# Application for consent for unapproved medical devices that are non-compliant with the Essential Principles

**Racheal Aye**

A/g Assistant Director,

Medical Devices Surveillance Branch

Department of Health and Aged Care, TGA

# Acknowledgement of Country

In the spirit of reconciliation, the Department of Health and Aged Care acknowledges the Traditional Custodians of country throughout Australia and their connections to land, sea and community.

We pay our respect to their Elders past and present and extend that respect to all Aboriginal and Torres Strait Islander peoples today

# Welcome

## Housekeeping

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**Closed captions are available**

Activate it with the speech bubble icon on the bottom left of your screen

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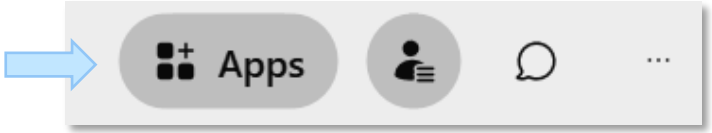
# Slido

## How to access and use Slido

### Through the Slido application in Webex




- Click on the **Apps** icon
- Select **Slido**
- Open the **Q&A** tab to ask questions
- Live Poll (use survey tab when prompted)

### Using the QR code

Scan the QR code to access Slido from your mobile device

# Application for consent for unapproved medical devices that are non-compliant with the Essential Principles

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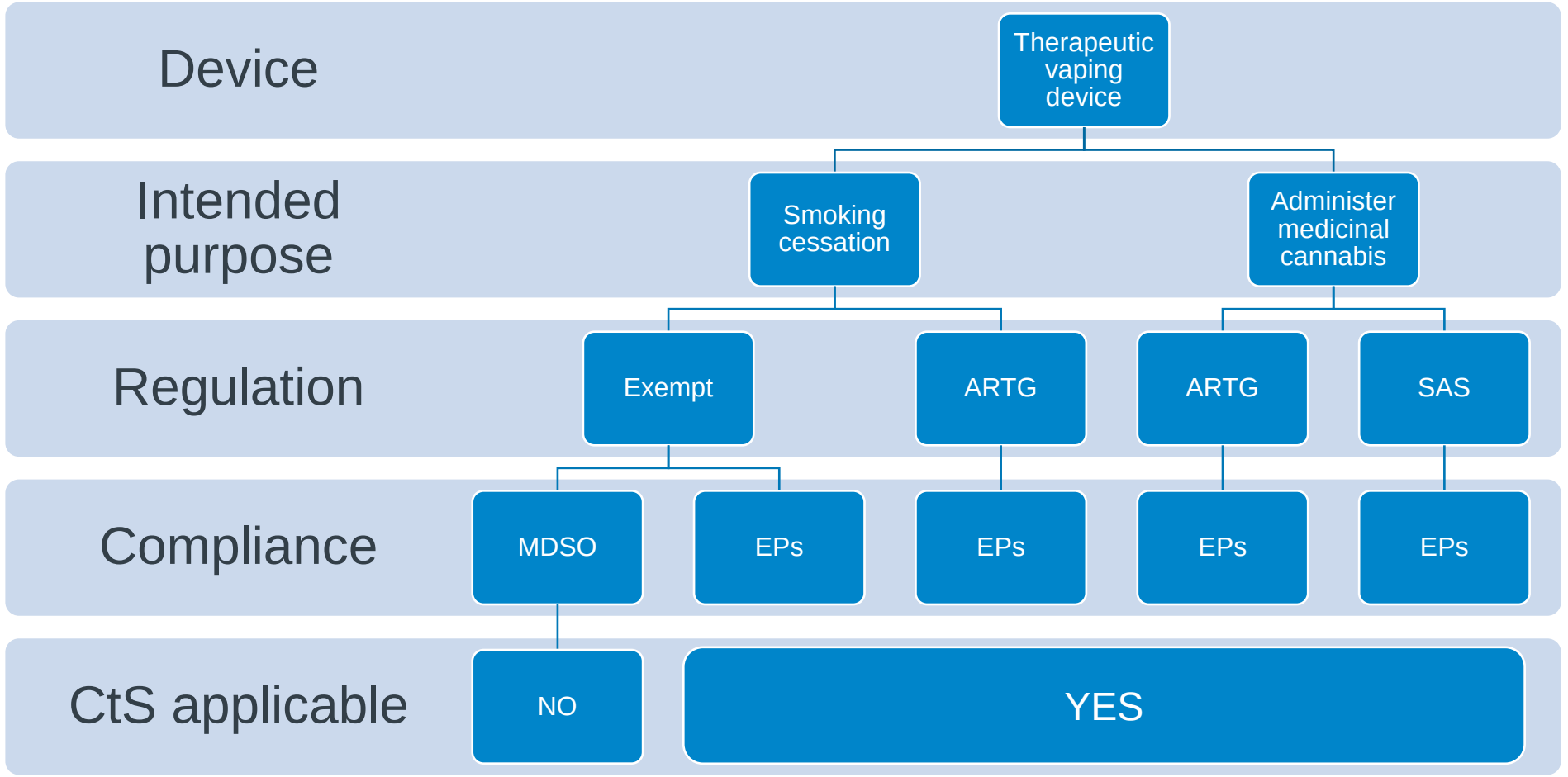
# Background

When to apply for consent for non-compliance with the essential principles

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| | |
|---|---|
| **Scope** | **Vaping device and device accessory including reusable vaping device, or an unfilled cartridge, capsule, pod, or other vessel for use in or with a reusable vaping device intended to administer a therapeutic vaping substance whose only purpose is for smoking cessation or the management of nicotine dependence.** |

**Pathways for nicotine substance:**

Application for consent to import, supply or export goods that do not comply with standards - section 14/14A

# Background

Criminal offences under section 41MA and civil penalties under section 41MAA of the *Therapeutic Goods Act 1989* for importing, supplying, or exporting medical devices that do not meet the Essential Principles (EPs) unless consent has been granted by the Secretary of the Department of Health and Aged Care

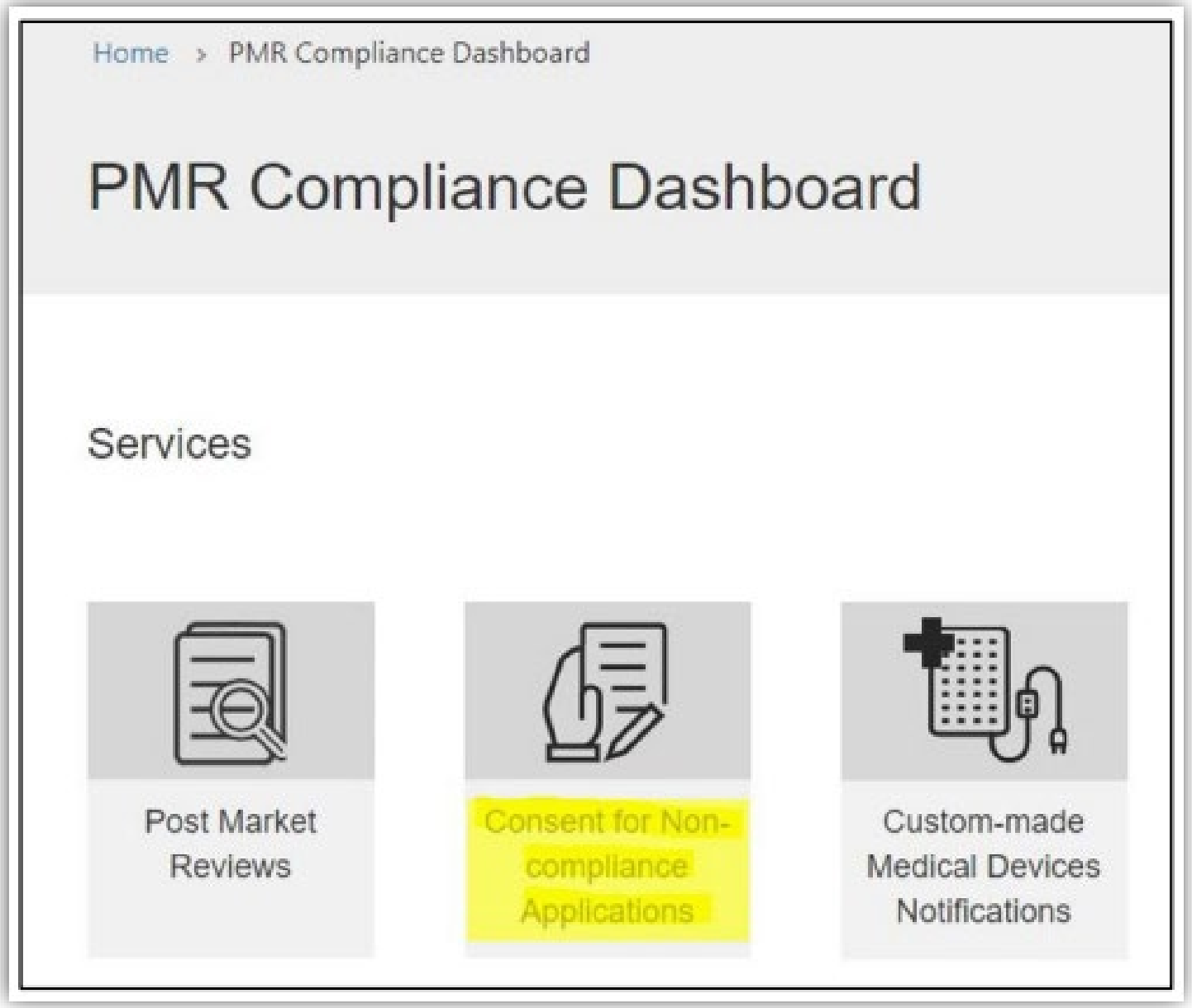
- Applications for consent are considered on case to case basis
- Consent is granted for a limited time of period
- When there are no safety and performance concerns

