Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

TGA response to NUVAXOVID JN.1 Pre-submission data package

s22

Document 1

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Document 1

Executive Summary

Biocelect Pty Ltd submitted two (2) data package sets, the first on 4 February and second on 17 February 2025, seeking feedback on new approaches implemented to the manufacture of Nuvaxovid JN.1 variant pre-filled syringe (PFS) to mitigate major quality issues raised in the application of the unregistered XBB.1.5 variant. The TGA agreed to provide a written response following the evaluation of these data in lieu of holding a pre-submission meeting. The major pending issues were:

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[redacted]

NOTE: ***It is important to be aware that as knowledge evolves over time, guidance from the TGA may become out of date or be superseded. For this reason, any guidance given by the TGA at this pre-submission assessment is considered nonbinding and is given without prejudice.***

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Department of Health, Disability and Ageing

Therapeutic Goods Administration

NUVAXOVID JN.1 [PM-2025-01693-1-2]

MODULE 3 – Assessment of Sponsor responses to TGA comments of pre-submission documents

Version 2.0, June 2025

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Document 2

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Document 2

Executive Summary

Biocelect Pty Ltd (on behalf of Novavax) submitted two (2) data package sets in February 2025, seeking feedback on new approaches implemented to the manufacture of NUVAXOVID JN.1 variant pre-filled syringe (PFS) to mitigate major quality issues raised in the application of the unregistered XBB.1.5 variant. The TGA provided a written response on 21 May 2025 following the evaluation of these data in lieu of holding a pre-submission meeting (TRIM: D25-1092009).

IMPORTANT NOTE: It was deemed difficult to provide specific advice about the approaches for the introduction of the NUVAXOVID JN.1 variant PFS as there were several data gaps in the pre-submission documents submitted in February 2025.

Following submission of documents for NUVAXOVID JN.1 variant PFS (PM-2025-01693-1-2) application for Milestone 2 acceptance for evaluation of the Category 1 application (pre-submission/filter stage), of which the data submitted were found ineffective from a Module 3 perspective, Biocelect Pty Ltd further submitted responses on 13 June 2025 to the outstanding issues previously raised by the TGA (TRIM: D25-2578731).

The responses submitted by Biocelect Pty Ltd were further assessed by Biomedicines Evaluation and Biotherapeutics Sections and concluded that the Sponsor has not sufficiently addressed and/or has not provided acceptable responses to the unresolved issues identified by the TGA (TRIM: D25-1092009).

Therefore, since the issues were not fully resolved, the submission remains ineffective from a Module 3 perspective.

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Therapeutic Goods Administration

NUVAXOVID JN.1 [PM-2025-01693-1-2]

MODULE 3 – Assessment of Sponsor responses to TGA comments of pre-submission documents

Version 3.0, July 2025

s22

Document 3

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Document 3

Executive Summary

Biocelect Pty Ltd (on behalf of Novavax) submitted two (2) data package sets in February 2025, seeking feedback on new approaches implemented to the manufacture of NUVAXOVID JN.1 variant pre-filled syringe (PFS) to mitigate major quality issues raised in the application of the unregistered XBB.1.5 variant. The TGA provided a written response on 21 May 2025 following the evaluation of these data in lieu of holding a pre-submission meeting (TRIM: D25-1092009).

IMPORTANT NOTE: It was deemed difficult to provide specific advice about the approaches for the introduction of the NUVAXOVID JN.1 variant PFS as there were several data gaps in the pre-submission documents submitted in February 2025.

Following submission of documents for NUVAXOVID JN.1 variant PFS (PM-2025-01693-1-2) application for Milestone 2 acceptance for evaluation of the Category 1 application (pre-submission/filter stage), of which the data submitted were found ineffective from a Module 3 perspective, Biocelect Pty Ltd further submitted responses on 13 June 2025 (TRIM: D25-2578731) to the outstanding issues previously raised by the TGA. These were assessed by the Biomedicines Evaluation and Biotherapeutics Sections as '*v2*' in the report (TRIM: D25-2708652) and concluded that the Sponsor has not sufficiently addressed and/or has not provided acceptable responses to the unresolved issues identified by the TGA.

However, the Sponsor noted that another response was previously sent to the TGA on 30 April 2025 to address the outstanding issues in Section 1.7.1 e005931 (0121-) - Response to TGA'S written feedback to pre-submission package received by Novavax on 19 Mar 2025. The Sponsor's responses submitted on 30 April 2025 and 13 June 2025 have been assessed together by Biomedicines Evaluation and Biotherapeutics Sections as '*v3*' in this report.

Since the issues were not fully resolved, the submission remains ineffective from a Module 3 perspective.

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From: Streamlined Submission
To: s22 [redacted]
Cc: s22 [redacted]; "Regulatory"; regulatorycorrespondence@novavax.com
Subject: RE: Stream 2 (E24-452789) - TGA Pre-submission meeting request: Nuvaxovid JN1 + PFS 2025 [SEC=OFFICIAL]
Date: Tuesday, 18 March 2025 7:53:10 AM
Attachments: image001.png
image003.png
image004.png
image005.png
TGA response to NUVAXOVID JN.1 Presubmission data package.pdf

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Dear s22 [redacted],

Please find the response from TGA as attached.

Feel free to reach out in case any clarification is required.

Kind regards
s22 [redacted]

From: Streamlined Submission <streamlinedsubmission@health.gov.au>
Sent: Monday, 3 March 2025 11:33 AM
To: s22 [redacted]@biocelect.com>; s22 [redacted]@biointelect.com>
Cc: s [redacted]@adriaus.com>; s22 [redacted]@biocelect.com>; s22 [redacted]@biocelect.com>; 'Regulatory' <Regulatory@biocelect.com>; regulatorycorrespondence@novavax.com
Subject: RE: Stream 2 (E24-452789) - TGA Pre-submission meeting request: Nuvaxovid JN1 + PFS 2025 [SEC=OFFICIAL]

Dear s22 [redacted]

I have heard back from the evaluation area, and we should expect a written response by 17 March 2025 at the latest.

Hope this helps.

Kind regards
s22 [redacted]

From: Streamlined Submission <streamlinedsubmission@health.gov.au>
Sent: Monday, 3 March 2025 10:34 AM
To: s22 [redacted]@biocelect.com>; s22 [redacted]@biointelect.com>
Cc: s22 [redacted]@adriaus.com>; s22 [redacted]@biocelect.com>; s22 [redacted]@biocelect.com>; Regulatory <Regulatory@biocelect.com>; regulatorycorrespondence@novavax.com
Subject: RE: Stream 2 (E24-452789) - TGA Pre-submission meeting request: Nuvaxovid JN1 + PFS 2025 [SEC=OFFICIAL]

Dear s22 ,

Thank you for your email, I have followed up with the evaluation area, awaiting response.

Please be assured I will keep you posted once further information is available.

Kind regards
s22

From: s22 @biocelect.com>
Sent: Friday, 28 February 2025 11:38 AM
To: Streamlined Submission <streamlinedsubmission@health.gov.au>; s22 @biointelect.com>
Cc: s22 @adriaus.com>; s22 @biocelect.com>; s22 @biocelect.com>; Regulatory <Regulatory@biocelect.com>; regulatorycorrespondence@novavax.com
Subject: RE: Stream 2 (E24-452789) - TGA Pre-submission meeting request: Nuvaxovid JN1 + PFS 2025 [SEC=OFFICIAL]

Dear s22

I am following up to see if you have an approximate date that I can pass onto our manufacturing partner of when a response to the submitted packages can be expected.

Please let me know if you require anything further from us.

Kind Regards,
s22
s22

Biocelect

Level 4, 143 Macquarie Street, Sydney NSW Australia 2000
Level 5, Wynn Williams House, 47 Hereford Street, Christchurch 8013, New Zealand

M s22 **T** s22 **E** s22 **@biocelect.com**
biocelect.com
Sydney | Christchurch


I acknowledge and pay my respects to the traditional owners and custodians on whose land I walk, work & live

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From: s22

Sent: Monday, 17 February 2025 11:42 AM

To: Streamlined Submission <streamlinedsubmission@health.gov.au>; s22 @biointelect.com>

Cc: s22 @adriaus.com>; s22 @biocelect.com>; s22 @biocelect.com>; Regulatory <Regulatory@biocelect.com>; regulatorycorrespondence@novavax.com

Subject: RE: Stream 2 (E24-452789) - TGA Pre-submission meeting request: Nuvaxovid JN1 + PFS 2025 [SEC=OFFICIAL]

Dear s22

Biocelect wished to advise you that we have uploaded the 2nd and final data package to GovTeams seeking feedback and alignment on the approach taken and data generated for resolution of the following CMC concerns, to be provided in the future JN.1 variant data package to apply for registration of the JN.1 variant DP in PFS.

It is noted that two additional topics for TGA feedback are also included in this Information Package, those being the Process Performance Qualification (PPQ) for drug substance (DS) and drug product (DP), and on container closure compatibility.

I have attached the cover letter which was included with the data package for your awareness as well as providing the topics and data included in the package in the table below:

Quality Topics and Related Data included in Information Package

Part 1 (provided on 4 Feb 2025)	**Part 2 (this submission)**
s22	

Please let me know if you have any questions or if we can assist in any way.

Kind Regards,

s22

s22 [redacted]

Biocelect

Level 4, 143 Macquarie Street, Sydney NSW Australia 2000
Level 5, Wynn Williams House, 47 Hereford Street, Christchurch 8013, New Zealand

M s22 [redacted] **T** s22 [redacted] **E** s22 [redacted] **@biocelect.com**
biocelect.com
Sydney | Christchurch

I acknowledge and pay my respects to the traditional owners and custodians on whose land I walk, work & live

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From: Streamlined Submission <streamlinedsubmission@health.gov.au>
Sent: Friday, 14 February 2025 12:00 PM
To: s22 [redacted] @biocelect.com>; s22 [redacted] @biointelect.com>
Cc: s [redacted] @adriaus.com>; s22 [redacted] @biocelect.com>; s22 [redacted] @biocelect.com>; Regulatory <Regulatory@biocelect.com>; regulatorycorrespondence@novavax.com
Subject: RE: Stream 2 (E24-452789) - TGA Pre-submission meeting request: Nuvaxovid JN1 + PFS 2025 [SEC=OFFICIAL]

Hi s22 [redacted]

Thank you for your email.

The Delegate is awaiting the second set of data to be able to provide any response.

Kind regards
s22 [redacted]

From: s22 [redacted] @biocelect.com>
Sent: Friday, 14 February 2025 11:55 AM
To: Streamlined Submission <streamlinedsubmission@health.gov.au>; s22 [redacted] @biointelect.com>
Cc: s22 [redacted] @adriaus.com>; s22 [redacted] @biocelect.com>; s22 [redacted] @biocelect.com>; Regulatory <Regulatory@biocelect.com>; regulatorycorrespondence@novavax.com

Subject: RE: Stream 2 (E24-452789) - TGA Pre-submission meeting request: Nuvaxovid JN1 + PFS 2025 [SEC=OFFICIAL]

Dear s22 and Streamlined Submissions,

I am following up with you to confirm our intent to submit the 2nd data package on Monday the 17th February.

If you have any questions or if we can assist in any way, please let me know.

Kind Regards,

s22
s22

Biocelect

Level 4, 143 Macquarie Street, Sydney NSW Australia 2000
Level 5, Wynn Williams House, 47 Hereford Street, Christchurch 8013, New Zealand

M s22 **T** s22 **E** s22 **@biocelect.com**
biocelect.com
Sydney | Christchurch

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From: s22
Sent: Tuesday, 4 February 2025 2:12 PM
To: Streamlined Submission <streamlinedsubmission@health.gov.au>; s22 @biointelect.com>
Cc: s22 @adriaus.com>; s22 @biocelect.com>; s22 @biocelect.com>; Regulatory <Regulatory@biocelect.com>; regulatorycorrespondence@novavax.com
Subject: RE: Stream 2 (E24-452789) - TGA Pre-submission meeting request: Nuvaxovid JN1 + PFS 2025 [SEC=OFFICIAL]

Dear s22

st

We have uploaded the 1 of 2 data packages as requested below to GovTeams seeking feedback and alignment on the approach taken and data generated for resolution of the following CMC concerns, to be provided in the future JN.1 variant data package to apply for registration of the JN.1 variant DP in PFS.

It is noted that the Information Package is being provided in two parts with Part 1 being provided with this letter and Part 2 to be provided by mid-February 2025.

I have attached the cover letter which was included with the data package for your awareness as well as providing the topics and data included in the package in the table below:

Quality Topics and Related Data included in Information Package	
Part 1 (provided on 4 Feb 2025)	**Part 2 (to be provided by mid-Feb 2025)**
s22	

Please let me know if you have any questions or if we can assist in any way.

Kind Regards,

s22

s22

Biocelect

Level 4, 143 Macquarie Street, Sydney NSW Australia 2000
Level 5, Wynn Williams House, 47 Hereford Street, Christchurch 8013, New Zealand

M s22 **T** s22 **E** s22 **@biocelect.com**

biocelect.com

Sydney | Christchurch

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From: Streamlined Submission <streamlinedsubmission@health.gov.au>
Sent: Friday, 10 January 2025 2:22 PM
To: s22 @biointelect.com>
Cc: s22 @biocelect.com>; s22 @adriaus.com>; s22 @biocelect.com>; s22 @biocelect.com>; Regulatory <Regulatory@biocelect.com>; regulatorycorrespondence@novavax.com
Subject: Stream 2 (E24-452789) - TGA Pre-submission meeting request: Nuvaxovid JN1 + PFS 2025 [SEC=OFFICIAL]

Dear s22 ,

Happy New Year,

Thank you for your email and the request. Please note the Module 3, Quality, Delegate has kindly agreed to provide a written response to the quality questions as below, upon receiving the related data.

Quality questions

s22

Kind regards
s22

From: s22 [redacted] @biointelect.com>
Sent: Monday, 23 December 2024 4:48 PM
To: Streamlined Submission <streamlinedsubmission@health.gov.au>
Cc: s22 [redacted] @biocelect.com>; s22 [redacted] @adriaus.com>; s22 [redacted] @biocelect.com>; s22 [redacted] @biocelect.com>; Regulatory <Regulatory@biocelect.com>; Regulatory Correspondence <regulatorycorrespondence@novavax.com>
Subject: TGA Pre-submission meeting request: Nuvaxovid JN1 + PFS 2025

Dear TGA,

Please find attached a TGA pre-submission meeting request on behalf of Biocelect and Novavax.

The requested target date is the 28th January 2025 or nearest possible date thereafter (except Mondays). We have requested a 9 am meeting time to allow both US and EU Novavax SMEs attendance.

Please find attached a meeting request form and background summary document. Novavax and Biocelect are committed to providing the required data to support the agenda, purpose, and questions ahead of the agreed meeting date.

We look forward to your earliest response.

Thanks and kind regards,
s22 [redacted]

s22 [redacted]
s22 [redacted]

Season's Greetings. The Biointelect team wishes you a Merry Christmas and a Happy New Year.

Please note the Biointelect office will be closed from the 25th December 2024 to the 3rd January 2025.

Happy holidays!

Level 4, 143 Macquarie Street, Sydney NSW Australia 2000
M s22 [redacted] **T** s22 [redacted] **E** s22 [redacted]@biointelect.com

biointelect.com Sydney | Melbourne

I acknowledge and pay my respects to the traditional owners and custodians on whose land I walk, work & live

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

TGA response to NUVAXOVID JN.1 Pre-submission data package

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Document 4

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Document 4

Executive Summary

Biocelect Pty Ltd submitted two (2) data package sets, the first on 4 February and second on 17 February 2025, seeking feedback on new approaches implemented to the manufacture of Nuvaxovid JN.1 variant pre-filled syringe (PFS) to mitigate major quality issues raised in the application of the unregistered XBB.1.5 variant. The TGA agreed to provide a written response following the evaluation of these data in lieu of holding a pre-submission meeting. The major pending issues were:

NOTE: ***It is important to be aware that as knowledge evolves over time, guidance from the TGA may become out of date or be superseded. For this reason, any guidance given by the TGA at this pre-submission assessment is considered nonbinding and is given without prejudice.***

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From: Streamlined Submission
To: s22 @biocelect.com; s22 @biointelect.com
Cc: Streamlined Submission
Subject: NUVAXOVID JN.1 - TGA/Biocelect discussion - Stream 2 [SEC=OFFICIAL]
Date: Tuesday, 15 April 2025 3:35:24 PM
Attachments: image001.png

Dear s22

Thank you for seeking clarification while preparing Biocelect's NUVAXOVID JN.1 submission. With respect to the questions raised after your call/meeting with s22, the following advice is provided,

- s22 /TGA would get back to Biocelect on appropriate application pathway:
  - *TGA advises that a Category 1 Type A (new chemical/biological entity) submission is appropriate. This will be a full fee submission – application fee $56.844 and evaluation fee $227,825.*
- No clinical data for JN.1 would be included but 4 CSRs as requested by TGA in feedback document would be included in the application to bridge JN1 reference standard to Wuhan (2019nCoV-**307**, 2019nCoV-**311**, 2019nCoV-**503**, 2019nCoV-**301**):
  - *Clinical (i.e. module 5) data is required for a Type A application. For further information please refer https://www.tga.gov.au/how-we-regulate/supply-therapeutic-good/supply-prescription-medicine/application-process-prescription-medicines and https://www.tga.gov.au/resources/guidance/understanding-fees-and-charges-prescription-medicine-applications.*
  - *Additionally, 4 CSRs are requested by TGA in feedback document to be included in the application to bridge JN1 reference standard to Wuhan (2019nCoV-**307**, 2019nCoV-**311**, 2019nCoV-**503**, 2019nCoV-**301**).*
- Biocelect noted intent to supply by September 2025, but TGA evaluation timelines would be dependent on quality of the dossier and application type
  - *Under the Category 1 Type A pathway a decision is made within the legislated 255 working days. Meaning if a submission is provided to the TGA today, 15 April 2025, and is considered effective, the milestone 2 notification letter will be provided on 31 May 2025. Evaluation of the dossier will commence, and the target milestone 7 date will be 15 May 2026. Unfortunately, the evaluation of the proposed data will not align with Biocelect intention to supply by September 2025.*

Please include streamlinedsubmission@health.gov.au in all communications related to category 1 applications, as Case Managers remain the contact point for all pre-submission and submission correspondence.

Regards,

s22
s22
Prescription Medicines Authorisation Branch
Medicines Regulation Division | Health Products Regulation Group
Australian Government, Department of Health and Aged Care
E: streamlinedsubmission@health.gov.au

The Department of Health and Aged Care acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

TGA USE ONLY

This form, when completed, will be classified as **'For official use only'**.
For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at <https://www.tga.gov.au/treatment-information-provided-tga>.

Pre-submission planning form

Category 1 and Category 2 applications

Refer to Information for applicants completing a pre-submission planning form when completing this form and in particular note prerequisites to be completed prior to submitting this form.

Notes:

- The *Pre-submission planning form* (PPF) and required attachments must be lodged with the TGA via eBS before the 1st of the month in which the PPF will be processed.
- A PPF is not required if the application is solely for the addition of new trade name/s.
- Information on data requirements, including minimum content, format, and condition of an application, is provided in CTD Module 1: Administrative information and prescribing information for Australia.
- Relevant technical guidelines (ICH, EU adopted in Australia and TGA guidelines) are available on the TGA website at <http://www.tga.gov.au>.
- When lodging the PPF, ensure any required data/documents are uploaded as attachments in eBS.
- Where the symbol ** is shown in the PPF, this indicates that the specified document **must** be uploaded as an attachment when the PPF is lodged.
- Ensure that the following, where required, have been lodged with the TGA prior to PPF lodgement and the relevant advice has been received from the TGA:
  - a notification of a proprietary ingredient for each new proprietary ingredient.
  - an application form to propose a new chemical name (AAN), biological name (ABN), and/or herbal name (AHN) for each new non-proprietary ingredient.
  - an application for orphan drug designation.
  - justification for a new fixed combination.
  - acceptance as a literature based submission.

For an application to be effective, the DMF/s, where required, must be received by the TGA **prior** to lodgement of the application.

Part 1 Applicant and product details

1.1 Applicant details

Applicant name	Biocelect Pty Ltd
eBS client ID	65474
Postal address	Level 4, 143 Macquarie Street, Sydney, NSW 200
Address for correspondence	Level 4, 143 Macquarie Street, Sydney, NSW 200

	Primary contact	Secondary contact
Contact person (for the pre-submission phase)	s22 [redacted]	s22 [redacted]
Position (e.g. regulatory affairs officer, agent)	s22 [redacted]	s22 [redacted]
Telephone number	s22 [redacted]	s22 [redacted]
Mobile number (optional)		
Facsimile number		
Email address	regulatory@biocelect.com	s22 [redacted]@biointelect.com

Note: The *Therapeutic Goods Act 1989* (the Act) provides penalties for making statements that are false or misleading in a material particular in, or in connection with, an application for registration of therapeutic goods.

1.2 Product details

Medicinal product details

Single active ingredient ☒ Multiple active ingredients ☐ Multiple components ☐

Is the product:

- a biological substance Y ☒ N ☐
- sterile Y ☒ N ☐

- composed of a sterile active ingredient that is not subjected to further sterilisation during drug product manufacture. Y ☒ N ☐
- intended for single use. If Yes, and if the formulation includes an anti-microbial preservative, include a scientific justification for the inclusion of the preservative. Y ☒ N ☐
- a product of a fermentation process. Y ☒ N ☐
- multi-dose usage (note: this does not refer to multi-strength). Y ☐ N ☒
- supplied with a device. Y ☒ N ☐

If the product is supplied with a device, provide details below:

Pre-filled syringe

Product table

Record the details of all products (registered and new) affected by this application.

AUST R (if appl.)	Active ingredient(s)	Trade (proprietary) name(s)	Strength	Dosage form	Pack/container
355139	SARS-CoV-2 rS (NVX-2373)	Nuvaxovid	10µg/ml	suspension, for injection	2 or 10 multidose vials per carton

Note: For more information see Information for applicants completing a pre-submission planning form. If more than eight, insert comment, 'see attached document' in the first row.

Nature of proposed application/s

Select all that apply, noting that there may be new registrations and variations.

Note: A PPF is **not required** if the application is solely for the **addition of new trade name/s.**

New registrations

Note: Applications for new registrations lodged under section 23 of the Act and to which regulation 16C applies. A new registration is one that requires a new ARTG entry by reason of being separate and distinct goods under section 16 of the Act. By the provisions in the Therapeutic Goods (Groups) Order 2001, not all new registrations will result in a new AUST R number being allocated if they are taken to be grouped.

