FOI 23/476

Dear

Thank you for your request of 24 June under the Freedom of Information Act (FOIA), we apologise for the delay in response. You requested:

1. *The MHRA has stated that this vaccine was approved "after meeting the MHRA's required safety, quality and effectiveness standards". Yet your own guidance document makes clear that there is no efficacy data, and minimal safety data for this vaccine. So what exactly are the required safety, quality and effectiveness standards?*

2. *As the vaccine is primarily intended for people previously unvaccinated why did you authorise its use for a country like the UK that is highly vaccinated? (see https://wherearethenumbers.substack.com/p/the-new-skycovion-vaccine-more-questions for details)*

3. *Are you dispensing the vaccine to already vaccinated people in the UK? if so what studies have been performed to show that it is safe and effective to be used in people previously vaccinated with AstraZeneca, Pfizer, Moderna and other vaccine combinations.*

4. *As the vaccine is licensed to over 18's, and appears to be not recommended to women who are pregnant or breast feeding, what information do you have about the effect of the vaccine on women who become pregnant some time after vaccination?*

5. *What information do you have about the impact on sperm count of men who receive this vaccine?*

6. *What studies have been performed on the sensitivity to safety and efficacy of the different dose accuracies that will inevitably result from the complex mixing process?*

7. *Did the change of role of the MHRA from regulator to enabler impact your decision to authorise this vaccine?*

Please find below our responses to each of your requests, included beneath each of your original questions.

1. The MHRA has stated that this vaccine was approved "after meeting the MHRA's required safety, quality and effectiveness standards". Yet your own guidance document makes clear that there is no efficacy data, and minimal safety data for this vaccine. So what exactly are the required safety, quality and effectiveness standards?

The Public Assessment Report (PAR) for SKYCovion suspension and emulsion for emulsion for injection, COVID-19 vaccine (PLGB 33611/0029) will be published soon. This will include the non-confidential aspects of the MHRA assessment of this

vaccine (including our assessment of the benefit/risk, and evaluation of “safety, quality and effectiveness”). Given the upcoming publication we are exempting the release of the information you have requested under Section 22 of the FOIA (information intended for future publication). Section 22 is a qualified exemption and as such we have considered the public interest in releasing information in advance of publication. However, given that we expect publication soon and that information is available within the Summary of Product Characteristics (SmPC) and Patient Information Leaflet (PIL), available on our website, we do not consider there is any public interest in releasing the information you have requested before the PAR is published.

You may wish to note that there is general guidance on the evaluation of new COVID vaccines which is published by the European Medicines Agency (EMA) and can be located at the links below:

https://www.ema.europa.eu/en/clinical-evaluation-new-vaccines-scientific-guideline
https://www.ema.europa.eu/en/ema-considerations-covid-19-vaccine-approval-scientific-guideline

2. As the vaccine is primarily intended for people previously unvaccinated why did you authorise its use for a country like the UK that is highly vaccinated? (see https://wherearethenumbers.substack.com/p/the-new-skycovion-vaccine-more-questions for details)

New vaccines are authorised by MHRA on the basis of a positive benefit/risk after assessment of the data submitted by the marketing authorisation holder. We do not authorise vaccines based on the numbers of vaccinated or unvaccinated persons in the UK population. It should also be considered that authorisation of a new vaccine can help members of the public who have been unable to receive a vaccine so far for individual reasons (for example, an allergy to any of the ingredients in any of the currently authorised vaccines).

You may wish to note that the Joint Committee on Vaccination and Immunisation (JCVI) takes decisions on the choices of vaccines used in immunisation campaigns. Further information can be found on their website: https://www.gov.uk/government/groups/joint-committee-on-vaccination-and-immunisation

3. Are you dispensing the vaccine to already vaccinated people in the UK? if so what studies have been performed to show that it is safe and effective to be used in people previously vaccinated with AstraZeneca, Pfizer, Moderna and other vaccine combinations.

MHRA is not involved in the dispensing of vaccine to the UK public. Information about the approved indications can be found in the SmPC (linked to above) and further information about the assessment can be found in the PAR, please refer to our reply to Q1, above.

4. As the vaccine is licensed to over 18's, and appears to be not recommended to women who are pregnant or breast feeding, what information do you have about the effect of the vaccine on women who become pregnant some time after vaccination?

Please see sections 4.6 and 5.3 of the SmPC for further information on use in pregnant women and the studies performed to determine its safety with regards to reproductive toxicity.

5. What information do you have about the impact on sperm count of men who receive this vaccine?

Please see the answer to Q4, above.

6. What studies have been performed on the sensitivity to safety and efficacy of the different dose accuracies that will inevitably result from the complex mixing process?

Please see the answer to Q1, above.

7. Did the change of role of the MHRA from regulator to enabler impact your decision to authorise this vaccine?

New vaccines are authorised by MHRA on the basis of a positive benefit/risk after assessment of the data submitted by the marketing authorisation holder. As referred to in Q1, information about our assessment will be made available in the PAR shortly.

If you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date you receive this response and addressed to: info@mhra.gov.uk
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
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Yours sincerely
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