**Aim:**

Guidance on how to apply for consent to import, supply or export medical devices that are not included in the ARTG and are non-compliant with the Essential Principles

# Dashboard overview



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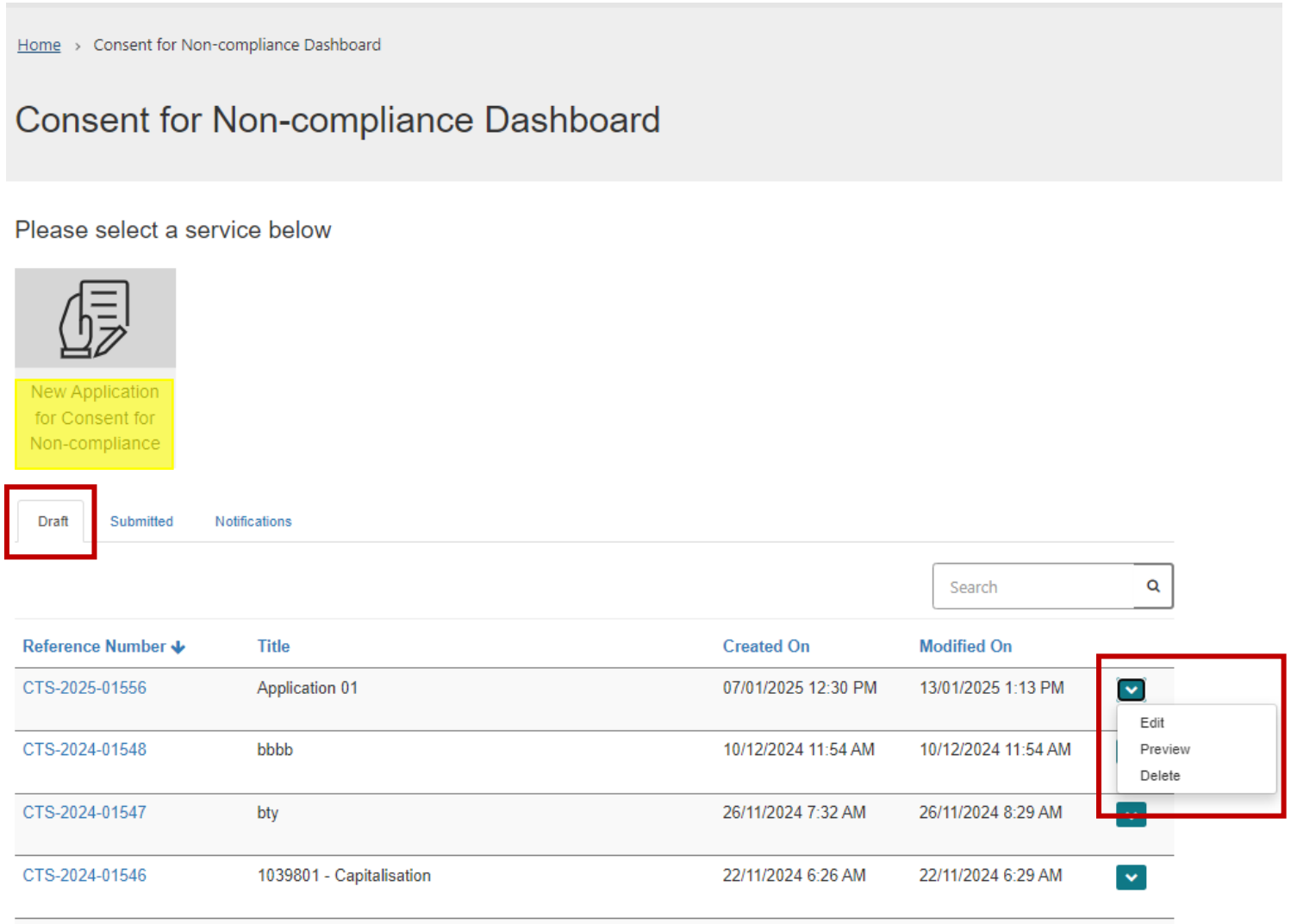
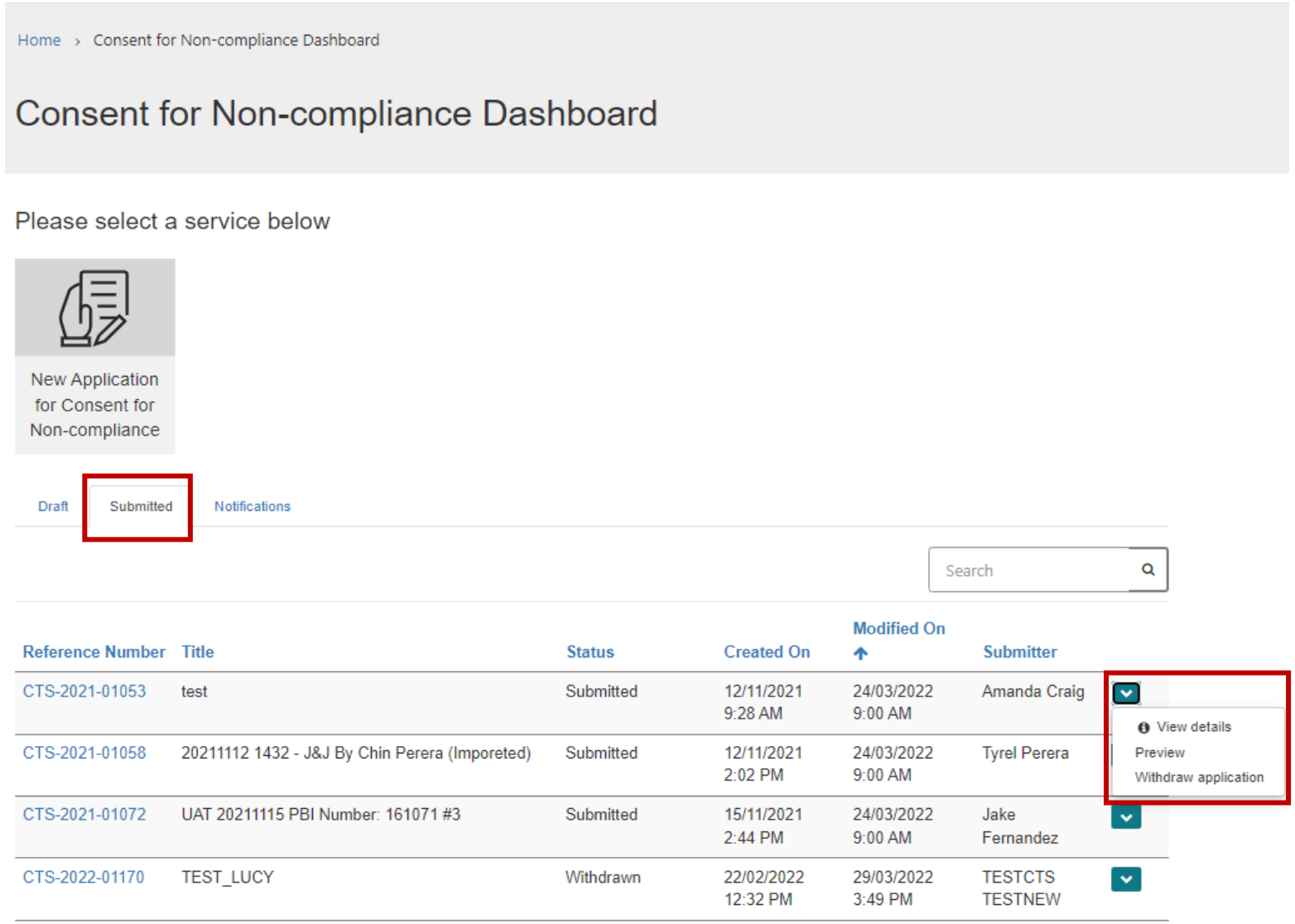
# Dashboard overview