☒ **new chemical/biological entity [A]**

☐ **new salt/ester/isomer/complex/derivative** of existing active ingredient having different safety or efficacy properties **[A]**

☐ **similar biological medicinal product [A]**

If a similar biological medicinal product, complete information on the reference medicinal product:

Reference product - active ingredient	Reference product – trade (proprietary) name

Is the reference product **registered in Australia**? Y ☐ N ☐

Does the reference product have the same **form**, **strength,** and **route of administration**? Y ☐ N ☐

Have additional **comparability studies** been conducted? Y ☐ N ☐

Has the same INN/ABN as the reference product been requested? Y ☐ N ☐

Has the protected information period for the innovator product under section 25A of the Act expired? Y ☐ N ☐

If no, will it expire before the application (dossier) lodgement date identified in section 1.4? Y ☐ N ☐

☐ new **fixed combination** medicine **[B]**

☐ **extension of indications [C]**

☐ new **generic** medicine **[D]**

If a new generic medicine, complete the information on the reference product.

Note: Where a salt/ester is different to the reference product, provide a scientifically-robust justification at 2.3 Justifications and further information to demonstrate that the safety and efficacy properties are unchanged.

Reference product - active ingredient	Reference product - dosage form	Reference product - trade (proprietary) name

Has the protected information period for the innovator product under section 25A of the Act expired?	Y ☐	N ☐
If no, will it expire before the application (dossier) lodgement date identified in section 1.4?	Y ☐	N ☐
Was an overseas reference product used for bioequivalence studies?	Y ☐	N ☐

☐ new **dosage form [F]**

☐ change/increase in **patient group [F]**

☐ change in **dosage**, e.g. dosage amount, frequency of use or dose regimen **[F]**

☐ new **strength [F]**

☐ new **route of administration [F]**

☐ change in **formulation [G]**

☐ change in **container type** (disregarding container size) **[G]**

Variation to register entry

Note: Applications to vary a Register entry lodged under section 9D(3) of the Act and to which regulation 16D applies.

☐ variation to Register entry resulting in a change of product information requiring evaluation of clinical, nonclinical, or bioequivalence data **[J]**

☐ **other variation** (requiring evaluation of clinical, nonclinical, or bioequivalence data) **[H]**

Provide further detail or justification for proposed application/s types as required.

Proposed schedule

For new substances, proposed Schedule	Schedule 4 - Prescription Only Medicine

1.3 Indication(s)

Proposed indication(s)

Is this an application for a new chemical/biological entity, new fixed combination, similar biological medicine or new generic medicine?	Y ☒	N ☐

If yes, provide the proposed indication(s) below.

Active immunisation to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2 in individuals 12 years of age and older. The use of this vaccine should be in accordance with official recommendations.

If no, is there a change to indication(s) included in the application? Y ☐ N ☐

If yes, provide the proposed indication(s) below.

Currently approved indication(s)

Provide currently approved indication(s) below. For a new generic medicine or a similar biological medicine, provide the approved indication(s) of the reference product in Australia.

Active immunisation to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2 in individuals 12 years of age and older. The use of this vaccine should be in accordance with official recommendations.

1.4 Application planning

Overview of application

Provide a brief overview of the application. This includes (but is not limited to) a description of the product/proposed variation, and a succinct summary of the following:

- pivotal studies
- patient population.

Further information is provided in: Information for applicants completing a pre-submission planning form.

s22

Dossier lodgement date

Date on which the dossier will arrive at the TGA:	(dd/mm/yyyy) 30/04/2025

Related applications

If the application is related to any other application currently under evaluation by the TGA, provide relevant submission numbers.

Further information is provided in: Information for applicants completing a pre-submission planning form

Submission ID	Details of application
e.g. PM-2009-12345-1-1	e.g. Category 1 – extension of indication

Resubmission

Is this a resubmission? Y ☐ N ☒

If yes, provide the submission/pre-submission ID no. of the previous application.	

Section 31 request response period

Nominated response time for the consolidated section 31 request for information:	30 calendar days ☒ 60 calendar days ☐

Part 2 Details of application

Note: Information on data requirements, including minimum content, format, and condition of an application, is provided in CTD Module 1: Administrative information and prescribing information for Australia. Relevant guidelines (ICH, EU adopted in Australia and TGA guidelines) are available on the TGA website at <http://www.tga.gov.au>.

Complete the following sections that are applicable to the application. When lodging the PPF upload any requested data/documents as unlocked attachments in PDF or Microsoft Office format.

Information provided with this PPF will be used for planning purposes prior to application lodgement.

****Indicates a document must be uploaded as an attachment when the PPF is lodged.**

2.1 General information

Section	Applicant checklist

Ingredients/proprietary ingredients

Note: All ingredient names must be approved by the TGA, or have an approval pending, prior to PPF lodgement.

Are there any new non-proprietary ingredients, or proprietary ingredients in the application? Y ☒ N ☐

If yes, ensure that the following have been lodged with the TGA prior to PPF lodgement:

- a notification of a proprietary ingredient for each new proprietary ingredient.
- an application form to propose a new chemical name (AAN), biological name (ABN), and/or herbal name (AHN) for each new non-proprietary ingredient.

**If forms for proposing a new chemical name (AAN), biological name (ABN), and/or herbal name (AHN) have been lodged with the TGA, attach copy/copies of the TGA's acknowledgement letter/s. Y ☒

Are any of the excipients used for purposes other than those purposes for which they are registered, for example, a new route of administration, or at an increased daily dose, or (for non-oral products) at an increased strength, compared with existing registered products? Y ☐ N ☒

If yes:

** Toxicology data will be provided to support the different usage. Attach an overview (Module 2.4) of additional supporting toxicology data to be provided to support the safety of the excipient for the intended purpose; OR Y ☐

Supporting toxicological data will not be provided in the application to support the different usage.

Provide an overview of the justification for its omission at *2.3 Justifications and further information*. Y ☐

Fixed combinations

Does this product contain a new fixed combination of active ingredients? Y ☐ N ☒

** If yes, attach a copy of the TGA's letter advising that the justification for the fixed combination is acceptable. Y ☐

2.2 CTD Modules 1–5

CTD module	Applicant checklist

1.1 Comprehensive table of contents

** Attach a draft comprehensive table of contents, in a text-based format, that includes as a minimum Modules 3, 4, & 5 (where applicable to the application type). Y ☒

Note: Refer to Information for applicants completing a pre-submission planning form for information to complete this section.

Note: Where a study has been previously submitted for evaluation by the TGA, the entry for that study in the draft comprehensive table of contents (CTD Module 1.1), must be clearly annotated with the previous TGA submission number.

1.3.1 Draft product information (PI)

Will the application result in a new or revised PI? Y ☒ N ☐

New PI

**Attach a draft PI document that states (as a minimum) the Australian: Y ☒

- proposed indication(s)
- dose form
- dose regimen
- patient population
- formulation.

Note: It is strongly recommended applicants provide with the PPF a draft PI document that has been prepared specifically for the Australian market. Applicants can provide the core data sheet, or a summary of product characteristics (Europe) or prescribing information (USA), as long as the data listed above represents the proposed Australian registered product.

Revision of an existing PI

**Attach a draft revised PI document, clearly highlighting the proposed changes applicable to this application.

Y ☒

Literature-based submissions

Is this a literature-based (bibliographic) submission (LBS) for:

- **Module 4?** **Y** ☐ **N** ☒
- **Module 5?** **Y** ☐ **N** ☒

**** If yes to either, attach copies of the TGA's advice that:**

- the literature search strategy is acceptable Y ☐
- the criteria for determining which of the papers identified by the search are to be included/excluded from the application are acceptable. Y ☐

Note: The TGA must approve the literature search strategy and criteria prior to PPF lodgement.

Note: Further details about the literature references will be required. See Module 4 and Module 5 sections for more information.

Orphan drug designation

If this application is for a new register entry, has this medicinal product been designated an orphan drug for the proposed indication and dose form? Y ☐ N ☒

** If yes, attach a copy of the TGA letter approving the designation. Y ☐

Genetically modified organisms

Does this product contain or consist of genetically modified organisms? Y ☐ N ☒

** If yes, attach a copy of any OGTR licence, acknowledgement of receipt, or other record of consent from OGTR. Y ☐

Is the product derived from a genetically modified organism that is manufactured in:

- Australia? Y ☐ N ☐
- Overseas? Y ☐ N ☐

**** If yes to Australia, attach a copy of any OGTR licence, acknowledgement of receipt, or other record of consent from OGTR or, a declaration of exemption.** **Y** ☐

1.6 DMF, PMF, and CEP

Indicate which of the following files, if any, the application will reference.

Drug master file (DMF) Y ☐

Active ingredient	DMF TGA file number

Note: For an application to be effective, the DMF must be received by the TGA prior to lodgement of the application.

If TGA file number unknown, provide name of DMF holder and/or code or version number of DMF.

CEP (Certificate of Suitability of Monographs of the European Pharmacopoeia) Y ☐

Active ingredient	CEP Reference number

Plasma master file (PMF) Y ☐

Has the PMF been approved by TGA? Y ☐ N ☐

Name of PMF	PMF TGA file number

CTD module	Applicant checklist

1.7 Good manufacturing practice

The *Therapeutic Goods Act 1989* requires GMP clearances/licences for sites involved in production of the medicine. See CTD Module 1, for legislative requirements.

Note: Requirements for GMP clearances, certifications, and manufacturing licence applications are available from the GMP section of the TGA website.

Will Module 3 form part of the application or does the application make reference to a previously submitted Module 3, DMF or PMF? Y ☒ N ☐

If yes, provide the following details for all proposed manufacturers.

Details of overseas manufacturers					
Currently cleared	Clearance required	GMP clearance or certification tracking number#	Manufacturer name	Country	Expiry date (if current)
☐	☐	(MI-YYYY-CL-NNNNN-N)	See attachment for list of manufacturers		
☐	☐				
☐	☐				
☐	☐				
☐	☐				
☐	☐				
☐	☐				
☐	☐				
☐	☐				

Applications must have been submitted (draft status is not acceptable).

**Indicates a document must be uploaded as an attachment when the PPF is lodged.

Details of Australian manufacturers			
Currently approved	Approval required	Licence or tracking number[#]	Manufacturer name
☐	☐	(MI-YYYY-LI-NNNNN-N)	
☐	☐		
☐	☐		
☐	☐		
☐	☐		
☐	☐		

[#] Applications must have been submitted (draft status is not acceptable).

Note: If there is insufficient room, include further details in an attached document.

CTD module	Applicant checklist

1.8.1 Meetings

Has written pre-submission advice been sought from TGA? Y ☒ N ☐

Has a pre-submission meeting been held with the TGA regarding this application? Y ☐ N ☒

Note: A meeting includes meetings conducted in any format (i.e. face to face, teleconference or videoconference).

** If yes, attach relevant documents (for example, copies of correspondence, meeting minutes, action items) and, where relevant, how/when any issues will be addressed. Y ☒

1.10.1 Overseas regulatory status

Has there been, or is there an intention to make similar applications for market approval in any of the following regions or countries? Y ☒ N ☐

If yes, indicate which countries.

Note: If insufficient room, include further details in an attached document.

Country/region	Date submitted or intend to submit	If approved	
		Approval date	Approved indications
s22			

For all application types other than PI changes, has this application ever been refused market approval or withdrawn in any region or country? Y ☐ N ☐

If yes, provide details.

CTD module	Applicant checklist

1.13 Pharmacovigilance

Will a risk management plan (RMP) be included in the application? Y ☒ N ☐

Note: Refer to the RMP guidelines to assess whether a RMP is required.

If no RMP is to be included, provide a justification below:

If yes, the current, unaltered EU-RMP (if available) and an Australian Specific Annex should be provided in the dossier. **Note:** An alternative to the EU RMP is acceptable only if there is no current EU-RMP.

CTD module	Applicant checklist

2 Summaries module

Will Module 2 form part of the application? (Note: Module 2 must be included with all applications under section 23 to which regulation 16C applies.) Y ☒ N ☐

Note: If yes, attach summaries (Module 2 documents or equivalent) of the proposed quality, nonclinical, and clinical evidence as described below. Equivalent documents may be provided; please refer to Information for applicants completing a pre-submission planning form for more details.

Note: Where an applicant believes the requirement for a document is 'not applicable' for a particular application, a justification must be included in section 2.3 Justifications and further information.

2.3 Quality

Where quality information will be submitted as part of the application, quality summaries must be submitted. The quality summaries (CTD 2.3.x) submitted should correspond to the data to be submitted in Module 3 (drug product / drug substance).

**Summary of Drug Substance (CTD 2.3.S or equivalent) Y ☒ N/A ☐

**Summary of Drug Product (CTD 2.3.P or equivalent) Y ☒ N/A ☐

2.4/2.6 Nonclinical

**Nonclinical Overview (CTD 2.4 or equivalent) Y ☐ N/A ☒

Where nonclinical information will be submitted as part of the application, written or tabulated summaries must be submitted. The nonclinical summaries (CTD 2.6.x) submitted should correspond to the data to be submitted in Module 4 (pharmacology / pharmacokinetics / toxicology).

Either:

**Pharmacology Written Summary (CTD 2.6.2 or equivalent) Y ☐ N/A ☐

Or

**Pharmacology Tabulated Summary (CTD 2.6.3 or equivalent) Y ☐ N/A ☐

Either:

**Pharmacokinetics Written Summary (CTD 2.6.4 or equivalent) Y ☐ N/A ☐

Or

**Pharmacokinetics Tabulated Summary (CTD 2.6.5 or equivalent) Y ☐ N/A ☐

Either:

**Toxicology Written Summary (CTD 2.6.6 or equivalent) Y ☐ N/A ☐

Or

**Toxicology Tabulated Summary (CTD 2.6.7 or equivalent) Y ☐ N/A ☐

2.5/2.7 Clinical

**Clinical Overview (CTD 2.5 or equivalent) Y ☐ N/A ☒

Where clinical information will be submitted as part of the application, clinical summaries and synopses must be submitted. The clinical summaries (CTD 2.7.x) submitted should correspond to the data to be submitted in Module 5 (biopharmaceutic / pharmacology / clinical efficacy / clinical safety).

**Summary of Biopharmaceutic Studies and Associated Analytical Methods (CTD 2.7.1 or equivalent) Y ☐ N/A ☐

**Summary of Clinical Pharmacology Studies (CTD 2.7.2 or equivalent) Y ☐ N/A ☐

**Summary of Clinical Efficacy (CTD 2.7.3 or equivalent) Y ☐ N/A ☐

**Summary of Clinical Safety (CTD 2.7.4 or equivalent) Y ☐ N/A ☐

Either:

** All synopses of clinical studies (CTD 2.7.6) Y ☐ N/A ☐

OR

** Synopses of pivotal phase III studies (minimum requirement) Y ☐ N/A ☐

3 Quality module

Will Module 3 form part of the application or does the application make reference to a previously submitted Module 3, DMF or PMF? Y ☒ N/A ☐

If no, go to *CTD Module 4*.

If yes, complete the following sections.

3.2.S Drug substance

Manufacturer name	Address	Manufacturing steps

Note: If insufficient space, include details in an attached document.

3.2.P Drug product

Manufacturer name	Address	Manufacturing steps

Note: If insufficient space, include details in an attached document.

Provide a description of the dosage form, including container and any delivery device that will be supplied with the product.

Provide a description of the container closure system.

CTD module	Applicant checklist

4 Nonclinical module

Will Module 4 form part of the application? Y ☐ N ☒

If no, go to *CTD Module 5.*

4.3 Are literature references (CTD Module 4.3) to be included in the application?

Y ☐ N ☐

If yes, specify the number of references to be included

The full bibliographic details of all the literature references proposed to be submitted are included in the comprehensive table of contents (CTD Module 1.1) Y ☐

Note: For a description of what types of documents constitute literature references, see page 46 of ICH M4E Common technical document for the registration of pharmaceuticals for human use—efficacy.

5 Clinical module

Will Module 5 form part of the application? Y ☒ N ☐

If no, go to *2.3 Justifications and further information*.

5.2 ** Tabular listing of all clinical studies (CTD Module 5.2)

Y ☐

Note:

- a tabular listing of clinical studies must be attached if clinical studies are to be submitted;
- the table must include all clinical studies to be evaluated by the TGA, including biopharmaceutic studies;
- where the study has been previously evaluated by the TGA, the entry in the table for that study must be clearly annotated with the previous TGA submission number.

5.4 Literature references (CTD Module 5.4)

Are literature references (CTD Module 5.4) to be included in the application?	Y ☒ N ☐
If yes, specify the number of references to be included.	12
The full bibliographic details of all the literature references proposed to be submitted are included in the comprehensive table of contents (CTD Module 1.1).	Y ☒

Note: For a description of what types of documents constitute literature references, see page 46 of ICH M4E Common technical document for the registration of pharmaceuticals for human use—efficacy.

Justifications and further information

Justification for not providing biopharmaceutic and/or absolute bioavailability data

Note: "Justification" shall be considered to mean "the action to show that a thing is right, just or valid".

The guideline *Biopharmaceutic studies* and a number of EU guidelines that have been adopted by the TGA, establish the requirements for the generation and provision of biopharmaceutic data.

Where the application requires the provision of biopharmaceutic data but this data will not be provided, will not be provided for all products, relies on an overseas comparator (Choice of reference product for bioequivalence of generic medicine) or otherwise will not meet the requirements set out in the relevant documents and guidelines, a robust scientific justification (with references as appropriate) must be included in the application. Further, where multiple guidelines/requirements have not been met, each guideline/requirement must be addressed.

Provide an overview of the justification/s related to the biopharmaceutic data to be included in the application. If the justification/s is/are included in the Module 2 documentation, please provide details and reference to location/s.

Justification for not meeting other guidelines

In relation to Modules 3, 4, and 5, if any other TGA-adopted or Australia-specific guidelines applicable to the application will not be fully met, robust scientific justification/s (with references as appropriate) must be included in the application to justify the reasons for not fully meeting these guidelines, including any anticipated critical omissions.

Provide an overview of the justification/s to be included in the application. If the justification/s is/are included in the Module 2 documentation, please provide details and reference to location/s.

Tradename for release whilst submission is under evaluation (for Type A-C applications)

For new medicines or new uses for existing medicines that are currently under evaluation, the TGA publishes a summary of the proposed indication(s) and proposed tradename (as well as applicant name and active ingredient) https://www.tga.gov.au/resources/prescription-medicines-under-evaluation1. The list of medicines under evaluation is updated each month.

Please provide a Trade name for release on TGA's website whilst this application undergoes evaluation (published at https://www.tga.gov.au/resources/prescription-medicines-under-evaluation[2]).

Tradename: Nuvaxovid JN.1

1 This page links to our database of applications for new medicines or new uses for xxisting medicines that are currently under evaluation by the TGA. The list of medicines under evaluation is updated each month. Information on three types of applications is included: Application type A: applications for a 'new medicine' containing a new active substance (new chemical entity or new biological entity) not currently approved in Australia. Application type B: applications for a 'new combination', where two or more already approved medicines are combined into a single product. Application type C: applications for a 'new indication', or additional therapeutic use, for an already approved medicine.

2 This page links to our database of applications for new medicines or new uses for xxisting medicines that are currently under evaluation by the TGA. The list of medicines under evaluation is updated each month. Information on three types of applications is included: Application type A: applications for a 'new medicine' containing a new active substance (new chemical entity or new biological entity) not currently approved in Australia. Application type B: applications for a 'new combination', where two or more already approved medicines are combined into a single product. Application type C: applications for a 'new indication', or additional therapeutic use, for an already approved medicine.

Real world data (RWD), real world evidence (RWE) and patient reported outcomes (PROs) usage declaration (for all applications where applicable)

Please provide information on any RWD, RWE and/or PROs included in this submission and the reasons for their inclusion (e.g. claims supported by the data):

a. Details of location in eCTD of the RWE/PRO studies:

eCTD hyperlinks preferred:

b. Detail reasons for inclusion and the claims supported by the RWE/PRO data:

e.g. Safety in	*supported by data in Study*

Further information

Is there any other information in relation to this PPF that is relevant to the TGA's consideration of this document, or that might otherwise be relevant to the assessment by the TGA of the resources required for the evaluation of the application?

2.4 Summary of attachments

Note: This section identifies attachments the Applicant may be required to upload with this PPF and should be considered a reference guide/check list only. Refer to the Information for applicants completing a pre-submission planning form.

2.1 General information

- Copy or copies of the TGA's acknowledgement letter/s for lodgement of forms for proposing a new chemical name (AAN), biological name (ABN), and/or herbal name (AHN).
- An overview of additional supporting toxicology data to be provided to support the safety of an excipient for a different purpose.
- Copy of the TGA's letter advising that the justification for the fixed combination is acceptable.

2.2 CTD Modules 1-5

- Comprehensive table of contents, in a text-based format, for Modules 3, 4, & 5 (CTD 1.1).
- Draft document for a new or revised PI (CTD 1.3.1).
- For a LBS, copies of TGA's advice that:

  - the criteria for determining which of the papers identified by the search are to be included/excluded from the application are acceptable (CTD 1.5.1.1).
  - the literature search strategy is acceptable (CTD 1.5.1.2).
- Copy of TGA letter approving orphan drug designation (CTD 1.5.2).
- Copy of any OGTR licence, acknowledgement of receipt, or other record of consent from OGTR or, a declaration of exemption (CTD 1.5.3).
- Details of compliance with pre-submission meetings (CTD 1.8.1).
- Copy of the advice from the Office of Product Review stating that a risk management plan is not required (CTD 1.13).
- Summary of drug substance (CTD 2.3.S or equivalent).
- Summary of drug product (CTD 2.3.P or equivalent).
- Nonclinical Overview (CTD 2.4 or equivalent).
- Written Summaries of nonclinical data (CTD 2.6.2, 2.6.4, 2.6.6 or equivalent) or Tabulated Summaries of nonclinical data (CTD 2.6.3, 2.6.5, 2.6.7 or equivalent).
- Clinical Overview or equivalent (CTD 2.5).
- Clinical Summaries (CTD 2.7.1, 2.7.2, 2.7.3, 2.7.4 or equivalent).
- Either:
  - Draft synopses of clinical studies (CTD 2.7.6) OR
  - Synopses of pivotal phase III studies (minimum requirement).
- Tabular listing of clinical studies (draft CTD 5.2).

