FOI 23/851

Dear

Many thanks for your request for information, dated 05 November 2023, where you asked:

> *I would like to know, what TRULY independent testing of production vaccines with certifiable custody chain has MHRA or the EMA done on these 'mRNA EUA vaccines'? So, I ask again, can you categorically confirm that the Pfizer mRNA Covid-19 vaccine in use/past use in the UK does NOT contain the SV40 large T antigen?*

Our response:
Simian vacuolating virus 40 (SV40) is a virus present in monkey kidney cells. We are not aware of any Covid-19 vaccine containing SV40 virus or SV40 antigens. A short sequence of the nucleic acid from the SV40 virus is present in the Pfizer/BioNTech Covid-19 vaccine, but this is not the sequence coding for the SV40 large T antigen (see Figure 1 of 'BNT162b vaccines protect rhesus macaques from SARS-CoV-2' : https://www.nature.com/articles/s41586-021-03275-y) and therefore the vaccine cannot direct the synthesis of that antigen.

Biological medicines (such as vaccines, monoclonal antibodies used to treat cancers and immunological diseases, certain clotting factors used to treat haemophilia, etc) utilise living cells in their manufacturing process and all cells contain DNA. Since no purification process is 100% effective, and since modern analytical methods are extremely sensitive, it is known that there will be low levels of DNA impurities in these medicines. There are international guidelines on the acceptable levels of DNA in such products. Covid-19 vaccines have purity specifications and all batches must pass these specifications before they can be released. All released batches of the Pfizer/BioNTech Covid-19 vaccines have passed their specifications.

As previously described in our response to FOI 23/743, Independent laboratory testing of vaccines is carried out by the National Institute for Biological Standards and Control (NIBSC). Batches of vaccine that meet the specifications in the approval are certificated, allowing the manufacturer to market them in the UK for use before the batch expiry date.

All vaccine manufacturers must operate to Good Manufacturing Practices and their facilities are licensed, and are inspected periodically.

We now consider this request to be closed. If you are unhappy with our decision, you may ask for it to be reviewed. That review will be undertaken by a senior member of the Agency who has not previously been involved in your request. If you wish to pursue that option please email: info@mhra.gov.uk

After that, if you remain dissatisfied, you may write to the Information Commissioner at;
The Information Commissioner's Office Wycliffe House Water Lane
Wilmslow Cheshire SK9 5AF