From: s 22
To: s 22
Cc: Streamlined Submission; s 22 s22 ; s 22
Subject: RE: Nuvaxovid (SARS-CoV-2 rS [NVX-CoV2373]) COVID-19 Vaccine/ Request for TGA pre-submission meeting regarding monovalent vaccine update with XBB.1.5 strain [SEC=OFFICIAL]
Date: s 47
Attachments: image001.png
image002.png
image005.png
image006.png
image009.png

---

s 22

s 22

General comments

The TGA is processing COVID-19 vaccine strain update applications as Cat.1 Type G, provided there are no other proposed changes. If there are other proposed changes, and depending on the type of changes, a Type F may be more appropriate. The TGA target timeframe for a strain update to the Novavax vaccine would be approx. 45-100 WD, dependent on a complete dossier, and includes consideration by ACV - this timeframe is significantly shorter than a regular Cat.1 submission.

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s 22 [redacted]

s 22 [redacted]

s 22 [redacted]

s 22 [redacted]

s 22 [redacted]

s 22 [redacted]

s 22 [redacted]

s 22 [redacted]

s 22 [redacted]
pplication and Advisory Management
Prescription Medicines Authorisation Branch
Medicines Regulation Division | TGA
Australian Government, Department of Health and Aged Care
T: s 22 [redacted] | E: s 22 [redacted] @health.gov.au
Location: TGA, 27 Scherger Drive, Fairbairn ACT 2609

PO Box 100, Woden ACT 2606, Australia

From: s 22 [redacted]
Sent: [redacted]
To: s22 [redacted] s47F [redacted] s 22 [redacted] health.gov.au>
Cc: s 22 [redacted] @health.gov.au>; s22 [redacted] s22 [redacted] @biointelect.com>; s22 [redacted] @biocelect.com>; s22 [redacted] s22 [redacted] @biocelect.com>; s22 [redacted] @biointelect.com>; s22 [redacted] s22 [redacted] @biointelect.com>; s22 [redacted] s22 [redacted]
Subject: RE: Nuvaxovid (SARS-CoV-2 rS [NVX-CoV2373]) COVID-19 Vaccine/ Request for TGA pre-submission meeting regarding monovalent vaccine update with XBB.1.5 strain [SEC=OFFICIAL]

Hi s 22 [redacted]

s 22 [redacted]

In terms of a proposed pre-submission meeting, a number of key TGA staff are out of the office in s 47 [redacted] appy to confirm a meeting date later, once TGA availability is secured.

Regards,
s 22 [redacted]

s 22 [redacted]
s 22 [redacted] **Application and Advisory Management**
Prescription Medicines Authorisation Branch
Medicines Regulation Division | TGA
Australian Government, Department of Health and Aged Care
T: s 22 [redacted] | E: s 22 [redacted] @health.gov.au
Location: TGA, 27 Scherger Drive, Fairbairn ACT 2609
PO Box 100, Woden ACT 2606, Australia

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 elders both past and present.

This response is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met.

Please note that this email is intended only for the use of the addressee and may contain confidential or legally privileged information. If you receive this email in error, please notify the sender immediately and delete all copies of this email.

From: s22 [redacted] s47F [redacted]

Sent:
To: s 22 @health.gov.au>; s22
s22 @health.gov.au>
Cc: s 22 @health.gov.au>; s22
s22 @biointelect.com>; s22 @biocelect.com>; s22
s22 @biocelect.com>; s22 @biointelect.com>; s22
s22 @biointelect.com>; s22
s22
Subject: RE: Nuvaxovid (SARS-CoV-2 rS [NVX-CoV2373]) COVID-19 Vaccine/ Request for TGA pre-submission meeting regarding monovalent vaccine update with XBB.1.5 strain [SEC=OFFICIAL]

s 22

We have noted that the TGA may provide written responses in lieu of a meeting; however, we wish to note that Biocelect's and Novavax's preference is for a pre-submission meeting with the TGA.

s 22

s47F

[redacted]

+s22 [redacted]

s22 [redacted] s47F [redacted]

s47F [redacted]

From: s22 [redacted]

Sent: s 47 [redacted]

To: s 22 [redacted] @health.gov.au>; s 22 [redacted] @health.gov.au>

Cc: s 22 [redacted] @health.gov.au>; s22 [redacted] @biointelect.com>; s22 [redacted] @biocelect.com>; s22 [redacted] @biocelect.com>; s22 [redacted] @biointelect.com>; s22 [redacted] @biointelect.com>; s22 [redacted]

Subject: RE: Nuvaxovid (SARS-CoV-2 rS [NVX-CoV2373]) COVID-19 Vaccine/ Request for TGA pre-submission meeting regarding monovalent vaccine update with XBB.1.5 strain [SEC=OFFICIAL]

s 22 [redacted]

[redacted]

[redacted]

[redacted]

[redacted]

s47F [redacted]

s 22 [redacted]

s 22 [redacted]

s47F [redacted]

From: s 22 @health.gov.au>
Sent: s 47
To: s22 s47F ; s22
s22 @health.gov.au>
Cc: s 22 @health.gov.au>; s22
s22 @biointelect.com>; s22 @biocelect.com>; s22
s22 @biocelect.com>; s22 @biointelect.com>; s22
s22 @biointelect.com>; s22
s22
Subject: RE: Nuvaxovid (SARS-CoV-2 rS [NVX-CoV2373]) COVID-19 Vaccine/ Request for TGA pre-submission meeting regarding monovalent vaccine update with XBB.1.5 strain [SEC=OFFICIAL]

s 22

s 22
pplication and Advisory Management
Prescription Medicines Authorisation Branch
Medicines Regulation Division | TGA
Australian Government, Department of Health and Aged Care
T: s 22 | E: s 22 @health.gov.au
Location: TGA, 27 Scherger Drive, Fairbairn ACT 2609
PO Box 100, Woden ACT 2606, Australia

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From: s22 s47F
Sent: s 47
To: s 22 @health.gov.au>; s 22
@health.gov.au>
Cc: s 22 @health.gov.au>; s22
s22 @biointelect.com>; s22 @biocelect.com>; s22
s22 @biocelect.com>; s22 @biointelect.com>; s22
s22 @biointelect.com>; s22
s22
Subject: RE: Nuvaxovid (SARS-CoV-2 rS [NVX-CoV2373]) COVID-19 Vaccine/ Request for TGA pre-submission meeting regarding monovalent vaccine update with XBB.1.5 strain [SEC=OFFICIAL]

s 22

s 22 [redacted]

Biocelect and Novavax are working on the slide deck and questions for the TGA, and expect to provide to the TGA no later than on s 47 [redacted] The ETA for submission of the application to TGA will be covered in the slide deck.

s 22 [redacted]

[redacted]

[redacted]

[redacted]

s47F [redacted]

s 22 [redacted]

s 22 [redacted]

s47F [redacted]

From: s 22 [redacted] @health.gov.au>
Sent: s 47 [redacted]
To: s22 [redacted] @s47F [redacted] ; s22 [redacted]
s22 [redacted] @health.gov.au>
Cc: s22 [redacted] @health.gov.au>; s22 [redacted]
s22 [redacted] @biointelect.com>; s22 [redacted] @biocelect.com>; s22 [redacted]
s22 [redacted] @biocelect.com>; s22 [redacted] @biointelect.com>; s22 [redacted]
s22 [redacted] @biointelect.com>; s22 [redacted]
s22 [redacted]
Subject: RE: Nuvaxovid (SARS-CoV-2 rS [NVX-CoV2373]) COVID-19 Vaccine/ Request for TGA pre-submission meeting regarding monovalent vaccine update with XBB.1.5 strain [SEC=OFFICIAL]

s 22 [redacted]

The TGA has received your request for a meeting on the proposed Novavax monovalent XBB.1.5

vaccine.

Regarding strain selection, TGA is aligned with international recommendations on strain selection; the ICMRA statement of [redacted] noted further discussion was warranted for strain selection for the Southern Hemisphere. Grateful if you could provide an ETA for the application to TGA, noting that Australia is moving into s 47 [redacted] in the coming months.