# Dashboard overview





# Dashboard overview



Please select a service below

New Application for Consent for Non-compliance

Draft Submitted Notifications

Search

| Notification ID | Application name | Notification type | Notification status | Response due date | Received date | |
|---|---|---|---|---|---|---|
| CTS-2024-01535 - Imposing conditions on approval - 06 | QA1111_01 | Imposing conditions on approval | Completed | 10/11/2025 11:30 PM | 16/12/2024 8:29 AM | |
| CTS-2024-01544 - Imposing conditions on approval - 12 | Consent Withdrawal | Imposing conditions on approval | Sent/Awaiting Response | 18/03/2025 11:30 PM | 23/12/2024 1:18 PM | |
| CTS-2022-01321 - Approved - 01 | Suspension revocation_Response due hidden in portal | Consent approved | Sent/Awaiting Response | 07/02/2025 7:30 AM | 22/07/2022 11:39 AM | |
| CTS-2024-01516 - Approved - 01 | Srini 2910 - Non ARTG | Consent approved | Sent/Awaiting Response | 30/01/2025 11:30 PM | 20/12/2024 8:39 AM | |

Draft
View details
Preview

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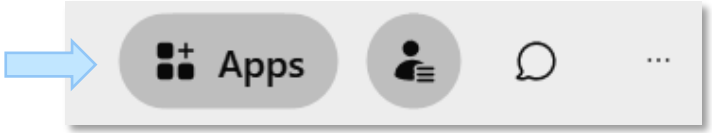
# Questions are now open

### Through the Slido application in Webex




- Click on the **Apps** icon
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- Live Poll (use survey tab when prompted)

### Using the QR code

Scan the QR code to access Slido from your mobile device

New Application for Consent for Non-compliance

# New Application for Consent for Non-compliance

**Provide a relevant name for your application. It will enable you to differentiate multiple applications over time.** *

**This application seeks consent for non-compliance for:** *

- ○ Device(s) included in the ARTG
- ○ Device(s) included in Application(s) for Inclusion
- ◉ Device(s) NOT included in the ARTG or Application(s) for Inclusion

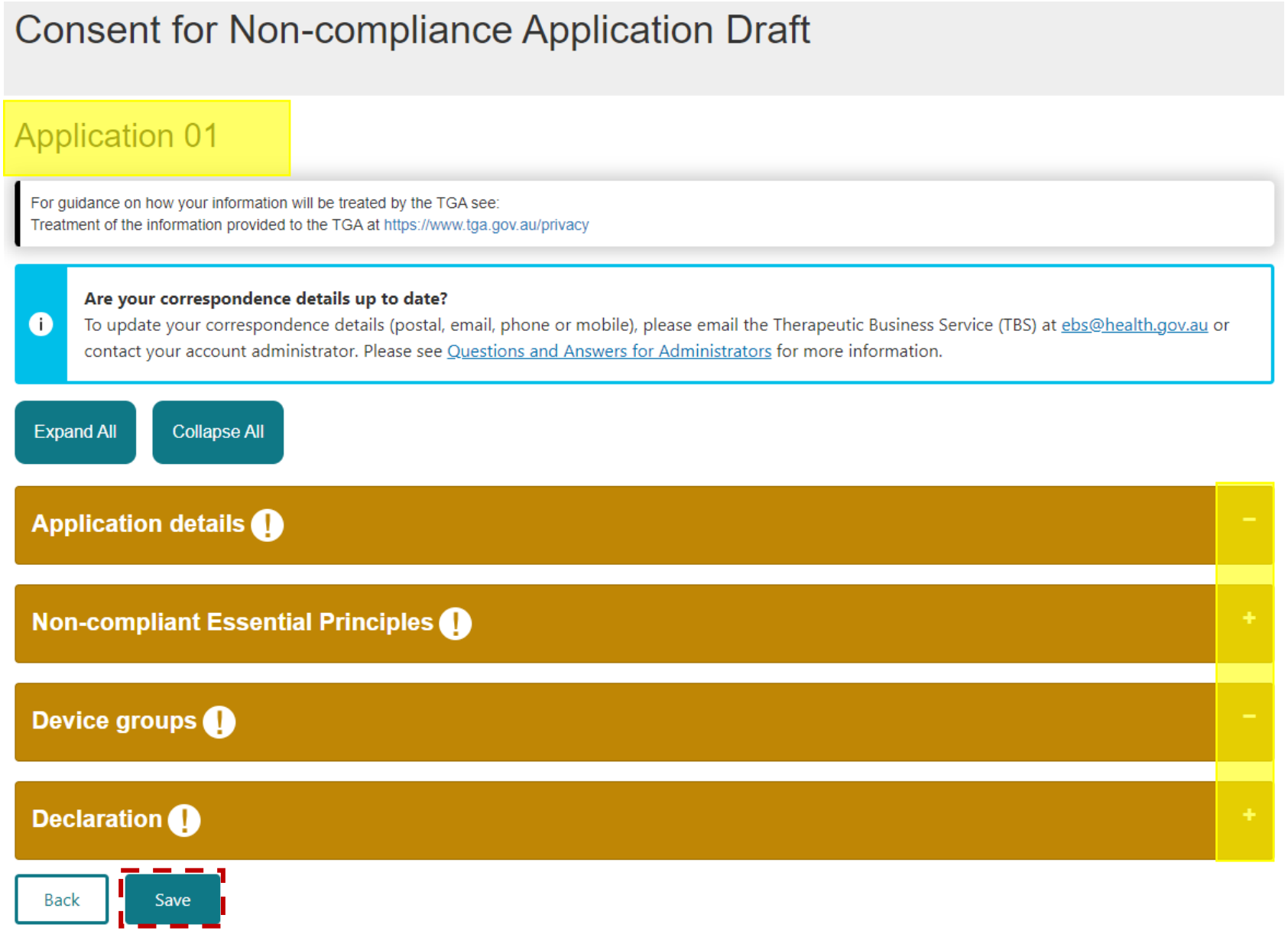
**Select device category** *

Select

Select
Vaping device
Other

Back Create

# Create application



# Application details

Non-compliant Essential principles Device groups Declaration

## Application details

**Reference number**

CTS-2025-01556

**If you would like to change the name of this application, you can do so in the field below.** *

Application 01

**Sponsor** *

Johnson & Johnson Pacific Pty LTD

**This application seeks consent for non-compliance for:**

Device(s) NOT included in the ARTG or Application(s) for Inclusion

**Device category**

Vaping device

Are you seeking consent for your device(s) to be: *

Select one or more application type(s) from the list below.

- [x] Imported?
- [x] Exported?
- [x] Supplied?

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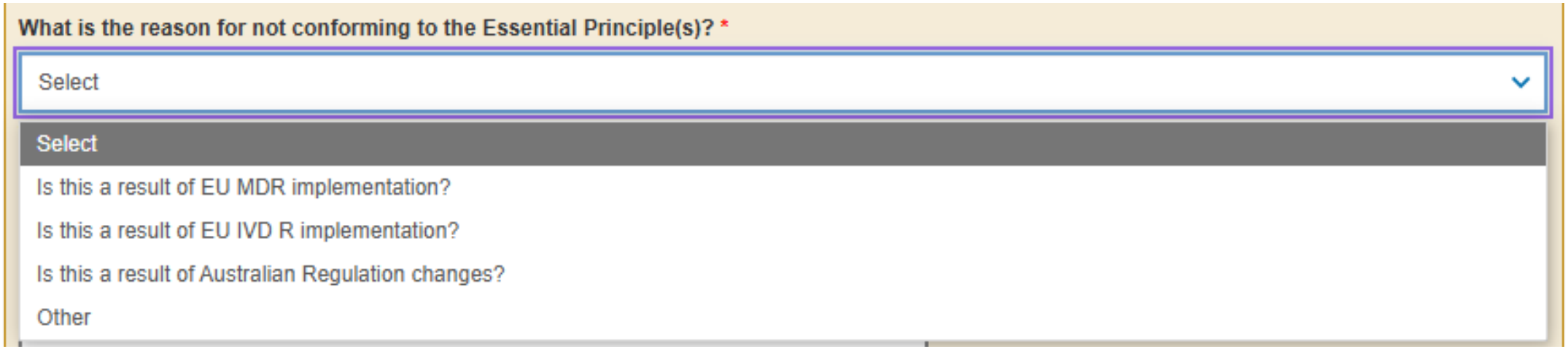

What is the reason for not conforming to the Essential Principle(s)? *
Select
Select
Is this a result of EU MDR implementation?
Is this a result of EU IVD R implementation?
Is this a result of Australian Regulation changes?
Other

# Application details

Non-compliant Essential principles Device groups Declaration

**What are the real or potential risks associated with the non-conformance if the non-conforming device(s) were to be imported, exported or supplied?** *

Please type your answer in box provided or upload a document by using the "add files" button. If you are providing your explanation in an attached document, please write "document attached" in the box below.

