Medicines & Healthcare products Regulatory Agency

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[redacted]

28 November 2023

Dear [redacted]

Thank you for your request for information dated 31 October 2023. We have provided our answers beneath each of your questions, as listed below.

1. **So health Canada have found traces of SV40 in Covid19 Vaccines Vials unknowingly to health Canada before the authorisation was given the pharmaceutical hid this from them which was Fraudulent by Pharmaceutical companies it not first this has happen by Pharmaceutical companies Pfizer is worst Offender they admit to fraud before in court was MHRA aware of this also before it was give EUA and full Authorisations please give answers without useing fact Checkers MHRA should no this**

Our response:

SV40 stands for Simian Virus 40. It is a naturally occurring virus and the virus itself is not included in either starting material, plasmid DNA, or in the finished product of the Pfizer-BioNTech COVID-19 vaccine. However, specific, non-infectious parts of the SV40 sequence, called promoters and terminators, are commonly used in the pharmaceutical industry. It is important to distinguish between the entire SV40 virus sequence and the non-infectious SV40 sequence parts. These non-infectious SV40 sequence parts present in starting material used by Pfizer and BioNTech do not contain oncogenes which are genes that may have the potential to cause cancer. The MHRA does not hold any reports that indicate that the Pfizer/BioNTech Covid-19 vaccine induces DNA mutations or cancers.

2. **with Plasmid DNA used in Covid19 Vaccines and Pfizer and both modern both admitted it Gene therapies technology used considered by FDA do now MHRA admit Pfizer and Moderna Covid19 Vaccines are considered Gene Therapy Products**

Our response:

A gene therapy product contains genes that treat, prevent or diagnose a disease. They work by inserting 'recombinant' genes into the body, usually to treat a variety of diseases, including genetic disorders, cancer or long-term diseases. A recombinant gene is a stretch of DNA that is created in the laboratory, bringing together DNA from different sources.

The full legal definition of a gene therapy product is provided in the Human Medicines Regulation 2012, as amended:

[2A Definition of advanced therapy medicinal product etc]

[(1) In these Regulations, in their application to products for sale or supply in Great Britain only, "advanced therapy medicinal product" means any of the following products—

(a) a gene therapy medicinal product;

(b) a somatic cell therapy medicinal product; or

(c) a tissue engineered product.

(2) A "gene therapy medicinal product" is a biological medicinal product which has the following characteristics—

(a) it contains an active substance which contains or consists of a recombinant nucleic acid used in or administered to human beings with a view to regulating, repairing, replacing, adding or deleting a genetic sequence; and

(b) its therapeutic, prophylactic or diagnostic effect relates directly to the recombinant nucleic acid sequence it contains, or to the product of genetic expression of this sequence.

(3) A vaccine against infectious diseases is not to be treated as a gene therapy medicinal product. [bold formatting added for emphasis]

By this definition, the Covid-19 vaccines are not gene therapy products.

3. **Does the MHRA and NHS hold any Conflict of interest in Gene Therapy products/research in Gene Therapy companies in which why you working together to debunk Covid19 Vaccines which people consider Gene Therapy product is because MHRA have invested interest in them and technology**

Our response:

The MHRA staff are not permitted to hold any interest in any pharmaceutical company, which includes gene therapy companies. Please see our Conflict of Interest Policy below:

https://assets.publishing.service.gov.uk/media/6544ca771f1a600010360d51/Corporate-Conflicts-of-Interest-Policy-Procedure.pdf

4. **have only the MHRA independently checked in laboratory settings tested Moderna and Pfizer Covid19 Vaccines Vials to see if the ingredients which both manufacturers say are in they viles [sic] that post be they no Contamination ingredients like Plasmid DNA or SV40 DNA is in they vaccines**

Our response:

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. This does not include tests for residual plasmid DNA or SV40 sequences in mRNA 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.

Please see the link below for further information on the independent batch release testing process:
Independent batch release testing of COVID-19 (coronavirus) vaccines by the NIBSC - GOV.UK (www.gov.uk)

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

5. **with Graphine oxide and in Pfizer Covid19 Vaccines and even Pfizer own Covid19 Vaccines data says Reduced Graphine oxide is in they Covid19 Vaccines Vials do MHRA finally going to admit GO is in Pfizer Vaccines Pfizer document which confirms GO in they Covid19 Vaccines I'll also highlight it in picture provided**

Our response:
All of the ingredients of the Pfizer-BioNTech COVID-19 vaccines can be found in the Summaries of Product Characteristics and Patient Information Leaflets at the following link:
https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19

The Pfizer-BioNTech COVID-19 vaccines do not contain graphene oxide.

6. **how much does it take to take MHRA to take pharmaceutical products off market for being unsafe for Human Use what steps How many deaths and Injuries does it take**
   1 in 800
   1 in 10.000
   1 in 100 000
   In Adverse Reactions

Our response:

We do not hold the information requested as the MHRA does not have a threshold for the number of suspected Adverse Drug Reaction (ADR) reports required to take specific regulatory actions, such as revoking a marketing authorisation. Our signal detection processes focus on highlighting drug event combinations of concern based on a combination of statistical disproportionality and a rule-based approach. These drug event combinations are assessed by a group of scientists, physicians and pharmacists to determine if risk-minimisation measures need to be implemented, taking into account other sources of information and independent expert opinion where appropriate.

It is important to note that an ADR report is not proof of a side effect occurring but a suspicion by the reporter that the drug may have caused the side effect. The fact that symptoms occur after a drug is given does not mean that they are caused by the drug itself as underlying or undiagnosed illnesses and other factors may be responsible.

Furthermore, the number of reports received via the Yellow Card Scheme does not directly equate to the number of people who suffer adverse reactions to drugs for a number of reasons. ADR reporting rates may be influenced by the seriousness of reactions, their ease of recognition, extent of use of a particular drug or vaccine and promotion and publicity about a drug or vaccine.

If you disagree with how we have interpreted the Freedom of Information Act 2000 in answering your request, you can ask for an internal review. Please reply to this email, within two months of this reply, specifying that you would like an Internal Review to be carried out. 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 online via an electronic form:
https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/

Or

by writing to:
Information Commissioner’s Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Yours sincerely
MHRA Customer Service Centre
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