[redacted]

s 22 [redacted]
pplication and Advisory Management
Prescription Medicines Authorisation Branch
Medicines Regulation Division | TGA
Australian Government, Department of Health and Aged Care
T: [redacted] | E: [redacted]@health.gov.au
Location: TGA, 27 Scherger Drive, Fairbairn ACT 2609
PO Box 100, Woden ACT 2606, Australia

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From: s22 [redacted] s47F [redacted]
Sent s 47 [redacted]
To: s 22 [redacted]@health.gov.au>; s 22 [redacted]@health.gov.au>
Cc: s 22 [redacted]@health.gov.au>; [redacted] s22 [redacted]@biointelect.com>; s22 [redacted]@biocelect.com>; [redacted] s22 [redacted]@biocelect.com>; s22 [redacted]@biointelect.com>; s22 [redacted] s22 [redacted]@biointelect.com>; s22 [redacted] s22 [redacted]

Subject: Nuvaxovid (SARS-CoV-2 rS [NVX-CoV2373]) COVID-19 Vaccine/ Request for TGA pre-submission meeting regarding monovalent vaccine update with XBB.1.5 strain

s 22 [redacted]

Nuvaxovid / Request for TGA pre-submission meeting regarding monovalent vaccine update

with XBB.1.5 strain

Biocelect Pty Ltd (Biocelect) and Novavax Inc. (Novavax) hereby seek a 1.5-hour TGA pre-submission meeting to discuss data proposals and plans to update the monovalent Nuvaxovid (SARS-CoV-2 rS [NVX-CoV2373]) COVID-19 Vaccine composition with the XBB.1.5 strain.

The meeting is proposed for s 47 and our preference is for a video meeting if that would be convenient to the TGA.

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s 22

s47F

s47F [redacted]

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

TGA USE ONLY

Submission Assessment Form

s 22 [redacted]

Submission Details

s 22 [redacted]	
[redacted]	
[redacted]	
PPF Lodged:	s 47 [redacted]
Nominated application type:	F - Major variation (change in strength dose form route of admin patient group or dosage) [F]
Sponsor:	Biocelect Pty Ltd
Trade name:	Nuvaxovid XBB.1.5-SARS-CoV-2 rS Omicron XBB.1.5
Active ingredient:	SARS-CoV-2 rS (Omicron XBB.1.5)
s 22 [redacted]	
s 22 [redacted]	
[redacted]	[redacted]
Due date for completion of assessment:	s 47 [redacted]
Nominated section 31 response time:	30 Days
s 22 [redacted]	

s 22 [redacted]

[redacted]	
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

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RMP

Risk Management Plan

Recommendation

No RMP evaluation required

Information for Case Manager

Information for Case Manager
No RMP has been provided. The sponsor states the EMA requested the EU RMP (version 4.1 for XBB.1.5) be removed from the EMA variant application and be resubmitted once the variant application is approved as a separate type II variation. Sponsor plans to submit EU RMP (version 4.2) after EMA approval of the XBB.1.5 variant vaccine. However, the delegate has been requested to consider if RMP evaluation is required to address any specific safety concerns.

Information for other evaluation area

Information for other evaluation area
No RMP has been provided by the sponsor and it is acceptable at this stage. The changes proposed in this application are not significant from an RMP Perspective. However, if the delegate considers an RMP is required to address any specific safety concerns, an RMP evaluation will be conducted.

External advice to the Sponsor

Issues to be raised to the sponsor
Absence of an RMP evaluation is acceptable at this stage. However, if any safety concerns that need to be addressed in an RMP are identified during the evaluation phase or if the delegate requests one, an RMP will be required. We have noted your commitment to provide EU RMP (version 4.2) after EMA approval.

Completed by

RMP Officer s 22 [redacted] Date s 47 [redacted]

s 22

[redacted]

RMP	**No RMP has been provided. The sponsor states the EMA requested the EU RMP (version 4.1 for XBB.1.5) be removed from the EMA variant application and be resubmitted once the variant application is approved as a separate type II variation. Sponsor plans to submit EU RMP (version 4.2) after EMA approval of the XBB.1.5 variant vaccine.** **However, the delegate has been requested to consider if RMP evaluation is required to address any specific safety concerns.**

[redacted]

RMP	**Absence of an RMP evaluation is acceptable at this stage. However, if any safety concerns that need to be addressed in an RMP are identified during the evaluation phase or if the delegate requests one, an RMP will be required. We have noted your commitment to provide EU RMP (version 4.2) after EMA approval.**

s 22

From: s22
To: s22 ; Streamlined Submission; eSubmissions
Cc: Regulatory; s22
s22
Subject: Re: Nuvaxovid XBB.1.5 COVID-19 Vaccine - Sequence uploaded to GovTeams: PM-2023-05081-1- e005931 - Sequence 0104 [SEC=OFFICIAL]
Date: s 47
Attachments: image003.png
image004.png

s22

From: s22 @health.gov.au>
Sent: s 47
To: s22 @biointelect.com>; s22
s22 @health.gov.au>; s22 @health.gov.au>
Cc: s22 @biocelect.com>; s22 @novavax.com
s22 @novavax.com>; s22
s22 s47F ; s22
s22 @health.gov.au>; s22
s22 @health.gov.au>; s22
s22 @health.gov.au>
Subject: RE: Nuvaxovid XBB.1.5 COVID-19 Vaccine - Sequence uploaded to GovTeams: PM-2023-05081-1- e005931 - Sequence 0104 [SEC=OFFICIAL]

Hi s22

Further my call just now. To allow for the delegate to make a decision regarding the changes to the PI, grateful if you can please submit a Type F application in addition to your Type G (formulation change).

s22

Kind regards s22

s22
s22 – Application and Advisory Management Section

Prescription Medicines Authorisation Branch, TGA
Australian Government, Department of Health and Aged Care
T: s22 | M: s22 | E: s22 @health.gov.au
PO Box 100, Woden ACT 2606, Australia

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From: s22 @biointelect.com>
Sent: s 47
To: s22 @health.gov.au>; s22 s22 @health.gov.au>
Cc: s22 @biocelect.com>; s22 @novavax.com; s22 s22 s47F ; s22 s22 @health.gov.au>; s22 @health.gov.au>; s22 s22 @health.gov.au>; s22 s22 @health.gov.au>
Subject: Nuvaxovid XBB.1.5 COVID-19 Vaccine - Sequence uploaded to GovTeams: PM-2023-05081-1- e005931 - Sequence 0104

Dear Streamlined submissions and eSubmissions teams,

Following the PPF lodgement for PM-2023-05081-1, the Category 1G application to register Nuvaxovid XBB.1.5 vaccine, sequence 0104 containing the full eCTD package has been uploaded to GovTeams today, into the **Biocelect Pty Ltd** folder.

EMA CHMP opinion

The content of this dossier is aligned to what had been formally submitted to EMA, up to and including the latest sequence of s 47 . At the time of publishing this package, evaluation was ongoing with EMA.

On s 47 a positive CHMP opinion was received. The European Commission is expected to adopt a decision in the coming days in accordance with the EC procedure. A copy of the CHMP opinion and final EMA SmPC is attached.

Differences between this submitted dossier and details finally approved by EMA will be communicated in the next week.

A confirmation of successful receipt of the package is kindly requested.

eCTD details:

Tradename	Nuvaxovid XBB.1.5
Active ingredient name	SARS-CoV-2 rS (Omicron XBB.1.5)
Dosage form	suspension for injection
AUST R	Pending
Sequence	0104
Related sequence	0104
Sequence type	G- Change in formulation
Sequence description	Initial

Type of media	Zip file (zip file size ~655MB)
Validation result	Warning: 4.1.28 Lifecycle operations Module 1.3 This warning is expected as labels reflect an additional new product under the same eCTD application.

Please reach out if further information is required at this stage.

Kind regards,
s22
s22

M s22 **E** s22

Please note my usual work days are Mon-Tues-Wed-Thurs

Biointelect

From: s22
Sent: s 47
To: s22 @health.gov.au>; s22
s22 @health.gov.au>
Cc: s22 @biocelect.com>; s22 @novavax.com; s22
s22 s47F s22
s22 @health.gov.au>; s22 @health.gov.au>; s22
s22 @health.gov.au>
Subject: PPF submitted for PM-2023-05081-1- Nuvaxovid XBB.1.5 COVID-19 Vaccine

Dear Streamlined submissions and AET,

I am pleased to share a PPF for PM-2023-05081-1, the Category 1 application to register Nuvaxovid XBB.1.5 vaccine has been submitted via TGA eBS today, as an update to the original Nuvaxovid vaccine (AUST R 355139). The approval letter for full registration of Nuvaxovid was received on s 47 .

Initial TGA pre-submission advice on this application was received in s 47 .

The delivery of this dossier is planned by s 47 . Please reach out if further information is required at this stage.