Part 3 Declaration

I acknowledge that the *Therapeutic Goods Act 1989* provides for offences and penalties for making statements that are false or misleading in a material particular in or in connection with an application for registration of therapeutic goods.	☒
I declare I have read Information for applicants completing a pre-submission form and completed this form in accordance with the instructions in that document.	☒
I declare that the information provided in this pre-submission planning form is, to the best of my knowledge, complete, current, and correct.	☒
I understand that, in order for the application to be effective:	
a. I must provide to the TGA the complete application by the date specified in section 1.4, and that its contents must align with the information that I have provided in this form.	☒
b. the complete application must be prepared in accordance with any requirements of the Secretary under subsections 23(1) or (2), or subsection 9D(6) of the *Therapeutic Goods Act 1989* in relation to its form and the information to be provided and with the TGA's requirements as set out in Mandatory requirements	☒

for an effective application[3] acknowledging that selected information may not be required for my specific application or by approved exemptions.

c. the dossier, as received by the TGA, will be considered to be the full and complete dossier, notwithstanding any further data requested by the TGA (including under section 31 of the Act) and/or new safety data, which I am obliged to bring to the TGA's attention. ☒

I understand that my application will be processed by the TGA in accordance with the procedures set out in Prescription medicine registration process.[4] ☒

I understand that, in accordance with the *Therapeutic Goods Act 1989*, if the application is not effective as defined under section 23 or section 9D(7) of the Act, my application will not be evaluated by the TGA. ☒

Name of authorised officer	s22 [redacted]
Position/relationship to applicant	s22 [redacted]
Telephone number	s22 [redacted]
Facsimile number	
Email address	regulatory@biocelect.com
Date	17April2025

[3] This document reflects requirements for an application to be considered effective under the *Therapeutic Goods Act 1989*. This document does not contain all the regulatory requirements for applications. Rather, it highlights a subset of requirements which applicants frequently overlook.
[4] This document explains the prescription medicine registration process and references regulatory and supporting documents.

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

TGA USE ONLY

Submission Assessment Form

PPF-Only

Submission Details

Submission Number:	PM-2025-01693-1-2
eSubmission Identifier (link):	e005931 - (0121)
PPF Lodged:	April
Primary application type:	A - New chemical entity or new salt or ester of a previously approved active ingredient [A]
Additional application type(s):	
Reduced Fee Major Variation (Type U):	
Sponsor:	Biocelect Pty Ltd
Trade name:	Nuvaxovid JN.1
Active ingredient:	SARS-CoV-2 rS (NVX-2373)
Strength:	10µg/ml
Dosage Form:	suspension, for injection
TRIM reference for files:	E25-208167 – Coordination E25-208173 – Quality E25-208169 – Clinical
Due date for completion of assessment:	9th May 2025
Nominated section 31 response time:	30 days
Key dates:	D19-5973645

Evaluation Plan

Milestone	Description	Date	Correct Premier Dates
2	Outcome of submission assessment - Notification Letter	~~30/06/2025~~	31/05/2025
3	Outcome of 1st round evaluation - Consolidated s.31 request	~~30/11/2025~~	31/10/2025
4	End of nominated (30 days) s.31 response period	~~31/12/2025~~	30/11/2025
5	Completion of evaluation phase	~~31/01/2026~~	31/12/2025
	Deadline for notification to the TGA of errors/omissions in evaluation reports	~~(2 weeks after Milestone 5)~~	(2 weeks after Milestone 5)
	Delegate's request for ACM advice	~~03/03/2026~~	03/03/2026
	Pre-ACM response	~~17/03/2026~~	17/03/2026
	Proposed ACM meeting	~~03/04/2026~~	03/04/2026
6	ACM outcomes	~~24/04/2026~~	24/04/2026
7	Initial decision by Delegate – Decision Letter	~~15/05/2026~~	15/05/2026
8	Completion of administrative and registration activities	~~30/06/2026~~	30/06/2026

Application Entry Team

Application Form Check

Check	Tick if Yes
Signed by an authorised person for the sponsor or TBS application form	✓ ☐
Includes full details regarding: The trade name(s), active ingredient name(s), dosage forms and strengths of the medicine(s)	✓
The required number of applications has been added to Premier? Are the applications in the correct format?	☐ Pending ☐
For - Type D (Generic) submissions; - Type F (Major Variation) that include Type D (Generic) applications within the submission:	
Data exclusivity checked by AET	☐
Innovator Product Name:	[Innovator Product Name]

Data Check

Item	Tick if Yes
Biological medicine	✓
Genetically Modified Organism (GMO)	☐
Sterile	✓
Fermentation	☐
Risk Management Plan (RMP)	✓
Australia specific information for COR-A / COR-B	☐

Decision letter / prior approval	Tick if received	
Priority	☐	Date approved:
Provisional	☐	Date approved:
Orphan Drug	☐	Date approved:
Literature-Based Submissions	☐	Date approved:
Fixed Dose Combination	☐	Date approved:

Information for Others

Case Manager	**Premier dates are incorrect.**
Other Area	

AET Assessor	s22 [redacted]	Date	2/05/2025

External Evaluations Summary (for External Evaluations team use only)

Evaluation areas please note that this is a summary page that draws information from other parts of the form.
Input from your relevant sections of the SAF will be reflected here for the External Evaluations team.
To update the table, select the whole table and press F9

Module	Module 3	Module 4	Module 5
Evaluation	**Yes - Internal**	**Yes - Internal**	**Yes - External**
Estimated time (hrs)			
Justification	Choose an item.	Choose an item.	Choose an item.
ACCESS reports requested to assist in the evaluation			
HC - Health Canada	✓	☐	☐
HSA - Singapore	✓	☐	☐
SMC - Switzerland	☐	☐	☐
MHRA – UK	✓	☐	☐

International Evaluation Summary

To be populated by the International Evaluations Team, where required

ACCESS

Participating ACCESS partners	
HC - Health Canada	Choose an item.
HSA - Health Sciences Authority	Choose an item.
SMC - Swiss Medic	Choose an item.
MHRA – UK regulator	Choose an item.
General Comments	
(eg. a module being split or done in parallel, ACM timing, etc)	

Allocation of evaluation work	
Module 3 PCRS / BSS / BES	Choose an Agency
Module 3 Secondaries Please see guidance at D23-5105642. Work-sharing procedures differ depending on whether the TGA is the Module 3 lead.	
Module 4 Toxicology	Choose an Agency
Module 5 Clinical	Choose an Agency
Population PK	Choose an Agency

Project Orbis

To be populated by the International Evaluations Team, where required

Details	
Project Orbis #	
Orbis Type	Choose an item.
FDA: Target Action Date	Click or tap to enter a date.
FDA: PDUFA Date	Click or tap to enter a date.
General Comments	(eg. multiple FDA applications and/or Orbises bundled into a single TGA submission; FDA CMC reviews already available, therefore Mod 3 is Type C; etc)
FDA Assessment Aid(s)	
Assessment Aid(s) received	Choose an item.
TRIM Links	
CMC	
Multidisciplinary	
If Assessment Aid(s) not received: The date when it is expected (2-4 weeks after the FDA takes action)	Click or tap to enter a date.

Module 3

PCRS / BSS / BES

Evaluation and Application

Evaluation	
Is a Module 3 evaluation required?	Yes - Internal
Is the application type correct?	**Correct**
If the application type is incorrect, provide reasons in the **Information for Case Manager** section below	

Secondary Evaluations

The following Secondary Evaluations are requested:

Module 3 Secondary Evaluation	
Sterility/Microbiology	✓
Endotoxin	✓
Infectious Disease Safety	✓
Container Safety	✓
Scientific Evaluation Branch	
Fermentation Product (BSS)	☐
Drug conjugate product (PCRS) e.g. antibody-drug conjugate	☐
Radiopharmaceutical (PCRS)	☐
Prescription Medicines Authorisation Branch	
Clinical Advice	☐
Medical Devices	
Devices	☐

Requests to the External Evaluation team

Completed overseas regulator report/s

Evaluation areas please note that this request is not applicable to ACCESS/Worksharing submissions

For Orbis submissions, please provide a justification for requesting Access reports in addition to FDA reports

Please source the following completed overseas regulator reports:

International Regulatory Agency	
HC - Health Canada	✓
HSA - Singapore	✓
SMC - Switzerland	☐
MHRA – UK Kingdom	✓

External Evaluator

Procurement Information	
Justification why the evaluation needs to be completed externally:	Choose an item.
Estimated number of hours required for completion of the evaluation:	
Comments for the External Evaluation team	

Information for the Module 3 Evaluator

Evaluation Requirements

Data	Tick if Yes
Chemical and biopharmaceutical data	☐
Chemical data only	☐
Biopharmaceutical data only	☐
Drug Master File (DMF)	☐
Module 1 + 3.2R	☐
Biological Medicines	☐
Certificate of Suitability (CEP)	☐
Plasma Master File (PMF)	☐
Novel excipient	☐
New route of administration for an existing excipient	☐

Record any issues for the Module 3 Evaluator *(external evaluators cannot access TRIM)*

Module 3 Quality Checklist

Quality Checklist	Sufficient Data Y / N / NA
Labels and PI Where the sponsor is using another company's name and/or livery on labels, a letter of authorisation from the company owning the name/livery must be provided.	Yes
Module 2 requirements for generic medicines	
A Module 2.4 must be supplied for all new generic applications where the active ingredient is a different salt/ester from the innovator's active ingredient.	Choose an item.
Module 2.5 must be supplied for all new generic applications, except where the Bioequivalence Study Information Form (BSIF) or BCS-based biowaiver template is provided.	Choose an item.
Module 2.7 must be supplied for new generic applications where • biopharmaceutic studies have been provided in support of the application, and • neither BSIF nor BCS-based biowaiver template is provided.	Choose an item.
3.2.S: Drug Substance	
DMF received by TGA (check TRIM)	Choose an item.
CEP documentation as per ARGPM Appendix 11C and Module 1.6	Choose an item.
Drug substance is fully described in 3.2.S	Choose an item.

Quality Checklist	Sufficient Data Y / N / NA
Control of Drug Substance • The full quality control specifications applied to the bulk active ingredient by the finished product manufacturer must be provided in Module 3.2.S. This should include: • Details and scientific justifications must be provided for any additional tests and requirements (e.g. for particle size distribution, polymorphic form, etc.) applied to the bulk drug substance before use in the manufacture of the drug product(s). • Validation data must be provided for these additional tests. • Batch analytical data generated by both the drug substance and the finished product manufacturer(s) supplied for typical batches of bulk active substance from each supplier.	Choose an item.
3.2.P: Drug Product	
Nitrosamine Impurities Risk Assessment • Potential for nitrosamine impurities, eg, of the DS, process impurities, solvents, reagents, synthetic impurities of degradants, formation on storage and therefore testing required	Yes
• Nitrosamine impurities test results provided	No
Proposed Formulation The composition of each product and strength must be clearly defined. (If generic, API, dosage form and strength consistent with ARTG for innovator or otherwise justified/appropriate?) For injections that are intended for single use, anti-microbial preservatives must not be included in the formulation *(unless they are used for a purpose other than as a preservative)*	Yes
Australian Approved/Biological Names (AANs/ABNs) or Novel Excipients All ingredients must be listed as Australian Approved/Biological Names (AANs/ABNs) or appropriate documentation submitted to the TGA for a new AAN/ABN to be created (also see 1.2.2 and Module 4). Safety data (non-clinical and/or clinical) must be provided for any new ingredient which has not been included in the ARTG previously or any ingredient administered via a new route of administration or intended to be used for a different purpose.	Choose an item.
Release and expiry specifications Impurity limits which are above the ICH threshold(s) must be qualified by toxicology data or by reference to an appropriate pharmacopoeial monograph. For generic medicine submissions, limits above the ICH threshold may also be qualified by comparison with the Australian innovator product near or just past expiry date.	Choose an item.
Sponsor has provided both release and expiry (shelf life) specifications where required	Choose an item.

Quality Checklist	Sufficient Data Y / N / NA
Batch Analysis data (Biological Medicines only) Batch analyses must include consecutive data from multiple campaigns (e.g. development, validation (PPQ), clinical, commercial etc)	Yes
Analytical method details Details of all analytical methods used for DP release All raw data supplied (e.g. SDS-PAGE photos or HPLC traces) must be clear and legible.	Yes
Analytical method validation data	Yes
3.2.P.7 Container Closure System	
• Relevant safety data provided • The immediate and outer packaging and packaging materials (e.g. type of glass or plastic), pack sizes, any dosing device, any induction seals and any desiccant or cotton wool contained in the package must be defined and described – samples are not required. • The full specifications (e.g. based on Ph. Eur. or USP monographs) and routine tests on the proposed marketing containers and closures must be provided.	Choose an item.
• If the product is packaged in a child-resistant container, an assurance must be provided that full details of compliance with TGO 95 are held by the applicant and are available for submission to the TGA upon request.	Choose an item.
3.2.P.8 Stability data	
• In the case of liquid products in a stoppered container, stability trials carried out on the product stored under the worst case conditions must be provided (often samples stored both upright and inverted are required). • If there were any changes in test procedures during the course of the stability trials, comparison and correlation of results generated by the alternative methods must be provided. • Size of batches in line with EU guidelines • Length of stability data provided meets minimum requirements • Batches used in support of stability studies comply with Stability Guidelines (e.g. *Stability testing for prescription medicines*)	Choose an item.
Breakability data If tablets are scored to allow division, data must be provided to confirm that splitting is clean and the portions produced comply with pharmacopoeial limits for uniformity of weight/content.	Choose an item.
Ethanol studies For modified release dosage forms, investigation of the effect of ethanol on *in vitro* dissolution/release must be included.	Choose an item.
3.2R Biosimilars Comparability (if applicable)	

Quality Checklist	Sufficient Data Y / N / NA
Reference medicine is • A biological medicine registered in Australia (on the ARTG) based on full quality, safety and efficacy data • Sourced in Australia or if it is EU- or US-sourced comparability includes bridging study to a product on the ARTG and sourced in Australia.	Choose an item.

Biopharmaceutics Checklist

Biopharmaceutics Checklist	Sufficient Data Y / N / NA
Mod 1.9 Summary form is provided using: • Summary of a bioavailability or bioequivalence study form	Choose an item.
• Bioequivalence Study Information Form (BSIF)	Choose an item.
Is the Test formulation the same as proposed for registration? If not, was there data to justify the differences between the formulation used in the BE study and the formulation for registration?	Choose an item.

Bioavailability Data

Bioavailability Data	Sufficient Data Y / N / NA
This submission contains a justification for not performing certain bioavailability studies, which requires evaluation.	Choose an item.

A preliminary scrutiny of the data provided has been carried out within the Pharmaceutical Chemistry Evaluation Section to assess the relevance of the studies.

Full evaluation required *	
Study Number	**Comments**

Summary only required *	
Study Number	**Comments**

Evaluation not required *	
Study Number	**Comments**

** It is emphasised that the final judgement as to which studies are to be evaluated, and to what extent, rests with the evaluator, who should take into account in making the judgement, the formulation(s) proposed for registration, any claims made in the product information document, any reason that may have been provided by the company for submitting the studies (e.g. cross-referencing to efficacy/safety studies), and any other relevant factors.*

Module 3 Recommendation

Recommendation

Not Effective - see External Advice for Sponsor

Information for Case Manager

Information for Case Manager

Information for other evaluation area

Information for other evaluation area

External advice to Sponsor

Issues to be raised to the sponsor
s22 [redacted]

Completed by

Module 3 Assessor	s22 [redacted]	Date	5/05/2025

Microbiology

Module 3 Secondary Evaluation

Microbiology Recommendation

Effective - Data sufficient for evaluation

Information for Case Manager

Information for Case Manager

Information for other evaluation area

Information for other evaluation area

External advice to Sponsor

Issues to be raised to the sponsor

Completed by

Microbiology Assessor	s22 [redacted]	Date	6/05/2025

Endotoxin

Module 3 Secondary Evaluation

Endotoxin Recommendation

Effective - Data sufficient for evaluation

Information for Case Manager

Information for Case Manager

Information for other evaluation area

Information for other evaluation area
s22 [redacted]

External advice to Sponsor

Issues to be raised to the sponsor

Completed by

Endotoxin Assessor	s22 [redacted]	Date	2/05/2025

Infectious Disease Safety (IDS)

Module 3 Secondary Evaluation

IDS Recommendation

Effective - Data sufficient for evaluation

Information for Case Manager

Information for Case Manager

Information for other evaluation area

Information for other evaluation area

External advice to Sponsor

Issues to be raised to the sponsor

Completed by

IDS Assessor	s22 [redacted]	Date	7/05/2025

Container Safety

Module 3 Secondary Evaluation

Container Safety Recommendation

Effective - Data sufficient for evaluation

Information for Case Manager

Information for Case Manager

Information for other evaluation area

Information for other evaluation area

External advice to Sponsor

Issues to be raised to the sponsor

Completed by

Container Safety Assessor	s22 [redacted]	Date	9/05/2025

Module 4

Toxicology

Evaluation and Application

Evaluation	
Is a Module 4 evaluation required?	Yes - Internal
Is the application type correct?	**Incorrect**
If the application type is incorrect, provide reasons in the **Information for Case Manager** section below	
s22 [redacted]	

Requests to the External Evaluation team

Completed overseas regulator report/s

Evaluation areas please note that this request is not applicable to ACCESS/Worksharing submissions

For Orbis submissions, please provide a justification for requesting Access reports in addition to FDA reports

Please source the following completed overseas regulator reports:

International Regulatory Agency	
HC - Health Canada	☐
HSA - Singapore	☐
SMC - Switzerland	☐
MHRA – UK Kingdom	☐

External Evaluator

Procurement Information	
Justification why the evaluation needs to be completed externally:	Choose an item.
Estimated number of hours required for completion of the evaluation:	
Comments for the External Evaluation team	

Module 4 Recommendation

Recommendation

Not Effective - see External Advice for Sponsor

Information for Case Manager

Information for Case Manager
The studies in Module 4 should have meaningful names in accordance with the mandatory requirements:

Information for other evaluation area

Information for other evaluation area

External advice to Sponsor

Issues to be raised to the sponsor
Module 4 does not comply with TGA's requirements for electronic documents and eCTD dossiers: "Electronic folder and file names should indicate the content and allow documents to be easily identified within the structure of the electronic dossier. https://www.tga.gov.au/resources/guidance/general-dossier-requirements#folder-and-file-names "Make title elements short, precise and informative." https://www.tga.gov.au/sites/default/files/ectd-au-module-1-and-regional-information.pdf Document titles used throughout Module 4 are uninformative, merely containing study numbers. These do not indicate the contents of the document (e.g., the particular test article investigated, species and route used, duration, or the type of study). Please re-submit data with appropriate name.

SAF Not effective- D25-2583042

Acceptable - D25-2617083

Completed by

Module 4 Assessor	s22 [redacted]	Date	9/05/2025

Module 5

Clinical

Evaluation and Application

Evaluation	
Is a Module 5 evaluation required?	Yes - External
Is the application type correct?	**Choose a recommendation**
Please provide reasons in the **Information for Case Manager** section below if the application type is: • incorrect; or • eligible for a Reduced Fee Major Variation (Type U)	

ACM

Is ACM likely to be required?	✓ **YES**
	☐ **NO**
	☐ **To be advised during the evaluation**

Evaluation Requirements

Delegate and Evaluator

Proposed Delegate Section	**CES**
Primary Evaluator	External
Secondary Evaluator (eg for peer review)	None

Requests to the External Evaluation team

Completed overseas regulator report/s

Evaluation areas please note that this request is not applicable to ACCESS/Worksharing submissions

For Orbis submissions, please provide a justification for requesting Access reports in addition to FDA reports

Please source the following completed overseas regulator reports:

International Regulatory Agency	
HC - Health Canada	☐
HSA - Singapore	☐
SMC - Switzerland	☐
MHRA – UK Kingdom	☐

External Evaluator

Procurement Information	
Justification why the evaluation needs to be completed externally:	Choose an item.
Estimated number of hours required for completion of the evaluation:	
Comments for the External Evaluation team	

Population Pharmacokinetics Evaluation

PopPK assessment	
Is there PopPK data in the submission?	☐ Yes ☐ No
The following PopPK studies/documents require evaluation:	
List documents here	
If expert popPK advice is required: clinical evaluator to liaise with external evaluations team and delegate to formulate specific question for the external popPK evaluator.	

Information for the Module 5 Evaluator

Type	Required	List Documents
EU Guidelines	☐	
ACM minutes	☐	
Overseas evaluation	☐	
Previous evaluation	☐	
Other PIs	☐	
Other Documents	☐	

Information for the Module 5 Evaluator *(external evaluators cannot access TRIM)*

The applicant has provided information on the submission in section 1.4 of the Pre-submission Planning form (PPF).

Product background

-

Studies (see Table of Contents and Module 5.2: Tabular listing of all clinical studies for further details)

-

The evaluator must comment on the following issues in their evaluation report

-

Additional information

-

Other information to be considered in the evaluation report

- The clinical evaluator must evaluate all elements of Module 5 and the relevant parts of Module 1 and 2.
- The relevant TGA Clinical Evaluation Report template, eg Standard, Priority, Type J, etc, must be used to complete the reportExternal evaluators will be provided with the template by the External Evaluation team.

  http://sharepoint.central.health/divisions/mrd/teams/pmabces/SitePages/Templates%20and%20Process%20documents.aspx
- All proposed clinical statements in the PI must be carefully assessed by the evaluator who must decide whether there is sufficient and appropriate evidence in the clinical data presented to support those statements. The PI format must be assessed against the criteria on the TGA website at https://www.tga.gov.au/resources/resource/guidance/form-providing-product-information
- The evaluator should comment in their Recommendation section on whether any conditions should be imposed post-registration (if applicable) on the product/sponsor.
- Where an RMP is provided. Please examine carefully the safety specifications section of the Risk Management Plan (RMP) in Module 1 and assess whether the adverse event profile in the clinical trial data you have evaluated in the dossier is consistent with the adverse event profile summarized in the safety specifications section of the RMP. An explicit statement summarizing the issue is required under the appropriate heading in the clinical evaluation report. The RMP is located in Module 1 of the dossier. It is critical that the safety specifications identified by the sponsor in the RMP are consistent with the adverse event/safety profile from the clinical trial data and the clinical evaluator must be able to state explicitly that this is the case. If the latter is not the case, then the clinical evaluator must state how the safety specifications and the clinical trial data are different.
- The TGA has adopted a range of clinical guidelines at https://www.tga.gov.au/resources/international-scientific-guidelines-adopted-australia These guidelines may be helpful to you in conducting the evaluation, especially under General guidelines and Pharmacology.

If you require any further information from the applicant which is not included, please inform the TGA Case Manager (internal evaluators) / External Evaluation team (external evaluators). They will arrange for the information to be sent to you.

Module 5 Recommendation

Recommendation

Not Effective - see External Advice for Sponsor

Information for Case Manager

Information for Case Manager

Information for other evaluation area

Information for other evaluation area

External advice to Sponsor

Issues to be raised to the sponsor
s22 [redacted]

SAF Effective - D25-2583278

Completed by

Module 5 Assessor	s22 [redacted]	Date	2/05/2025

RMP

Risk Management Plan

Recommendation

RMP required - Effective - Data sufficient for evaluation

Information for Case Manager

Information for Case Manager
RMP required for this Type A application refer D25-1896368

Information for other evaluation area

Information for other evaluation area

External advice to the Sponsor

Issues to be raised to the sponsor
Please advise the sponsor the following: An RMP is required and the sponsor has provided an RMP. Data are sufficient to accept submission for evaluation.

