Medicines & Healthcare products
Regulatory Agency

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[redacted]

8 November 2023

Dear [redacted]

FOI 23/767

Thank you for your request for information dated 11 October 2023. In this request you asked a number of questions which have been repeated below, our answers are provided beneath each question in italics.

"1) The tests to confirm if there is plasmid DNA genetic contamination in mRNA vaccines costs a few pounds and a couple of hours to perform. How often has anyone associated with or employed by the MHRA carried out these tests, when did this occur and what were the results?"

In addition to the manufacturer's full battery of batch release tests, the National Institute for Biological Standards and Control (NIBSC), which is the UK's Official Medicines Control Laboratory at the MHRA, undertakes a series of specific laboratory tests on sample vials from batches of COVID vaccines. This does not include tests for plasmid DNA or SV40 sequences in mRNA vaccines.

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.

“2) Similarly with SV40 fragments in Pfizer mRNA vaccines, how often has anyone associated with or employed by the MHRA tested for the presence of these or other contaminants, when did this occur and what were the results?”

See above.

“3) As the Pharmacovigilance Team responsible for ensuring patient safety, please let me know how long the vaccine components (LNPs etc) and derivatives (spike protein etc) stay detectable in the human bloodstream and organs? We know from autopsies that they are detectable for months after injection. How long before they are no longer detectable?”

The MHRA does not hold information in relation to the length of time the LNPs and Spike proteins remain detectable in the human bloodstream, and this information was not required for authorisation. The public assessment reports for the COVID-19 vaccines explain the information and data provided to support these authorisations.

“4) How long after maternal injection are the vaccine components and derivatives still detectable in foetal blood, placental blood, maternal milk or in the baby's blood? Have these studies been done and, if so, when?”

Observational data tend to be catered toward monitoring adverse pregnancy outcomes rather than studying specific ingredients/components. For example, in relation to Comirnaty 30 micrograms/dose dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified):

> “A large amount of observational data from pregnant women vaccinated with Comirnaty during the second and third trimester have not shown an increase in adverse pregnancy outcomes. While data on pregnancy outcomes following vaccination during the first trimester are presently limited, no increased risk for miscarriage has been seen. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryo/foetal development, parturition or post-natal development. Comirnaty can be used during pregnancy”
>
> “No effects on the breastfed newborn/infant are anticipated since the systemic exposure of breast-feeding woman to Comirnaty is negligible. Observational data from women who were breast-feeding after vaccination have not shown a risk for adverse effects in breastfed newborns/infants. Comirnaty can be used during breast-feeding.”

However, research groups may conduct studies with a narrower focus, for example, in relation to the detection of vaccine components and derivatives in the ‘foetal blood, placental blood, maternal milk or in the baby's blood’. MHRA do not hold literature (information) in relation to these specific topics.

“5) Does cell division still occur in human cells which contain non-self genetic material (such as modified RNA, bacterial plasmid DNA and / or simian viral DNA or RNA)? If so, is it the case that parts of the non-self genetic material can be incorporated into the human DNA?” “Have such studies on modification of human DNA (for example, in liver cells and in reproductive cells) been done in relation

specifically to the mRNA vaccine components, derivatives and / or contaminants and, if so, when, by whom and what are the results? If not, when do you intend to carry out these tests?"

> *As regard to RNA molecules: target cells them take up, translate these to proteins inside the cytoplasm, and then, the protein viral antigen is expressed on the cell surface. It is not expected that the delivered mRNA enters the cell nucleus or interacts with the genome. mRNA molecules are non-replicating and are only expressed transiently in cells. No risk of insertional mutagenesis is considered for the modRNA moiety (specific part of the vaccine that is primarily responsible for its action), and there is no evidence that mRNA from COVID--19 vaccines causes adverse effects through interaction with DNA.*

If you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date you receive this response and addressed to: info@mhra.gov.uk

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 at:

Information Commissioner's Office
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Yours sincerely
HQ&A FOI Team