

From: [GMP](#)
To: [s47F](#) [@commercialeyes.com.au](#)
Subject: Alternative Evidence - Re-inspection Application - [s47G](#)
 [SEC=OFFICIAL]
Date: Thursday, 9 January 2025 12:18:42 PM
Attachments: [image001.png](#)

Dear Sponsor,

it is possible that an inspection by another regulatory authority may allow you to apply for a GMP clearance via the CV pathway for [s47G](#)

Whether or not the evidence obtained through this inspection is sufficient to obtain a CV Clearance is not something that can be assessed without an application being submitted.

For further information please see [International agreements for GMP Clearance](#).

Please note that the scope of the inspection needs to cover the products on the ARTG, be at a pharmaceutical level (not food) and the assessed standard needs to meet the PIC/S Guide. For further information, please see [PE009 - PIC/S guide to GMP for medicinal products](#).

If you believe that this evidence meets the requirements and wish to go down the CV pathway please advise us of your course of action via email.

I also suggest reaching out to GMP Clearance GMPclearance@health.gov.au for assistance in determining whether a CV assessment pathway would be acceptable.

[s47G](#)

Thanks,

Kind regards,

[s22](#)

GMP Operations and Strategy Section

Medical Devices and Product Quality Division | Health Products Regulation Group

Manufacturing Quality Branch

Australian Government Department of Health and Aged Care

T: 1800 020 653 | E: GMP@health.gov.au

Location: Gulgana Building, 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.

Important:

This response contains general information given to you without prejudice; it is not binding on the TGA. The information provided does not constitute legal advice and you should get your own independent legal advice to ensure that all of the legislative

requirements are met.

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.



[Key deadlines](#) for your TGA account and annual obligations as the sponsor of a good in the Australian Register of Therapeutic Goods (ARTG) or as the holder of a manufacturing licence.

From: s 11C(1)(a)
To: TBS Helpdesk
Subject: Re: TOPELIA AUST LIMITED (s47G) - Agent Authorisation [SEC=OFFICIAL]
Date: Wednesday, 29 January 2025 12:52:16 PM
Attachments: [image001.png](#)
[image002.png](#)
[image118437.png](#)

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Much appreciated thank you s22

Kind regards

s 11C(1)(a)



s 11C(1)(a)

t: s22 | m: s22
 e: s 11C(1)(a)@topeliaaustralia.com | w: www.topeliaaustralia.com
 a: Level 1, 229 Great North Road, Five Dock, NSW, 2046

From: TBS Helpdesk <eBS@health.gov.au>
Sent: Wednesday, January 29, 2025 12:10 pm
To: s 11C(1)(a)@topeliaaustralia.com>
Subject: TOPELIA AUST LIMITED (s47G) - Agent Authorisation [SEC=OFFICIAL]

Dear s 11C(1)(a)

The TBS Helpdesk have processed the request to add **PharmaLex Pty Ltd (client ID s47G)** as an **Agent for TOPELIA AUST LIMITED (client ID s47G)**.

Please note: due to overnight system replication of data, you will be able to view this connection from tomorrow.

Kind regards

s22

TGA Business Services (TBS) Helpdesk
 Regulatory Assistance Section
 Regulatory Engagement Branch

Phone: 1800 010 624
 Email: ebs@health.gov.au

Therapeutic Goods Administration
 Australian Government, Department of Health and Aged Care
 PO Box 100

Woden ACT 2606

www.tga.gov.au

From: s 11C(1)(a) @topeliaaustralia.com>

Sent: Tuesday, 28 January 2025 4:12 PM

To: TBS Helpdesk <eBS@health.gov.au>

Subject: Appointment of Agent - Topelia Aust Limited

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.

Good afternoon

Please see the attached document appointing Pharmalex as an agent of Topelia.

Kind regards

s 11C(1)(a)



s 11C(1)(a)

s22

www.topeliaaustralia.com

s 11C(1)(a) @topeliaaustralia.com

Topelia Aust Limited ACN 652 771 670

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s 11C(1)(a)



t: s22 | m: s22
e: David@topeliaaustralia.com | w: www.topeliaaustralia.com
a: Level 1, 229 Great North Road, Five Dock, NSW, 2046



Australian Government
Department of Health
 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
<http://www.tga.gov.au/treatment-information-provided-tga>.

Add or remove an Agent from your organisation

Complete this form if you wish to authorise or remove an Agent (e.g. a regulatory affairs consultant) or people external to your company to undertake regulatory correspondence with us.

