FOI 26-2651
The scope of the request is as follows:

'..For this request, "Matrix-M / Matrix-M1" includes any reference to the Quillaja saponin adjuvant used with Nuvaxovid, including "Matrix-M adjuvant", "Matrix-M1", "Quillaja saponaria", "Quillaja saponins", "saponin" or "saponin fractions".

(1) All final and near-final draft versions of the Australian Public Assessment Report (AusPAR) for Nuvaxovid (SARS-CoV-2 rS vaccine with Matrix-M adjuvant) that were circulated internally for review, clearance, or approval, including tracked-changes versions and attached clearance comments, within the above date range.

This request includes drafts circulated to senior decision-makers or communications/publication areas, but does not seek purely administrative formatting drafts.

(2) All internal communications and evaluation records that set out or discuss the rationale for not requiring an in vivo genotoxicity study for Matrix-M / Matrix-M1 in relation to Nuvaxovid, including any documents that discuss or support statements to the effect that:

"No in vivo genotoxicity study was performed/required; this was considered acceptable due to negative in vitro genotoxicity results and/or the plant-derived nature and/or food-additive history of Quillaja saponins."

This includes (but is not limited to): internal emails, meeting notes or minutes, briefing notes, evaluation commentaries, records of decision or decision rationales.

Personal identifiers may be redacted. Where present, please retain position title and business area.

(3) All internal memoranda, briefing notes, meeting summaries, or evaluation commentaries generated by TGA officers within the date range that discuss whether Matrix-M / Matrix-M1 should be assessed under regulatory principles analogous to delivery systems, including (but not limited to) frameworks applied to: gene therapy vectors, lipid nanoparticles, biologic carrier or intracellular delivery systems, and including any recorded decision not to pursue such a classification or assessment approach.

This request is limited to documents containing substantive scientific or regulatory reasoning, and excludes purely administrative scheduling correspondence.'

The timeframe of this request is from 01/06/2021 to date 31/03/2022.

Schedule of Relevant Documents

Doc. No.	TRIM Folder Number	TRIM Document Number	Author	Addressee	Date	Description	Pages	Third Parties to be Consulted	Contact details of Third Parties	Relevant Sections of the FOI Request
1	E22-500848	D22-5062788, Specifically Revision 9 – please be sure to redact names although may wish to confirm comments are from "the Delegate".	TGA	TGA	19/01/2022	DRAFT AusPAR FINAL	100	Biocelect Pty Ltd		Part 1
2	2010/002390	D21-2247953	TGA s22(1)(a)(ii)	TGA	12 Jan 2022	Nonclinical evaluation report (TGA copy)	94	Biocelect Pty Ltd	Biocelect Pty Ltd.	2
3	E21-227411	D22-5005720	TGA s22(1)(a)(ii)	TGA	3 Jan 2022	Nonclinical evaluation report (Sponsor copy)	94	Biocelect Pty Ltd	As above	2

*The authors' names from the evaluation report will require redaction if this document is released to the FOI enquirer.
#Australian Office details as per website (www.biocelect.com).

ATTACHMENT A