## FOI 23/829

Thank you for your request for information dated 30 October 2023, where you asked:

"Who must test each mRNA COVID -19 batche [sic] before they are released if MHRA has not full list of the ingredients?

If you have the full list of the ingredients in pfizer and Monterna mRNA COVID -19 vaccines please share."

## Our response:

The batches of mRNA COVID-19 vaccines for Pfizer and Moderna are tested by the company before they are released; the batches are then also tested by MHRA (formerly NIBSC, note the website is due to be updated).

## NIBSC - Independent batch release testing at the NIBSC

In terms of the full list of ingredients. MHRA holds the information you have requested. However, as the information held by the MHRA is in the public domain we will, under section 21 of the FOIA (information accessible to the applicant by other means), refer you to the published source.

The active substance, and excipients for each vaccine are present on the MHRA products website, please refer to the patient information leaflet, or Sections 2, and 6.1 of the Summary of Product Characteristics SmPC. Companies must disclose the active substance/s and all excipients as is detailed in the Human Medicines Regulations 2012.

Regulatory approval of Pfizer/BioNTech vaccine for COVID-19 - GOV.UK (www.gov.uk)

Regulatory approval of Spikevax (formerly COVID-19 Vaccine Moderna) - GOV.UK (www.gov.uk)

## Your right to seek a review

If you disagree with how we have interpreted the Freedom of Information Act 2000 in answering your request, you can ask us to review our actions and decisions by writing to: info@mhra.gov.uk, and requesting an internal review.

Please note that your internal review request must be in a recordable format (email, letter, audio tape etc.), and that you have 40 working days upon receipt of this letter to ask for a review. We aim to provide a full response to your review request within 20 working days of its receipt. Please quote

the reference number above in any future communications.

If you are not content 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: <a href="https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/">https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/</a>

Or in writing to: Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF

Yours sincerely,

**HQA FOI Team**