Documents attached

Before uploading supporting documentation, please check that folders have been created. **To provide supporting documentation, please click the 'Add files' button or click on the relevant folder.**

**Sometimes there is a delay in creating the folders. If they do not appear after a few minutes or refreshing the page, refer to the guidance document for some quick trouble shooting.**

**Documents uploaded before folders have been created will not be included in your submission.**

Add files

| Name | Modified | |
|---|---|---|
| CTS-2025-0155601 | 2 months ago | |
| CTS-2025-0155602 | 13/01/2025 10:53 AM | |

# Non-compliant Essential Principles

## Non-compliant Essential Principles !

Identify all the Essential Principles (EPs) that the device(s) are non-compliant with. You will need to select one EP at a time and provide details as to why the device(s) are non-compliant with each EP.

| Non-compliant EP ↑ | How device(s) do not conform to the selected EP? |
| --- | --- |

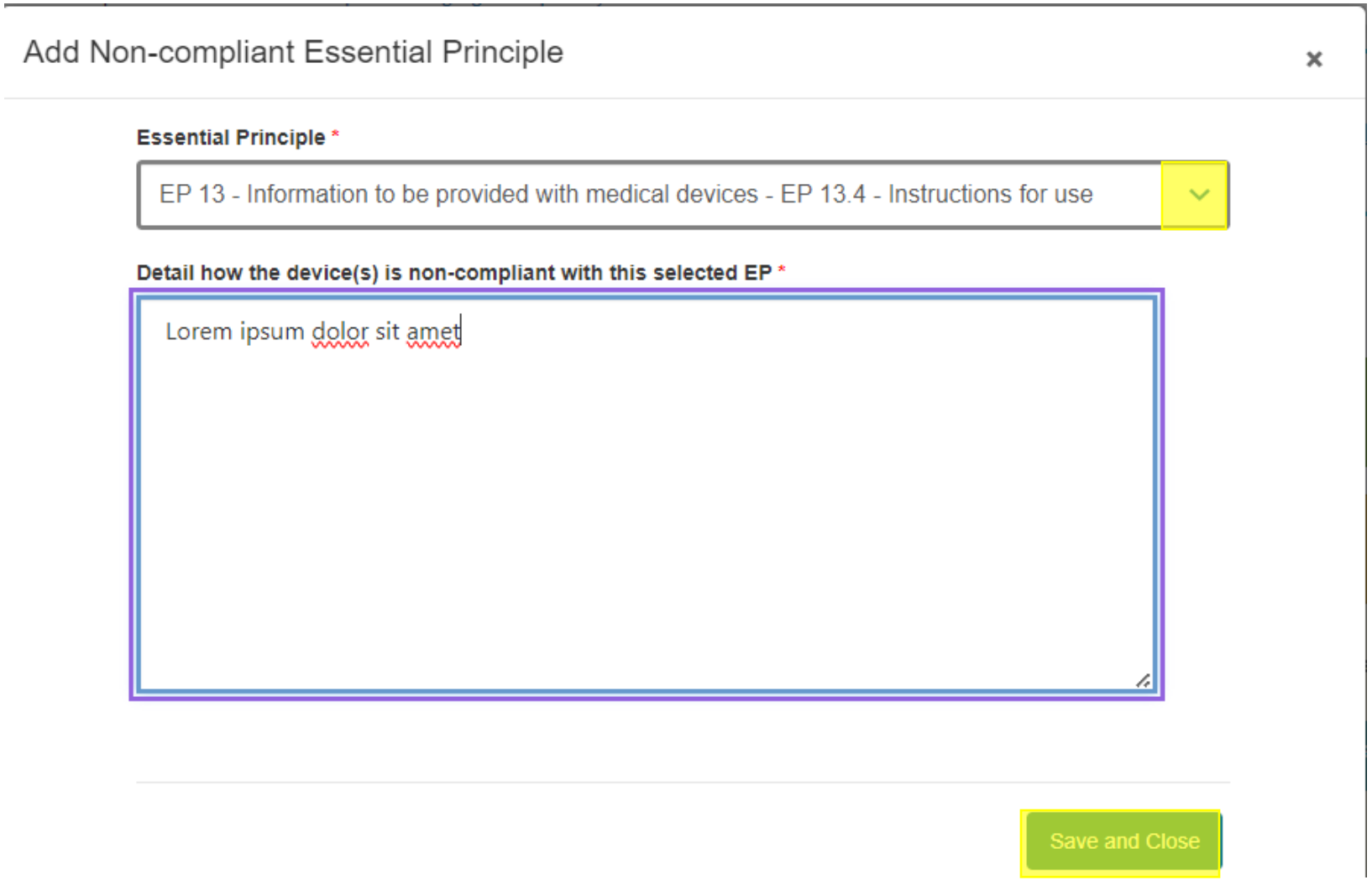
Add breached Essential Principle

There are no records to display.

SLIDO

# Non-compliant Essential Principles

Add breached Essential Principle



# Non-compliant Essential Principles

## Non-compliant Essential Principles

**Identify all the Essential Principles (EPs) that the device(s) are non-compliant with. You will need to select one EP at a time and provide details as to why the device(s) are non-compliant with each EP.**

Add breached Essential Principle

| Non-compliant EP | How device(s) do not conform to the selected EP? |
|---|---|
| EP 13 - Information to be provided with medical devices - EP 13.4 - Instructions for use | Lorem ipsum dolor sit amet |
| EP 14 - Clinical evidence | abcdef |

Edit
Delete

## Device groups

You can group the unapproved devices with the same proposed start and end dates, and the same implementation plan for this consent application.

Add device group

| Group name ↑ | Unapproved device(s) linked to the group | Notification number(s) linked to the group | Proposed start date | Proposed end date | Group data completed | Created on |
|---|---|---|---|---|---|---|

There are no records to display.

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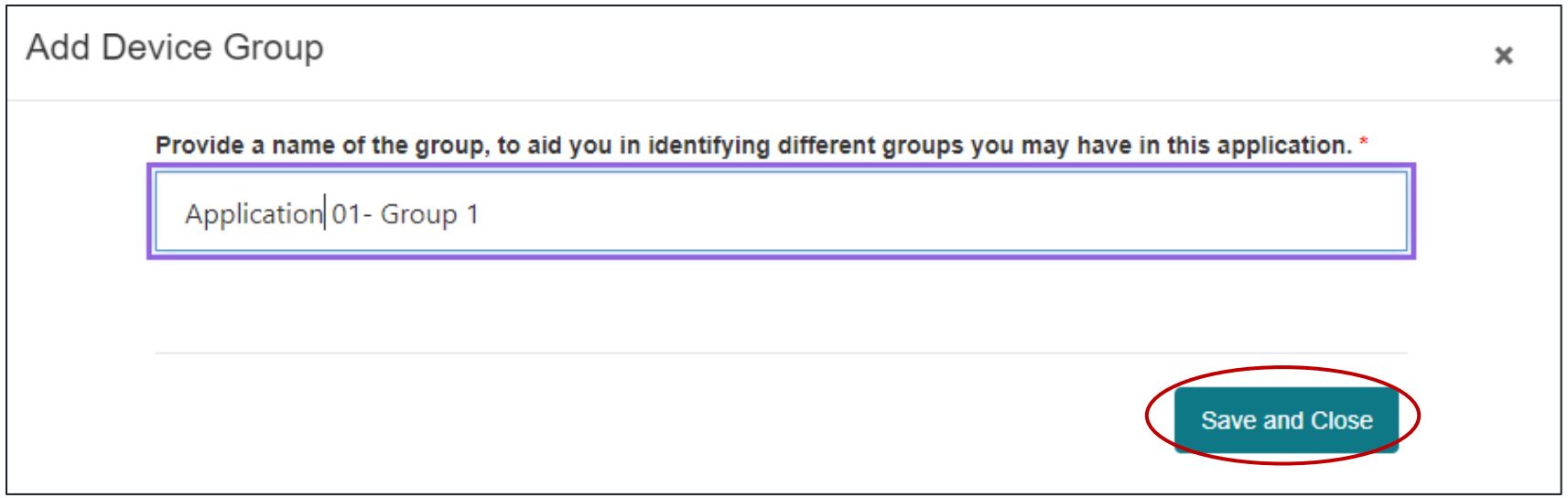
Add device group



