FOI 23/855
FOI 23/856

I am replying to your two requests FOI 23/855 and FOI 23/856.

Thank you for your clarification email dated 07 November 2023 in which you requested the documents as stated below for ***the original application (PLGB 53632/0002)(sic) for approval of the first version of the Spikevax vaccine and for the original application (PLGB 53632/0001, "BNT162b2")(sic) for approval of the first version of the Comirnaty vaccine.***

1. **Common Technical Document - Module 2: Summaries:**

2.3: Quality Overall Summary – Introduction
a. 2.3.S Quality Overall Summary – Drug Substance
b. 2.3.P Quality Overall Summary – Drug Product

2. **Common Technical Document - Module 3: Quality:**

3.2: Body of Data
a. 3.2.S – Drug Substance
b. 3.2.P – Drug Product.

Our response:

Please note that there are some errors in the PL numbers that you quoted in your requests. We have included the correct numbers below and we've considered the request as being for these (correct) numbers.

Assessment of the original Pfizer/BioNTech (PL 53632/0001) and Moderna (PL 53720/0001) vaccines was conducted through an expedited rolling review. A 'rolling review' can be used to complete the assessment of a promising medicine or vaccine during a public health emergency in the shortest time possible. This is done as the packages of data become available from ongoing studies on a staggered basis. Authorisation under Regulation 174 permits the supply of identified vaccine batches, based on the safety, quality and efficacy data submitted to MHRA. These authorisations do not constitute a marketing authorisation.

Each of the vaccines was subsequently granted a conditional marketing authorisation, as follows:
Pfizer/BioNTech vaccine (Comirnaty; PLGB 53632/0002) following a European Commission (EC) decision on 21 December 2020.
Moderna vaccine (Spikevax; PLGB 53720/0002) on 31 March 2021.

Further information is available on the MHRA website and the EMA website, links are provided below:
https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19

https://www.ema.europa.eu/en/medicines/human/EPAR/comirnaty

https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-moderna

https://www.ema.europa.eu/en/medicines/human/EPAR/covid-19-vaccine-moderna

We confirm that the information that you have requested is held, however, the release of this information is exempt under Section 41 (S41 – information provided in confidence), Section 43 (S43 – commercial interests) and Section 21 (S21 – Information accessible by other means) of the Freedom of Information Act (FOIA)

Section 41(1)
Information provided to us in confidence, with the expectation that it will not be released, is exempt from disclosure under the FOI Act. Information will be covered by Section 41 if: it was obtained by the authority from any other person; its disclosure would constitute a breach of confidence; a person or organisation could bring a court action for that breach of confidence; and that court action would be likely to succeed.

Section 43(2)
Information where disclosure would be likely to prejudice the commercial interests of any person, including third parties or the public authority that holds the information. Section 43 is a qualified exemption, which means that we have considered whether the public interest in releasing the information is outweighed by the public interest in not giving the information. In favour of disclosure, we consider that there may be a general public benefit from having access to quality data submitted for a product used in COVID-19. However, we consider that the public interest in releasing the information does not outweigh 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. Releasing the information would also prejudice the Agency's commercial interests in this case and in future. As a market regulator, it is vital that the Agency can freely engage in dialogue with organisations about commercial activities. In this case we have not identified any issues which would benefit the public as a whole by being brought to their attention (examples of issues would be a major public health risk or a major procedural failure or irregularity).

Exemption under S41 and S43 is in line with the Heads of Medicines Agencies (HMA)/European Medicines Agency (EMA) guidance on transparency – see the below-linked document:
HMA/EMA GUIDANCE DOCUMENT ON THE IDENTIFICATION OF COMMERCIALLY CONFIDENTIAL INFORMATION (europa.eu)

Section 21
This is an absolute exemption and states that there is no right of access to information via FOI if it is reasonably available to the applicant by another route. Non-confidential quality information, such as information on the nomenclature, structure, general properties of the active substance and qualitative composition of the medicinal products, can be found in the public domain, for example in the links above or in the product information which is published here: https://www.gov.uk/guidance/find-product-information-about-medicines

We now consider this request closed. If you are unhappy with our decision, you may ask for it to be reviewed. That review will be undertaken by a senior member of the Agency who has not previously been involved in your request. If you wish to pursue that option please email: info@mhra.gov.uk

After that, if you remain dissatisfied, you may write to the Information Commissioner at;
The Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

They will make a decision on whether or not we have interpreted the FOIA correctly in handling your request.

Yours sincerely,

HQA FOI Team