Thank you and kind regards,
s22

Please note my usual work days are Mon-Tues-Wed-Thurs

Biointelect

Level 4, 142 Macquarie Street, Sydney NSW Australia 2000

M +s22 [redacted] **T** 1300 800 984 **E** s22 [redacted]

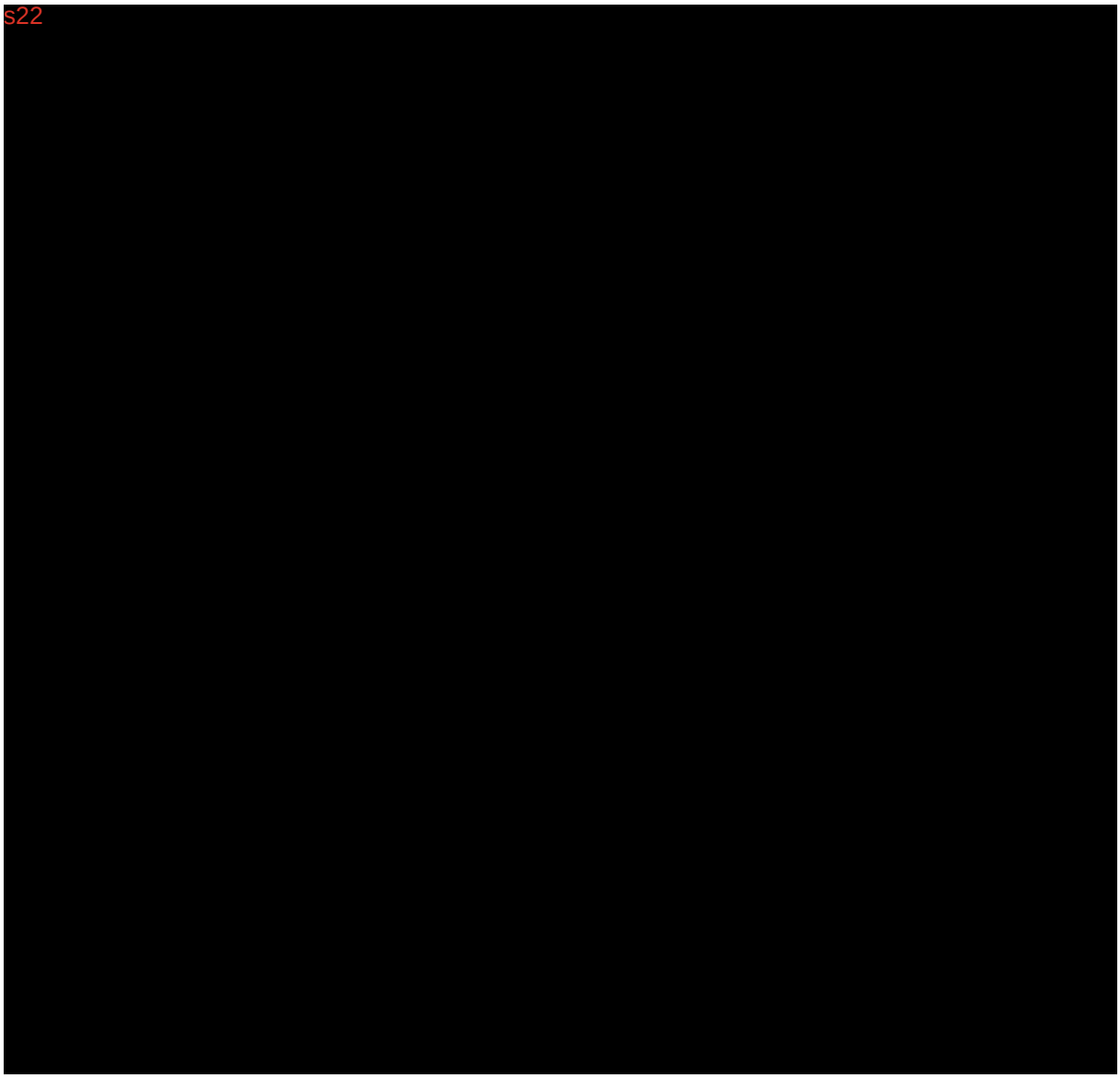
biointelect.com Sydney | Melbourne

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

s22

s22

s22



From: [redacted]@health.gov.au>
Sent: [redacted]
To: [redacted]@Health.gov.au>; [redacted]@health.gov.au>; [redacted]@health.gov.au>; [redacted]@health.gov.au>; [redacted]@Health.gov.au>; [redacted]@health.gov.au>; [redacted]@health.gov.au>
Cc: [redacted]@health.gov.au>; [redacted]@health.gov.au>; [redacted]@health.gov.au>
Subject: Submission Assessment form - [redacted] - PM-2023-05081-1-2 -Nuvaxovid XBB.1.5-SARS-CoV-2 rS Omicron XBB.1.5 - URGENT [SEC=OFFICIAL]

Dear all,

The TGA has received a submission as follows:-

Submission Number:	PM-2023-05081-1-2
eSubmission Identifier (link):	e005931 - (0104)
Validation Report:	
PPF Lodged:	[redacted]

Nominated application type:	F - Major variation (change in strength dose form route of admin patient group or dosage) [F]
Sponsor:	Biocelect Pty Ltd
Trade name:	Nuvaxovid XBB.1.5-SARS-CoV-2 rS Omicron XBB.1.5
Active ingredient:	SARS-CoV-2 rS (Omicron XBB.1.5)
Strength:	10µg/ml
Dosage Form:	suspension, for injection
TRIM reference for coordination file:	E23-341301
Due date for completion of assessment:	s 47
Nominated section 31 response time:	30 Days
Key dates:	D19-5973645

s22

[redacted]

s22

From: s 22 on behalf of Streamlined Submission
To: s 22 Streamlined Submission
Cc: Regulatory s 22
Subject: RE: Nuvaxovid XBB.1.5 COVID-19 Vaccine - Submission: PM-2023-05081-1/ s 22
Date: s 47
Attachments: image001.png
image002.png
D23-3978764 PM-2023-05081-1-2 - Milestone 2 Notification Letter (effective) - FINAL 9-11-2023.pdf

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s 22

Please find attached the Milestone 2 Notification letter for **PM-2023-05081-1-2.**
For your planning, please be advised the TGA are currently targeting s 47 ACV.

s 22

Kind regards
s 22

s 22
Application and Advisory Management
Prescription Medicines Authorisation Branch
Medicines Regulation Division | Health Products Regulation Group
Australian Government Department of Health
T: s 22 | E: s 22 @health.gov.au
Location: Symonston ACT
PO Box 100, Woden ACT 2606, Australia

The Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.
This response is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met

---

From: s22 s47F
Sent: s 47
To: s22 @health.gov.au>
Cc: s22 @biocelect.com>; s22 @novavax.com; s22 @health.gov.au>; s22 s22 @health.gov.au>; s22 @biointelect.com>; s22 s22 @biocelect.com>
Subject: Nuvaxovid XBB.1.5 COVID-19 Vaccine - Submission: PM-2023-05081-1 s 22

Dear Streamlined Submissions,

s 22 [redacted]

Kind regards

s 22 [redacted]

s 22 [redacted]

s47F [redacted]

s 22 [redacted]

s 22 [redacted]

s47F [redacted]

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Submission ID: PM-2023-05081-1-2
eSubmission Identifier: e005931

The Managing Director
Biocelect Pty Ltd
Suite 5 02 Level 5
139 Macquarie street
Sydney NSW 2000
Australia

Attention: s 22 [redacted]

Dear Sponsor

NOTICE OF APPLICATION PASSING PRELIMINARY ASSESSMENT – Milestone 2

Submission details – PM-2023-05081-1-2	
Pathway	PPF Only
Application type	F - Major variation (change in strength dose form route of admin patient group or dosage) [F]
Active ingredient	SARS-CoV-2 rS (NVX-CoV2373)
Product name	Nuvaxovid XBB.1.5-SARS-CoV-2 rS Omicron XBB.1.5

I refer to your application made under section 23 of the *Therapeutic Goods Act 1989* ('the Act') to register the above product(s) in the Australian Register of Therapeutic Goods ('the ARTG').

s 22 [redacted]

Outcome of the preliminary assessment

I am writing to notify you that, as a delegate of the Secretary for the purposes of section 23B of the Act, I am satisfied your application meets the requirements in section 23B(2) and has **passed preliminary assessment**.

s 22 [redacted]

PO Box 100 Woden ACT 2606 ABN 40 939 406 804
Phone: s 22 [redacted] Fax: s 22 [redacted]
Email: s 22 [redacted] @health.gov.au https://www.tga.gov.au

s 22 [redacted]

[redacted]

[redacted]

Good Manufacturing Practice (GMP)

The GMP clearance for each of the proposed manufacturing sites must remain current on an ongoing basis. Failure to adequately plan for GMP currency may delay the registration process.