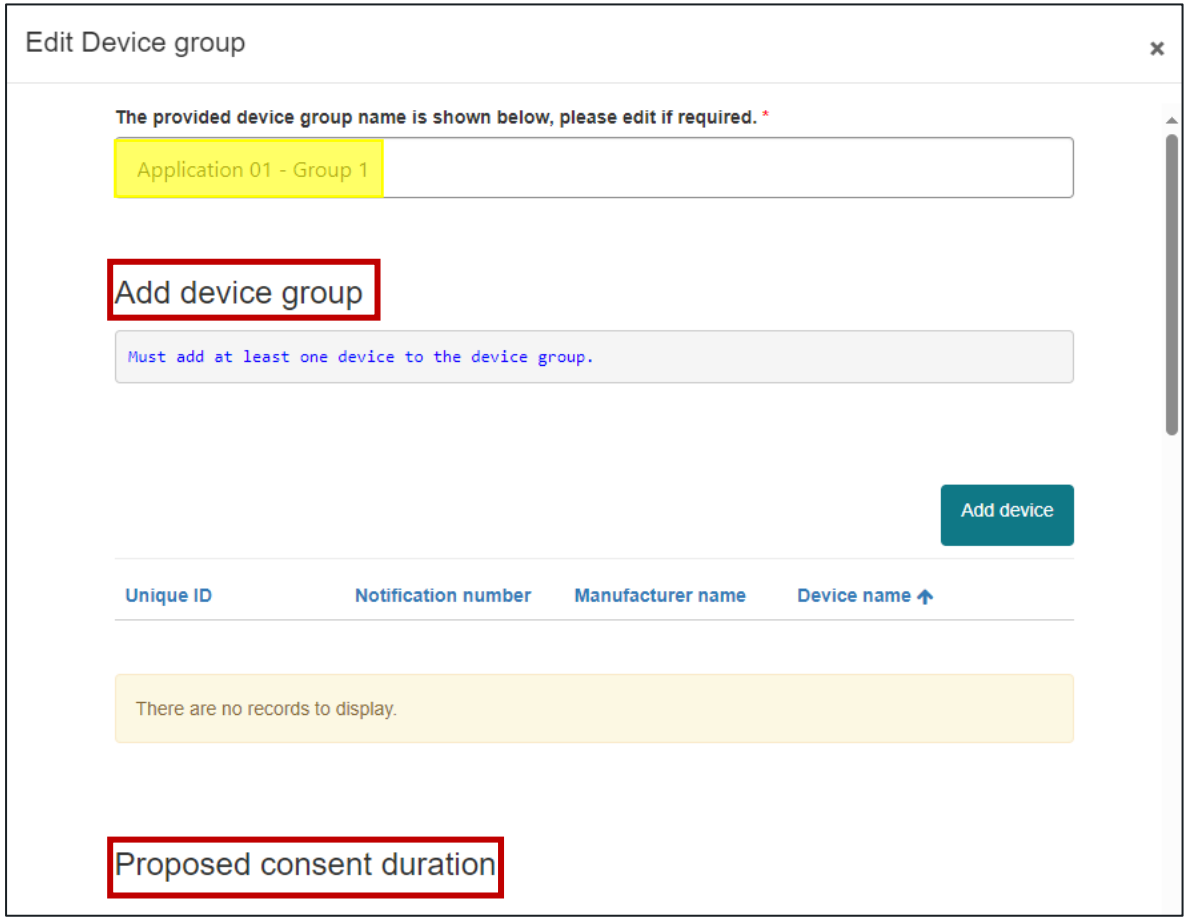
## Device groups

**You can group the devices with the same proposed start and end dates, and the same implementation plan for this consent application.**

Add Device group

| Group name | Device(s) linked to the Group | Proposed start date | Proposed end date | Group data completed | Created On | |
|---|---|---|---|---|---|---|
| Application 01 - Group 1 | | | | No | 25/02/2025 11:33 AM | Edit Delete |

# Edit device group

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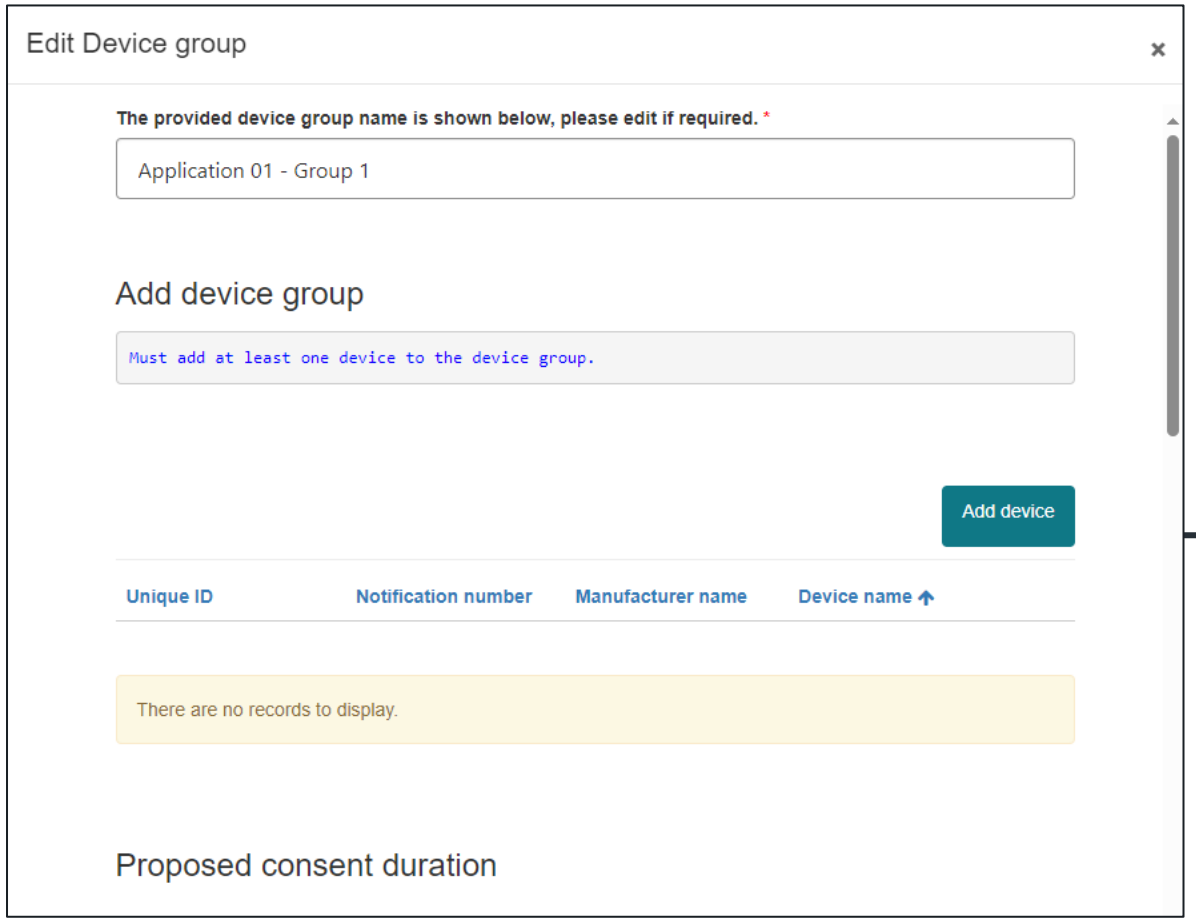
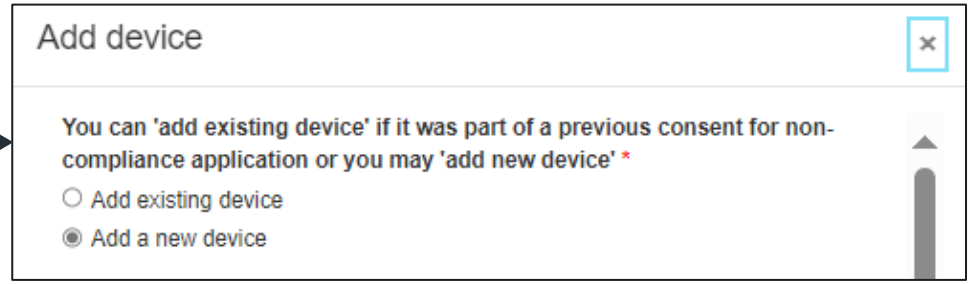
## Edit device group

