2)*
*We can confirm that the only material we have redacted under this Section is that which concerns personal data: this information is withheld as it falls under the exemption in sections 40(2) and 40(3)(a)(i) of the FOIA, which relates to the personal data of which the applicant is not the data subject. Section 40(2) of the FOIA provides that personal data relating to other persons is exempt information if disclosure would breach the Data Protection Act 1998 (DPA). We consider that disclosure of this information is likely to breach the first data protection principle in Schedule 1 to the DPA, which relates to the fair and lawful processing of personal data. Therefore, we have concluded that this information is exempt from disclosure under section 40(2) read in conjunction with section 40(3)(a)(i) of the FOIA.*

*Section 43(2)*
*Section 43(2) of FOIA states that information is exempt if its disclosure would, or would be likely to, prejudice the commercial interests of any person, including the public authority holding it. Disclosure would be likely to prejudice Pfizer-BioNTech's commercial interests. The redacted information is confidential data relevant to the above company. This information, if released, could be used by competitors for their commercial advantage. For example, to inform research and development into rival products that could result in other manufacturers overcoming many regulatory hurdles in their product's development. As well as undermining the relationship with the particular manufacturer in this case. The main factors in the public interest related to the furthering of public debate, an increase in transparency, and consequently improved trust in regulators; these considerations have led to the disclosure of a large amount of information within the minutes. However, for certain passages, we consider that the public interest favours maintaining the exemption where this is necessary to protect commercial interests.*

*Please note, for the minutes of Wednesday 28th October 2020, these contain a series of passages on an unrelated item which is out of the scope of your request. This item has been redacted as unrelated to the BNT162b2 vaccine so not related to your request.*

6. How many batches of the vaccine used in the UK after the batch granted the TUA was used up were sent by the MHRA for evaluation by the independent control laboratory?

Our response:
*In the period since authorisation and the end of June 2023, the MHRA independent control laboratory certified 99 batches for the UK market.*

7. What was the independent control laboratory asked to evaluate and what tests did it run?

Our response:
*Independent batch release testing includes a range of techniques specific to the product and includes a range of visual, molecular, serological, cell-based tests to confirm identity of material, potency, integrity https://nibsc.org/control_testing/batch-release.aspx, and review of the manufacturer's own data.*

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**