Completed by

RMP Officer	s22	Date	6/05/2025

Case Management

Module recommendations

This section is automatically populated from information in the form. Please do not type information here.
To update the table, select the whole table and press F9

Module	Recommendation
Module 3	**Not Effective - see External Advice for Sponsor**
Microbiology	**Effective - Data sufficient for evaluation**
Endotoxin	**Effective - Data sufficient for evaluation**
IDS	**Effective - Data sufficient for evaluation**
Container	**Effective - Data sufficient for evaluation**
Module 4	**Not Effective - see External Advice for Sponsor**
Module 5	**Not Effective - see External Advice for Sponsor**
RMP	**RMP required - Effective - Data sufficient for evaluation**

Information for Case Managers

This section is automatically populated from information in the form. Please do not type information here.

To update the table, select the whole table and press F9

Module	Information for Case Managers
AET	**Premier dates are incorrect.**
Module 3	
Microbiology	
Endotoxin	
IDS	
Container	
Module 4	**The studies in Module 4 should have meaningful names in accordance with the mandatory requirements:**
Module 5	
RMP	**RMP required for this Type A application refer D25-1896368**

Issues for Sponsor

This section is automatically populated from information in the form. Please do not type information here.

To update the table, select the whole table and press F9

Module area	Issues to be raised with the Sponsor
Module 3	s22 [redacted]
Microbiology	
Endotoxin	

Module area	Issues to be raised with the Sponsor
IDS	
Container Safety	
Module 4	**Module 4 does not comply with TGA's requirements for electronic documents and eCTD dossiers:** **"Electronic folder and file names should indicate the content and allow documents to be easily identified within the structure of the electronic dossier.** **https://www.tga.gov.au/resources/guidance/general-dossier-requirements#folder-and-file-names** **"Make title elements short, precise and informative."** **https://www.tga.gov.au/sites/default/files/ectd-au-module-1-and-regional-information.pdf** **Document titles used throughout Module 4 are uninformative, merely containing study numbers. These do not indicate the contents of the document (e.g., the particular test article investigated, species and route used, duration, or the type of study).** **Please re-submit data with appropriate name.**
Module 5	**The Cover letter notes that permission not to submit module 2 has been sought on 17 April, but it has not been approved by TGA. As per that advice, please submit module 2 documents relevant to module 5.** **4. As per pre submission advice, including in response to information sent 30 April 2025, clinical data supporting efficacy against JN1 is necessary. The Sponsors assertion that 'no additional clinical claims' are being made is not relevant, the efficacy of the product for the indication being sought has to be established and the only registered strain for this product is now 5 years out of date.** **Provide a tabulated summary of clinical studies submitted in the dossier.**
RMP	**Please advise the sponsor the following:** **An RMP is required and the sponsor has provided an RMP. Data are sufficient to accept submission for evaluation.**

Case Manager Checklist

- Do additional Premier secondary events need to be created?
- For a Reduced Fee Major Variation?
    - Liaise with AET been advised
    - enter the TRIM reference for the draft decision letter (do not sign the letter at this stage):
    - Has the Reduced Fee Decision Letter been drafted? (refer to PES)
    - The reduced fee decision letter template is at D18-11177183 .
- Is there Population PK required? If yes, email External Evaluations team
- For Type D generic applications – has the Module 5 Round 2 Premier event been allocated to PES Allocation?
- For Type F Major Variation applications with no Clinical Evaluation – has the Module 5 Round 2 Premier event been allocated to PES Allocation?
- Have GMP clearances been checked for validity at Milestone 7?

Submission Notes

Please note any changes to the submission during preliminary assessment

Details	
COR eligibility	None
Application type	None
Stream re-allocations	None

Overall Preliminary Assessment Outcome

For the Case Manager to complete

Failed to pass Preliminary Assessment

Completed by

Case Manager s22 Date Click or tap to enter a date.

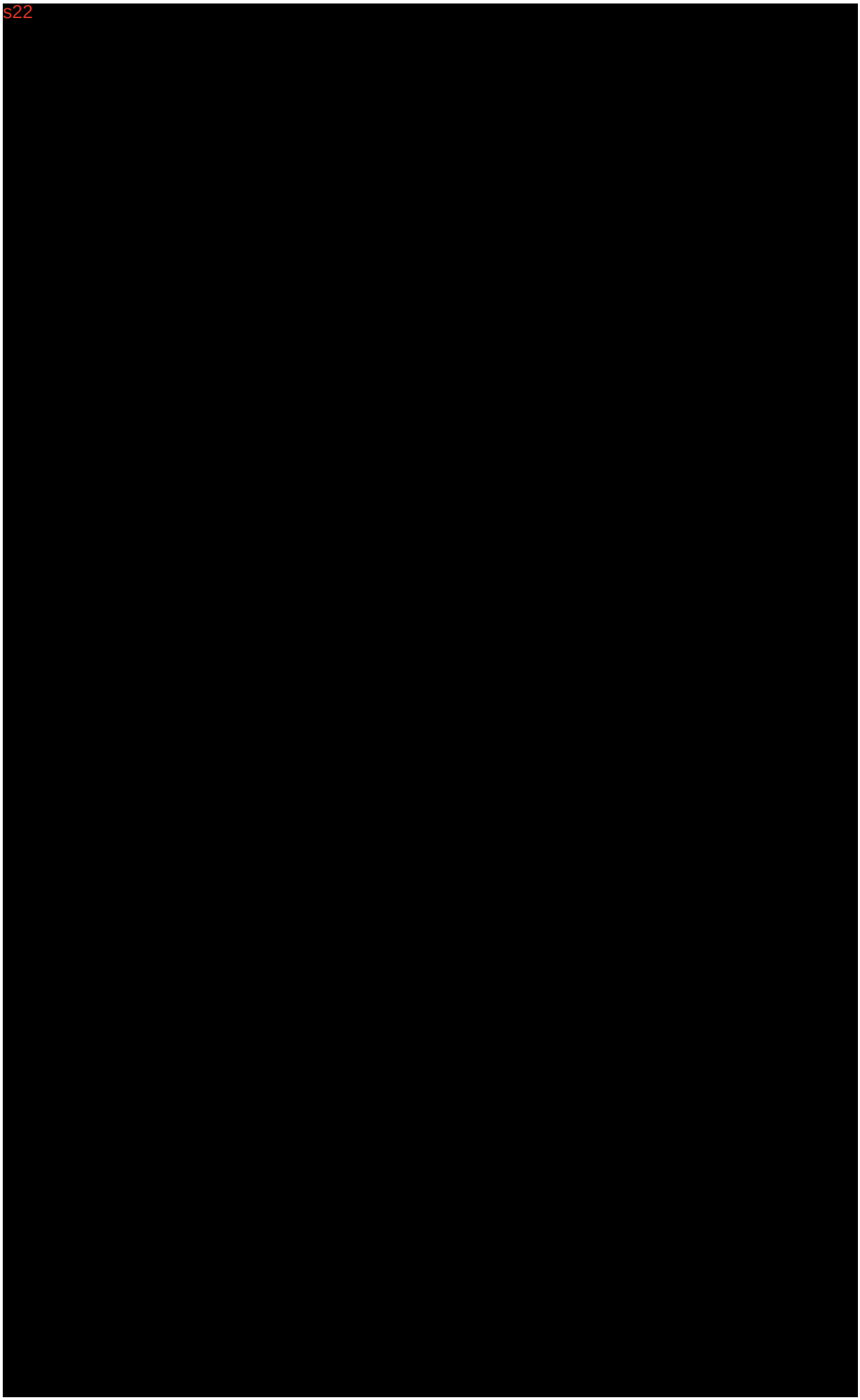
From: Streamlined Submission
To: s22 [redacted]
Cc: "Regulatory"; s22 [redacted]
Subject: PM-2025-01693-1-2 - Dossier not effective [SEC=OFFICIAL]
Date: Wednesday, 21 May 2025 9:10:41 AM
Attachments: image001.png
image002.png
image004.png

Dear Sponsor,

Thank you for your submission **PM-2025-01693-1-2.**

During the data screening stage, the dossier has been found *not effective* by the TGA evaluation areas.

s22 [redacted]


s22

Kindly provide your response addressing all the issues **in eCTD sequence by 28 May 2025;** please let me know if this timeframe is not achievable.

Please also be aware that Milestone 2 will be delayed until the above issues are satisfactorily resolved.

s22
s22
Prescription Medicines Authorisation Branch

Medicines Regulation Division | Health Products Regulation Group (Therapeutic Goods Administration)
Australian Government, Department of Health, Disability and Ageing
T: s22 | E: streamlinedsubmission@health.gov.au

This email comes to you from Ngunnawal Country
Location: Fairbairn ACT
PO Box 100, Woden ACT 2606, Australia

The Department of Health, Disability and Ageing acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: Streamlined Submission
To: s22 [redacted]
Cc: External Evaluations; RMP Coordinator; Microbiology Evaluations; Infectious Disease Safety; Container Safety Evaluations; s22 [redacted]
Subject: FW: PM-2025-01693-1-2 - Nuvaxovid JN.1 - Dossier not effective [SEC=OFFICIAL]
Date: Friday, 23 May 2025 1:38:53 PM
Attachments: image005.png
image007.png
image008.png
image010.png

Hi everyone,

Hope all is well.

Fyi, the sponsor for submission: **PM-2025-01693-1-2 - Nuvaxovid JN.1 – Type A**, has requested till 13 June 2025, to provide a response to the deficiencies identified during preliminary assessment.

The submission would be moved batches, now tentatively aiming at **MS2: 30 June 2025**.

I will keep everyone posted once the submission is ready to be accepted and the change in subsequent milestones.

Kind regards
s22 [redacted]

From: s22 [redacted] @biocelect.com>
Sent: Friday, 23 May 2025 12:55 PM
To: Streamlined Submission <streamlinedsubmission@health.gov.au>
Cc: Regulatory <Regulatory@biocelect.com>; s22 [redacted] @biointelect.com>; s22 [redacted] @adriaus.com>
Subject: RE: PM-2025-01693-1-2 - Dossier not effective [SEC=OFFICIAL]

Dear s22 [redacted]

I am requesting an extension to provide the response until the 13th June, noting the difficulty in coordinating a response between Novavax and 3rd party manufacturers which we are seeking to include updates to clinical modules and new testing results.

Please let me know if this is not acceptable or if you would like more information in the interim.

Kind Regards,
s22 [redacted]
s22 [redacted]

Level 4, 143 Macquarie Street, Sydney NSW Australia 2000
Level 5, Wynn Williams House, 47 Hereford Street, Christchurch 8013, New Zealand

M s22 [redacted] **T** s22 [redacted] **E** s22 [redacted] **@biocelect.com**
biocelect.com
Sydney | Christchurch

I acknowledge and pay my respects to the traditional owners and custodians on whose land I walk, work & live

---

From: Streamlined Submission <streamlinedsubmission@health.gov.au>
Sent: Wednesday, 21 May 2025 9:11 AM
To: s22 [redacted] @biocelect.com>
Cc: Regulatory <Regulatory@biocelect.com>; s22 [redacted] @biointelect.com>; s22 [redacted] @adriaus.com>
Subject: PM-2025-01693-1-2 - Dossier not effective [SEC=OFFICIAL]

Dear Sponsor,

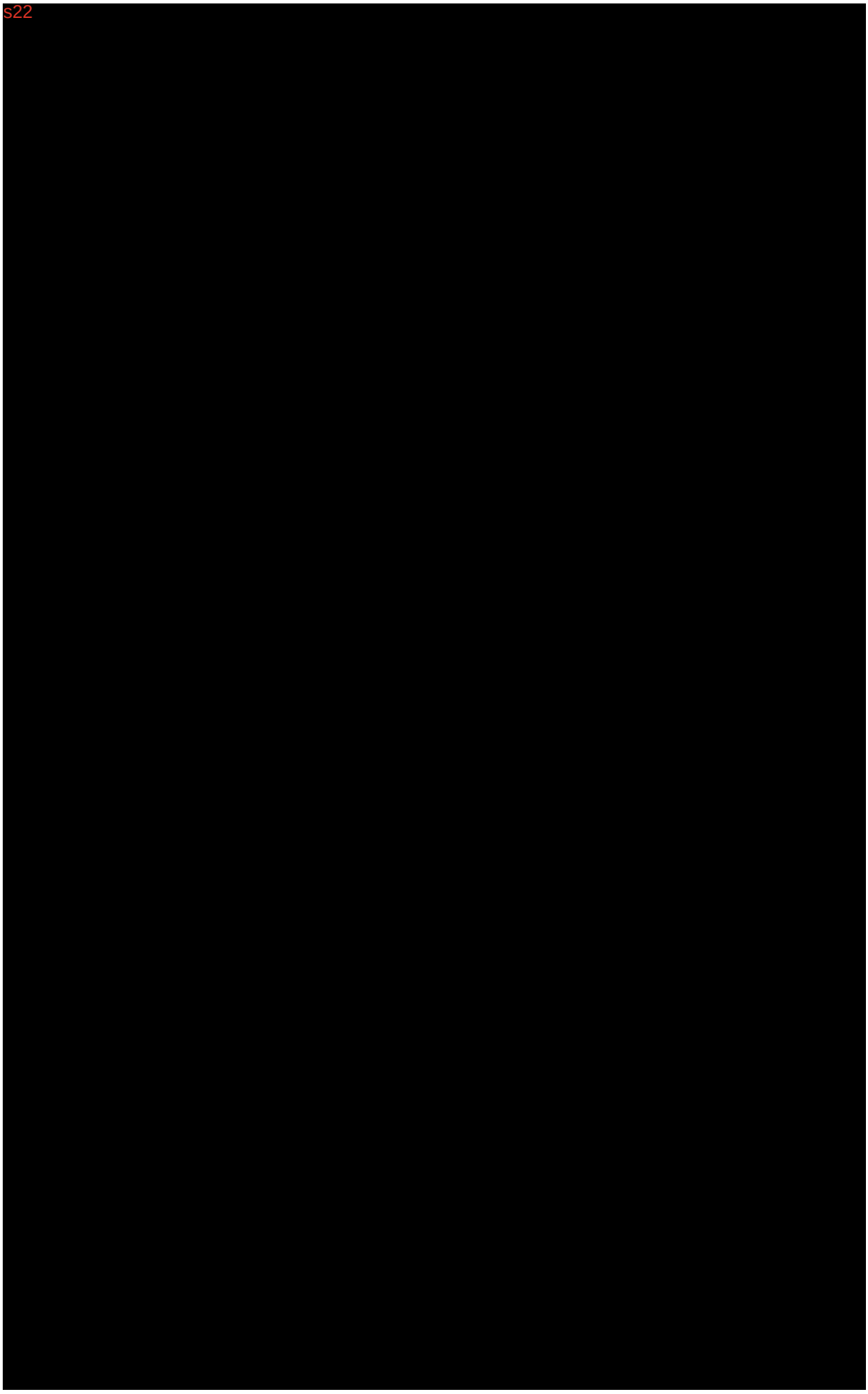
Thank you for your submission **PM-2025-01693-1-2.**

During the data screening stage, the dossier has been found *not effective* by the TGA evaluation areas.

Please refer below:

s22 [redacted]

s22



s22

[redacted]

Kindly provide your response addressing all the issues **in eCTD sequence by 28 May 2025;** please let me know if this timeframe is not achievable.

Please also be aware that Milestone 2 will be delayed until the above issues are satisfactorily resolved.

s22
s22
Prescription Medicines Authorisation Branch

Medicines Regulation Division | Health Products Regulation Group (Therapeutic Goods Administration)
Australian Government, Department of Health, Disability and Ageing
T: s22 | E: streamlinedsubmission@health.gov.au

This email comes to you from Ngunnawal Country
Location: Fairbairn ACT
PO Box 100, Woden ACT 2606, Australia

The Department of Health, Disability and Ageing acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: s22
To: Streamlined Submission; s22
Subject: RE: PM-2025-01693-1-2 - Dossier not effective [SEC=OFFICIAL]
Date: Monday, 16 June 2025 2:02:41 PM
Attachments: image001.png
image002.png
image004.png
image005.png
image007.png

Hi,

It is effective from a module 5 perspective.

Regards,
s22

From: Streamlined Submission <streamlinedsubmission@health.gov.au>
Sent: Monday, 16 June 2025 12:34 PM
To: s22 @health.gov.au>; s22 @health.gov.au>; s22 @Health.gov.au>
Cc: Streamlined Submission <streamlinedsubmission@health.gov.au>
Subject: FW: PM-2025-01693-1-2 - Dossier not effective [SEC=OFFICIAL]

Hi all,

Hope all is good.

The sponsor has provided their response to the major deficiencies identified during the preliminary assessment for sub: **PM-2025-01693-1-2 - SARS-CoV-2 rS (NVX-2373)**

Please find it on **D25-2578731**

SAF Trim link: D25-1856627

Please advice if the response suffices and the submissions can be made effective for **MS2: 30 June 2025**.

Kind regards
s22

From: eSubmissions <eSubmissions@health.gov.au>
Sent: Monday, 16 June 2025 11:53 AM
To: Streamlined Submission <streamlinedsubmission@health.gov.au>
Subject: RE: PM-2025-01693-1-2 - Dossier not effective [SEC=OFFICIAL]

Hi All,

The following sequence has been uploaded via the Govteams portal:

The attached data has not been submitted as a formal NeeS/eCTD sequence so cannot be uploaded to docuBridge, please save to TRIM and action as required.

TRIM link: D25-2578731

Kind Regards,

s22
s22 **– Application Entry, Support and Export Section**

Prescription Medicines Authorisation Branch | Medicines Regulation Division
Health Products Regulation Group (Therapeutic Goods Administration)
Australian Government Department of Health and Aged Care
E: s22 @health.gov.au
Location: Fairbairn, A.C.T.
PO Box 100, Canberra ACT 2601, Australia

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: Streamlined Submission <streamlinedsubmission@health.gov.au>
Sent: Monday, 16 June 2025 7:33 AM
To: eSubmissions <eSubmissions@health.gov.au>
Cc: Streamlined Submission <streamlinedsubmission@health.gov.au>
Subject: FW: PM-2025-01693-1-2 - Dossier not effective [SEC=OFFICIAL]

Dear Submissions colleagues,

Referring to the email below from sponsor, could I please request DB upload of the sequence.

Kind regards
s22

From: s22 @biocelect.com>
Sent: Friday, 13 June 2025 10:25 AM
To: Streamlined Submission <streamlinedsubmission@health.gov.au>
Cc: Regulatory <Regulatory@biocelect.com>; s22 @biointelect.com>; s22 @adriaus.com>

Subject: RE: PM-2025-01693-1-2 - Dossier not effective [SEC=OFFICIAL]

Dear s22

Biocelect would like to advise that a response (~159mb) has been uploaded to GovTeams in eCTD (Seq0122) addressing the issues identified below for the registration of Nuvaxovid JN.1 in a Pre-filled syringe (PFS) under application PM-2025-01693-1-2 which was found not effective.

A response document to TGA raised issues and relevant justifications is provided in Module 1.0.3 Response.

Please let me know if we can assist further.

Kind Regards,

s22
s22

Biocelect

Level 4, 143 Macquarie Street, Sydney NSW Australia 2000
Level 5, Wynn Williams House, 47 Hereford Street, Christchurch 8013, New Zealand

M s22 **T** s22 **E** s22 **@biocelect.com**
biocelect.com
Sydney | Christchurch

I acknowledge and pay my respects to the traditional owners and custodians on whose land I walk, work & live

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From: Streamlined Submission <streamlinedsubmission@health.gov.au>
Sent: Friday, 23 May 2025 1:38 PM
To: s22 @biocelect.com>
Cc: Regulatory <Regulatory@biocelect.com>; s22 @biointelect.com>; s22 @adriaus.com>
Subject: RE: PM-2025-01693-1-2 - Dossier not effective [SEC=OFFICIAL]

Dear s22

Thank you for your email. We will look forward to the response by 13 June 2025.

Meanwhile, I will keep you posted if any further information is required.

Kind regards
s22

From: s22 @biocelect.com>
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Dear s22

I am requesting an extension to provide the response until the 13th June, noting the difficulty in coordinating a response between Novavax and 3rd party manufacturers which we are seeking to include updates to clinical modules and new testing results.

Please let me know if this is not acceptable or if you would like more information in the interim.

