FOI 23/189

Dear

Thank you for your request dated 10 March 2023, we apologise for the long delay in response.

> *Subject: Freedom of Information request - Section 3.2.P.1 for all approved COVID-19 vaccines*
>
> *Please disclose all versions of Section 3.2.P.1, Description and Composition of the Drug Product, ever filed with the MHRA for all COVID-19 vaccines . This request covers all such products approved for use in the UK: Moderna, Pfizer/BioNTech, Novavax, AstraZeneca, Janssen, and Valneva.*
>
> *For transparency, please ensure these are provided in fully unredacted form, including Table 3.2.P.1-1, Composition of the Drug Product. The public interest case for this data is to publicly demonstrate compliance with Schedule 8 Part 2 of The Human Medicines Regulations 2012, as concerning the contents of the Summary of Products Characteristics (SmPC). [1]*

As you know, during the handling of your request we have been considering the public interest in disclosure for a number of records relevant to your request. In parallel, we have continued to retrieve further relevant records as initially, it was thought that all material covered by the scope of your request could be returned within the limits of Section 12.

However, during the process it has become apparent that our systems are mainly designed to return the currently approved documents with ease, or to return specific documents granted within a specific regulatory procedure. Therefore, a greater amount of time has been needed to locate and retrieve previous versions and to be confident that ‘all versions’ have been captured.

Furthermore, we have noted that the wording of your request mentions ‘all versions […] ever filed with the MHRA’; this scope is broader than originally considered as it would require a check of email servers to confirm if any formulation documents have been sent through email at any point for any of the authorised vaccines.
Your request mentions 6 vaccines, but there are more than 6 COVID-19 vaccines authorised in the UK, this conflicts with the other wording in your request “This request covers all such products approved for use in the UK”. Please also note there are also many different formulations, for example, due to the different variants and to cover paediatric doses.

To confirm having reviewed your request, we estimate that compliance with the request, would exceed the appropriate costs limit under S.12 Freedom of Information Act 2000. Public authorities are not obliged to work past the appropriate costs limit under section 12(1) of the Freedom of Information Act 2000. We apologise that we did not recognise this sooner.

Based on the work we have done to date, we can offer guidance as to what would be manageable under the costs limit in terms of refinement.

We suggest you refine your request to one specified vaccine, or two at the most, citing the specific PL numbers. We would also advise that you limit your request to information currently held in the lifecycle database for Valneva PL 43185/0002 and Janssen PLGB 00242/0742.

If you do submit a refined request, this will be a new request following this refusal, and the 20 working day statutory time limit will begin from the date your refined request is received. In the absence of a refined request, we will send an official response to your original request, engaging the costs limit exemption under section 12(1) of the Freedom of Information Act 2000 within the 20 working day limit.

If you disagree with how we have interpreted the Freedom of Information Act 2000 in answering your request, you can ask for an internal review. Please reply to this email, within two months of this reply, specifying that you would like an Internal Review to be carried out.

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 online via an electronic form: https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/
Or
by writing to:
Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF
Many thanks for your understanding,

Yours sincerely,
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Medicines and Healthcare products Regulatory Agency
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