# Add devices to the device group





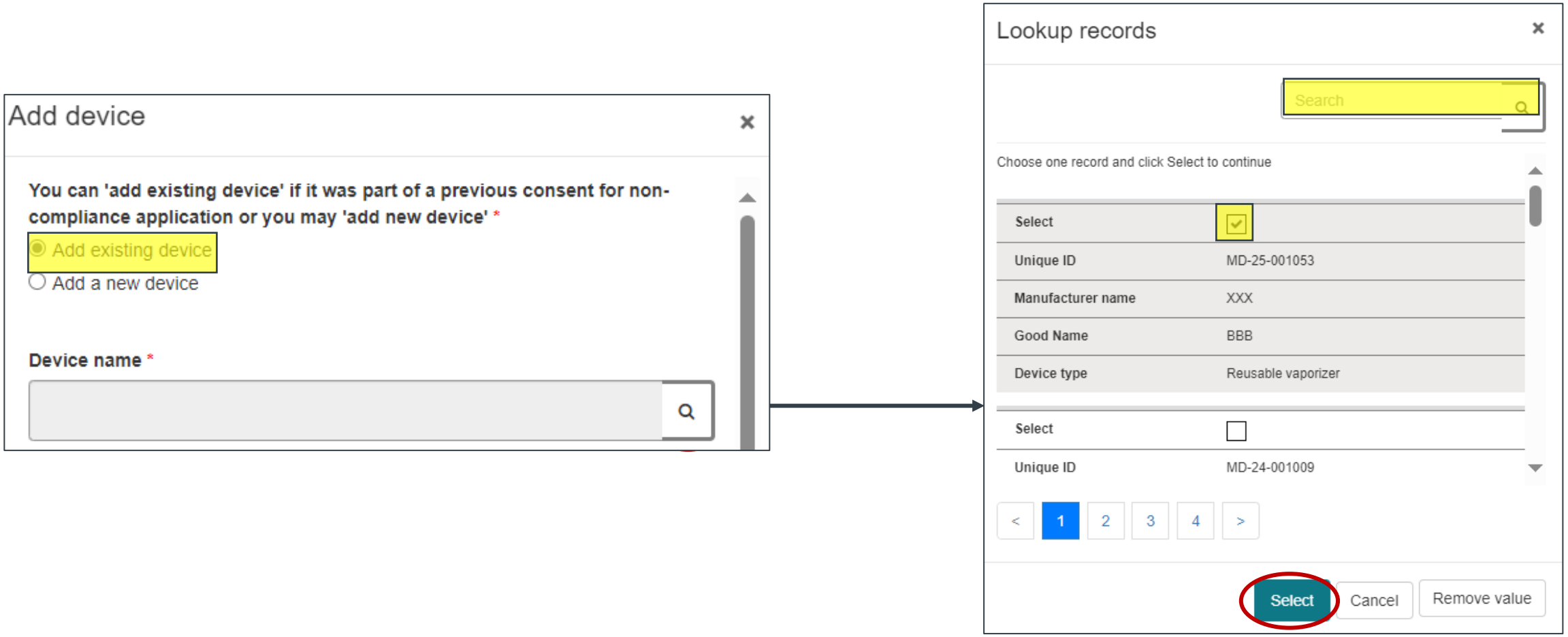



# Edit device group

## Add devices to the device group



### Add existing device

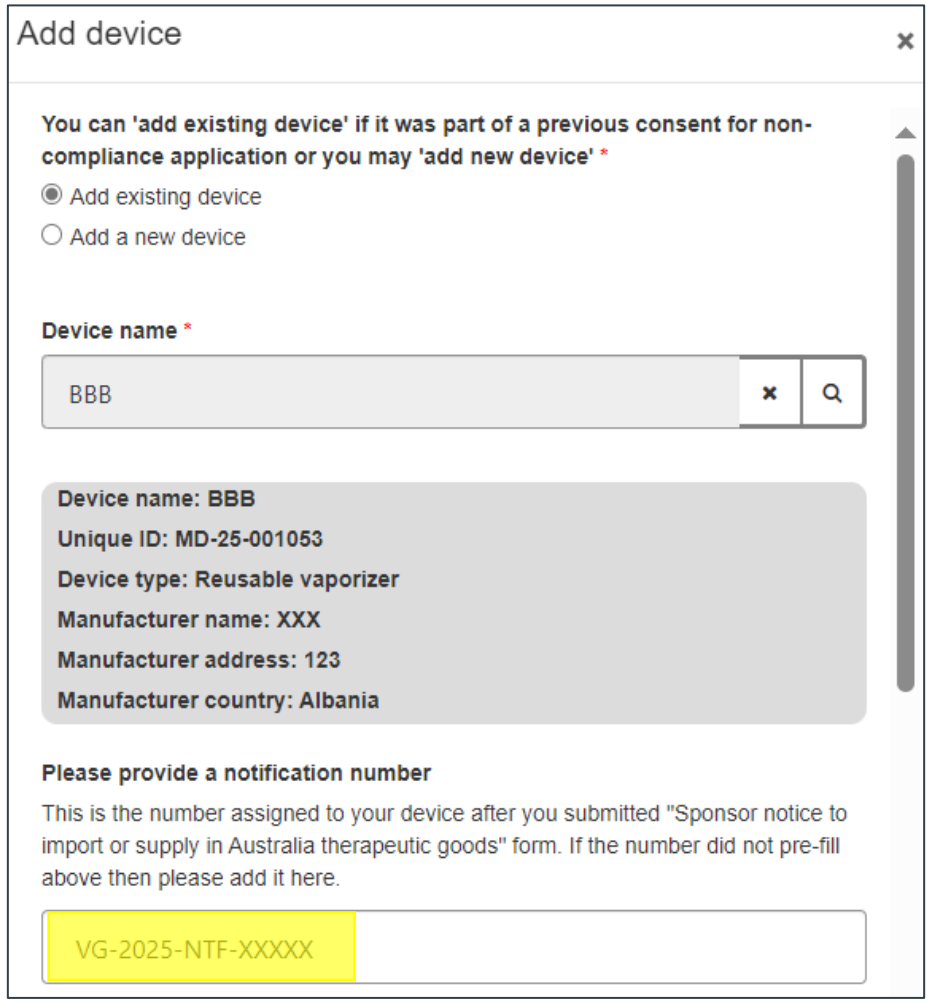


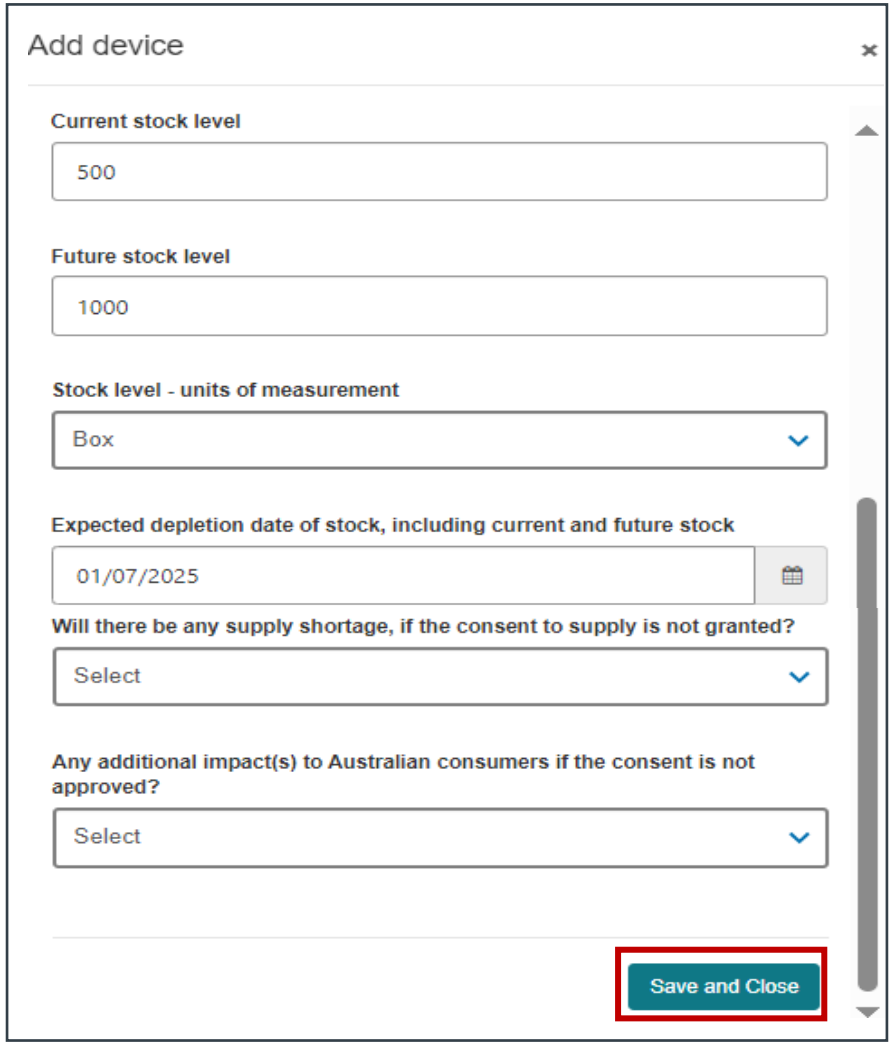
# Edit device group

## Add devices to the device group



### Add existing device

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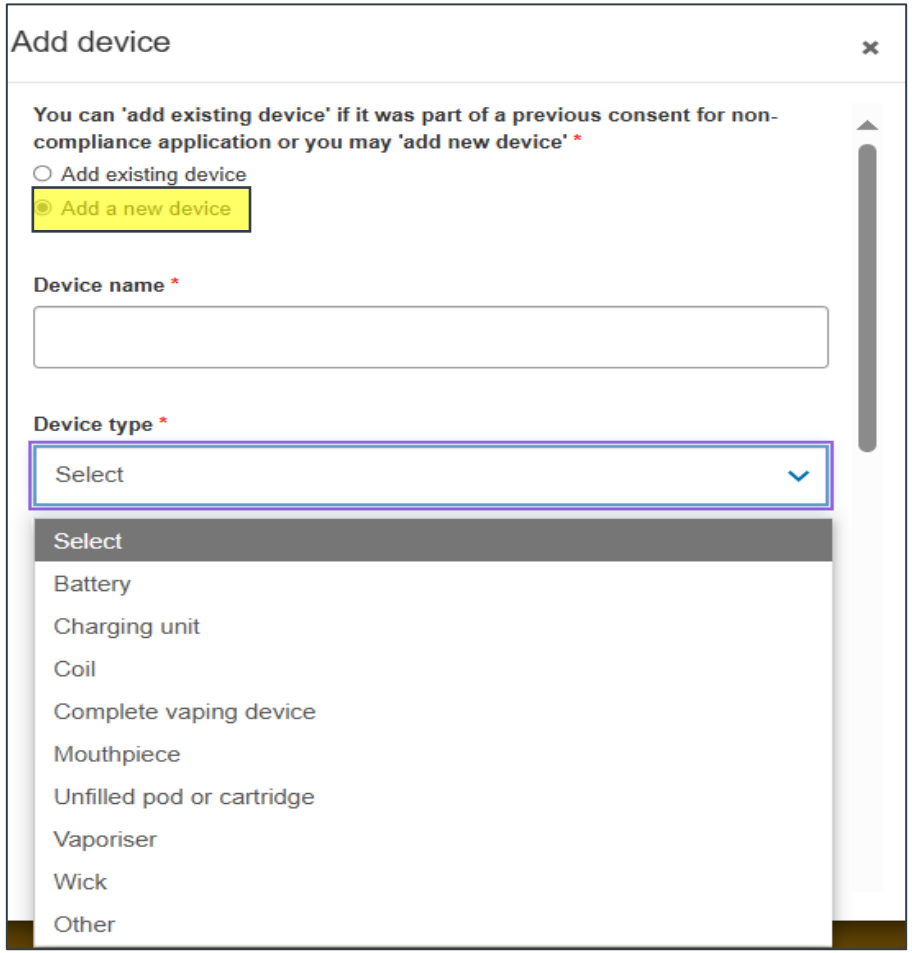
# Edit device group

