FOI 23/918

Dear

Thank you for your request for information, dated 27 November 2023, where you requested the following:

> *I note from your web site that your organisation is responsible for ensuring quality standards for each batch of Covid vaccines, prior to deployment.*
>
> *"As is the case for current, licensed vaccines, the quality of each batch of any potential COVID-19 vaccine will be evaluated by an independent laboratory. The independent laboratory will also carry out a thorough review of the manufacturer batch documentation that describes the production process and quality control testing performed by the company"*
>
> *In view of the many concerns about potential contamination / adulteration of Covid 19 vaccines can you please provide the following information:-*
> *1) A description of the procedures and processes that are in place to ensure compliance with the above commitment.*
> *2) How many physical quality tests have actually been completed since the introduction of the Covid 19 vaccines.*
> *3) Can you provide confirmation that such tests have been applied to all Covid 19 vaccine batches prior to deployment into the public domain.*
> *4) Can you confirm that these quality tests are capable of detecting any unwanted genetic material either plasmid or chromasomal , along with any other nanoparticles that are not specified by the manufacturer.*

Please find our response beneath each of your questions below.

1) A description of the procedures and processes that are in place to ensure compliance with the above commitment.
Independent laboratory testing of vaccines is carried out by the MHRA's Official Medicines Control Laboratory (OMCL). The independent testing assesses key parameters that focus on biological quality of the product, such as Potency/sequence ratio, identity, RNA encapsulation, RNA content, RNA integrity, for example. Independent assessment also confirms that the manufacturer has reported on its wide-ranging tests on the product. 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.

Please see the link below for further information on the independent batch release testing process:
NIBSC - Independent batch release testing at the NIBSC

Please also note, all vaccine manufacturers must operate to Good Manufacturing Practices and their facilities are licensed, and are inspected periodically.

2) How many physical quality tests have actually been completed since the introduction of the Covid 19 vaccines.

The MHRA's OMCL undertake a series of specific laboratory tests on sample vials from batches of COVID vaccines. A certificate is applied to those batches that meet the specifications in the product authorisation. This certificate is required by the authorisation holder (the manufacturer / company) before the batch can be released onto the market for use. Over 360 compliant batches across all COVID-19 vaccines authorised for use in the UK have been certificated since December 2020. Typically, between 3 and 5 tests are applied to each batch, depending on the product.

3) Can you provide confirmation that such tests have been applied to all Covid 19 vaccine batches prior to deployment into the public domain.
As described above, the MHRA's OMCL undertake a series of specific laboratory tests on sample vials from batches of COVID vaccines. A certificate is applied to those batches that meet the specifications in the product authorisation. This certificate is required by the authorisation holder (the manufacturer / company) before the batch can be released onto the market for use.

4) Can you confirm that these quality tests are capable of detecting any unwanted genetic material either plasmid or chromasomal , along with any other nanoparticles that are not specified by the manufacturer.
In addition to the manufacturer's full battery of batch release tests, the MHRA undertakes a series of specific laboratory tests on sample vials from batches of COVID vaccines. Our lab-based tests do not include tests for residual plasmid DNA or chromosomal DNA.

We hope that you find the above information useful. We now consider this request 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

They will make a decision on whether or not we have interpreted the FOIA correctly in handling your request.

Yours sincerely,
FOI Team