FOI 23/056 - Request for Further Information letters which MHRA sent to Pfizer, AstraZeneca and Moderna

Dear

Many thanks for your email. Regarding your request for:

> **'copies of the Request for Further Information letters which MHRA sent to Pfizer, AstraZeneca and Moderna during MHRA's assessment of their submissions leading to Temporary Authorisation of each Covid vaccine. If you refuse this request under an FOI Exemption, please provide the following information :**
> **a) the document references (inc dates) of those letters**
> **b) how many questions were included in each RFI letter.**
>
> **If you sent no RFI letters per se because you conducted so-called Rolling Review,s please can you tell me :**
> **c) how many questions/clarifications you asked each of those manufacturers**
> **d) in what form the questions were asked (eg email, telephone, in person)'**

We are exempting the release of this information under Section 41 (information provided in confidence), Section 43 (commercial interests) and Section 38 (health and safety) of the Freedom of Information (FOI) Act.

Section 41 is an absolute exemption and no consideration of the public interest is required, except to state that requests for further information (RFIs) and responses to these are discussions held in confidence between MHRA and the marketing authorisation holder (MAH) about their product. To release this information would inhibit the free discussions that MHRA has with MAHs on their marketing authorisation applications, which would be detrimental to the public as a whole.

The use of Section 43 requires that we consider the public interest. We have considered the public interest and can find no public interest argument that outweighs the commercial harm caused by revealing commercially sensitive information that can be used by competitors in the development of their own products (which engages Section 43(1)). Further, we can find no public interest argument that outweighs the commercial harm that would be caused through publishing RFIs that could be misinterpreted if taken out of context (which engages Section 43(2)).

The use of Section 38 requires that we consider the public interest. We have considered the public interest and can find no public interest argument that outweighs the harm caused by publishing the RFIs and responses. We have stated above the commercial harm that can be caused by taking the RFIs out of context. However, there is also a public health risk in members of the public misinterpreting the information in the RFIs/responses or this information could be used to support false messages about vaccine safety that could lead to a reduction in vaccine uptake.

MHRA have published Public Assessment Reports (PARs), which represent the non-confidential parts of the assessment reports generated for each vaccine. Links to these have been provided to you previously.

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
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