FOI 22/1128 - Host Cell Protein (HCP) Impurities in COVID-19 Vaccines

MHRA RESPONSE
31 March 2023

Thank you for your request (22/1128) under FOIA, where you asked:

> **"For all of the COVID-19 vaccines "authorised" by the MHRA (Pfizer/BioNTech, Moderna, AstraZeneca, Janssen and Novavax), please provide the following data concerning host cell protein (HCP) impurities:**
> **i) manufacturers' results provided to the MHRA, including the HCP assays used (e.g., ELISA)**
> **ii) MHRA specification limits for HCPs**
> **iii) National Institute for Biological Standards and Control (NIBSC) results, including the HCP assays used**
>
> ***Please confirm all HCP results known to the MHRA conform to MHRA specification limits.***
>
> **Peer-reviewed research from the University of Ulm has characterised 44-71% of total protein content from all 4 AstraZeneca lots tested as being of human origin. [1] Please therefore also disclose any communication between the MHRA and AstraZeneca on human HCPs and any actions taken by the MHRA in response to the study results.**
> **[1] https://elifesciences.org/articles/78513"**

Our response:
In terms of parts i) and ii) and [1] of your request these data are exempt under Sections 41 and 43 of the FOI act.

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.

Section 41 (Information given 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 specifications and batch data, it would be highly unlikely for MHRA to release the limits and results publicly, and therefore, Marketing Authorisation Holder expect these data to be handled in confidence, with sharing of the data only occurring via agreed regulatory mechanisms / procedures. An exception to this would be a major public health risk related to a major procedural failure or irregularity). For example, if the journal article

you have cited identified a clear risk to public health, then the public interests aspects of Section 43 and 41 would need to be re-considered.

We hereby confirm that batch release specifications for HCP were met by all batches.

Our response to part iii)

The MHRA's laboratory-based testing does not include HCP assessment. The manufacturer's Lot Release Protocol (LRP) is checked to confirm that the manufacturer has conducted the test/s (as specified in the MA) and that the results meet met the specification. All vaccine batches that have been independently certificated will meet those specification/s.

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 at:

Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Yours sincerely

MHRA Customer Service Centre

Medicines and Healthcare products Regulatory Agency
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