Please note: Agents will have full access to all of your approved records.



TGA Business Services (TBS) Terms and Conditions

Organisation for which the Agent relationship is being amended

Organisation business name: TOPELIA AUST PTY LIMITED

Organisation ID:

s47G

I want to:

- ☒ Add an Agent
☐ Remove an Agent

Details of Agent

Agency name:

PharmaLex Pty Ltd

Agency organisation ID:

s47G

Telephone:

s22

Fax:

N/A

Declaration

Printed name:	s47F	
Position in organisation:	Director	
Signature:	s47F	Date: 13/1/25

From: [GMPclearance](#)
To: s47F
Subject: RE: Extension approved with Condition - s47G
 [SEC=OFFICIAL]
Date: Wednesday, 12 March 2025 2:59:39 PM
Attachments: [image001.jpg](#)
[image002.gif](#)
[image003.jpg](#)
[image004.png](#)
[image005.png](#)

Delayed processing timeframes



There are currently delayed processing times for all GMP Clearances due to high volumes. We are working through these as quickly as possible.

Where your application needs prioritisation for a delegate's decision or to complete a product submission, please provide us with all relevant details to assist with your request.

Dear s47F

Thank you for your email.

As per your request, I have updated the contact details for application s47G. This update should be visible within 24 hours in your portal.

I can confirm we have received all required evidence for application s47G. If further evidence is requested during assessment, an evaluator will be in contact with you.

As for your extension request, as you are an approved contact for the application, please submit an extension application through the portal. You are able to submit an extension up to 30 days from the expiry of the application.

If you have any further questions, please let us know.

Kind regards,

s22

GMP Clearance

GMP Clearance Section | Manufacturing Quality Branch
 Phone: 1800 020 653 | Email: GMPclearance@health.gov.au

Therapeutic Goods Administration

Department of Health and Aged Care
 PO Box 100
 Woden ACT 2606
www.tga.gov.au



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GMP clearance guidance title has been updated

Our GMP Clearance Guidance has had a name change to [How to obtain GMP clearance through inspection reliance](#)



GMP Clearance: Sponsor Information Dashboard (SID)

SID provides industry with information about current processing times, workload, priorities, and key messages for GMP Clearance applications. Please refer to the [notice](#) and [GMP clearance Sponsor Information Dashboard \(SID\) webpage](#) for further information.

From: s47F [REDACTED]@pharmalex.com>

Sent: Tuesday, 11 March 2025 10:19 AM

To: GMPclearance <GMPclearance@health.gov.au>

Subject: FW: Extension approved with Condition - s47G [REDACTED]

[SEC=OFFICIAL]

Dear s22 [REDACTED],

Hope this finds you well.

I refer to the correspondence below, regarding the outstanding supporting documents from s47G [REDACTED]

We received confirmation from s47G [REDACTED] that the outstanding documents were submitted directly to the TGA on 10 Mar 2025 (see attached cover letter). Kindly please confirm the documents were successfully received by TGA.

In addition, on behalf of Topelia Aust Limited (Client ID: s47G [REDACTED]), we would like to request an extension to the current GMP clearance for s47G [REDACTED]

As communicated below (see email trail), PharmaLex is now the new agent for Topelia Aust Limited. Since the application s47G [REDACTED] was submitted by the previous agent Commercial Eyes Pty Ltd, (and the application is not viewable to the new agent) we are unable to access this particular clearance to process an extension application in eBS.

We understand it is not possible to update the agent information of this application, but the TGA can

update the contact details of the application.

Kindly please update the contact details of this application to:

Contact Name: s47F

Phone: s22

Email: s47F@pharmalex.com

Thank you for your kind assistance. It is greatly appreciated.

Should you require further information, please do not hesitate to let me know.

Kind regards,

s47F

s47F

PharmaLex Pty Ltd (Sydney)
Senior Specialist, Regulatory Affairs

Mobile: s22

Level 10, 1 Chandos Street
St Leonards NSW 2065, Australia
www.pharmalex.com

We continue to operate as PharmaLex, a part of Cencora. At Cencora, we are united in our responsibility to create healthier futures.

From: GMPclearance <GMPclearance@health.gov.au>

Sent: Friday, 14 February 2025 11:01 AM

To: s47F@pharmalex.com>

Subject: RE: Extension approved with Condition - s47G

[SEC=OFFICIAL]

Delayed processing timeframes



There are currently delayed processing times for all GMP Clearances due to high volumes. We are working through these as quickly as possible.