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Subject: PM-2025-01693-1-2 - Dossier not effective [SEC=OFFICIAL]

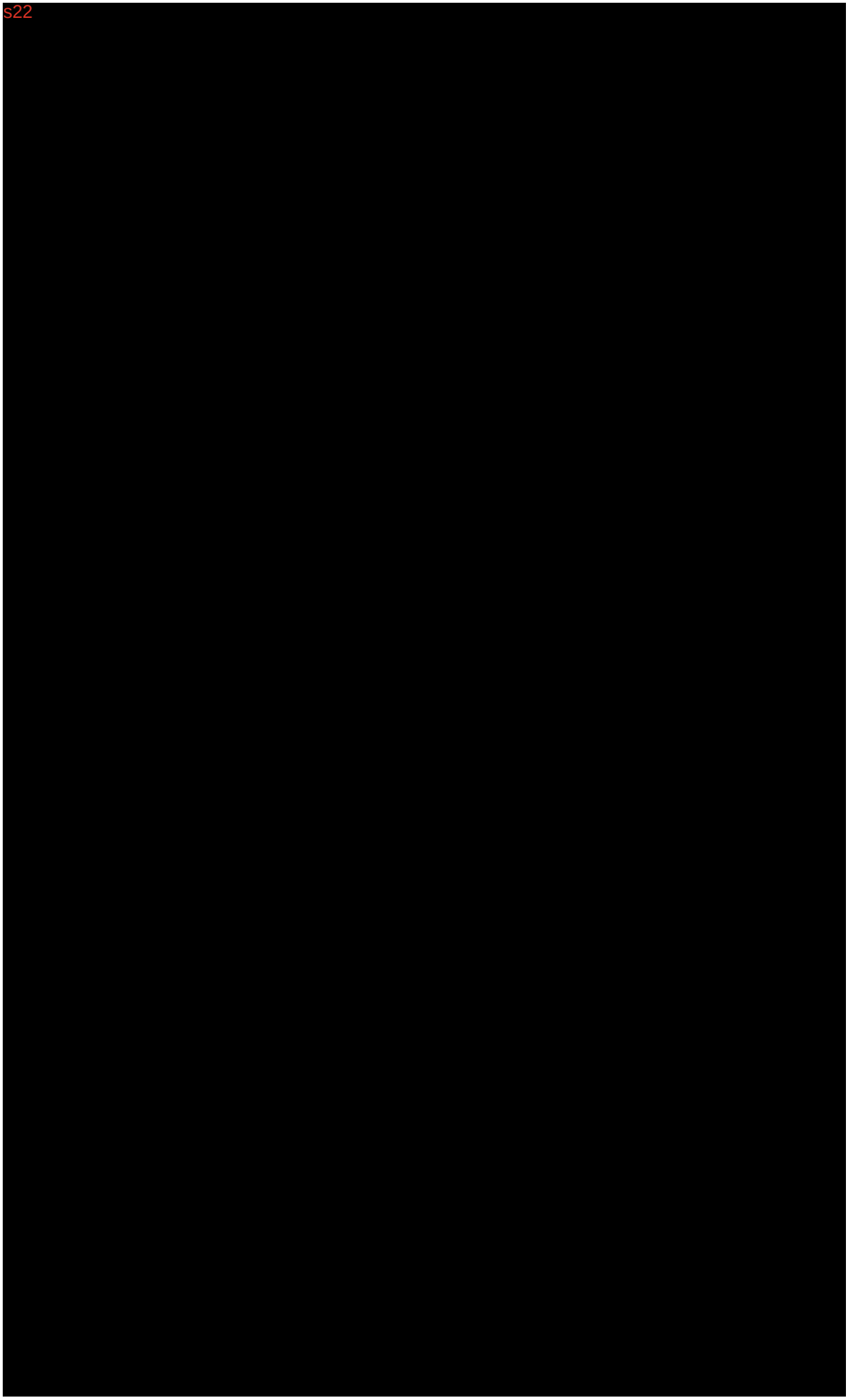
Dear Sponsor,

Thank you for your submission **PM-2025-01693-1-2.**

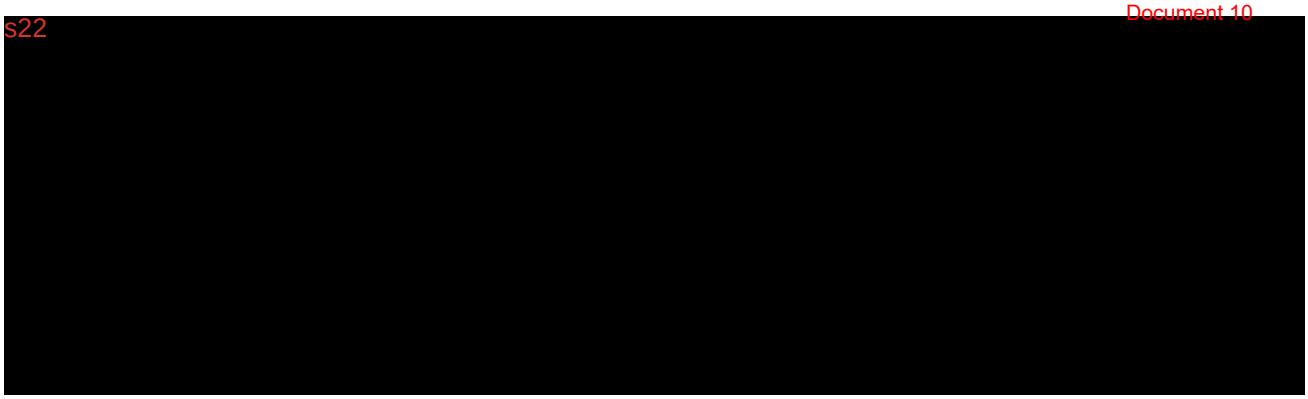
During the data screening stage, the dossier has been found *not effective* by the TGA evaluation areas.

Please refer below:

s22


s22

s22 [redacted]



Kindly provide your response addressing all the issues **in eCTD sequence by 28 May 2025;** please let me know if this timeframe is not achievable.

Please also be aware that Milestone 2 will be delayed until the above issues are satisfactorily resolved.

s22 [redacted]
s22 [redacted] **– Application and Advisory Management Section**
Prescription Medicines Authorisation Branch

Medicines Regulation Division | Health Products Regulation Group (Therapeutic Goods Administration)
Australian Government, Department of Health, Disability and Ageing
T: s22 [redacted] | E: streamlinedsubmission@health.gov.au

This email comes to you from Ngunnawal Country
Location: Fairbairn ACT
PO Box 100, Woden ACT 2606, Australia

The Department of Health, Disability and Ageing acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: Streamlined Submission
To: s22
Cc: "Regulatory"; s22
Subject: RE: PM-2025-01693-1-2 - Dossier not effective [SEC=OFFICIAL]
Date: Monday, 16 June 2025 2:45:17 PM
Attachments: image001.png
image003.png
image004.png
image006.png

Dear s22

Thank you for the response to the deficiencies.

Please be advised that the Module 4 Delegate has confirmed the SAF still cannot be considered effective due to the following reasons.

s22

Please provided a response to the above by **COB 20 June 2025.**

We are still awaiting comments on the acceptability from Module 3 Delegate, I will keep you posted/reach out if further information is required.

Kind regards
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Subject: RE: PM-2025-01693-1-2 - Dossier not effective [SEC=OFFICIAL]

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Cc: Regulatory <Regulatory@biocelect.com>; s22 @biointelect.com>; s22 @adriaus.com>
Subject: PM-2025-01693-1-2 - Dossier not effective [SEC=OFFICIAL]

Dear Sponsor,

Thank you for your submission **PM-2025-01693-1-2.**

During the data screening stage, the dossier has been found *not effective* by the TGA evaluation areas.

Please refer below:

s22

s22

[redacted]

s22 [redacted]

Kindly provide your response addressing all the issues **in eCTD sequence by 28 May 2025;** please let me know if this timeframe is not achievable.

Please also be aware that Milestone 2 will be delayed until the above issues are satisfactorily resolved.

s22 [redacted]
s22 [redacted] **– Application and Advisory Management Section**
Prescription Medicines Authorisation Branch

Medicines Regulation Division | Health Products Regulation Group (Therapeutic Goods Administration)
Australian Government, Department of Health, Disability and Ageing
T: s22 [redacted] | E: streamlinedsubmission@health.gov.au

This email comes to you from Ngunnawal Country
Location: Fairbairn ACT
PO Box 100, Woden ACT 2606, Australia

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From: Streamlined Submission
To: s22
Subject: RE: PM-2025-01693-1-2 - Dossier not effective [SEC=OFFICIAL]
Date: Wednesday, 18 June 2025 7:33:48 AM
Attachments: image001.png
image002.png
image004.png
image005.png
image007.png

Dear s22

Thank you for your email and hope everything is fine on your end.

I will coordinate with the sponsor with the advised changes.

Kind regards
s22

From: s22 @Health.gov.au>
Sent: Tuesday, 17 June 2025 5:13 PM
To: Streamlined Submission <streamlinedsubmission@health.gov.au>
Subject: RE: PM-2025-01693-1-2 - Dossier not effective [SEC=OFFICIAL]

Hi s22

Apologise I have been in s22 and s22 .
I have some time now, and I had a look to my urgent emails.

I confirm that the Proposed file label: '702-207- in vivo-135 days-mouse-IM-immuno- SARS-CoV-2 rS variants-primary and boosters' is acceptable
I confirm that the Proposed file label: '702-173- in vivo- 408 days ongoing- rhesus macaques-IM-immuno- SARS-CoV-2 rS prototype and variants-primary and boosters' is acceptable

I also confirm that the 2.4 Nonclinical Overview and 2.6 Nonclinical Summary documents submitted under seq 0121 are acceptable.

Thanks,

s22

s22
s22
Scientific Evaluation Branch

Medicines Regulation Division | Health Products Regulation Group
Australian Government, Department of Health, Disability and Ageing
T: s22 | E: s22 @health.gov.au

Location: Brisbane QLD 4000

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From: Streamlined Submission <streamlinedsubmission@health.gov.au>
Sent: Tuesday, 17 June 2025 2:06 PM
To: s22 @Health.gov.au>
Cc: Streamlined Submission <streamlinedsubmission@health.gov.au>
Subject: FW: PM-2025-01693-1-2 - Dossier not effective [SEC=OFFICIAL]

Dear s22

Hope all is well.

The sponsor has sought some clarification on the advice provided on the unacceptability of Dossier for **sub: PM-2025-01693-1-2 - Nuvaxovid JN.1**.

Please refer to the email below for complete text.

Grateful for your response.

Kind regards
s22

From: s22 @biocelect.com>
Sent: Tuesday, 17 June 2025 2:01 PM
To: Streamlined Submission <streamlinedsubmission@health.gov.au>
Cc: Regulatory <Regulatory@biocelect.com>; s22 @biointelect.com>; s22 @adriaus.com>
Subject: RE: PM-2025-01693-1-2 - Dossier not effective [SEC=OFFICIAL]

Dear s22

Thank you for yesterday's email. We are seeking clarity from the Module 4 Delegate ahead of our response to ensure it is complete and adequate.

s22

s22 [redacted]

If any information or clarification is needed, please let me know.

Kind Regards,

s22 [redacted]

s22 [redacted]

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Cc: Regulatory <Regulatory@biocelect.com>; s22 @biointelect.com>; s22 @adriaus.com>
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Dear s22

Thank you for the response to the deficiencies.

Please be advised that the Module 4 Delegate has confirmed the SAF still cannot be considered effective due to the following reasons.

s22 [redacted]

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From: Streamlined Submission <streamlinedsubmission@health.gov.au>
Sent: Wednesday, 21 May 2025 9:11 AM
To: s22 [redacted] @biocelect.com>
Cc: Regulatory <Regulatory@biocelect.com>; s22 [redacted] @biointelect.com>; s22 [redacted] @adriaus.com>
Subject: PM-2025-01693-1-2 - Dossier not effective [SEC=OFFICIAL]

Dear Sponsor,

Thank you for your submission **PM-2025-01693-1-2.**

During the data screening stage, the dossier has been found *not effective* by the TGA evaluation areas.

Please refer below:

s22 [redacted]

s22

[redacted]

s22

[redacted]

Kindly provide your response addressing all the issues **in eCTD sequence by 28 May 2025;** please let me know if this timeframe is not achievable.

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s22 [redacted]
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Australian Government, Department of Health, Disability and Ageing
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contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission."

From: Streamlined Submission
To: s22
Cc: s22 Regulatory
Subject: RE: PM-2025-01693-1-2 - Dossier not effective [SEC=OFFICIAL]
Date: Friday, 20 June 2025 4:13:24 PM
Attachments: image001.png
image003.png
image004.png
image006.png

Dear s22

Thank you for your email.

Could I please gently remind to upload all sequences as formal eCTD sequences for future references and copy eSubmissions Team (eSubmissions@health.gov.au).

For any further clarification, please feel to reach out to eSubmissions team.

This would ensure timely action and allocation of any data coming to TGA.

Kind regards
s22

From: s22 @biocelect.com>
Sent: Friday, 20 June 2025 9:09 AM
To: Streamlined Submission <streamlinedsubmission@health.gov.au>
Cc: s22 @biointelect.com>; s22 @adriaus.com>; Regulatory <Regulatory@biocelect.com>
Subject: RE: PM-2025-01693-1-2 - Dossier not effective [SEC=OFFICIAL]

Dear s22

Biocelect would like to advise that a response (~36mb) has been uploaded to GovTeams in eCTD (Seq0123) addressing the issues identified below for the registration of Nuvaxovid JN.1 in a Pre-filled syringe (PFS) under application PM-2025-01693-1-2 which was found not effective.

The package contains a response document and attachments in Module 1.0.3 Response and retitled nonclinical study reports.

Please let me know if we can assist further.

Kind Regards,
s22
s22

Level 4, 143 Macquarie Street, Sydney NSW Australia 2000
Level 5, Wynn Williams House, 47 Hereford Street, Christchurch 8013, New Zealand

M s22 **T** s22 **E** s22 **@biocelect.com**
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Subject: RE: PM-2025-01693-1-2 - Dossier not effective [SEC=OFFICIAL]

Dear s22

Thank you for your email and the clarification sought.

s22 [redacted]

Looking forward to an updated sequence by **COB 20 June 2025.**

Kind regards
s22

From: s22 @biocelect.com>
Sent: Tuesday, 17 June 2025 2:01 PM
To: Streamlined Submission <streamlinedsubmission@health.gov.au>
Cc: Regulatory <Regulatory@biocelect.com>; s22 @biointelect.com>; s22 @adriaus.com>
Subject: RE: PM-2025-01693-1-2 - Dossier not effective [SEC=OFFICIAL]

Dear s22

Thank you for yesterday's email. We are seeking clarity from the Module 4 Delegate ahead of our response to ensure it is complete and adequate.

s22

s22 [redacted]

Due to the short turnaround request and requirement to consult with international partners at Novavax, we kindly appreciate a timely response to above queries.

If any information or clarification is needed, please let me know.

Kind Regards,

s22 [redacted]
s22 [redacted]

Biocelect

Level 4, 143 Macquarie Street, Sydney NSW Australia 2000
Level 5, Wynn Williams House, 47 Hereford Street, Christchurch 8013, New Zealand

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Response.

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s22 [redacted]

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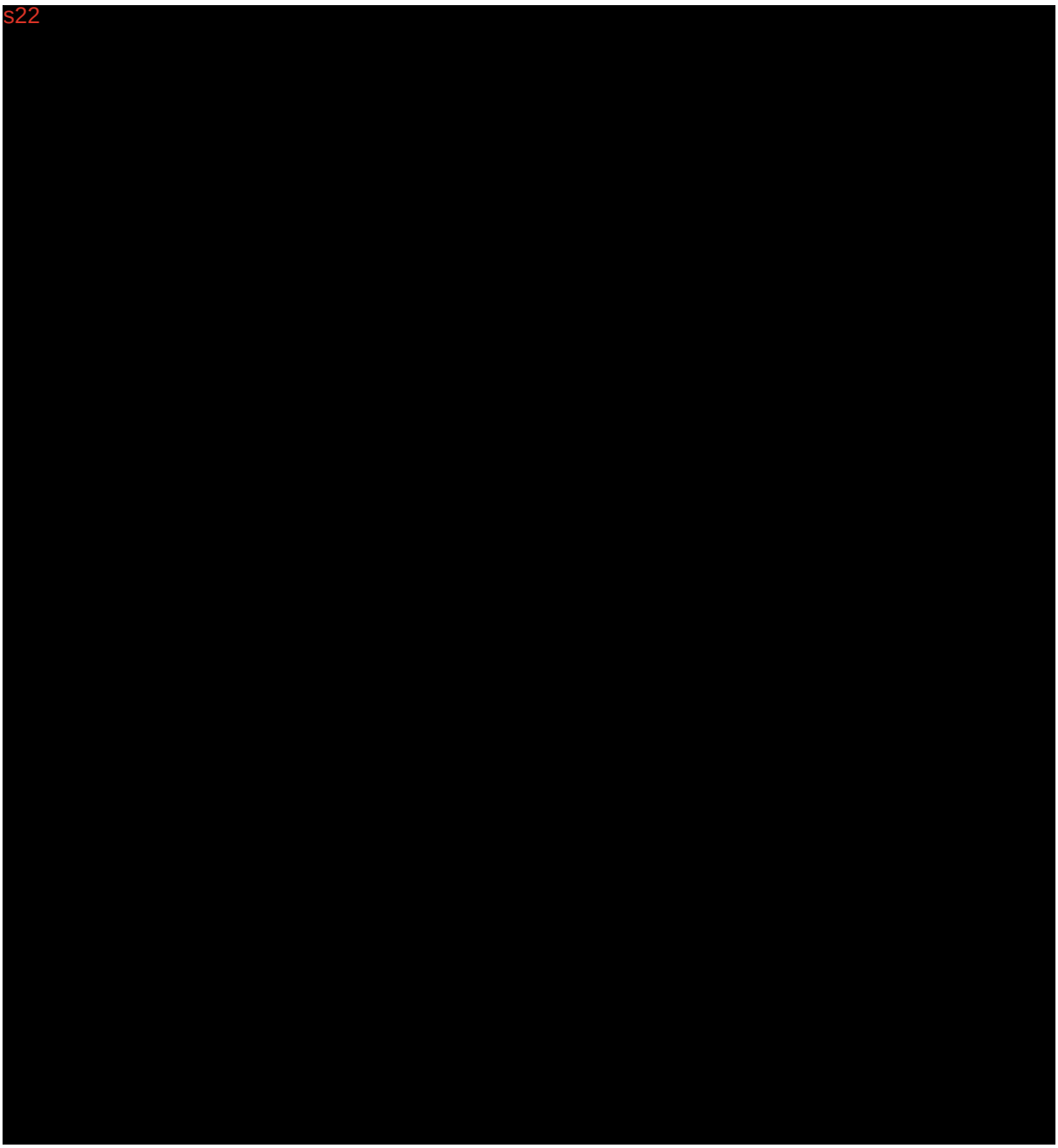
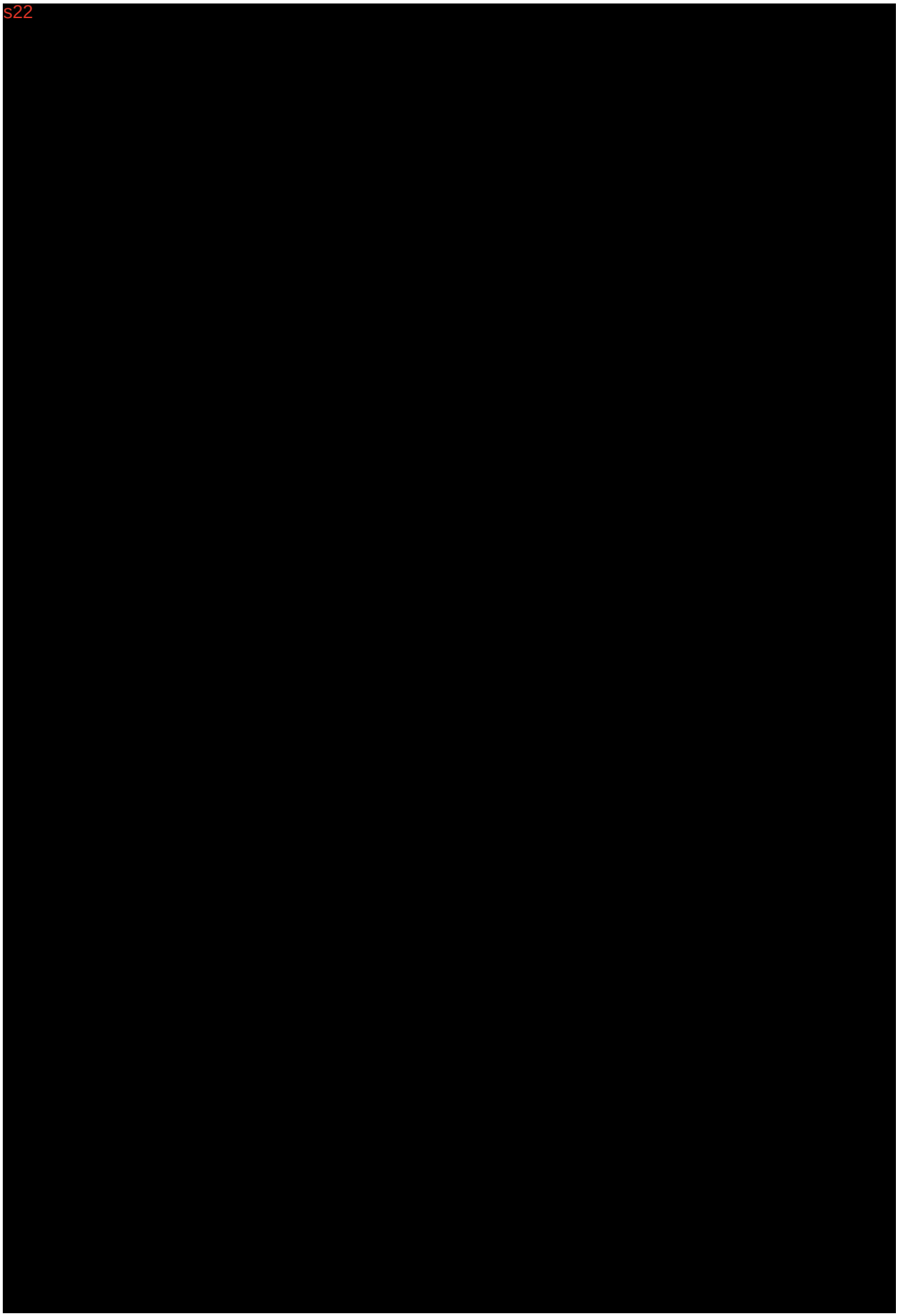
Please refer below:

s22



s22



Kindly provide your response addressing all the issues **in eCTD sequence by 28 May 2025;** please let me know if this timeframe is not achievable.

Please also be aware that Milestone 2 will be delayed until the above issues are satisfactorily resolved.

s22
s22 – Application and Advisory Management Section
Prescription Medicines Authorisation Branch

Medicines Regulation Division | Health Products Regulation Group (Therapeutic Goods Administration)
Australian Government, Department of Health, Disability and Ageing
T: s22 | E: streamlinedsubmission@health.gov.au

This email comes to you from Ngunnawal Country
Location: Fairbairn ACT
PO Box 100, Woden ACT 2606, Australia

The Department of Health, Disability and Ageing acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: s22
To: Streamlined Submission; s22
Cc: s22 KERR, Lisa
Subject: RE: PM-2025-01693-1-2 - Dossier not effective [SEC=OFFICIAL]
Date: Friday, 27 June 2025 5:12:05 PM
Attachments: image001.png
image002.png
image004.png
image005.png
image007.png

Dear s22

Hope all is well.

Please be advised that Biomedicines Evaluation and Biotherapeutics Section have reviewed the Sponsor responses and have the following conclusion:

'The Sponsor has not sufficiently addressed and/or have not provided acceptable responses to the unresolved issues identified by the TGA previously.

***IMPORTANT NOTE:* Since the issues have not been fully resolved, the submission is *ineffective* from a Module 3 perspective.'**

The full report discussing the Sponsor responses and this conclusion can be found in TRIM: D25-2708652.

Please let me know if anything else is needed.

Kind regards

s22

From: Streamlined Submission <streamlinedsubmission@health.gov.au>
Sent: Monday, 16 June 2025 2:47 PM
To: s @health.gov.au>; s22 @health.gov.au>; s22 @Health.gov.au>
Cc: s22 @Health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @Health.gov.au>; s22 @health.gov.au>
Subject: RE: PM-2025-01693-1-2 - Dossier not effective [SEC=OFFICIAL]

Dear s22

Thank you for your email.

I will wait for any comments.