## Add devices to the device group



### Add a new device

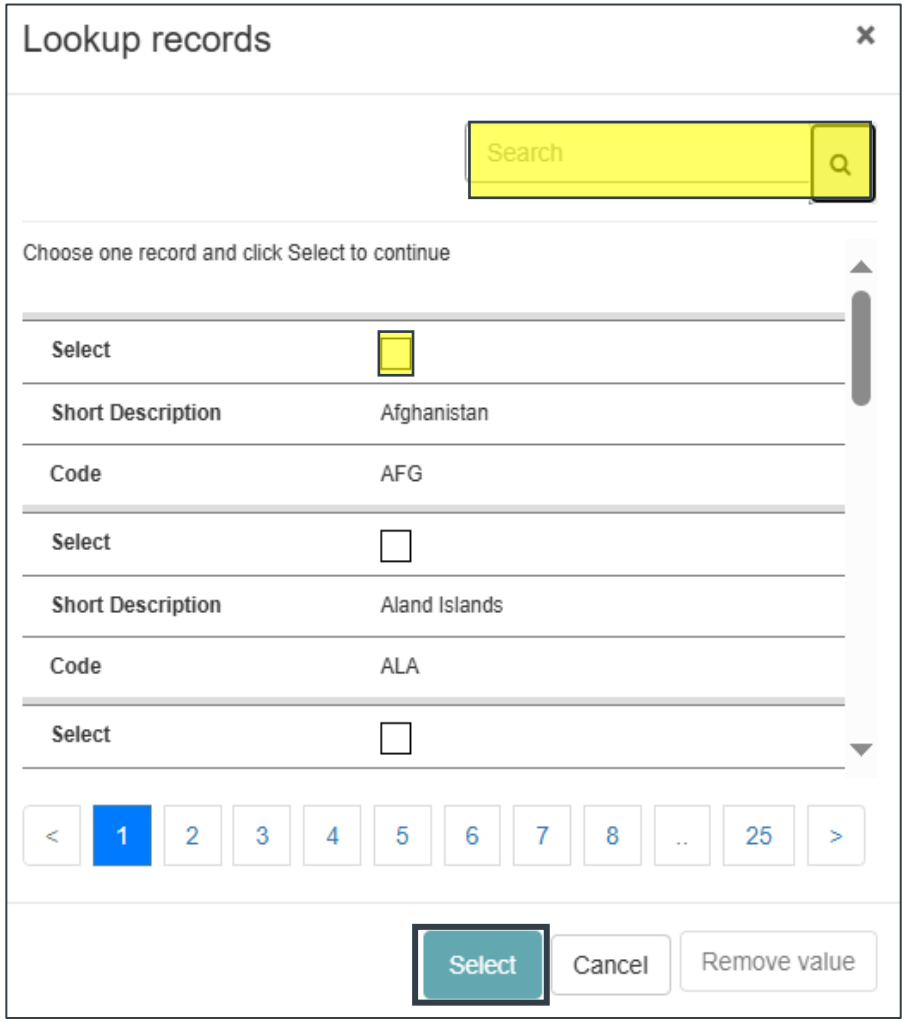


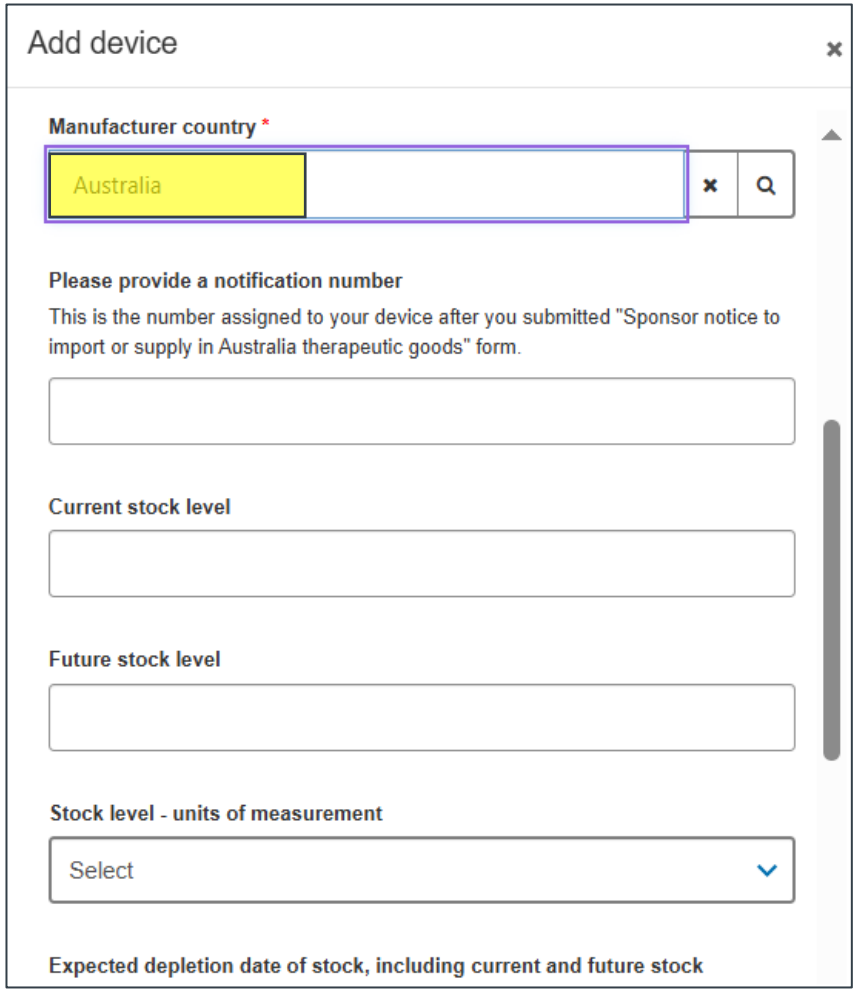

# Edit device group

## Add devices to the device group



### Add