FW: FOI 24/212 DNA contamination present in the mRNA COVID vaccines, SV40 promoter sequence etc

FOILicensing <FOILicensing@mhra.gov.uk>
Thu 28/03/2024 14:46
To:MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>
Cc [redacted]

[redacted]

I've checked and it's now populated on the WDTK request thread:

https://www.whatdotheyknow.com/request/test_data_and_results_for_each_b#incoming-2019280

[redacted]

From: FOILicensing <FOILicensing@mhra.gov.uk>
Sent: Thursday, March 28, 2024 2:35 PM
To: request-818888-00b85afa@whatdotheyknow.com
Subject: RE: FOI 24/212 DNA contamination present in the mRNA COVID vaccines, SV40 promoter sequence etc

Dear Lee Proctor

Regarding your email of 27 February 2024, please see below our response to your questions concerning the Pfizer vaccine (Comirnaty).

1) *Is the MHRA aware of DNA contamination present in the mRNA COVID vaccines?*

Our response:

We are not aware of DNA contamination in the mRNA COVID-19 vaccines, contamination as a term tends to relate to external material. Residual DNA which is considered as a process-related impurity is tightly controlled in all authorised Pfizer vaccines (Comirnaty). The purification and quality control process ensures that leftover DNA is within acceptable regulatory limits.

2) *Is the MHRA aware of the SV40 promoter sequence being present as a contaminant?*

Our response:

No safety concerns related to residual DNA in the vaccine have been identified for any of the authorised vaccines

The Pfizer-BioNTech COVID-19 vaccine does not contain simian virus 40 (SV40). The presence of the SV40 promoter enhancer sequence is not the same as the presence of the whole virus itself. The SV40 promoter enhancer sequence was found to be a residual DNA fragment in Pfizer-BioNTech COVID-19 vaccine. The fragment is inactive, has no functional role, and was measured to be consistently below the limit required by regulators.

3) *Is the MHRA aware the DNA is protected within the LNPs and as such will transfect human cells?*

Our response: see below

4) *Is the MHRA aware of the potential risk that contaminated DNA transfected into cells is a potential factor for promotion of cancer and genome integration?*

Our response to questions 3 and 4:

We are aware that the residual DNA is could potentially be encapsulated within the LNPs, however, we do not agree that residual DNA in the LNPs will transfect human cells.

We are also not aware of any scientific evidence showing that the small amounts of residual DNA that may be present in the vaccine, could transfect into cells and integrate into the DNA of a vaccinated person. We are not aware of any scientific evidence showing that the small amounts of residual DNA that may be present in the vaccine could be a potential factor for cancer promotion."

Advice and assistance

The request that you have made is a series of questions seeking the MHRA's view rather than requests for recorded information. While we have responded on this occasion you may wish to view the ICO's guidance on making effective requests.

https://ico.org.uk/for-the-public/official-information/

Yours sincerely,

HQA FOI Team

Appeal rights

We trust that you will understand this position and the response. However, 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: https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/

Or in writing to:

Information Commissioner's Office,

Wycliffe House,

Water Lane,

Wilmslow,

Cheshire,

SK9 5AF