Medicines & Healthcare products
Regulatory Agency

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Dr Rosamond Jones, MBBS, MD, FRCPCH
On behalf of the North group
By email: NORTHunitedkingdom@proton.me

Reference: CEC 205981, CEO 20195

22 May 2025

Dear Dr Jones,

Concerns over DNA contamination of the Covid-19 vaccines

Thank you for your correspondence of 25 November 2024 and 13 January 2025 where on behalf of the North group you outlined concerns surrounding the Pfizer/BioNTech Covid-19 vaccine. We have also noted that a Lay Summary document was appended to your letter of 25 November 2024. We have addressed the questions raised within your letters that are within the remit of the MHRA.

We will address your concerns following the order that your concerns were raised in your correspondence.

Set up of an independent and transparent public and forensic inquiry
The COVID-19 inquiry will independently review the UK response to the Covid-19 pandemic. Module 4 of the Inquiry alongside a number of other topics will consider “The development, procurement, manufacture and approval of vaccines during the pandemic, including the effectiveness of UK-wide decision-making, in particular, the role of the UK Vaccine Taskforce [...]” as well as “Vaccine safety issues including post marketing surveillance, such as the Yellow Card monitoring and reporting system and a suggested correlation between Covid-19 vaccines and cardiovascular issues”

Initiating and prioritising research
This query is within the remit of the Department of Health and Social Care who can be contacted at dhsc.publicenquiries@dhsc.gov.uk.

Request to appraise new scientific evidence - student research project
We cannot confirm the validity of the study performed. However, it is important to note that all the Covid-19 vaccines released in the UK to date have passed their release specifications for DNA levels. The specifications are set in line with, and in accordance to, their respective

controlled manufacturing process, as well as the WHO guidance on the quality, safety and efficacy of vaccines. The purification and quality control process ensures that any residual DNA is within acceptable regulatory limits.

In the study you have cited, the authors put forward the following conclusion: "It is conceivable that testing more commercial mRNA vaccines will build public trust and accumulate data to enable setting a statistically confident limit for pDNA". A report linked below from the Therapeutic Goods Administration (TGA) provides scientific evidence confirming that residual DNA and endotoxin levels meet internationally agreed limits. We hope that your group finds these results to be reassuring.
https://www.tga.gov.au/resources/publication/tga-laboratory-testing-reports/summary-report-residual-dna-and-endotoxin-covid-19-mrna-vaccines-conducted-tga-laboratories

Request to appraise new scientific evidence - raw data files from a peer reviewed publication
The reference provided is on a pre-print server. However, there is no mention of any University, other academic affiliation, or the author's qualifications. We cannot comment on the credibility of the pre-print paper.

Any potential DNA present (if found in the vaccine) has been quality control tested and met the required specifications prior to release.

Evidence demonstrating no risk of harm
The mRNA Covid-19 vaccines authorised for use in the UK, such as the Pfizer/BioNTech and Moderna vaccines, work by delivering a small piece of genetic material called messenger RNA (mRNA) into the muscle cells.

There is no strong scientific evidence that there is i) any residual DNA (beyond the acceptable level), and ii) that any residual DNA below the acceptable level could transfect into cells and integrate into the DNA of a vaccinated person. Similarly, the MHRA is also not aware of any scientific consensus that the small amounts of residual DNA could be a potential factor for cancer promotion.

SV40
The Pfizer-BioNTech Covid-19 vaccine does *not* contain simian virus 40 (SV40).

It is important to distinguish between the entire SV40 virus sequence and the non-infectious SV40 sequence parts. Specific, non-infectious parts of the SV40 sequence, called promoters and terminators, are commonly used in the pharmaceutical industry. No safety concerns related to residual DNA in the vaccine have been identified for any of the authorised vaccines.

I hope this response addresses the questions set out in your recent correspondence.

Yours sincerely,

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