Further information about manufacturing requirements for medicines can be found at www.tga.gov.au/manufacturing-medicines

Risk Management Plan (RMP)

Absence of an RMP evaluation is acceptable at this stage. However, if any safety concerns that need to be addressed in an RMP are identified during the evaluation phase or if the delegate requests one, an RMP will be required. We have noted your commitment to provide EU RMP (version 4.2) after EMA approval.

s 22 [redacted]

[redacted]

Other matters

Please note the fact that your application has passed preliminary assessment does not provide any indication, of itself, as to whether your application for registration will be successful. The information provided in support of your application will be fully considered in the evaluation process, with a decision to be made on whether to register the goods after completion of the evaluation.

s 22 [redacted]

[redacted]

[redacted]

Yours sincerely

(Signed Electronically)

s 22
Delegate of the Secretary
Prescription Medicines Authorisation Branch

s 47

s22

s22 [redacted]

From: s22 [redacted] @health.gov.au> **On Behalf Of** Streamlined Submission
Sent: s 47 [redacted]
To: s22 [redacted] s47F [redacted] ; Streamlined Submission s22 [redacted] @health.gov.au>
Cc: s22 [redacted] @biocelect.com>; s22 [redacted] @novavax.com; s22 [redacted] @health.gov.au>; s22 [redacted] s22 [redacted] @biointelect.com>; s22 [redacted] @biocelect.com>
Subject: [SEC=OFFICIAL] RE: Nuvaxovid XBB.1.5 COVID-19 Vaccine - Submission: PM-2023-05081-1/ Request for provisional AUST R number

Hi s22 [redacted] and s22 [redacted]

Please find attached the Milestone 2 Notification letter for **PM-2023-05081-1-2.**
For your planning, please be advised the TGA are currently targeting s 47 [redacted] ACV.

s22 [redacted]

s22 [redacted]

Kind regards
s22 [redacted]

s22 [redacted]
s22 [redacted]
Prescription Medicines Authorisation Branch

Medicines Regulation Division | Health Products Regulation Group
Australian Government Department of Health
T: s22 [redacted] | E: s22 [redacted] @health.gov.au
Location: Symonston ACT
PO Box 100, Woden ACT 2606, Australia

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s22 [redacted]

s22 [redacted]

From: s 22 [redacted] @health.gov.au> **On Behalf Of** Streamlined Submission
Sent: s 47 [redacted]
To: s 22 [redacted] @health.gov.au>
Cc: s 22 [redacted] @health.gov.au>; Streamlined Submission
s 22 [redacted] @health.gov.au>
Subject: RE: status of PM-2023-05081-1-2 [SEC=OFFICIAL]

s 22 [redacted]

[redacted]

With regard to submission PM-2023-05081-1-2, I advise the following:

Module/Evaluation Area	**Status**	**Comments/TRIM link**
Quality	In progress	
Quality (secondaries)	Micro: Rd1 complete, Rd2 pending Endo: In progress Container: In progress Viral/pathogen: Completed, no issues	Rd1 Micro: D23-4359840 Viral safety report: D23-4568030
Nonclinical	Round 1 eval completed	Rd 1 NER at D23-4694173
Clinical	Initial clinical evaluation completed	No CER, Delegate's clinical comments sent to sponsor, pending sponsor response
RMP	Not required	

Hi s 22 my understanding is that we are aiming for s 47 ACV and the DO is expected around s 47 . Also wanted to gently check if we are taking this submission to ACV while the Module 3 evaluation is still underway, like previous covid submissions?

s22

s 22

From: s 22 @health.gov.au>
Sent: s 47
To: Streamlined Submission <s 22 @health.gov.au>
Subject: status of PM-2023-05081-1-2

Hello s 22

s 22

Could you give me an update on status of PM-2023-05081-1-2 (Nuvaxovid XBB.1.5), including if ACV likely to be needed. If ACV advice is needed on s 47 , the sponsor's preACV response is needed by s 47 s 47

Thanks
s 22

s 22
Advisory Committee on Vaccines team and AusPAR team – Business Systems Review and Reporting Section
Prescription Medicines Authorisation Branch

Medicines Regulation Division | Health Products Regulation Group
Australian Government, Department of Health and Aged Care
T: s 22 | E: s 22 @health.gov.au
Location: 27 Scherger Drive, Fairbairn, ACT
PO Box 100, Woden ACT 2606, Australia

From: s22
To: Streamlined Submission
Cc: s22 Regulatory; s22 @novavax.com
Subject: Nuvaxovid XBB.1.5 COVID-19 Vaccine - Submission: PM-2023-05081-1-2 - MHRA authorisation
Date: s 47
Attachments: image001.png

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

As courtesy, Biocelect advises that on s 47, the Medicines and Healthcare products Regulatory Agency (MHRA) has granted marketing authorisation for Nuvaxovid XBB.1.5 COVID-19 vaccine for active immunisation to prevent COVID-19 in individuals aged 12 and older.

Please do let me know of any questions.

Kind regards

s22

s22

s47F

+s22

s22 s47F

s47F

From: s 22
To: s 22 Streamlined Submission
Cc: Regulatory; s22 @novavax.com; s22 ; SIMPSON, Andrew; s22
Subject: RE: Nuvaxovid XBB.1.5 COVID-19 Vaccine - Submission: PM-2023-05081-1-2/ Regulatory Authority GMP Certification for Novavax Inc, 620 Professional Drive, Gaithersburg [SEC=OFFICIAL]
Date: s 47
Attachments: image002.png
image003.png
image006.png
image007.png
MNJ_OOS_24_005__DP_&__DS_Manufacturing_Investigation_Signed.pdf

---

s 22

Dear s 22

Thank you for considering our request. Novavax and Biocelect are on standby for any clarifying questions from the TGA by any means or mechanism . We remain open to a TGA meeting to discuss these outstanding matters to progress the final stages of this evaluation.

s 22

-
-
-

s 22

Regulatory Affairs

Biointelect

Level 4, 143 Macquarie Street, Sydney NSW Australia 2000
M s 22 T 1300 800 984 E s22 @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

From: s 22 @health.gov.au>
Sent s 47
To: s22 @biointelect.com>; Streamlined Submission <s 22 @health.gov.au>
Cc: s22 @biocelect.com>; s22 @novavax.com; s22 @Health.gov.au>; s22 s22 @health.gov.au>; s 22 health.gov.au>; s22 s22 @biocelect.com>; s22 s47F s22 s22 @health.gov.au>; SIMPSON, Andrew <Andrew.Simpson@health.gov.au>
Subject: RE: Nuvaxovid XBB.1.5 COVID-19 Vaccine - Submission: PM-2023-05081-1-2/ Regulatory Authority GMP Certification for Novavax Inc, 620 Professional Drive, Gaithersburg [SEC=OFFICIAL]

Hi s 22

Thank you for your response on the GMP clearance issues for Novavax XBB (your dot points below); the quality team will consider your request as part of further evaluation of the additional data provided in response to TGA's questions.

- s 22

The TGA notes that regulatory approvals granted by some international regulators relied on different regulatory processes than those employed by the TGA. As per normal business processes, a GMP Clearance is generally required for each site used in the manufacturing process.

Further, there are some ongoing challenges with quality data supporting this application, as the information that has been provided in response to TGA current LoQs does not provide sufficient details to address the specific concerns as raised. Hence, the TGA is looking to provide you with additional clarifying questions shortly (within the next 2 weeks), to address the gaps in information you provided in response to the previous LoQs.

s22

Thanks

Kind regards[redacted]

[redacted]
Application and Advisory Management Section

Prescription Medicines Authorisation Branch, TGA
Australian Government, Department of Health and Aged Care
T: [redacted] | M: [redacted] | E: [redacted]@health.gov.au
PO Box 100, Woden ACT 2606, Australia

The Department of Health 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 elders both past and present.

From: [redacted]@biointelect.com>
Sent: [redacted]
To: [redacted]@health.gov.au>
Cc: [redacted]@biocelect.com>; [redacted]@novavax.com; [redacted]@Health.gov.au>; [redacted]@health.gov.au>; [redacted]@health.gov.au>; [redacted]@health.gov.au>; [redacted]@biocelect.com>; [redacted]
Subject: RE: Nuvaxovid XBB.1.5 COVID-19 Vaccine - Submission: PM-2023-05081-1-2/ Regulatory Authority GMP Certification for Novavax Inc, 620 Professional Drive, Gaithersburg [SEC=OFFICIAL]

Dear [redacted]

Thank you for your email related to outstanding GMP clearance issues of the Working Virus Stock (WVS)/Working Virus Bank (WVB) manufacturing site at Novavax Inc., 620 Professional Drive, Gaithersburg, MD 20879. It is noted that the Master Virus Stock (MVS) is also manufactured at the site and recognise that this step does not require GMP clearance.