Where your application needs prioritisation for a delegate's decision or to complete a product submission, please provide us with all relevant details to assist with your request.

Dear s47F

Thank you for your enquiry.

I note that there is still outstanding evidence for application s47G

s47G

In relation to your request to update the agent details of this application, unfortunately we are unable to update the agent of an application. Given that Topelia Aust Limited has an approved sponsor/agent relationship to PharmaLex Pty Ltd in the system, we are however, able to change the contact details of the application.

If you wish to update the contact details for your application, please send us a confirmation of the details via email.

Please note that upon updating the contact details of an application, unfortunately clearances that are currently under assessment will not be viewable by the new agent/contact until the application has been issued. If you require future updates for the application whilst it is under assessment, please contact our team and we will be happy to be of assistance.

If you have any further questions please let us know.

Kind regards,

s22

GMP Clearance

GMP Clearance Section | Manufacturing Quality Branch
Phone: 1800 020 653 | Email: GMPclearance@health.gov.au.

Therapeutic Goods Administration

Department of Health and Aged Care
PO Box 100
Woden ACT 2606
www.tga.gov.au



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From: s47F [REDACTED] <[REDACTED]@pharmalex.com>

Sent: Thursday, 13 February 2025 1:05 PM

To: GMPclearance <GMPclearance@health.gov.au>

Subject: FW: Extension approved with Condition - s47G [REDACTED]

[SEC=OFFICIAL]

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],

Hope this finds you well.

I am writing on behalf of Topelia Aust Limited (Client ID: s47G [REDACTED]).

Could you please advise if TGA already received the outstanding documents requested on your email below? Our follow up with s47G [REDACTED] has not yet been successful and we need to find out if the outstanding documents were already sent to the TGA so that we could submit an extension to the clearance which is expiring s47G [REDACTED].

Additionally, we would like to advise that PharmaLex Pty Ltd (Client ID: s47G [REDACTED]) is now the new agent for Topelia Aust Limited.

Could you please change the applicant's name on this clearance application from Commercial Eyes to PharmaLex Pty Ltd so that we are able to access this application and review the application status in eBS.

Please see changes below:

Current applicant name:	Change to:
Applicant Name: Commercial Eyes Pty Ltd	Applicant name: PharmaLex Pty Ltd
Client ID: s47G [REDACTED]	Client ID: s47G [REDACTED]
Who to contact for further information: s47F [REDACTED]	Who to contact for further information: s47F [REDACTED]

Thank you very much for your kind assistance.

Kind regards,

s47F

s47F

PharmaLex Pty Ltd (Sydney)
Senior Specialist, Regulatory Affairs

Mobile: s22

Level 10, 1 Chandos Street
St Leonards NSW 2065, Australia
www.pharmalex.com

We continue to operate as PharmaLex, a part of Cencora. At Cencora, we are united in our responsibility to create healthier futures.

We were trying

s22







From: [GMPclearance](#)
To: [s47F](#) [@pharmalex.com](#)
Subject: Extension approved with Condition - [s47G](#)
 [SEC=OFFICIAL]
Date: Tuesday, 18 March 2025 2:16:11 PM
Attachments: [image001.png](#)
[image003.jpg](#)
[image005.gif](#)
[image002.png](#)
[image006.jpg](#)

Delayed processing timeframes



There are currently delayed processing times for all GMP Clearances due to high volumes. We are working through these as quickly as possible.

Where your application needs prioritisation for a delegate's decision or to complete a product submission, please provide us with all relevant details to assist with your request.

Dear Sponsor,



Your GMP clearance has been extended.

Extension application [s47G](#) for [s47G](#)
[s47G](#) has now been considered.

An extension has been granted for **Greater than 6 months** from the date of the previous expiry. The new expiry date is now [s47G](#).

Please note the following condition(s) placed on the original clearance remains:

1. **GMP Clearance issued on the condition that** [s47G](#)
[s47G](#)

You may find further information in relation to the GMP clearance application by logging in to your [TGA eBusiness Services](#) account. Please ensure requests to extend your GMP clearances are submitted well before the expiry date.

Please use the tracking number [s47G](#) when lodging a variation application for a product listing or registration.

Should you have any questions about the outcome of the TGA's assessment of your application, please [contact us](#).

Kind regards,

[s22](#)

Therapeutic Goods Administration

Department of Health and Aged Care

PO Box 100

Woden ACT 2606

www.tga.gov.au

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