FOI 23/043 - Pfizer/BioNTech vaccine protocol and testing

Dear

Thank you for your request under the Freedom of Information Act, we apologise for the long delay in this reply.

In this response we have numbered the questions you asked us and have provided our responses beneath each question:

1. **Provide the test protocol used to ensure that the method of mixing outlined in the Pfizer/BioNTech vaccine Information for UK Healthcare professionals ensured each of the 6 doses withdrawn from a single vial contained the correct amount of active ingredients.**

We confirm that we do hold these data. However, they are considered to be commercially confidential as outlined in the HMA Transparency guideline (page 4, point 3.1.1), this is a document that we use to promote consistency in FOI handling and was compiled following a public consultation. Details and the background to the production of this document can be found here: Heads of Medicines Agencies: Guideline for transparency (hma.eu). We therefore, exempt this information under Sections 41 (1) (information in confidence)* and Section 43(2) (commercial interests)* of the Freedom of Information Act.

2. **Confirm whether any testing was done on mixing prior to approval (yes or no) & if testing was undertaken, the test report.**

As for all medicinal products, appropriate validation data was provided by the manufacturer of BNT162b2 / Comirnaty vaccine to provide reassurance that the required quantity of active substance is found in the drug product following reconstitution, as per the approved finished product specifications. Relevant data, supporting the compatibility and stability with the recommended diluent for reconstitution, was also provided to ensure the product is of a satisfactory quality for administration. This general description aside, as with point 1, above, we confirm that we hold information in scope of your question, but we consider it to be exempt under Sections 41 (1) (information in confidence)* and Section 43(2) (commercial interests)* of the Freedom of Information Act.

3. **Confirm what testing was undertaken on batches mixed in vaccination centres, what the sampling methodology was & provide an example test report.**

We are unclear on the reference to ‘batches’ in this question. Could you please confirm by reply whether you are referring to the re-constitution of the vaccine at the point of administration?

***Section 43 (Commercial interests)** the release of all, or part of, the information would, or would be likely to, cause harm to the third party's commercial interests.

The exemption is to safeguard the commercially sensitive information/commercial enterprise. This exemption is conditional on the public interest in releasing it not outweighing the company's/commercial enterprise's right to confidentiality and the probable damage that the company/commercial enterprise could suffer as a result of the information being released. We have considered the balance of the public interest when applying this exemption and consider that applying the exemption is appropriate.

***Section 41 (Information provided in confidence)** is an absolute exemption, and no consideration of the public interest is necessary, except to state that the release of this information withheld under this section of the FOI Act would be considered an actionable breach by the MHRA. When a company submits their pharmaceutical development data, with the exception of a major public health risk related to a major procedural failure or irregularity, it would be highly inadvisable for MHRA to release this information publicly, because Marketing Authorisation Holders expect these data to be handled in confidence, with sharing of the data only occurring via agreed regulatory mechanisms / procedures.

We appreciate that given the delay in response you have followed up and requested an Internal Review. We do not consider this reply to be the internal review, as you have not an opportunity to consider our reply to your request or to respond to our clarification question.

If you disagree with how we have interpreted the Freedom of Information Act 2000 with regards to your request, you can ask for the decision to be reviewed. The review will be carried out by a senior member of the Agency who was not involved with the original decision.

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
Communications and engagement team