Biocelect requests that the TGA consider our request seeking alignment on GMP for this site with regulatory approvals granted by EMA, MHRA and Health Canada as part of their XBB.1.5 registration approvals. Our request is based on the low-risk nature of this site to the overall

quality of the final XBB.1.5 vaccine and the medical needs of the Australian population requiring a protein-based platform XBB1.5 strain vaccine. s22

s22

s22

To support our request and in the absence of a current GMP certificate (pending the SUKL inspection in s 47) for this site from a recognised regulatory agency, we attach the EU Qualified person declaration concerning GMP compliance of the active substance manufacture. Although not adopted under Australian regulations, the EU Qualified person provides a certified and independent level of rigour comparable to a recognised regulatory agency due to this position's training, experience and personal responsibility and liability. This declaration covers the site in question (PART A). Further, under PART D, "QP declaration of GMP compliance", the QP confirms the evaluation of the 3rd party inspection of Novavax Inc., 620 Professional Drive, Gaithersburg, MD 20879 and declares the audits were conducted by properly qualified and trained staff, in accordance with approved procedure with appropriate technical contractual arrangements in place. All the associated documentation supporting this declaration is readily available to a recognised regulatory agency.

s22

s22 [redacted]

s 22 [redacted]
s 22 [redacted]

[redacted] Regulatory Affairs

Biointelect

Level 4, 143 Macquarie Street, Sydney NSW Australia 2000
M s 22 [redacted] T 1300 800 984 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

From: s 22 [redacted] @health.gov.au> **On Behalf Of** Streamlined Submission
Sent: s 47 [redacted]
To: s22 [redacted] @biocelect.com>; s22 [redacted] s47F [redacted]
Cc: s22 [redacted] @biocelect.com>; s22 [redacted] @novavax.com; s22 [redacted] @Health.gov.au>; s 22 [redacted] @health.gov.au>; s 22 [redacted] @health.gov.au>; s22 [redacted] s22 [redacted] @biointelect.com>; Streamlined Submission <s 22 [redacted] @health.gov.au>; s 22 [redacted] @health.gov.au>
Subject: RE: Nuvaxovid XBB.1.5 COVID-19 Vaccine - Submission: PM-2023-05081-1-2/ Regulatory Authority GMP Certification for Novavax Inc, 620 Professional Drive, Gaithersburg [SEC=OFFICIAL]
Importance: High

Hi s 22

The TGA notes that there are outstanding GMP clearance issues associated with this application. You have indicated "*The TGA GMP clearance application will be lodged immediately upon the receipt of relevant documents issued following the close out of the scheduled GMP inspection by SUKL in* s 47 ."

As per normal business process processes, in the absence of appropriate GMP clearances, a positive regulatory decision is not possible. TGA notes that further sponsor information to support the granting of GMP clearances will not be available until s 47 (as per your response dated s 47). Please note that this delay will adversely impact the decision timeline for this application.

Given the above, grateful if you could please let me know how you want to manage this timeline.

Kind regards,

s 22

s 22

Application & Advisory Management

Prescription Medicines Authorisation Branch

Medicines Regulation Division | Health Products Regulation Group
Australian Government Department of Health and Aged Care
T: s 22 | E: s 22 @health.gov.au
Therapeutic Goods Administration
PO Box 100, Woden ACT 2606, Australia

The Department of Health 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 elders both past and present.

Important:*This response is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met.*
All enquiries related to the Prescription Medicine Registration Process are to be directed to streamlinedsubmission@health.gov.au. If your enquiry relates to a specific application, please include the submission number in the subject line so that the email is directed to the appropriate case manager.

From: s22 @biocelect.com>
Sent: s 47
To: s 22 @health.gov.au>; Streamlined Submission <s 22 @health.gov.au>; s 22 @health.gov.au>
Cc: s22 @biocelect.com>; s22 @novavax.com; s22 s22 s47F s22 s22 @Health.gov.au>
Subject: Nuvaxovid XBB.1.5 COVID-19 Vaccine - Submission: PM-2023-05081-1-2/ Regulatory Authority GMP Certification for Novavax Inc, 620 Professional Drive, Gaithersburg

Dear s22 ,

Biocelect and Novavax Inc. (Novavax) are providing the attached document proactively for consideration by (i) TGA evaluators involved with quality evaluation and of the Nuvaxovid XBB.1.5 COVID-19 Vaccine application and (ii) the GMP clearance team.

As background, Novavax Inc. at 620 Professional Drive, Gaithersburg, MD 20879, USA [NVX (620)] is a facility that manufactures Master Virus Stock (MVS) and Working Virus Stock (WVS)/Working Virus Bank (WVB) that is used in the production of SARS-CoV-2 rS XBB.1.5 variant drug substance. The NVX (620) site has not yet been inspected for Good Manufacturing Practice (GMP) by any Regulatory Authority and thus a Regulatory Authority issued GMP certificate is not available nor expected to be available at time of TGA decision following the targeted Advisory Committee Meeting in s 47 . The first known Regulatory Authority GMP inspection will be at the request of European Medicines Agency (EMA) to be undertaken during 2024 as a post-approval commitment for the EMA approved Nuvaxovid XBB.1.5 vaccine.

The attached document presents a discussion why the sponsor and Novavax consider it reasonable to rely on the s 47 EMA GMP inspection of NVX (620) and propose that GMP certification of NVX (620) is included as a post-approval commitment for the pending positive TGA decision of the Nuvaxovid XBB.1.5 vaccine.

s22

Kind Regards,

s 22
Regulatory Affairs Associate

Biocelect

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

M s 22 **T** 1300 907 411 **E** s22 **@biocelect.com**

biocelect.com

Sydney | Christchurch

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From: HENDERSON, Nick
To: s22 ; SIMPSON, Andrew; s22
Cc: s 22
Subject: RE: Novavax [SEC=OFFICIAL]
Date: s 47

---

s 22

- The Clinical delegate would prefer the quality concerns to be addressed prior to going to ACV

If Novavax knew about s 47 do you think that would hurry them along?

From: s 22 @health.gov.au>
Sent: s 47
To: HENDERSON, Nick <Nick.Henderson@health.gov.au>; SIMPSON, Andrew <Andrew.Simpson@health.gov.au>; s 22 @health.gov.au>
Cc: s 22 @health.gov.au>; s 22 @health.gov.au>; s 22 @health.gov.au>; s 22 @health.gov.au>; s 22 @health.gov.au>
Subject: Novavax [SEC=OFFICIAL]

Hi all,

Just spoke to Novavax s 22 – they will submit their answers to quality questions in 2 tranches – the first set will be soon. Unclear when the second tranche is coming

- There are outstanding quality concerns that is likely to require additional data to be generated.
- GMP Clearance may also be required for one site – Novavax to provide further information in s47G(1)(a)
- The Clinical delegate would prefer the quality concerns to be addressed prior to going to ACV
- It is unlikely that Novavax quality concerns will be addressed by the s47G(1)(a) to enable it to be considered on the s 47 ACV
- To my knowledge, ACV on s 47 has not been raised with Novavax
- TGA provides weekly updates to DOHA procurement team on this vaccine.

Noting the above – Nick are you comfortable if we place Novavax on the agenda for the next ACV s 47 ?

Kind regards s 22

s 22
Application and Advisory Management Section

Prescription Medicines Authorisation Branch, TGA
Australian Government, Department of Health and Aged Care

T: s 22 | M: s 22 | E: s 22 @health.gov.au
PO Box 100, Woden ACT 2606, Australia

The Department of Health 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 elders both past and present.

From: s 22
To: KERR, Lisa; s 22
Cc: HENDERSON, Nick; SIMPSON, Andrew; Streamlined Submission
Subject: Update: NVX - Submission: PM-2023-05081-1-2 [SEC=OFFICIAL:Sensitive]
Date: s 47
Attachments: image001.gif

Hi all,
I had a phone call from s 22 today.

- NVX were canvassing the option for a MTSC for the current appln. I indicated that this was not possible, as the quality team were of the opinion that on the basis of the current data package, they would recommend rejection of the appln to TGA decision delegate.
- s47G(1)(a)
- s47G(1)(a)
-
- s 22 seems comfortable with this advice, and was keen to have the next mtg with Quality team.