Kind regards
s22

From: s22 @health.gov.au>
Sent: Monday, 16 June 2025 2:38 PM
To: s22 @health.gov.au>; Streamlined Submission <streamlinedsubmission@health.gov.au>; s22 @Health.gov.au>
Cc: s22 @Health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @Health.gov.au>; s22 @health.gov.au>
Subject: RE: PM-2025-01693-1-2 - Dossier not effective [SEC=OFFICIAL]

Hi s22

Hope all is well.

Thank you for sending through the Sponsor responses for NUVAXOVID. Since Module 3 had the majority of the issues/questions, BES and s22 are now going over the responses and will let you know of the effectiveness of the documents provided before 30 June.

Regards

s22

From: s22 @health.gov.au>
Sent: Monday, 16 June 2025 2:03 PM
To: Streamlined Submission <streamlinedsubmission@health.gov.au>; s22 @health.gov.au>; s22 @Health.gov.au>
Subject: RE: PM-2025-01693-1-2 - Dossier not effective [SEC=OFFICIAL]

Hi,

It is effective from a module 5 perspective.

Regards,
s22

From: Streamlined Submission <streamlinedsubmission@health.gov.au>
Sent: Monday, 16 June 2025 12:34 PM
To: s22 @health.gov.au>; s22 @health.gov.au>; s22 @Health.gov.au>
Cc: Streamlined Submission <streamlinedsubmission@health.gov.au>
Subject: FW: PM-2025-01693-1-2 - Dossier not effective [SEC=OFFICIAL]

Hi all,

Hope all is good.

The sponsor has provided their response to the major deficiencies identified during the preliminary assessment for sub: **PM-2025-01693-1-2 - SARS-CoV-2 rS (NVX-2373)**

Please find it on **D25-2578731**

SAF Trim link: D25-1856627

Please advice if the response suffices and the submissions can be made effective for **MS2: 30 June 2025**.

Kind regards
s22

From: eSubmissions <eSubmissions@health.gov.au>
Sent: Monday, 16 June 2025 11:53 AM
To: Streamlined Submission <streamlinedsubmission@health.gov.au>
Subject: RE: PM-2025-01693-1-2 - Dossier not effective [SEC=OFFICIAL]

Hi All,

The following sequence has been uploaded via the Govteams portal:

The attached data has not been submitted as a formal NeeS/eCTD sequence so cannot be uploaded to docuBridge, please save to TRIM and action as required.

TRIM link: D25-2578731

Kind Regards,

s22
– Application Entry, Support and Export Section

Prescription Medicines Authorisation Branch | Medicines Regulation Division
Health Products Regulation Group (Therapeutic Goods Administration)
Australian Government Department of Health and Aged Care
E: s22 @health.gov.au
Location: Fairbairn, A.C.T.
PO Box 100, Canberra ACT 2601, Australia

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: Streamlined Submission <streamlinedsubmission@health.gov.au>
Sent: Monday, 16 June 2025 7:33 AM
To: eSubmissions <eSubmissions@health.gov.au>
Cc: Streamlined Submission <streamlinedsubmission@health.gov.au>
Subject: FW: PM-2025-01693-1-2 - Dossier not effective [SEC=OFFICIAL]

Dear Submissions colleagues,

Referring to the email below from sponsor, could I please request DB upload of the sequence.

Kind regards
s22

From: s22 @biocelect.com>
Sent: Friday, 13 June 2025 10:25 AM
To: Streamlined Submission <streamlinedsubmission@health.gov.au>
Cc: Regulatory <Regulatory@biocelect.com>; s22 @biointelect.com>; s22 @adriaus.com>
Subject: RE: PM-2025-01693-1-2 - Dossier not effective [SEC=OFFICIAL]

Dear s22

Biocelect would like to advise that a response (~159mb) has been uploaded to GovTeams in eCTD (Seq0122) addressing the issues identified below for the registration of Nuvaxovid JN.1 in a Pre-filled syringe (PFS) under application PM-2025-01693-1-2 which was found not effective.

A response document to TGA raised issues and relevant justifications is provided in Module 1.0.3 Response.

Please let me know if we can assist further.

Kind Regards,
s22
s22

Biocelect
Level 4, 143 Macquarie Street, Sydney NSW Australia 2000
Level 5, Wynn Williams House, 47 Hereford Street, Christchurch 8013, New Zealand

M s22 **T** s22 **E** s22 **@biocelect.com**
biocelect.com
Sydney | Christchurch


I acknowledge and pay my respects to the traditional owners and custodians on whose land I walk, work & live

---

From: Streamlined Submission <streamlinedsubmission@health.gov.au>
Sent: Friday, 23 May 2025 1:38 PM
To: s22 @biocelect.com>
Cc: Regulatory <Regulatory@biocelect.com>; s22 @biointelect.com>; s22 @adriaus.com>
Subject: RE: PM-2025-01693-1-2 - Dossier not effective [SEC=OFFICIAL]

Dear s22

Thank you for your email. We will look forward to the response by 13 June 2025.

Meanwhile, I will keep you posted if any further information is required.

Kind regards
s22

From: s @biocelect.com>
Sent: Friday, 23 May 2025 12:55 PM
To: Streamlined Submission <streamlinedsubmission@health.gov.au>
Cc: Regulatory <Regulatory@biocelect.com>; s22 @biointelect.com>; s22 @adriaus.com>
Subject: RE: PM-2025-01693-1-2 - Dossier not effective [SEC=OFFICIAL]

Dear s22

I am requesting an extension to provide the response until the 13th June, noting the difficulty in coordinating a response between Novavax and 3rd party manufacturers which we are seeking to include updates to clinical modules and new testing results.

Please let me know if this is not acceptable or if you would like more information in the interim.

Kind Regards,

s22 [redacted]
s22 [redacted]

Biocelect

Level 4, 143 Macquarie Street, Sydney NSW Australia 2000
Level 5, Wynn Williams House, 47 Hereford Street, Christchurch 8013, New Zealand

M s22 [redacted] **T** s22 [redacted] **E** s22 [redacted] **@biocelect.com**
biocelect.com
Sydney | Christchurch

I acknowledge and pay my respects to the traditional owners and custodians on whose land I walk, work & live

---

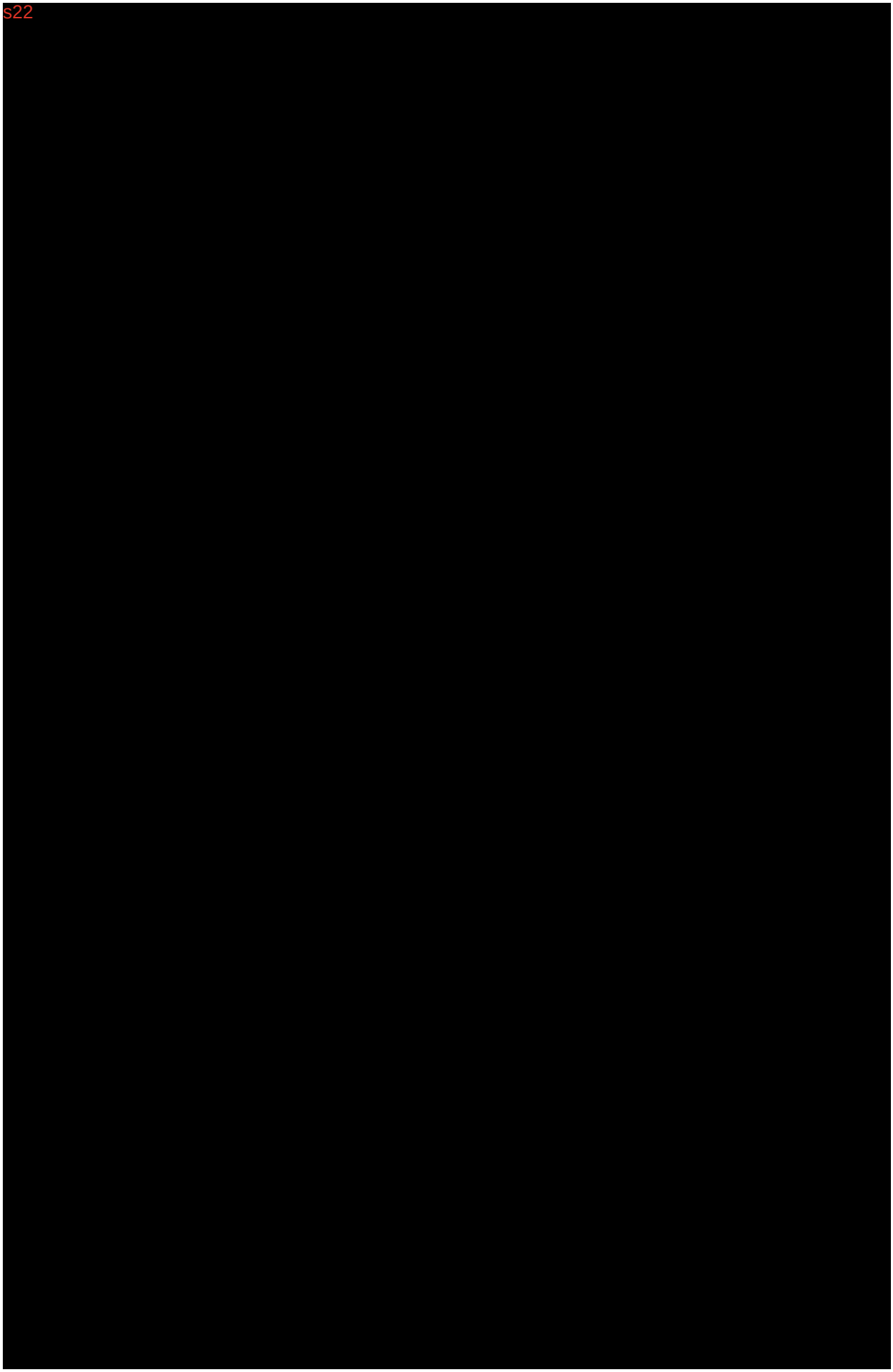
From: Streamlined Submission <streamlinedsubmission@health.gov.au>
Sent: Wednesday, 21 May 2025 9:11 AM
To: s [redacted] @biocelect.com>
Cc: Regulatory <Regulatory@biocelect.com>; s22 [redacted] @biointelect.com>; s22 [redacted] @adriaus.com>
Subject: PM-2025-01693-1-2 - Dossier not effective [SEC=OFFICIAL]

Dear Sponsor,

Thank you for your submission **PM-2025-01693-1-2.**

During the data screening stage, the dossier has been found *not effective* by the TGA evaluation areas.

Please refer below:


s22

s22 [redacted]

Kindly provide your response addressing all the issues **in eCTD sequence by 28 May 2025;** please let me know if this timeframe is not achievable.

Please also be aware that Milestone 2 will be delayed until the above issues are satisfactorily resolved.

s22 [redacted]
s22 [redacted] **– Application and Advisory Management Section**
Prescription Medicines Authorisation Branch

Medicines Regulation Division | Health Products Regulation Group (Therapeutic Goods Administration)
Australian Government, Department of Health, Disability and Ageing
T: 02 5132 5096 | E: streamlinedsubmission@health.gov.au

This email comes to you from Ngunnawal Country
Location: Fairbairn ACT

PO Box 100, Woden ACT 2606, Australia

The Department of Health, Disability and Ageing acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: Streamlined Submission
To: s22
Subject: RE: PM-2025-01693-1-2 - Dossier not effective [SEC=OFFICIAL]
Date: Monday, 30 June 2025 1:43:14 PM
Attachments: image001.png
image003.png
image004.png
image006.png
NUVAXOVID JN.1 - PM-2025-01693-1-2 - TGA response to pre-submission data package [2.0] - FILTER.pdf

---

Dear s22

Re: PM-2025-01693-1-2 - Nuvaxovid JN.1

The Module 3 Delegate has advised that the response provided to address the deficiencies identified during the preliminary assessment of the Dossier is unsatisfactory.

As a result, the submission is currently considered ineffective from a Module 3 perspective.

Please be advised that the submission will not be deemed as effective unless the issues outlined in the *attached* report are adequately addressed.

However, the Delegate has granted a final extension, allowing the response to be submitted to the TGA no later than **20 July 2025**.

They have also emphasized that if the revised response remains unsatisfactory, the sponsor is strongly encouraged to withdraw the submission, as no further extensions will be granted.

Looking forward to a timely response.

Regards

s22
s22 **– Application and Advisory Management Section**
Prescription Medicines Authorisation Branch

Medicines Regulation Division | Health Products Regulation Group (Therapeutic Goods Administration)
Australian Government, Department of Health, Disability and Ageing
Email: streamlinedsubmission@health.gov.au

This email comes to you from Ngunnawal Country
Location: Fairbairn ACT
PO Box 100, Woden ACT 2606, Australia

The Department of Health, Disability and Ageing acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: s22 @biocelect.com>
Sent: Friday, 20 June 2025 4:28 PM
To: eSubmissions <eSubmissions@health.gov.au>
Cc: Streamlined Submission <streamlinedsubmission@health.gov.au>
Subject: RE: PM-2025-01693-1-2 - Dossier not effective [SEC=OFFICIAL]

Hi s22

I have re-submitted Seq0122 for your convenience. For your awareness this was initially submitted on 13th June.

Kind Regards,

s22
s22

Biocelect
Level 4, 143 Macquarie Street, Sydney NSW Australia 2000
Level 5, Wynn Williams House, 47 Hereford Street, Christchurch 8013, New Zealand

M s22 **T** s22 **E** s22 **@biocelect.com**
biocelect.com
Sydney | Christchurch

I acknowledge and pay my respects to the traditional owners and custodians on whose land I walk, work & live

---

From: eSubmissions <eSubmissions@health.gov.au>
Sent: Friday, 20 June 2025 4:20 PM
To: s22 @biocelect.com>
Cc: Streamlined Submission <streamlinedsubmission@health.gov.au>
Subject: RE: PM-2025-01693-1-2 - Dossier not effective [SEC=OFFICIAL]

UNOFFICIAL

Good Afternoon,

It appears we are missing sequence sequence 0122, please send this through to resolve the issues in 0123.

Regards,

s22
s22 Application Entry, Support and Export Section
Medicines Regulation Division | Health Products Regulation Group
Prescription Medicines Authorisation Branch
Department of Health and Aged Care
E: s22 @health.gov.au
Location: Fairbairn
PO Box 100, Woden ACT 2606, Australia

UNOFFICIAL

From: s22 @biocelect.com>
Sent: Friday, 20 June 2025 9:09 AM
To: Streamlined Submission <streamlinedsubmission@health.gov.au>
Cc: s22 @biointelect.com>; s22 @adriaus.com>; Regulatory <Regulatory@biocelect.com>
Subject: RE: PM-2025-01693-1-2 - Dossier not effective [SEC=OFFICIAL]

Dear s22

Biocelect would like to advise that a response (~36mb) has been uploaded to GovTeams in eCTD (Seq0123) addressing the issues identified below for the registration of Nuvaxovid JN.1 in a Pre-filled syringe (PFS) under application PM-2025-01693-1-2 which was found not effective.

The package contains a response document and attachments in Module 1.0.3 Response and retitled nonclinical study reports.

Please let me know if we can assist further.

Kind Regards,

s22
s22

Biocelect
Level 4, 143 Macquarie Street, Sydney NSW Australia 2000
Level 5, Wynn Williams House, 47 Hereford Street, Christchurch 8013, New Zealand

M s22 **T** s22 **E** s22 **@biocelect.com**

biocelect.com
Sydney | Christchurch


I acknowledge and pay my respects to the traditional owners and custodians on whose land I walk, work & live

From: Streamlined Submission <streamlinedsubmission@health.gov.au>
Sent: Wednesday, 18 June 2025 7:38 AM
To: s22 @biocelect.com>
Cc: s22 @biointelect.com>; s22 @adriaus.com>; Regulatory <Regulatory@biocelect.com>
Subject: RE: PM-2025-01693-1-2 - Dossier not effective [SEC=OFFICIAL]

Dear s22

Thank you for your email and the clarification sought.

s22 [redacted]

Looking forward to an updated sequence by **COB 20 June 2025.**

Kind regards
s22

From: s22 @biocelect.com>
Sent: Tuesday, 17 June 2025 2:01 PM
To: Streamlined Submission <streamlinedsubmission@health.gov.au>
Cc: Regulatory <Regulatory@biocelect.com>; s22 @biointelect.com>; s22 @adriaus.com>

Subject: RE: PM-2025-01693-1-2 - Dossier not effective [SEC=OFFICIAL]

Dear s22

Thank you for yesterday's email. We are seeking clarity from the Module 4 Delegate ahead of our response to ensure it is complete and adequate.

s22

[redacted]

Due to the short turnaround request and requirement to consult with international partners at

Novavax, we kindly appreciate a timely response to above queries.

If any information or clarification is needed, please let me know.

Kind Regards,
s22 [redacted]
s22 [redacted]

Level 4, 143 Macquarie Street, Sydney NSW Australia 2000
Level 5, Wynn Williams House, 47 Hereford Street, Christchurch 8013, New Zealand

M s22 [redacted] **T** s22 [redacted] **E** s22 [redacted] **@biocelect.com**
biocelect.com
Sydney | Christchurch

I acknowledge and pay my respects to the traditional owners and custodians on whose land I walk, work & live

---

From: Streamlined Submission <streamlinedsubmission@health.gov.au>
Sent: Monday, 16 June 2025 2:45 PM
To: s22 [redacted] @biocelect.com>
Cc: Regulatory <Regulatory@biocelect.com>; s22 [redacted] @biointelect.com>; s22 [redacted] @adriaus.com>
Subject: RE: PM-2025-01693-1-2 - Dossier not effective [SEC=OFFICIAL]

Dear s22 [redacted]

Thank you for the response to the deficiencies.

Please be advised that the Module 4 Delegate has confirmed the SAF still cannot be considered effective due to the following reasons.

s22 [redacted]

Please provided a response to the above by **COB 20 June 2025.**

We are still awaiting comments on the acceptability from Module 3 Delegate, I will keep you posted/reach out if further information is required.

Kind regards

From: @biocelect.com>
Sent: Friday, 13 June 2025 10:25 AM
To: Streamlined Submission <streamlinedsubmission@health.gov.au>
Cc: Regulatory <Regulatory@biocelect.com>; @biointelect.com>; @adriaus.com>
Subject: RE: PM-2025-01693-1-2 - Dossier not effective [SEC=OFFICIAL]

Dear

Biocelect would like to advise that a response (~159mb) has been uploaded to GovTeams in eCTD (Seq0122) addressing the issues identified below for the registration of Nuvaxovid JN.1 in a Pre-filled syringe (PFS) under application PM-2025-01693-1-2 which was found not effective.

A response document to TGA raised issues and relevant justifications is provided in Module 1.0.3 Response.

Please let me know if we can assist further.

Kind Regards,

Level 4, 143 Macquarie Street, Sydney NSW Australia 2000
Level 5, Wynn Williams House, 47 Hereford Street, Christchurch 8013, New Zealand

M s22 **T** s22 **E** s22 **@biocelect.com**
biocelect.com
Sydney | Christchurch


I acknowledge and pay my respects to the traditional owners and custodians on whose land I walk, work & live

---

From: Streamlined Submission <streamlinedsubmission@health.gov.au>
Sent: Friday, 23 May 2025 1:38 PM
To: s [redacted] @biocelect.com>
Cc: Regulatory <Regulatory@biocelect.com>; s22 [redacted] @biointelect.com>; s22 [redacted] @adriaus.com>
Subject: RE: PM-2025-01693-1-2 - Dossier not effective [SEC=OFFICIAL]

Dear s22 [redacted]

Thank you for your email. We will look forward to the response by 13 June 2025.

Meanwhile, I will keep you posted if any further information is required.

Kind regards
s22 [redacted]

From: s22 [redacted] @biocelect.com>
Sent: Friday, 23 May 2025 12:55 PM
To: Streamlined Submission <streamlinedsubmission@health.gov.au>
Cc: Regulatory <Regulatory@biocelect.com>; s22 [redacted] @biointelect.com>; s22 [redacted] @adriaus.com>
Subject: RE: PM-2025-01693-1-2 - Dossier not effective [SEC=OFFICIAL]

Dear s22

I am requesting an extension to provide the response until the 13th June, noting the difficulty in coordinating a response between Novavax and 3rd party manufacturers which we are seeking to include updates to clinical modules and new testing results.

Please let me know if this is not acceptable or if you would like more information in the interim.

Kind Regards,

s22
s22

Biocelect

Level 4, 143 Macquarie Street, Sydney NSW Australia 2000
Level 5, Wynn Williams House, 47 Hereford Street, Christchurch 8013, New Zealand

M s22 **T** s22 **E** s22 **@biocelect.com**
biocelect.com
Sydney | Christchurch

I acknowledge and pay my respects to the traditional owners and custodians on whose land I walk, work & live

---

From: Streamlined Submission <streamlinedsubmission@health.gov.au>
Sent: Wednesday, 21 May 2025 9:11 AM
To: s22 @biocelect.com>
Cc: Regulatory <Regulatory@biocelect.com>; s22 @biointelect.com>; s22 @adriaus.com>
Subject: PM-2025-01693-1-2 - Dossier not effective [SEC=OFFICIAL]

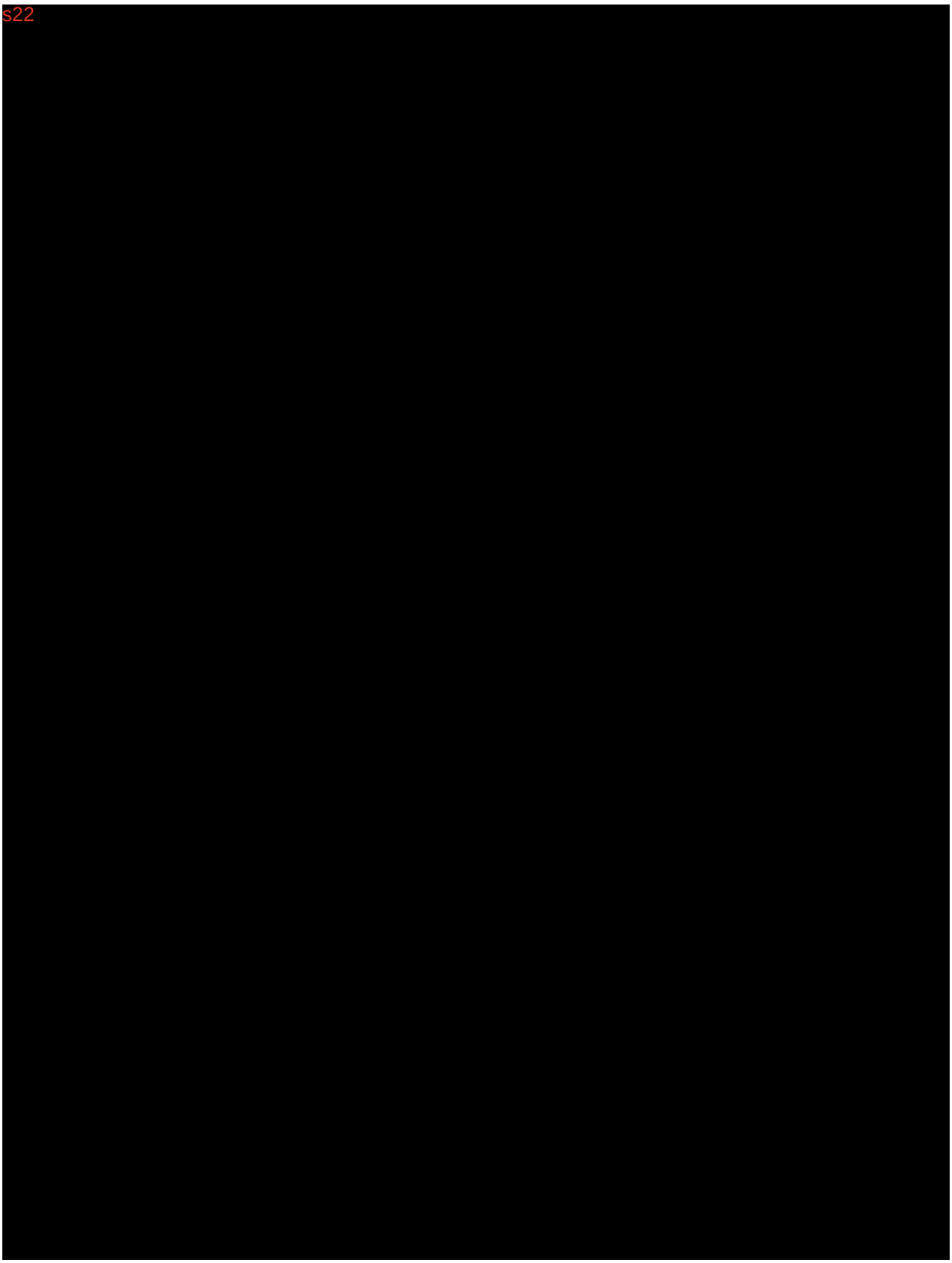
Dear Sponsor,

Thank you for your submission **PM-2025-01693-1-2.**

During the data screening stage, the dossier has been found *not effective* by the TGA evaluation areas.

