Medicines & Healthcare products
Regulatory Agency

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

[redacted]

By email [redacted]

9 April 2024

Dear [redacted]

FOI 24/189

Thank you for your request for information dated26 February 2024, where you asked:

Our response:

We apologise for the delay in responding to this request.

Information disclosed
We are providing theMHRA submission to theminister for this R.174 authorisation. This meets the description given in your request forfull details ofthe information provided to the Minister. Please note, ministerial submissions are a concise summation of the MHRA's assessment of theCovid-19 vaccines. Therefore, please bear in mind the series of steps and considerable assessment efforts which led to the finalised submission. For example, the MHRA's careful review of the quality, non-clinical and clinical data for the vaccines which shaped the understanding that the benefits of these vaccines outweighed the risks and that these vaccines are effective and acceptably safe. As noted in the submission, the views of the independent Commission on Human Medicines (CHM) and its COVID-19 vaccine benefit-risk expert working group were solicited prior to temporary authorisation of the C-19 vaccines authorised under Regulation 174. The public assessment report is available online and this captures the detailed assessment of the quality, safety and efficacy that

underpinned the recommendation for each vaccine made in the ministerial submissions. The PAR relevant for your request is noted in the footnote below.[1]

Please note, these are the final versions as sent to the minister at DHSC.

In terms of the conditions list,we note thatthis wasprovided separately to DHSC via our separate legal team. We are however providingthe copy held by the MHRA. Please note, the conditions lists were also publicly available on Gov.uk at the time of approval of the vaccines.

Information withheld

A small amount of information has been withheld under section 40(2)(personal information) and certain sections of the submissions undersection 42 (legal professional privilege) of the FOI Act.

Section 40(2)

We can confirm that the only material we have redacted under thisexemption is that which concerns personal data in the form of certainMHRA and DHSCstaff names, signatures and roles: 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 relatingto 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 42

This exemption applies when disclosurewould contravenethe protections in place on legal advice. In this case, the exemption applies tothe withheldsections of the submissions which contain confidential communicationsfor the purpose of giving legal advice.

This sectionof the FOIAis not an absolute exemption; rather it is subject to a public interest test. We have considered the application of the public interest test to section 42 in the circumstances of your request.

There is a public interest that decision-making processes of a publicauthority should be open to scrutiny. There is a countervailing public interest that staff should be able to seek legal advice, and that lawyers should be able to provide that advice without concern that it should be released into the public domain; this maintains the important principle of legal professional privilege.After weighing the factorsfor the engagement ofsection 42 it is our

[1] Regulatory approval of Pfizer/BioNTech vaccine for COVID-19 - GOV.UK (www.gov.uk)

view that the public interest in maintaining the exemption outweighs the public interest in disclosing the information.

Additional context for specific excerpts from the attachments

To assist further, we have provided some additional context below to help contextualise certain paragraphs within the disclosures. This option was taken with a view towards increasing transparency and avoiding redaction where at all possible to do so.

Each heading below refers to an extract from the disclosures and provides additional lines of explanation.

Pfizer/BioNtech Vaccine BNT162b2

*Ministerial submission, point 8 paragraph c***.**

> *Pre-clinical testing The CHM noted a gap in pre-clinical testing in terms of reproductive toxicology studies and agreed that until data are provided and are reassuring the vaccine should not be recommended for use in pregnancy. The CHM agreed that there should be clear advice in the product information and that women of childbearing potential should receive appropriate information and where necessary counselling.*

Regarding thedevelopmental and reproductive toxicology (DART), we can explain that the high-level conclusion/outcome was that the non-clinical data reveal no special hazard for humans based on conventional studies of repeat dose toxicity and reproductive and developmental toxicity.

Ministerial submission, point 8 paragraph e.

> *Surveillance In terms of further studies, the CHM heard from PHE about the planned studies of vaccine effectiveness and also the plans for an investigation into vaccine failures. In order to prepare for the safety surveillance of COVID -19 vaccines the MHRA had previou sly consulted the CHM on its proposals for a proactive safety monitoring strategy. The report of an ad hoc Expert Working Group which met 4 times and made recommendations for safety surveillance is attached at Annex B.*

We would like to explain that t *vaccine failures not* specific to **vaccine BNT162b2,** this is a safety surveillance measure to understand the effectiveness of the vaccines and the overall programme . Monitoring and investigation of suspected vaccine failures by UKHSA, MHRA and the vaccine manufacturersis applicable to all vaccines used in UK/GB rollouts.

Ministerial submission,point 11:

> *The National Institute for Biological Standards and Control (NIBSC) is currently in the process setting up and verifying the analytical methods that will be used as part of the control strategy. As of 30 November, 3 out of the 5 tests have been implemented by*

NIBSC, and by 3rd December all 5 will be available for batch testing. Until 3rd December batches can be released on a risk-based approach as advised by CHM. Once the company is informed of the regulation 174 authorisation, they can submit a request to NIBSC for release of a batch. Following receipt of this request and review of the manufacturer Lot Release Protocol (which will be submitted with the request) NIBSC will be able to complete the independent batch release process and issue a certificate. For the batch identified for immediate allocation, completion of this process is anticipated within 24 hours of receipt of the request and the Lot Release Protocol from the company.

Please note that the information above from the submission has been superseded. Prior to release of the first batch of vaccine BNT162b2 for supply/roll-out, full batch testing was in place for 5 of 5 tests, rather than 3 of 5 tests as stated above.

Ministerial submission, point 10:

The CHM proposed a range of conditions to be applied to the authorisation (see Annex C). Given that the company is developing its product from vaccine used in the clinical trials through to full commercialisation, there are some significant process changes between batches. The authorisation is therefore given on the basis of specific and identified batch approval. Other conditions seek to replicate some of the regulatory controls that accompany a normal licence, such as ensuring adherence to Good ClinicalPractice, Good Manufacturing Practice and Good Laboratory Practice.

We can explain that the manufacturing process changes referencedin this extract relate to process up-scale. We provide further explanationunder the heading *Manufacturing Process Scalability* below.

Manufacturing Process Scalability

To provide helpful context and background, in the early stages of the pandemic, before BNT162b2 was authorised or approved, improvements were made to the manufacturing process to adjust the scalability, robustness, and productivity in preparation for large scale manufacture (Process 2); scaling of manufacturing processes is a common occurrence in the manufacture of medicines. Manufacturing steps that were not scalable were replaced with those designed to provide a similar or better impurity profile.

-by-side comparability studies and heightened characterisation testing. The process was validated at all manufacturing sites and submitted for review and approval. Vaccines produced byboth

such changes can be supported by analytical data; however, due to the nascent regulatory landscape for COVID-19 vaccines, in October 2020 an exploratory objective was added in the C4591001 study to describe safety and immunogenicity of vaccines produced by

exploratory objective was removed and documented in protocol amendment 20 in

Thus, this process comparison was not conducted as part of the formal documentation within the protocol amendment.

As with all vaccines and medicines, the safety of COVID-19 vaccines is being continuously monitored. For all COVID-19 vaccines, the overwhelming majority of reports relate to injection-site reactions (sore arm for example) and generalised symptoms such as - illness, headache, chills, fatigue (tiredness), nausea (feeling sick), fever, dizziness, weakness, aching muscles, and rapid heartbeat. Generally, these happen shortly after the vaccination and are not associated with more serious or lasting illness.

We hope that the information andadditional explanation provided are helpful.

Yours sincerely,

HQA FOI Team

Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU

Appeal rights

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 40working 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:

Wycliffe House,
Water Lane,
Wilmslow,
Cheshire,
SK9 5AF