Kind regards s22
s 22
s 22 Application and Advisory Management Section
Prescription Medicines Authorisation Branch, TGA
Australian Government, Department of Health and Aged Care
T: s 22 | M: s 22 | E: s 22 @health.gov.au
PO Box 100, Woden ACT 2606, Australia

The Department of Health 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 elders both past and present.

From: Streamlined Submission
To: s22
Cc: s22 ; s22 ; Streamlined Submission; AUSPARS
Subject: Completion of Evaluation Phase - Biointelect - Nuvaxovid XBB.1.5 - PM-2023-05081-1-2 [SEC=OFFICIAL]
Date: s 47
Attachments: image001.png
image002.png
image004.png
image005.png
image009.png
image010.png
image012.png
PM-2023-05081-1-2 - Completion of the Evaluation Phase - Milestone 5.pdf
Att A - NUVAXOVID XBB.1.5 (SARS-CoV-2 rS [NVX-CoV2601]) COVID-19 VACCINE - Biocelect Pty Ltd - PM-2023-05081-1-2 - Category 1 (Type G) - Final Report - BES.pdf
Att B - SARS-CoV-2 rS Omicron XBB.1.5 (NUVAXOVID XBB.1.5) [PM-2023-05081-1-2] - Nonclinical Evaluation Report {SPONSOR COPY - MS5}.PDF

Hi s22

My apologies for the delay in getting back to you as the delegate was awaiting the finalisation of the nonclinical evaluation report.

Please find attached the Milestone 5 Completion of Evaluation Phase letter, Round 2 Nonclinical Evaluation report and Final Quality report for this submission. The delegate has advised that the evaluation phase of this submission is now complete and the submission is now in the decision phase, with a delegate overview to be provided after the Milestone 5 Completion of Evaluation Phase response due date. The delegate has also confirmed that he will not be seeking ACV advice for this submission.

Whilst the decision to withdraw and timeframe of withdrawal of this submission remains a business decision for the sponsor, the delegate has asked me to remind you that the timing of withdrawal will impact whether or not an AusPAR will be published for this submission. My understanding is that if the submission was to be withdrawn after the response due date for the Milestone 5 Completion of Evaluation Phase letter s 47) an AusPAR will be published for this submission as this submission will not be taken to ACV. I have cc'd the AusPAR team into this email and they can address any queries that you may have regarding this.

Could you please confirm receipt of the two attached documents.
The delegate is happy to have a quick chat with you regarding the above timelines for the submission if any further clarification is required. If this is the case, please advise your availability and I will ask him to give you a call.

Kind regards,

s22
s22
s22
Application and Advisory Management Section
Prescription Medicines Authorisation Branch
Email: s22 @health.gov.au

Therapeutic Goods Administration
Australian Government, Department of Health and Aged Care

PO Box 100
Woden ACT 2606
www.tga.gov.au

[redacted]

From: Streamlined Submission s22 [redacted] @health.gov.au>
Sent: s 47 [redacted]
To: s22 [redacted] @biocelect.com>
Cc: s22 [redacted] @biointelect.com>; s22 [redacted] s22 [redacted] @biointelect.com>; s22 [redacted] @biocelect.com>; Streamlined Submission s22 [redacted] @health.gov.au>
Subject: RE: Final Quality Report - Biointelect - Nuvaxovid XBB.1.5 - PM-2023-05081-1-2 [SEC=OFFICIAL]

Hi s22 [redacted]

Thank you for confirming receipt of this report. I am awaiting on confirmation from the delegate regarding expectations/next steps. I will let you know as soon as I have this information.

Kind regards,

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

Medicines Regulation Division| Health Products Regulation Group
Australian Government, Department of Health and Aged Care
T: s22 [redacted] | E: s22 [redacted] @health.gov.au
Location: Fairbairn
PO Box 100, Woden ACT 2606, 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: s22 @biocelect.com>
Sent: S 47
To: Streamlined Submission s22 @health.gov.au>
Cc: s22 @biointelect.com>; s22
s22 @biointelect.com>; s22 @biocelect.com>
Subject: RE: Final Quality Report - Biointelect - Nuvaxovid XBB.1.5 - PM-2023-05081-1-2 [SEC=OFFICIAL]

Hi s22

Thank you for this, I am confirming receipt.

We are in discussion with Novavax regarding the withdrawal, do you have a time when this may be expected by the TGA?

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** 1300 907 411 **E** s22 **@biocelect.com**
biocelect.com
Sydney | Christchurch

From: Streamlined Submission s22 @health.gov.au>
Sent: S 47
To: s22 @biocelect.com>
Cc: s22 @biointelect.com>; s22

s22 @biointelect.com>; s22 @biocelect.com>; Streamlined Submission s22 @health.gov.au>
Subject: Final Quality Report - Biointelect - Nuvaxovid XBB.1.5 - PM-2023-05081-1-2 [SEC=OFFICIAL]

Hi s22

Please find attached the final quality report for submission PM-2023-05081-1-2 (SARS-CoV-2 rS Omicron XBB.1.5,Nuvaxovid XBB.1.5 - Type F,G) recommending rejection.

Can you please advise whether the sponsor intends to withdraw this submission.

Kind regards,

s22

Application and Advisory Management Section
Prescription Medicines Authorisation Branch
Email: s22 @health.gov.au

Therapeutic Goods Administration
Australian Government, Department of Health and Aged Care
PO Box 100
Woden ACT 2606
www.tga.gov.au

s22

s22

s22 [redacted]

From: s22 [redacted] @health.gov.au>
Sent: [redacted]
To: s22 [redacted] @biointelect.com>; s22 [redacted] s22 [redacted] @health.gov.au>
Cc: s22 [redacted] @health.gov.au>; HENDERSON, Nick <Nick.Henderson@health.gov.au>; SIMPSON, Andrew <Andrew.Simpson@health.gov.au>; KERR, Lisa <Lisa.Kerr@health.gov.au>; DUFFY, Tracey <Tracey.Duffy@health.gov.au>; LAWLER, Tony <Anthony.LAWLER@Health.gov.au>; s22 [redacted] @health.gov.au>; s22 [redacted] s22 [redacted] @health.gov.au>; Streamlined Submission s22 [redacted] @health.gov.au>; s22 [redacted] s47F [redacted] s22 [redacted] @biocelect.com>; s22 [redacted] @biocelect.com>; s22 [redacted]

s22 @Novavax.com>; s22 @Novavax.com>; s22 s22 @biointelect.com>
Subject: RE: Biointelect - Nuvaxovid XBB.1.5 ACV discussion [SEC=OFFICIAL]

Hi s22

Just a courtesy email to let you know that we have received your request. s22 s22 .

s22

Kind regards s22

s22

Prescription Medicines Authorisation Branch, TGA
Australian Government, Department of Health and Aged Care
T: s22 | M: s22 | E: s22 @health.gov.au
PO Box 100, Woden ACT 2606, Australia

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From: s22 @biointelect.com>
Sent: s 47
To: s22 @health.gov.au>
Cc: s22 @health.gov.au>; s22 s22 @health.gov.au>; HENDERSON, Nick <Nick.Henderson@health.gov.au>; SIMPSON, Andrew <Andrew.Simpson@health.gov.au>; KERR, Lisa <Lisa.Kerr@health.gov.au>; DUFFY, Tracey <Tracey.Duffy@health.gov.au>; LAWLER, Tony <Anthony.LAWLER@Health.gov.au>; s22 @health.gov.au>; s22 s22 @health.gov.au>; Streamlined Submission s22 @health.gov.au>; s22 s47F s22 @biocelect.com>; s22 @biocelect.com>; s22 s22 @Novavax.com>; s22 @Novavax.com>; s22 s22 @biointelect.com>
Subject: RE: Biointelect - Nuvaxovid XBB.1.5 ACV discussion [SEC=OFFICIAL]

Dear s22

I wanted to inform you that Biocelect and Novavax have submitted the final responses to the

TGA's analysis and comprehensive list of clarifying questions today. s22 [redacted]

Reaching this milestone in the application process is significant as we have heard from the COVID-19 Taskforce that there are, increasingly, inquiries from healthcare professionals and the wider community seeking access to Nuvaxovid XBB. 1.5. s22 [redacted]

s22 [redacted]

Thanks and kind regards,

s22 [redacted]

s22 [redacted]

[redacted]

Level 4, 143 Macquarie Street, Sydney NSW Australia 2000

M s22 [redacted] **T** 1300 800 984 **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