Please refer below:

s22



s22

[redacted]

Kindly provide your response addressing all the issues **in eCTD sequence by 28 May 2025;** please let me know if this timeframe is not achievable.

Please also be aware that Milestone 2 will be delayed until the above issues are satisfactorily resolved.

s22
s22 **– Application and Advisory Management Section**
Prescription Medicines Authorisation Branch

Medicines Regulation Division | Health Products Regulation Group (Therapeutic Goods Administration)
Australian Government, Department of Health, Disability and Ageing
T: s22 | E: streamlinedsubmission@health.gov.au

This email comes to you from Ngunnawal Country
Location: Fairbairn ACT
PO Box 100, Woden ACT 2606, Australia

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"Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission."

From: Streamlined Submission
To: s22
Cc: "Regulatory"; regulatorycorrespondence@novavax.com; s22
Subject: RE: PM-2025-01693-1-2 - Dossier not effective [SEC=OFFICIAL]
Date: Thursday, 3 July 2025 4:34:40 PM
Attachments: image001.png
image003.png
image004.png
image006.png

Dear s22

As per your conversation and request for reconsideration, the module 3 evaluators have reviewed the information and responses submitted. Overall, the initial conclusion for the pre-submission/filter phase remains:

'The Sponsor has not sufficiently addressed and/or have not provided acceptable responses to the unresolved issues identified by the TGA previously.

***IMPORTANT NOTE:* Since the issues have not been fully resolved or addressed, the submission is *ineffective* from a Module 3 perspective.'**

Since this is a pre-submission assessment for completion of Milestone 2, there will be no further reports, assessment of responses or feedback from Module 3 evaluators provided to the Sponsor.

The dossier has been found **ineffective** from a Module 3 perspective, as well as Module 4, at Milestone 2. Therefore, the Sponsor is strongly recommended to withdraw the application, otherwise it will be formally rejected.

Kind regards

s22

From: s22 @biocelect.com>
Sent: Tuesday, 1 July 2025 9:34 AM
To: s22 @health.gov.au>
Subject: FW: PM-2025-01693-1-2 - Dossier not effective [SEC=OFFICIAL]

FYI

Kind Regards,

s22

s22 [redacted]

Biocelect

Level 4, 143 Macquarie Street, Sydney NSW Australia 2000
Level 5, Wynn Williams House, 47 Hereford Street, Christchurch 8013, New Zealand

M s22 [redacted] **T** s22 [redacted] **E** s22 [redacted] **@biocelect.com**
biocelect.com
Sydney | Christchurch

I acknowledge and pay my respects to the traditional owners and custodians on whose land I walk, work & live

---

From: s22 [redacted]
Sent: Monday, 30 June 2025 6:12 PM
To: Streamlined Submission <streamlinedsubmission@health.gov.au>
Cc: Regulatory <Regulatory@biocelect.com>; Regulatory Correspondence <regulatorycorrespondence@novavax.com>; s22 [redacted] @biointelect.com>; s22 [redacted] @adriaus.com>
Subject: RE: PM-2025-01693-1-2 - Dossier not effective [SEC=OFFICIAL]

Dear s22 [redacted]

Biocelect is very appreciative of the review and time spent responding to the application from the Module 3 evaluation team and from the wider TGA team.

Could I confirm with you that the Module 3 evaluation team was aware of the response document found in 1.7.1 (Seq 0121) of the initial submission, which was also submitted in the earlier package (through GovTeams) on the 17th April 2025?

From my interpretation, it does appear that the module 3 documents have been reviewed in isolation, where within the assessment it is noted "*The Sponsor has not addressed Issue* [x] *in their email response*" however all issues had a response and justifications where appropriate within the above (attached) – for example the purity method was provided with the necessary data (a validation report with JN1) but noted in the TGA assessment "**The Sponsor has not addressed this issue in their response**".

Biocelect and Novavax will also review the TGA's helpful assessment regarding the gaps of the data that were evaluated and will look to provide a consolidated response urgently once we hear from you.

Thank you again for your patience.

Kind Regards,

s22 [redacted]
s22 [redacted]

Biocelect

Level 4, 143 Macquarie Street, Sydney NSW Australia 2000
Level 5, Wynn Williams House, 47 Hereford Street, Christchurch 8013, New Zealand

M s22 [redacted] **T** s22 [redacted] **E** s22 [redacted] **@biocelect.com**
biocelect.com
Sydney | Christchurch

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From: Streamlined Submission <streamlinedsubmission@health.gov.au>
Sent: Monday, 30 June 2025 1:43 PM
To: s22 [redacted] @biocelect.com>
Subject: RE: PM-2025-01693-1-2 - Dossier not effective [SEC=OFFICIAL]

Dear s22 [redacted]

Re: PM-2025-01693-1-2 - Nuvaxovid JN.1

The Module 3 Delegate has advised that the response provided to address the deficiencies identified during the preliminary assessment of the Dossier is unsatisfactory.

As a result, the submission is currently considered ineffective from a Module 3 perspective.

Please be advised that the submission will not be deemed as effective unless the issues outlined in the *attached* report are adequately addressed.

However, the Delegate has granted a final extension, allowing the response to be submitted to the TGA no later than **20 July 2025**.

They have also emphasized that if the revised response remains unsatisfactory, the sponsor is strongly encouraged to withdraw the submission, as no further extensions will be granted.

Looking forward to a timely response.

Regards

s22 [redacted]
s22 [redacted] **– Application and Advisory Management Section**
Prescription Medicines Authorisation Branch

Medicines Regulation Division | Health Products Regulation Group (Therapeutic Goods Administration)
Australian Government, Department of Health, Disability and Ageing
Email: streamlinedsubmission@health.gov.au

This email comes to you from Ngunnawal Country
Location: Fairbairn ACT
PO Box 100, Woden ACT 2606, Australia

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From: s22 [redacted] @biocelect.com>
Sent: Friday, 20 June 2025 4:28 PM
To: eSubmissions <eSubmissions@health.gov.au>
Cc: Streamlined Submission <streamlinedsubmission@health.gov.au>
Subject: RE: PM-2025-01693-1-2 - Dossier not effective [SEC=OFFICIAL]

Hi s22 [redacted]

I have re-submitted Seq0122 for your convenience. For your awareness this was initially submitted on 13th June.

Kind Regards,
s22 [redacted]
s22 [redacted]

Biocelect
Level 4, 143 Macquarie Street, Sydney NSW Australia 2000
Level 5, Wynn Williams House, 47 Hereford Street, Christchurch 8013, New Zealand

M s22 [redacted] **T** s22 [redacted] **E** s22 [redacted] **@biocelect.com**
biocelect.com
Sydney | Christchurch


I acknowledge and pay my respects to the traditional owners and custodians on whose land I walk, work & live

---

From: eSubmissions <eSubmissions@health.gov.au>
Sent: Friday, 20 June 2025 4:20 PM
To: s22 [redacted] @biocelect.com>
Cc: Streamlined Submission <streamlinedsubmission@health.gov.au>
Subject: RE: PM-2025-01693-1-2 - Dossier not effective [SEC=OFFICIAL]

UNOFFICIAL

Good Afternoon,

It appears we are missing sequence sequence 0122, please send this through to resolve the issues in 0123.

Regards,

s22 [redacted] – Application Entry, Support and Export Section
Medicines Regulation Division | Health Products Regulation Group
Prescription Medicines Authorisation Branch
Department of Health and Aged Care
E: s22 [redacted] @health.gov.au
Location: Fairbairn
PO Box 100, Woden ACT 2606, Australia

UNOFFICIAL

From: s22 @biocelect.com>
Sent: Friday, 20 June 2025 9:09 AM
To: Streamlined Submission <streamlinedsubmission@health.gov.au>
Cc: s @biointelect.com>; s22 @adriaus.com>; Regulatory <Regulatory@biocelect.com>
Subject: RE: PM-2025-01693-1-2 - Dossier not effective [SEC=OFFICIAL]

Dear s22

Biocelect would like to advise that a response (~36mb) has been uploaded to GovTeams in eCTD (Seq0123) addressing the issues identified below for the registration of Nuvaxovid JN.1 in a Pre-filled syringe (PFS) under application PM-2025-01693-1-2 which was found not effective.

The package contains a response document and attachments in Module 1.0.3 Response and retitled nonclinical study reports.

Please let me know if we can assist further.

Kind Regards,

s22
s22

Biocelect

Level 4, 143 Macquarie Street, Sydney NSW Australia 2000
Level 5, Wynn Williams House, 47 Hereford Street, Christchurch 8013, New Zealand

M s22 **T** s22 **E** s22 **@biocelect.com**
biocelect.com
Sydney | Christchurch

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---

From: Streamlined Submission <streamlinedsubmission@health.gov.au>
Sent: Wednesday, 18 June 2025 7:38 AM
To: s22 @biocelect.com>

Cc: s22 @biointelect.com>; s22 @adriaus.com>; Regulatory <Regulatory@biocelect.com>
Subject: RE: PM-2025-01693-1-2 - Dossier not effective [SEC=OFFICIAL]

Dear s22

Thank you for your email and the clarification sought.

The Module 4 Delegate has the following comments.

s22

Looking forward to an updated sequence by **COB 20 June 2025.**

Kind regards
s22

From: s @biocelect.com>
Sent: Tuesday, 17 June 2025 2:01 PM
To: Streamlined Submission <streamlinedsubmission@health.gov.au>
Cc: Regulatory <Regulatory@biocelect.com>; s22 @biointelect.com>; s22 @adriaus.com>
Subject: RE: PM-2025-01693-1-2 - Dossier not effective [SEC=OFFICIAL]

Dear s22

Thank you for yesterday's email. We are seeking clarity from the Module 4 Delegate ahead of our response to ensure it is complete and adequate.

s22

s22 [redacted]

Due to the short turnaround request and requirement to consult with international partners at Novavax, we kindly appreciate a timely response to above queries.

If any information or clarification is needed, please let me know.

Kind Regards,

s22 [redacted]
s22 [redacted]

Biocelect

Level 4, 143 Macquarie Street, Sydney NSW Australia 2000
Level 5, Wynn Williams House, 47 Hereford Street, Christchurch 8013, New Zealand

M s22 **T** s22 **E** s22 **@biocelect.com**
biocelect.com
Sydney | Christchurch


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---

From: Streamlined Submission <streamlinedsubmission@health.gov.au>
Sent: Monday, 16 June 2025 2:45 PM
To: s22 @biocelect.com>
Cc: Regulatory <Regulatory@biocelect.com>; s22 @biointelect.com>; s22 @adriaus.com>
Subject: RE: PM-2025-01693-1-2 - Dossier not effective [SEC=OFFICIAL]

Dear s22

Thank you for the response to the deficiencies.

Please be advised that the Module 4 Delegate has confirmed the SAF still cannot be considered effective due to the following reasons.

Module 4: Unfortunately, the Sponsor has not addressed our recommendations regarding Module 4.

Study titles should be concise, self-explanatory, and informative. We recommend including key details such as the study model (e.g., in vitro or in vivo), study duration (e.g., 57-day study), species used (e.g., rat, mouse, NHP), and the study type (e.g., repeat-dose toxicity, Ames test for genotoxicity, primary pharmacology variant X, immunogenicity, etc.) in the study name of the dossier.

Additionally, the Nonclinical Overview document is not aligned with the studies presented in the dossier (e.g., 702-188, 702-191). Conversely, some studies included in the dossier are not reflected in the Nonclinical Overview.

We kindly request that these discrepancies be addressed to ensure consistency and clarity across the submission.

Please provided a response to the above by **COB 20 June 2025.**

We are still awaiting comments on the acceptability from Module 3 Delegate, I will keep you posted/reach out if further information is required.

Kind regards
s22

From: s22 @biocelect.com>
Sent: Friday, 13 June 2025 10:25 AM
To: Streamlined Submission <streamlinedsubmission@health.gov.au>
Cc: Regulatory <Regulatory@biocelect.com>; s22 @biointelect.com>; s22 @adriaus.com>
Subject: RE: PM-2025-01693-1-2 - Dossier not effective [SEC=OFFICIAL]

Dear s22

Biocelect would like to advise that a response (~159mb) has been uploaded to GovTeams in eCTD (Seq0122) addressing the issues identified below for the registration of Nuvaxovid JN.1 in a Pre-filled syringe (PFS) under application PM-2025-01693-1-2 which was found not effective.

A response document to TGA raised issues and relevant justifications is provided in Module 1.0.3 Response.

Please let me know if we can assist further.

Kind Regards,
s22
s22

Biocelect
Level 4, 143 Macquarie Street, Sydney NSW Australia 2000
Level 5, Wynn Williams House, 47 Hereford Street, Christchurch 8013, New Zealand

M s22 **T** s22 **E** s22 **@biocelect.com**
biocelect.com
Sydney | Christchurch

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---

From: Streamlined Submission <streamlinedsubmission@health.gov.au>
Sent: Friday, 23 May 2025 1:38 PM
To: s22 @biocelect.com>
Cc: Regulatory <Regulatory@biocelect.com>; s22 @biointelect.com>; s22 @adriaus.com>
Subject: RE: PM-2025-01693-1-2 - Dossier not effective [SEC=OFFICIAL]

Dear s22

Thank you for your email. We will look forward to the response by 13 June 2025.

Meanwhile, I will keep you posted if any further information is required.

Kind regards
s22

From: s @biocelect.com>
Sent: Friday, 23 May 2025 12:55 PM
To: Streamlined Submission <streamlinedsubmission@health.gov.au>
Cc: Regulatory <Regulatory@biocelect.com>; s22 @biointelect.com>; s22 @adriaus.com>
Subject: RE: PM-2025-01693-1-2 - Dossier not effective [SEC=OFFICIAL]

Dear s22

I am requesting an extension to provide the response until the 13th June, noting the difficulty in coordinating a response between Novavax and 3rd party manufacturers which we are seeking to include updates to clinical modules and new testing results.

Please let me know if this is not acceptable or if you would like more information in the interim.

Kind Regards,
s22
s22

Level 4, 143 Macquarie Street, Sydney NSW Australia 2000
Level 5, Wynn Williams House, 47 Hereford Street, Christchurch 8013, New Zealand

M s22 **T** s22 **E** s22 **@biocelect.com**
biocelect.com
Sydney | Christchurch

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From: Streamlined Submission <streamlinedsubmission@health.gov.au>
Sent: Wednesday, 21 May 2025 9:11 AM
To: s22 @biocelect.com>
Cc: Regulatory <Regulatory@biocelect.com>; s22 @biointelect.com>; s22 @adriaus.com>
Subject: PM-2025-01693-1-2 - Dossier not effective [SEC=OFFICIAL]

Dear Sponsor,

Thank you for your submission **PM-2025-01693-1-2.**

During the data screening stage, the dossier has been found *not effective* by the TGA evaluation areas.

Please refer below:

s22

s22

[redacted]

s22 Document 16

Kindly provide your response addressing all the issues **in eCTD sequence by 28 May 2025;** please let me know if this timeframe is not achievable.

Please also be aware that Milestone 2 will be delayed until the above issues are satisfactorily resolved.

s22
s22 **– Application and Advisory Management Section**
Prescription Medicines Authorisation Branch

Medicines Regulation Division | Health Products Regulation Group (Therapeutic Goods Administration)
Australian Government, Department of Health, Disability and Ageing
T: s22 | E: streamlinedsubmission@health.gov.au

This email comes to you from Ngunnawal Country
Location: Fairbairn ACT
PO Box 100, Woden ACT 2606, Australia

The Department of Health, Disability and Ageing acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission."

"Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission."

From: Streamlined Submission
To: s22
Cc: s22
Subject: RE: Stream 2 - COVID-19 - Updated guidance [SEC=OFFICIAL]
Date: Monday, 14 July 2025 9:43:12 AM
Attachments: image001.png
image003.png
image004.png
image006.png
image007.png
image008.png
RE NUVAXOVID JN.1 - TGABiocelect discussion - Stream 2 SECOFFICIAL (47.6 KB).msg

---

Dear s22

Thank you for your email and the clarification requested.

Please note that the guidance provided in the email dated *01 July 2025* was general in nature and intended for all COVID-19 vaccine sponsors. It was issued in response to s22 initial enquiry and should not be interpreted as specific to the current submission: **PM-2025-01693-1-2.**

Re: PM-2025-01693-1-2 - Nuvaxovid JN.1

As previously advised, this submission will be accepted under *Category 1, Type A (new chemical/biological entity), see attached*.

Regarding your request for a fee reduction dated *02 July 2025*, the full evaluation fee for a Type A application remains applicable. As previously advised in the pre-submission meeting dated *14 October 2025* 45-day review target, a condition for reduced fee applications is unlikely, and the change in presentation from a multidose vial to a pre-filled syringe in the Nuvaxovid JN.1 application constitutes a major variation, further supporting the full Type A classification.

Also, due to the withdrawal of Omicron XBB.1.5 strain update and the JN.1 strain update not being closely related to the fully registered original Wuhan strain, the reduced fee eligibility is not met.

As previously outlined by Module 3 most recent email, dated *03 July 2025*, critical deficiencies remain unresolved and are expected to present significant challenges during the evaluation phase which would be required to be taken into consideration by the decision Delegate.

We would like to reiterate, if the application is not formally withdrawn and proceeds to evaluation, the full evaluation fee *($227,825)* will be required.

Please advise us how you wish to proceed as soon as possible or by COB Friday, 18 July 2025.

Kind regards

s22

From: s22 @biocelect.com>
Sent: Thursday, 10 July 2025 10:18 AM
To: Streamlined Submission <streamlinedsubmission@health.gov.au>
Cc: s22 @biointelect.com>
Subject: RE: Stream 2 - COVID-19 - Updated guidance [SEC=OFFICIAL]

Dear s22

I am following up on the below to confirm if the application type can be amended noting the guidance from you below:

If an application for a COVID-19 vaccine strain update has already been submitted and is in pre-submission phase awaiting acceptance for Milestone 2, then the Category 1 application 'TYPE' may be amended to 'Type A with reduced fees' in accordance with the new guidance.

Kind Regards,
s22
s22

Biocelect
Level 4, 143 Macquarie Street, Sydney NSW Australia 2000
Level 5, Wynn Williams House, 47 Hereford Street, Christchurch 8013, New Zealand

M s22 **T** s22 **E** s22 **@biocelect.com**
biocelect.com
Sydney | Christchurch

I acknowledge and pay my respects to the traditional owners and custodians on whose land I walk, work & live

---

From: s22

Sent: Wednesday, 2 July 2025 11:12 AM
To: Streamlined Submission <streamlinedsubmission@health.gov.au>
Cc: s22 [redacted]@biointelect.com>
Subject: RE: Stream 2 - COVID-19 - Updated guidance [SEC=OFFICIAL]

Dear s22 [redacted]

Thank you for the updated guidance.

Could I confirm with you the process to amend the application from '*Type A* ' to '*Type A with reduced fees*' as mentioned below?

I am also hoping you could clarify that we could expect a corresponding fee reduction (with refund) from $58,663 to $1,341 to match "*Application to register a vaccine for a new strain of COVID-19, respiratory syncytial virus or influenza, where the vaccine is closely related to an existing vaccine that is included in the Register in relation to the applicant*" for the application fee and a further reduction if the application progresses to the evaluation phase?

Thank you again for your assistance.

Kind Regards,
s22 [redacted]
s22 [redacted]

Biocelect
Level 4, 143 Macquarie Street, Sydney NSW Australia 2000
Level 5, Wynn Williams House, 47 Hereford Street, Christchurch 8013, New Zealand

M s22 [redacted] **T** s22 [redacted] **E** s22 [redacted] **@biocelect.com**
biocelect.com
Sydney | Christchurch

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From: Streamlined Submission <streamlinedsubmission@health.gov.au>
Sent: Tuesday, 1 July 2025 10:30 AM
To: s22 [redacted] @biointelect.com>
Cc: s22 [redacted] @biocelect.com>
Subject: Stream 2 - COVID-19 - Updated guidance [SEC=OFFICIAL]

Dear Sponsor,

Please be advised that there has been an updated guidance on COVID-19 vaccine strain updates published on the TGA website (COVID-19 vaccine strain updates | Therapeutic Goods Administration (TGA)), which states:

> *'Applications to update a new strain (variant) update for COVID-19 vaccines, will generally be considered a new chemical entry, and will be evaluated under a* ***Category 1 Type A (reduced fees)*** *application pathway involving an application for registration under section 23 of the Therapeutic Goods Act 1989, processed under the streamlined submission process.*
>
> *We will aim to evaluate applications under a target timeframe of* ***45 working days (mRNA vaccines)****, which is dependent on the availability of the complete dossier and the data required to support the application.'*

Therefore, a COVID-19 vaccine strain update should be submitted as a **Category 1, Type A application with reduced fees**. Please refer to the updated guidance for the summary of fees and charges (Summary of fees and charges to applications submitted to the TGA | Therapeutic Goods Administration (TGA)).

