



Senator GERARD RENNICK

Senator for Queensland

Blair Comley PSM, Secretary of the Department of Health and Aged Care
G.P.O. Box 9848
CANBERRA A.C.T. 2601

11th February 2025

Dear Secretary,

I request that the below information be tabled ahead of the 2024–25 additional budget estimates beginning on Monday, 24th February 2025, to ensure that the Department's responses can be discussed on the day.

May this advance notice be sufficient to allow me to perform my responsibilities on behalf of Queenslanders and the Department the ability to be adequately prepared for my questioning.

Please provide the following documents in relation to the product "Nuvaxovid" assessed in the Therapeutic Goods Administration's Australian Public Assessment Reports documented at <https://www.tga.gov.au/sites/default/files/auspar-sars-cov-2-rs-matrix-m-adjutant.pdf>

1. The TGA non-clinical evaluation report for this product (redactions should be severely limited to only phrases that are specifically required to protect proprietary information that is not in the public domain).
2. The batch assessment reports, in full, for the following batches: 4302MF021, 4302MF011, 4301MF005, 4301MF004. The reports should specifically include an assessment of DNA and/or plasmid levels in the product which should not be redacted.
3. The SOP (standard operating procedure or lab protocol) for the analysis of the batch assessment reports for the analyses specified in (2) and required by the TGA of the laboratory conducting the batch assessments.
4. If not specified in (3) please list the genomic sequence of the PCR primers specified to be used for the quantification by qPCR of residual plasmid in the batch assessment reports specified in (2).
5. If the PCR primers are not available or not able to be disclosed, please provide the plasmid map supplied by the sponsor to the TGA which was required by the TGA to conduct the batch assessment report to exclude plasmid contamination of the product.

Duplicates are not required.

Because this information is of public interest and in the interests of demonstrating transparency, I request that redactions are kept to an absolute minimum and each individual redaction, should it be required, is explained in full. Should redactions be claimed for proprietary information these should not include claims of secrecy in relation to the genomic sequence of the Nuvaxovid plasmid which is published in full or part at <https://www.ncbi.nlm.nih.gov/nucore/MX473672.1>

Providing this information at least three business days prior to the beginning of estimates will provide me the time to examine the documentation. Please acknowledge receipt of this request. Please do not hesitate to contact the Senate Standing Committee on Community Affairs if you require clarification.

Regards,

Gerard Rennick
Senator for Queensland