FOI 23/195

Dear

Thank you for your email and we apologise for the delay in response.

Please find below answers to the questions you have raised in blue below.

1. Please provide the conditions that are required to be met by the licensing authority that would signal a pause and reappraisal of the associated COVID-19 messenger RNA (mRNA) vaccines approved under Emergency Use Authorisation (EUA).

   Authorisation under Regulation 174 was for specific batches of vaccine at the start of the vaccine rollout programme. This has since been superseded by the marketing authorisations granted for the Pfizer vaccine (Comirnaty) and the AstraZeneca vaccine (Vaxzevria).

   Many different factors are considered when assessing the benefit risk balance of a medicinal product and include the number of people who have received the product, the seriousness of the disease being treated, the availability and effectiveness of other treatments, the seriousness and frequency of the adverse reactions(s) and the indication and efficacy of the product. The MHRA's continuous evaluation of the safety of the COVID-19 vaccines authorised in the UK supports our position that the benefits continue to outweigh the known risks for the vast majority of people.

2. Please provide copies of MHRA's Safety Audits since the rollout of COVID-19 mRNA vaccines approved under Emergency Use Authorisation.

   Information not held. The MHRA has a statutory obligation under the Human Medicines Regulations to audit its pharmacovigilance system every two years. During COVID-19, some elements of the audit programme were rescheduled using a controlled approach to ensure that resources were fully focused on signal detection and assessment. The systems used for signal detection have been subject to many previous internal and external audits with no significant findings and the approach was aligned to that taken by other international regulators

3. Please provide your updated Age Stratification Risk/Benefit Profile of COVID-19 mRNA vaccines approved under Emergency Use Authorisation.

   Information not held.

   The benefit-risk for the original authorisation of the vaccines under Regulation 174 is available in the Public Assessment Reports that were published. Our ongoing review supports the position that benefits outweigh known risks for all age groups in which vaccines are authorised.

4. Please provide your risk assessment of widely applied vaccination during a respiratory virus pandemic using an imperfect vaccine that does not disrupt transmission or infection.

   We hold no information specifically for a “widely applied vaccination during a respiratory virus pandemic using an imperfect vaccine that does not disrupt transmission or infection” and it is not a regulatory requirement to do so.

   We have provided our full assessment of all authorised vaccines, as have the European Medicines Agency, who have also published the clinical data submitted in their clinical repository.

5. Please provide a copy of the Genotoxicity studies performed on the mRNA COVID-19 vaccines before their approval and rollout.

   Please see page 20 of the below-linked PAR for the Pfizer vaccine. It states that “no genotoxicity studies are planned for BNT162b2, as the components of all vaccine constructs are lipids and RNA that are not expected to have genotoxic potential (WHO, 2005).”

   https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1112667/COVID-19_mRNA_Vaccine_BNT162b2__UKPAR___PFIZER_BIONTECH_ext_of_indication_11.6.2021.pdf

   Please see page 19 of the below-linked PAR for the AZ vaccine that states “no genotoxicity studies were performed.”

   https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1144485/CMA_UKPAR_COVID_19_Vaccine_AstraZeneca_PAR_PAR_update_Annex_I.pdf

6. Please provide your risk assessment of frequent mRNA boosters for COVID-19 disease and adverse effects to the hosts immune system, including Endoplasmic Reticulum (ER) Stress and IGG4 Class Switching.

   Information not held - ongoing review supports position that benefits outweigh known risks.

7. Please confirm if any of the vaccines approved under Emergency Use Authorisation against COVID-19 instruct a person’s own body to repeatedly manufacture the spike protein. If so, for how long.

   These vaccines stimulates the body’s natural defences (immune system). It causes the body to produce its own protection (antibodies) against the virus. This will help to protect an individual against COVID-19 in the future. This is no different to other immune reactions that occur.

8. Please confirm if MHRA have a Vaccine Crisis Communication Manual in the event of an untoward medical occurrence following immunisation against COVID-19, and as a result could potentially create uncertainty and/or erode the public's trust in vaccines and/or vaccination and the authorities delivering them.

   Information not held.

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

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