If an application for a COVID-19 vaccine strain update has already been submitted and is in pre-submission phase awaiting acceptance for Milestone 2, then the Category 1 application *'TYPE'* may be amended to *'Type A with reduced fees'* in accordance with the new guidance.

IMPORTANT NOTE: The TGA acknowledges that these types of applications are an update of the antigen composition of a COVID-19 vaccine in accordance with the recommendation of the WHO Technical Advisory Group on COVID-19 Vaccine Composition (TAG-CO-VAC; Statement on the antigen composition of COVID-19 vaccines). These application types are **NOT** 2025/2026 COVID-19 strain updates since there is currently **no distinct COVID-19 season**, as indicated by the US CDC National Center for Immunization and Respiratory Diseases (COVID-19 can surge throughout the year | NCIRD | CDC).

s22 [redacted]
s22 [redacted] **– Application and Advisory Management Section**
Prescription Medicines Authorisation Branch

Medicines Regulation Division | Health Products Regulation Group (Therapeutic Goods

Administration)
Australian Government, Department of Health, Disability and Ageing
Email: streamlinedsubmission@health.gov.au

This email comes to you from Ngunnawal Country
Location: Fairbairn ACT
PO Box 100, Woden ACT 2606, Australia

The Department of Health, Disability and Ageing acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: s22 [redacted] @biointelect.com>
Sent: Thursday, 1 May 2025 10:15 AM
To: s22 [redacted] @health.gov.au>
Cc: s22 [redacted] @biocelect.com>
Subject: Protein-based vaccine guideline

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Dear s22 [redacted]

I hope you are well.

I had a quick question related to the new guideline that is expected to be published soon. Is the guideline you flagged to us specific to covid protein-based vaccines, covid protein-based vaccine strain updates or protein-based vaccines in general?

Thanks and kind regards,

s22 [redacted]

s22 [redacted]
[redacted]

Level 4, 143 Macquarie Street, Sydney NSW Australia 2000
M s22 [redacted] **T** s22 [redacted] **E** s22 [redacted] @biointelect.com

biointelect.com Sydney | Melbourne

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From: s22
To: Streamlined Submission
Cc: s22 ; Regulatory; regulatorycorrespondence@novavax.com; s22
Subject: RE: NUVAXOVID JN.1 - TGA/Biocelect discussion - Stream 2 [SEC=OFFICIAL]
Date: Thursday, 17 April 2025 5:56:45 PM
Attachments: image002.png
image004.png

Dear s22

Thank you for the considered advice. Biocelect is providing below comments and seeking TGA agreement on proposals for submission of additional data during evaluation and on summary documents for Clinical Study Reports (CSR).

s22

s22 Document 17

[redacted]

Kind Regards,
s22 [redacted]
s22 [redacted]

Level 4, 143 Macquarie Street, Sydney NSW Australia 2000
Level 5, Wynn Williams House, 47 Hereford Street, Christchurch 8013, New Zealand

M s22 [redacted] **T** s22 [redacted] **E** s22 [redacted] **@biocelect.com**
biocelect.com
Sydney | Christchurch

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---

From: Streamlined Submission <streamlinedsubmission@health.gov.au>
Sent: Tuesday, 15 April 2025 3:35 PM
To: s22 [redacted] @biocelect.com>; s22 [redacted] @biointelect.com>
Cc: Streamlined Submission <streamlinedsubmission@health.gov.au>
Subject: NUVAXOVID JN.1 - TGA/Biocelect discussion - Stream 2 [SEC=OFFICIAL]

Dear s22

Thank you for seeking clarification while preparing Biocelect's NUVAXOVID JN.1 submission.

With respect to the questions raised after your call/meeting with s22, the following advice is provided,

- s22 /TGA would get back to Biocelect on appropriate application pathway:
  - *TGA advises that a Category 1 Type A (new chemical/biological entity) submission is appropriate. This will be a full fee submission – application fee $56.844 and evaluation fee $227,825.*

- No clinical data for JN.1 would be included but 4 CSRs as requested by TGA in feedback document would be included in the application to bridge JN1 reference standard to Wuhan (2019nCoV-**307**, 2019nCoV-**311**, 2019nCoV-**503**, 2019nCoV-**301**):
  - *Clinical (i.e. module 5) data is required for a Type A application. For further information please refer https://www.tga.gov.au/how-we-regulate/supply-therapeutic-good/supply-prescription-medicine/application-process-prescription-medicines and https://www.tga.gov.au/resources/guidance/understanding-fees-and-charges-prescription-medicine-applications.*
  - *Additionally, 4 CSRs are requested by TGA in feedback document to be included in the application to bridge JN1 reference standard to Wuhan (2019nCoV-**307**, 2019nCoV-**311**, 2019nCoV-**503**, 2019nCoV-**301**).*

- Biocelect noted intent to supply by September 2025, but TGA evaluation timelines would be dependent on quality of the dossier and application type
  - *Under the Category 1 Type A pathway a decision is made within the legislated 255 working days. Meaning if a submission is provided to the TGA today, 15 April 2025, and is considered effective, the milestone 2 notification letter will be provided on 31 May 2025. Evaluation of the dossier will commence, and the target milestone 7 date will be 15 May 2026. Unfortunately, the evaluation of the proposed data will not align with Biocelect intention to supply by September 2025.*

Please include streamlinedsubmission@health.gov.au in all communications related to category 1 applications, as Case Managers remain the contact point for all pre-submission and submission correspondence.

Regards,

s22
s22 – Application and Advisory Management
Prescription Medicines Authorisation Branch
Medicines Regulation Division | Health Products Regulation Group
Australian Government, Department of Health and Aged Care
E: streamlinedsubmission@health.gov.au

From: s22
To: Streamlined Submission
Cc: Regulatory; regulatorycorrespondence@novavax.com; s22
Subject: RE: PM-2025-01693-1-2 - Dossier not effective [SEC=OFFICIAL]
Date: Friday, 18 July 2025 9:08:38 AM
Attachments: image001.png
image003.png
image004.png
image006.png

Dear Streamlined submission,

We acknowledge your email correspondence on July 14th , reiterating the TGA position and your recommendation at the conclusion of the application screening phase. As you requested, Biocelect, as the sponsor of Nuvaxovid, hereby withdraws the application," PM-2025-01693-1-2 - Nuvaxovid JN.1"

We would like to arrange a meeting with the TGA experts to discuss Novavax's proposed remediation plan. This remediation plan focuses on addressing the root cause of the TGA's primary concerns regarding potency and the overall stability profile of Nuvaxovid. To support Novavax's planning and resources, it is critical that Novavax receive TGA's expectations for an acceptable file. In addition, we would like to understand if the data to support use of the new Wuhan Reference Standard could be submitted to the Wuhan application in advance of submission of a new application, to allow TGA to complete their review, as the JN.1 Reference Standard was calibrated against the Wuhan Reference Standard.

Biocelect and Novavax appreciate TGA's favourable consideration of the request to meet.

Kind Regards,

s22
s22

Biocelect

Level 4, 143 Macquarie Street, Sydney NSW Australia 2000
Level 5, Wynn Williams House, 47 Hereford Street, Christchurch 8013, New Zealand

M s22 **T** s22 **E** s22 **@biocelect.com**

biocelect.com

Sydney | Christchurch

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From: Streamlined Submission <streamlinedsubmission@health.gov.au>
Sent: Thursday, 3 July 2025 4:35 PM
To: s22 @biocelect.com>
Cc: Regulatory <Regulatory@biocelect.com>; regulatorycorrespondence@novavax.com; s22 @biointelect.com>; s22 @adriaus.com>
Subject: RE: PM-2025-01693-1-2 - Dossier not effective [SEC=OFFICIAL]

Dear s22

As per your conversation and request for reconsideration, the module 3 evaluators have reviewed the information and responses submitted. Overall, the initial conclusion for the pre-submission/filter phase remains:

'The Sponsor has not sufficiently addressed and/or have not provided acceptable responses to the unresolved issues identified by the TGA previously.

***IMPORTANT NOTE:* Since the issues have not been fully resolved or addressed, the submission is *ineffective* from a Module 3 perspective.'**

Since this is a pre-submission assessment for completion of Milestone 2, there will be no further reports, assessment of responses or feedback from Module 3 evaluators provided to the Sponsor.

The dossier has been found **ineffective** from a Module 3 perspective, as well as Module 4, at Milestone 2. Therefore, the Sponsor is strongly recommended to withdraw the application, otherwise it will be formally rejected.

Kind regards

s22

From: s22 @biocelect.com>
Sent: Tuesday, 1 July 2025 9:34 AM
To: s22 @health.gov.au>
Subject: FW: PM-2025-01693-1-2 - Dossier not effective [SEC=OFFICIAL]

FYI

Kind Regards,
s22 [redacted]
s22 [redacted]

Level 4, 143 Macquarie Street, Sydney NSW Australia 2000
Level 5, Wynn Williams House, 47 Hereford Street, Christchurch 8013, New Zealand

M s22 [redacted] **T** s22 [redacted] **E** s22 [redacted] **@biocelect.com**
biocelect.com
Sydney | Christchurch


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---

From: s22 [redacted]
Sent: Monday, 30 June 2025 6:12 PM
To: Streamlined Submission <streamlinedsubmission@health.gov.au>
Cc: Regulatory <Regulatory@biocelect.com>; Regulatory Correspondence <regulatorycorrespondence@novavax.com>; s22 [redacted] @biointelect.com>; s22 [redacted] @adriaus.com>
Subject: RE: PM-2025-01693-1-2 - Dossier not effective [SEC=OFFICIAL]

Dear s22 [redacted]

Biocelect is very appreciative of the review and time spent responding to the application from the Module 3 evaluation team and from the wider TGA team.

Could I confirm with you that the Module 3 evaluation team was aware of the response document found in 1.7.1 (Seq 0121) of the initial submission, which was also submitted in the earlier package (through GovTeams) on the 17th April 2025?

From my interpretation, it does appear that the module 3 documents have been reviewed in isolation, where within the assessment it is noted "*The Sponsor has not addressed Issue* [x] *in their email response*" however all issues had a response and justifications where appropriate

within the above (attached) – for example the purity method was provided with the necessary data (a validation report with JN1) but noted in the TGA assessment "**The Sponsor has not addressed this issue in their response**".

Biocelect and Novavax will also review the TGA's helpful assessment regarding the gaps of the data that were evaluated and will look to provide a consolidated response urgently once we hear from you.

Thank you again for your patience.

Kind Regards,
s22 [redacted]
s22 [redacted]

Biocelect
Level 4, 143 Macquarie Street, Sydney NSW Australia 2000
Level 5, Wynn Williams House, 47 Hereford Street, Christchurch 8013, New Zealand

M s22 [redacted] **T** s22 [redacted] **E** s22 [redacted] **@biocelect.com**
biocelect.com
Sydney | Christchurch

I acknowledge and pay my respects to the traditional owners and custodians on whose land I walk, work & live

---

From: Streamlined Submission <streamlinedsubmission@health.gov.au>
Sent: Monday, 30 June 2025 1:43 PM
To: s22 [redacted] @biocelect.com>
Subject: RE: PM-2025-01693-1-2 - Dossier not effective [SEC=OFFICIAL]

Dear s22 [redacted]

Re: PM-2025-01693-1-2 - Nuvaxovid JN.1

The Module 3 Delegate has advised that the response provided to address the deficiencies identified during the preliminary assessment of the Dossier is unsatisfactory.

As a result, the submission is currently considered ineffective from a Module 3 perspective.

Please be advised that the submission will not be deemed as effective unless the issues outlined in the *attached* report are adequately addressed.

However, the Delegate has granted a final extension, allowing the response to be submitted to the TGA no later than **20 July 2025**.

They have also emphasized that if the revised response remains unsatisfactory, the sponsor is strongly encouraged to withdraw the submission, as no further extensions will be granted.

Looking forward to a timely response.

Regards

s22 [redacted]
s22 [redacted] **– Application and Advisory Management Section**
Prescription Medicines Authorisation Branch

Medicines Regulation Division | Health Products Regulation Group (Therapeutic Goods Administration)
Australian Government, Department of Health, Disability and Ageing
Email: streamlinedsubmission@health.gov.au

This email comes to you from Ngunnawal Country
Location: Fairbairn ACT
PO Box 100, Woden ACT 2606, Australia

The Department of Health, Disability and Ageing acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: s22 [redacted] @biocelect.com>
Sent: Friday, 20 June 2025 4:28 PM
To: eSubmissions <eSubmissions@health.gov.au>
Cc: Streamlined Submission <streamlinedsubmission@health.gov.au>
Subject: RE: PM-2025-01693-1-2 - Dossier not effective [SEC=OFFICIAL]

Hi s22 [redacted]

I have re-submitted Seq0122 for your convenience. For your awareness this was initially submitted on 13th June.

Kind Regards,
s22 [redacted]

s22 [redacted]

Biocelect

Level 4, 143 Macquarie Street, Sydney NSW Australia 2000
Level 5, Wynn Williams House, 47 Hereford Street, Christchurch 8013, New Zealand

M s22 [redacted] **T** s22 [redacted] **E** s22 [redacted] **@biocelect.com**
biocelect.com
Sydney | Christchurch

I acknowledge and pay my respects to the traditional owners and custodians on whose land I walk, work & live

---

From: eSubmissions <eSubmissions@health.gov.au>
Sent: Friday, 20 June 2025 4:20 PM
To: s22 [redacted] @biocelect.com>
Cc: Streamlined Submission <streamlinedsubmission@health.gov.au>
Subject: RE: PM-2025-01693-1-2 - Dossier not effective [SEC=OFFICIAL]

UNOFFICIAL

Good Afternoon,

It appears we are missing sequence sequence 0122, please send this through to resolve the issues in 0123.

Regards,

s22 [redacted]
s22 [redacted] – Application Entry, Support and Export Section
Medicines Regulation Division | Health Products Regulation Group
Prescription Medicines Authorisation Branch
Department of Health and Aged Care
E: s [redacted] @health.gov.au
Location: Fairbairn
PO Box 100, Woden ACT 2606, Australia

UNOFFICIAL

From: s22 @biocelect.com>
Sent: Friday, 20 June 2025 9:09 AM
To: Streamlined Submission <streamlinedsubmission@health.gov.au>
Cc: s22 @biointelect.com>; s22 @adriaus.com>; Regulatory <Regulatory@biocelect.com>
Subject: RE: PM-2025-01693-1-2 - Dossier not effective [SEC=OFFICIAL]

Dear s22

Biocelect would like to advise that a response (~36mb) has been uploaded to GovTeams in eCTD (Seq0123) addressing the issues identified below for the registration of Nuvaxovid JN.1 in a Pre-filled syringe (PFS) under application PM-2025-01693-1-2 which was found not effective.

The package contains a response document and attachments in Module 1.0.3 Response and retitled nonclinical study reports.

Please let me know if we can assist further.

Kind Regards,

s22
s22

Biocelect

Level 4, 143 Macquarie Street, Sydney NSW Australia 2000
Level 5, Wynn Williams House, 47 Hereford Street, Christchurch 8013, New Zealand

M s22 **T** s22 **E** s22 **@biocelect.com**
biocelect.com
Sydney | Christchurch

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From: Streamlined Submission <streamlinedsubmission@health.gov.au>
Sent: Wednesday, 18 June 2025 7:38 AM
To: s22 @biocelect.com>
Cc: s22 @biointelect.com>; s22 @adriaus.com>; Regulatory <Regulatory@biocelect.com>
Subject: RE: PM-2025-01693-1-2 - Dossier not effective [SEC=OFFICIAL]

Dear s22

Thank you for your email and the clarification sought.

The Module 4 Delegate has the following comments.

Module 4: I confirm that the Proposed file label: '702-207- in vivo-135 days-mouse-IM-immuno-SARS-CoV-2 rS variants-primary and boosters' is *acceptable*

I confirm that the Proposed file label: '702-173- in vivo- 408 days ongoing- rhesus macaques-IM-immuno- SARS-CoV-2 rS prototype and variants-primary and boosters' is *acceptable*

I also confirm that the 2.4 Nonclinical Overview and 2.6 Nonclinical Summary documents submitted under seq 0121 are *acceptable*.

Looking forward to an updated sequence by **COB 20 June 2025.**

Kind regards
s22

From: s22 @biocelect.com>
Sent: Tuesday, 17 June 2025 2:01 PM
To: Streamlined Submission <streamlinedsubmission@health.gov.au>
Cc: Regulatory <Regulatory@biocelect.com>; s22 @biointelect.com>; s22 @adriaus.com>
Subject: RE: PM-2025-01693-1-2 - Dossier not effective [SEC=OFFICIAL]

Dear s22

Thank you for yesterday's email. We are seeking clarity from the Module 4 Delegate ahead of our response to ensure it is complete and adequate.

s22

s22 [redacted]

Due to the short turnaround request and requirement to consult with international partners at Novavax, we kindly appreciate a timely response to above queries.

If any information or clarification is needed, please let me know.

Kind Regards,

s22 [redacted]

s22 [redacted]

Biocelect

Level 4, 143 Macquarie Street, Sydney NSW Australia 2000
Level 5, Wynn Williams House, 47 Hereford Street, Christchurch 8013, New Zealand

M s22 **T** s22 **E** s22 **@biocelect.com**
biocelect.com
Sydney | Christchurch

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From: Streamlined Submission <streamlinedsubmission@health.gov.au>
Sent: Monday, 16 June 2025 2:45 PM
To: s22 @biocelect.com>
Cc: Regulatory <Regulatory@biocelect.com>; s22 @biointelect.com>; s22 @adriaus.com>
Subject: RE: PM-2025-01693-1-2 - Dossier not effective [SEC=OFFICIAL]

Dear s22

Thank you for the response to the deficiencies.

Please be advised that the Module 4 Delegate has confirmed the SAF still cannot be considered effective due to the following reasons.

s22

s22 [redacted]

Please provided a response to the above by **COB 20 June 2025.**

We are still awaiting comments on the acceptability from Module 3 Delegate, I will keep you posted/reach out if further information is required.

Kind regards
s22 [redacted]

From: s [redacted] @biocelect.com>
Sent: Friday, 13 June 2025 10:25 AM
To: Streamlined Submission <streamlinedsubmission@health.gov.au>
Cc: Regulatory <Regulatory@biocelect.com>; s22 [redacted] @biointelect.com>; s22 [redacted] @adriaus.com>
Subject: RE: PM-2025-01693-1-2 - Dossier not effective [SEC=OFFICIAL]

Dear s22 [redacted]

Biocelect would like to advise that a response (~159mb) has been uploaded to GovTeams in eCTD (Seq0122) addressing the issues identified below for the registration of Nuvaxovid JN.1 in a Pre-filled syringe (PFS) under application PM-2025-01693-1-2 which was found not effective.

A response document to TGA raised issues and relevant justifications is provided in Module 1.0.3 Response.

Please let me know if we can assist further.

Kind Regards,
s22 [redacted]
s22 [redacted]

Biocelect
Level 4, 143 Macquarie Street, Sydney NSW Australia 2000
Level 5, Wynn Williams House, 47 Hereford Street, Christchurch 8013, New Zealand

M s22 [redacted] **T** s22 [redacted] **E** s22 [redacted] **@biocelect.com**
biocelect.com
Sydney | Christchurch


I acknowledge and pay my respects to the traditional owners and custodians on whose land I walk, work & live

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From: Streamlined Submission <streamlinedsubmission@health.gov.au>
Sent: Friday, 23 May 2025 1:38 PM
To: s [redacted] @biocelect.com>
Cc: Regulatory <Regulatory@biocelect.com>; s22 [redacted] @biointelect.com>; s22 [redacted] @adriaus.com>
Subject: RE: PM-2025-01693-1-2 - Dossier not effective [SEC=OFFICIAL]

Dear s22 [redacted]

Thank you for your email. We will look forward to the response by 13 June 2025.

Meanwhile, I will keep you posted if any further information is required.

Kind regards
s22 [redacted]

From: s22 [redacted] @biocelect.com>
Sent: Friday, 23 May 2025 12:55 PM
To: Streamlined Submission <streamlinedsubmission@health.gov.au>
Cc: Regulatory <Regulatory@biocelect.com>; s22 [redacted] @biointelect.com>; s22 [redacted] @adriaus.com>
Subject: RE: PM-2025-01693-1-2 - Dossier not effective [SEC=OFFICIAL]

Dear s22 [redacted]

I am requesting an extension to provide the response until the 13th June, noting the difficulty in coordinating a response between Novavax and 3rd party manufacturers which we are seeking to include updates to clinical modules and new testing results.

Please let me know if this is not acceptable or if you would like more information in the interim.

Kind Regards,
s22 [redacted]
s22 [redacted]

Level 4, 143 Macquarie Street, Sydney NSW Australia 2000
Level 5, Wynn Williams House, 47 Hereford Street, Christchurch 8013, New Zealand

M s22 [redacted] **T** s22 [redacted] **E** s22 [redacted] **@biocelect.com**
biocelect.com
Sydney | Christchurch

I acknowledge and pay my respects to the traditional owners and custodians on whose land I walk, work & live

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From: Streamlined Submission <streamlinedsubmission@health.gov.au>
Sent: Wednesday, 21 May 2025 9:11 AM
To: s22 [redacted] @biocelect.com>
Cc: Regulatory <Regulatory@biocelect.com>; s22 [redacted] @biointelect.com>; s22 [redacted] @adriaus.com>
Subject: PM-2025-01693-1-2 - Dossier not effective [SEC=OFFICIAL]

Dear Sponsor,

Thank you for your submission **PM-2025-01693-1-2.**

During the data screening stage, the dossier has been found *not effective* by the TGA evaluation areas.

Please refer below:

s22 [redacted]

s22

[redacted]

Kindly provide your response addressing all the issues **in eCTD sequence by 28 May 2025;** please let me know if this timeframe is not achievable.

Please also be aware that Milestone 2 will be delayed until the above issues are satisfactorily resolved.

s22
s22 **– Application and Advisory Management Section**
Prescription Medicines Authorisation Branch

Medicines Regulation Division | Health Products Regulation Group (Therapeutic Goods Administration)
Australian Government, Department of Health, Disability and Ageing
T: s22 | E: streamlinedsubmission@health.gov.au

This email comes to you from Ngunnawal Country
Location: Fairbairn ACT
PO Box 100, Woden ACT 2606, Australia

The Department of Health, Disability and Ageing acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

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