---

From: s22 @health.gov.au>
Sent: S 47
To: s22 @biointelect.com>
Cc: s22 @health.gov.au>; s22
s22 @health.gov.au>; HENDERSON, Nick <Nick.Henderson@health.gov.au>;
SIMPSON, Andrew <Andrew.Simpson@health.gov.au>; KERR, Lisa <Lisa.Kerr@health.gov.au>;
DUFFY, Tracey <Tracey.Duffy@health.gov.au>; s22 @health.gov.au>;
s22 @health.gov.au>; Streamlined Submission
s22 @health.gov.au>; s22 @biointelect.com>;
s22 s47F ; s22 @biocelect.com>;
LAWLER, Tony <Anthony.LAWLER@Health.gov.au>; s22 @Novavax.com>; s22
s22 @biocelect.com>
Subject: RE: Biointelect - Nuvaxovid XBB.1.5 ACV discussion [SEC=OFFICIAL]

> Some people who received this message don't often get email from s22 @health.gov.au. Learn why this is important

Hi s22

s22

The TGA has received the submissions relating to quality issues with the Novavax COVID XBB vaccine.

s22

Kind regards

s2

s22

Prescription Medicines Authorisation Branch
Medicines Regulation Division | Therapeutic Goods Administration
Australian Government, Department of Health and Aged Care
T: s22 | E: s22 @health.gov.au
PO Box 100, Woden ACT 2606, Australia

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From: s22 @biointelect.com>
Sent: S 47
To: s22 @health.gov.au>
Cc: s22 @health.gov.au>; s22
s22 @health.gov.au>; HENDERSON, Nick <Nick.Henderson@health.gov.au>;
SIMPSON, Andrew <Andrew.Simpson@health.gov.au>; KERR, Lisa <Lisa.Kerr@health.gov.au>;
DUFFY, Tracey <Tracey.Duffy@health.gov.au>; s22 @health.gov.au>;
s22 @health.gov.au>; Streamlined Submission
s22 @health.gov.au>; s22 @biointelect.com>;
s22 s47F s22 @biocelect.com>;
s22 @Novavax.com>; s22 @biocelect.com>
Subject: RE: Biointelect - Nuvaxovid XBB.1.5 ACV discussion [SEC=OFFICIAL]

Dear s22

I wanted to update you that Biocelect has submitted a complete response with supporting data and updated CTD sections for the second tranche of questions.

s22

In light of our responses submitted today, can the TGA confirm the possibility of a late entry for the upcoming S 47 ACV meeting?

s22

Level 4, 143 Macquarie Street, Sydney NSW Australia 2000
M s22 **T** 1300 800 984 **E** s22 @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

s22 [redacted]

From: s22 [redacted] @biointelect.com>
Sent: s 47 [redacted]
To: s22 [redacted] @health.gov.au>
Cc: s22 [redacted] @health.gov.au>; s22 [redacted] s22 [redacted] @health.gov.au>; HENDERSON, Nick <Nick.Henderson@health.gov.au>; SIMPSON, Andrew <Andrew.Simpson@health.gov.au>; KERR, Lisa <Lisa.Kerr@health.gov.au>; DUFFY, Tracey <Tracey.Duffy@health.gov.au>; s22 [redacted] @health.gov.au>; s22 [redacted] @health.gov.au>; Streamlined Submission

s22 @health.gov.au>; s22 @biointelect.com>;
s22 s47F ; s22 @biocelect.com>;
s22 @Novavax.com>; s22 @biocelect.com>
Subject: RE: Biointelect - Nuvaxovid XBB.1.5 ACV discussion [SEC=OFFICIAL]

Dear s22

I wanted to update you that Biocelect have submitted a complete response, with supporting data and all updated CTD sections with the exception of 3.2.S.7 for the first tranche of questions.

s22

Level 4, 143 Macquarie Street, Sydney NSW Australia 2000
M s22 **T** 1300 800 984 **E** s22 @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

From: s22 @health.gov.au>

Sent: s 47
To: s22 @biointelect.com>
Cc: s22 @health.gov.au>; s22 s22 @health.gov.au>; HENDERSON, Nick <Nick.Henderson@health.gov.au>; SIMPSON, Andrew <Andrew.Simpson@health.gov.au>; KERR, Lisa <Lisa.Kerr@health.gov.au>; DUFFY, Tracey <Tracey.Duffy@health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; Streamlined Submission s22 @health.gov.au>; s22 @biointelect.com>; s22 s47F ; s22 @biocelect.com>; s22 @Novavax.com>; s22 @biocelect.com>
Subject: Biointelect - Nuvaxovid XBB.1.5 ACV discussion [SEC=OFFICIAL]

> You don't often get email from s22 @health.gov.au. Learn why this is important

Dear s22

Thank you for your email. As you are aware, the TGA has significant concerns with the Module 3 (quality) data submitted for this vaccine. These concerns impact on the TGA's assessment of both the efficacy and safety of the vaccine. On this basis, it is not appropriate or practical to proceed to ACV before these concerns are addressed.

s22

Kind regards

s22

s22
Prescription Medicines Authorisation Branch
Medicines Regulation Division | Therapeutic Goods Administration
Australian Government, Department of Health and Aged Care
T: s22 | E: s22 @health.gov.au
PO Box 100, Woden ACT 2606, Australia

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 elders both past and present

---

From: s22 @biointelect.com>
Sent: [redacted]
To: SIMPSON, Andrew <Andrew.Simpson@health.gov.au>
Cc: HENDERSON, Nick <Nick.Henderson@health.gov.au>; s22

s22 @health.gov.au>; s22 @health.gov.au>; Streamlined Submission s22 @health.gov.au>; s22 s22 @biointelect.com>; s22 s47F ; s22 s22 @biocelect.com>; s22 @Novavax.com>; s22 s22 @biocelect.com>

Subject: PM-2023-05081-1-2 - Nuvaxovid XBB.1.5 - Delegate's request [SEC=OFFICIAL]

Importance: High

Dear Andrew,

s22

Biocelect requests that TGA reinstate our Nuvaxovid XBB.1.5 application for the s 47 ACV meeting. On Friday, s 47 , Biocelect responded to the TGA delegates' questions concerning the product information, real-world evidence, and post-marketing surveillance, noting there were no questions concerning the non-clinical evaluation. Given that ACV analysis and advice focus on efficacy and safety, these responses form the basis for and merit inclusion on the s 47 ACV agenda. Our experience indicates that the current ACV panel would provide no consequential analysis and advice on the outstanding CMC questions, and concerns signalled to Biocelect by the TGA on s 47 .

We propose that ACV consider the safety and efficacy of Nuvaxovid XBB.1.5 at the s 47 meeting based upon responses submitted to the delegate and on condition that Biocelect simultaneously and comprehensively addresses all CMC-related questions and concerns as soon as formally issued and if needed, in parallel with the ACV process.

While the ATAGI advice remains consistent, the above proposal supports the government's strategy to increase vaccination rates during the upcoming winter flu season. Ensuring a protein subunit vaccine alongside the mRNA vaccine options will allow for maximal vaccine uptake. This position is aligned with the portfolio approach highlighted in the Halton review, the government's response to the review and the current objective of the COVID-19 Taskforce.

Biocelect and the global Novavax team are on standby to respond immediately to this application's open questions and concerns, with previous experience readily available following approvals with EMA, USFDA, Health Canada and an advanced evaluation process ongoing with Medsafe.

s22

s22 [redacted]

[redacted]

Level 4, 143 Macquarie Street, Sydney NSW Australia 2000
M s22 [redacted] **T** 1300 800 984 **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

From: s22 [redacted]@health.gov.au> **On Behalf Of** Streamlined Submission
Sent: S 47 [redacted]
To: s22 [redacted]@biocelect.com>; Streamlined Submission s22 [redacted]@health.gov.au>
Cc: s22 [redacted]@health.gov.au>; s22 [redacted] s22 [redacted] s47F s22 [redacted]@health.gov.au>; s22 [redacted] s22 [redacted]@biocelect.com>
Subject: RE: PM-2023-05081-1-2 - Nuvaxovid XBB.1.5 - Delegate's request [SEC=OFFICIAL]
Importance: High

Dear s22 [redacted]

s22 [redacted]

Regarding your query, I advise this submission will now be tabled for consideration by ACV in S 47 [redacted], for the following reasons:

- As the sponsor may be aware, significant concerns over quality matters were raised to the sponsor in the meeting between the sponsor and the TGA Laboratories dated [redacted] S 47 [redacted].
- s22 [redacted]
- [redacted]

s22

s22

From: s22 @biocelect.com>
Sent: s 47
To: Streamlined Submission s22 @health.gov.au>
Cc: s22 @health.gov.au>; s22
s22 s47F s22 @health.gov.au>; s22
s22 @biocelect.com>; s22 @biocelect.com>
Subject: RE: PM-2023-05081-1-2 - Nuvaxovid XBB.1.5 - Delegate's request [SEC=OFFICIAL]

Dear s22
s22

I am pleased to share 2 response packages relating to the application to register Nuvaxovid XBB.1.5 (PM-2023-05081-1-2):

1. Response to Delegate's Request and Non-clinical evaluation report
2. Response to Round 1 Microbiology Report

s22

s22

s22

s22

s22

From: s22
To: Streamlined Submission
Cc: s22
Subject: RE: Completion of Evaluation Phase - Biointelect - Nuvaxovid XBB.1.5 - PM-2023-05081-1-2 [SEC=OFFICIAL]
Date: s 47
Attachments: image005.png
image013.png
image014.png
image016.png
image018.png
image019.png
image021.png

Dear s22

Thank you for sharing the milestone 5 completion of evaluation letter and confirming our understanding of the withdrawal process and key date of the s 47.

Following an internal Novavax/Biocelect discussion of the advice received during the s 47 s 47 TGA meeting and further documented in the TGA final Quality Evaluation Report received on the s 47, the sponsor wishes to voluntarily and formally withdraw the application: Nuvaxovid XBB.1.5 - PM-2023-05081-1-2. It is our understanding that taking this action now will result in no AUSPAR being published in relation to this application.

Novavax and Biocelect will be in touch regarding a resubmission and proposed dates for a TGA pre-submission meeting.

Kind Regards,

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** 1300 907 411 **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.

s 47

Streamlined submissions
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606 Australia

Dear Sir/Madam,

Re: NUVAXOVID XBB.1.5 (SARS-CoV-2 rS [Omicron XBB1.5]) COVID-19 VACCINE
Withdrawal of CATEGORY 1 APPLICATION – Change to formulation (Variant strain change) to XBB.1.5 strain
eSubmission Identifier e:005931, Sequence 0115 , Related Sequence 104

The Australian Sponsor Biocelect Pty Ltd (Biocelect) is submitting a withdrawal sequence for the application for registration for NUVAXOVID XBB.1.5 as a strain update to the fully registered NUVAXOVID vaccine (AUST R: 355139).

Please find attached the withdrawal email notification.

As the updates were independent of the Wuhan strain, these files will be removed rather than replaced.

eCTD details

The electronic Common Technical Document (eCTD) dossier is published by Novavax Inc. The e-submission data and validation assurances are provided as an attachment.

Contact details

If any clarification or further information is needed, please do not hesitate to contact the relevant person below.

Submission contact 1	s22 s22 @biocelect.com
Submission contact 2	s22 s22 @biointelect.com

Yours sincerely,

s22

Regulatory Affairs
Biocelect Pty Ltd

From: s22
To: s22
Cc: s22
Subject: Withdrawal Acknowledgement - Biointelect - Nuvaxovid XBB.1.5 - PM-2023-05081-1-2 [SEC=OFFICIAL]
Date: s 47
Attachments: image002.png
image004.png
image005.png
image007.png
image009.png
image010.png
image012.png
image013.png

You don't often get email from s22 @health.gov.au. Learn why this is important

Dear s22

I acknowledge receipt of your email below dated [s 47 advising the TGA of the withdrawal of Submission number [PM-2023-05081-1-2 – Type F].

This application has now been finalised and will not be reactivated. Should you wish to seek approval at a later date, you will need to reapply with the necessary data and relevant fees.

As s22 has mentioned below, if not already processed, please submit a withdrawal sequence to s22 @health.gov.au so that your electronic Common Technical Document (eCTD) dossier/Non eCTD electronic Submission (NeeS) dossiers are correct – see eCTD withdrawals (tga.gov.au).

Many thanks

s22
s22 |Application Support Team
Application Entry, Support and Export Section
Prescription Medicines Authorisation Branch
Medicines Regulation Division | Health Products Regulation Group
Australian Government Department of Health

T: s22 | E: s22 @health.gov.au
Location: TGA 27 Scherger Drive, Fairbairn ACT
PO Box 100, Woden ACT 2606, Australia

I acknowledge the Traditional Custodians of Australia and their continued connection to land, sea and community. I pay my respect to all Elders past and present.

From: Streamlined Submission s22 @health.gov.au>
Sent: s 47
To: s22 @biocelect.com>
Cc: s22 @biointelect.com>; s22 s22 @biointelect.com>; s22 @biocelect.com>; s22 s22 @health.gov.au>; s22 s47F Streamlined Submission s22 @health.gov.au>
Subject: RE: Completion of Evaluation Phase - Biointelect - Nuvaxovid XBB.1.5 - PM-2023-05081-1-2 [SEC=OFFICIAL]

Hi s22

Thank you for your email advising that the sponsor wishes to withdraw submission PM-2023-05081-1-2.

The TGA will being the process of withdrawing submission PM-2023-05081-1-2. Please submit a withdrawal sequence for the eCTD e005931. Information is available on the TGA website for eCTD withdrawals - please feel free to contact s22 @health.gov.au if you require assistance with the withdrawal sequence.

Kind regards,

s22
Application and Advisory Management Section
Prescription Medicines Authorisation Branch
Email: s22 @health.gov.au

Therapeutic Goods Administration
Australian Government, Department of Health and Aged Care
PO Box 100
Woden ACT 2606
www.tga.gov.au

This response is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met.

s22

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MINUTE TO DEPUTY SECRETARY LAWLER

To:	Professor Anthony Lawler
SUBJECT	NUVAXOVID XBB.1.5 – Category 1
Purpose:	Module 3 – Recommendation to reject/non-approval
Timing:	Requires **noting** as soon as possible.

Background:

Biocelect Pty Ltd applied to register a new strain for NUVAXOVID COVID-19 VACCINE, where the original, Wuhan strain-based vaccine has been updated to Omicron XBB.1.5.

Issues:

- **Potency:** XBB.1.5 product is not comparable to the original, which is expected for a strain update.NO Specifications were significantly amended by the Sponsor with a higher percentage range. The XBB1.5 product behaves differently in the potency assay compared the registered product.
- **Potency testing:** XBB.1.5 products manufactured, as well as tested, at different sites generates different batch potency results. This indicates potency variability of the manufactured product across manufacturing sites and generates doubts about the validation of the potency test.
- ***'Transient particulate equilibration phenomenon'*:** This is a Sponsor-developed term, which describes 15-25 days post-manufacture phenomenon where the product displays highly variable potency. This was not observed with original product. The Sponsor is unable to provide a plausible or robust scientific justification. The TGA has not seen this occur with any other biological medicine.
- **TGA Laboratory Testing:** One (1) batch of the XBB.1.5 product failed to meet potency specification. For a protein-based product, it is important to understand any change in protein potency during storage. The test results and data provided indicate the XBB.1.5 product does not meet the quality standard for Australian registration. The TGA Laboratories has significant concerns about the fragility of the product. Samples of the same batch sent to New Zealand and returned to the manufacturer for retesting also failed potency testing.
- **Critical quality attributes** directly related to quality, safety and efficacy of the product were changed without adequate justification from the original product. Changes included testing methods and specifications for potency, protein concentration, and particle size, with no valid assay to assess purity of the XBB.1.5 product.
- **Stability:** Reduction in potency was consistently observed with the XBB.1.5 product during storage. Data indicates that a product released at the lowest potency acceptance limit would not remain within the proposed specifications at the end of the 9-month shelf-life.
- **Manufacturer:** A primary manufacturer, Novavax Inc., USA manufactures a critical starting material but does not have GMP clearance. GMP inspection is anticipated in s 47 with no date for GMP clearance submission.

Commented [s22]: Noting that, for a strain update, comparability is what would be expected.

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- s22 [redacted]
- **Conclusion:** Evidence submitted in the application indicates the control strategy and understanding by the Sponsor and manufacturer of the quality aspects is inadequate to ensure that the XBB.1.5 product is manufactured consistently and will remain within specification throughout the shelf life.

Recommendation

That you **note**:

- Registration of the Novavax SARs-Cov-2 XBB1.5 variant vaccine has been recommended for rejection by the Module 3/Quality Evaluators
- The recommendation to reject the application has been conveyed to Biocelect and Novavax and the National Covid-19 Vaccine Program Division on s 47 [redacted]

Noted

Signed electronically (email D24-1471271)

Professor Anthony Lawler
s 47 [redacted]

Attachments: **NA**

Contact officer:	s22 [redacted]
Phone:	s22 [redacted]
TRIM ref:	D24-1418337
Cleared by:	Dr Lisa Kerr