a new device

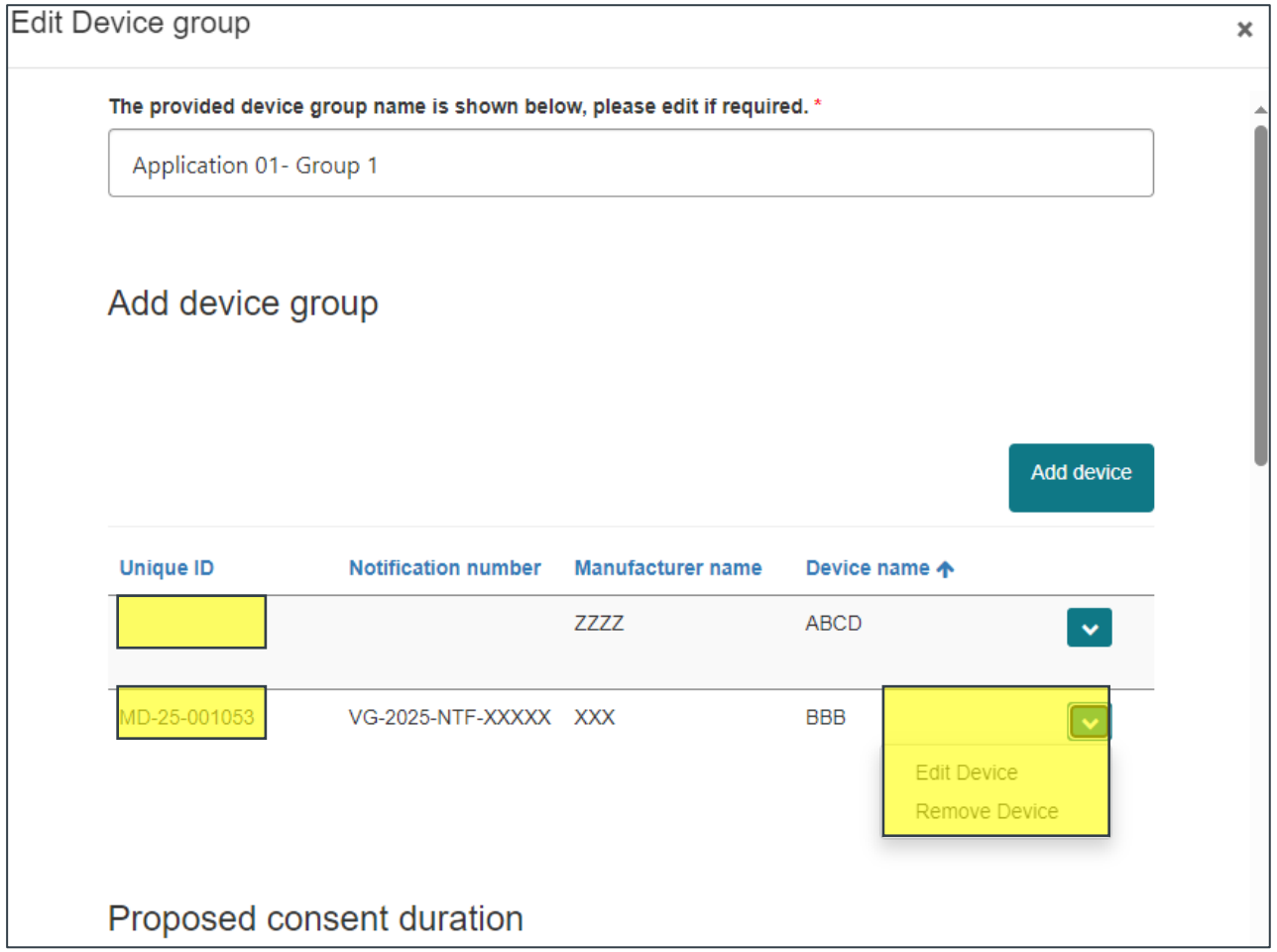


# Edit device group

## Add devices to the device group



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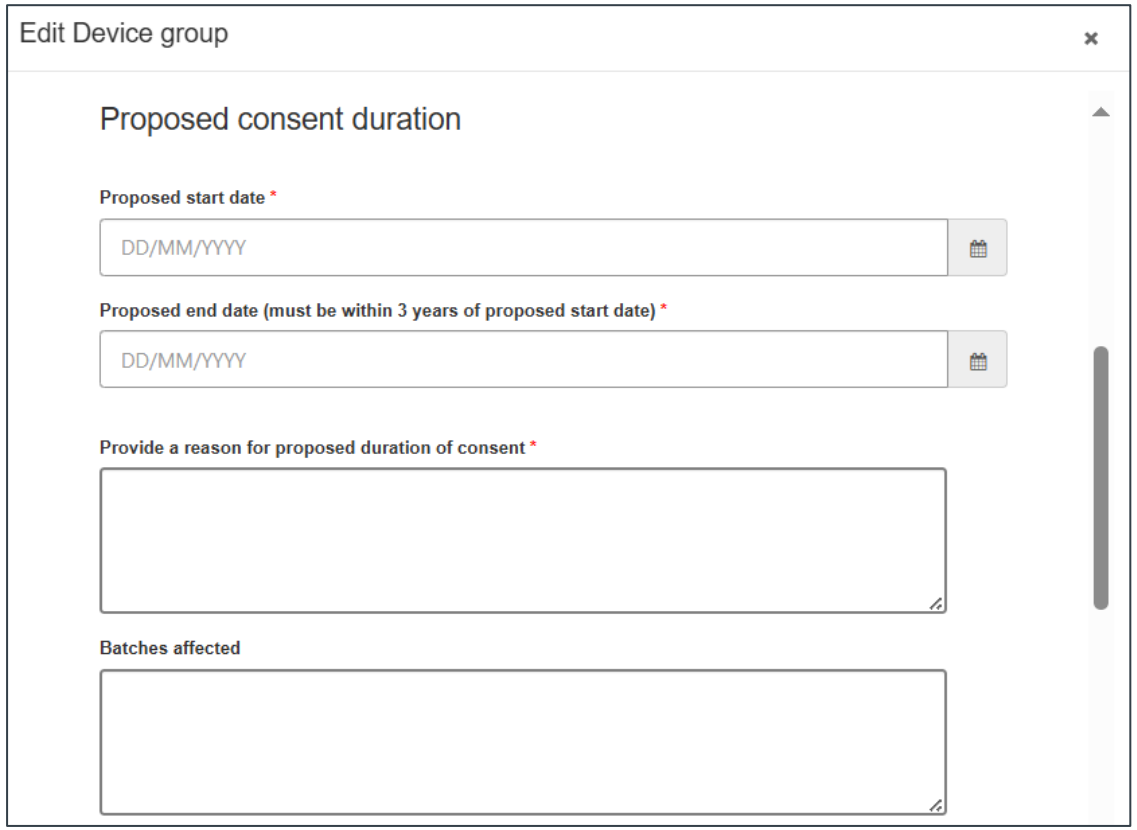
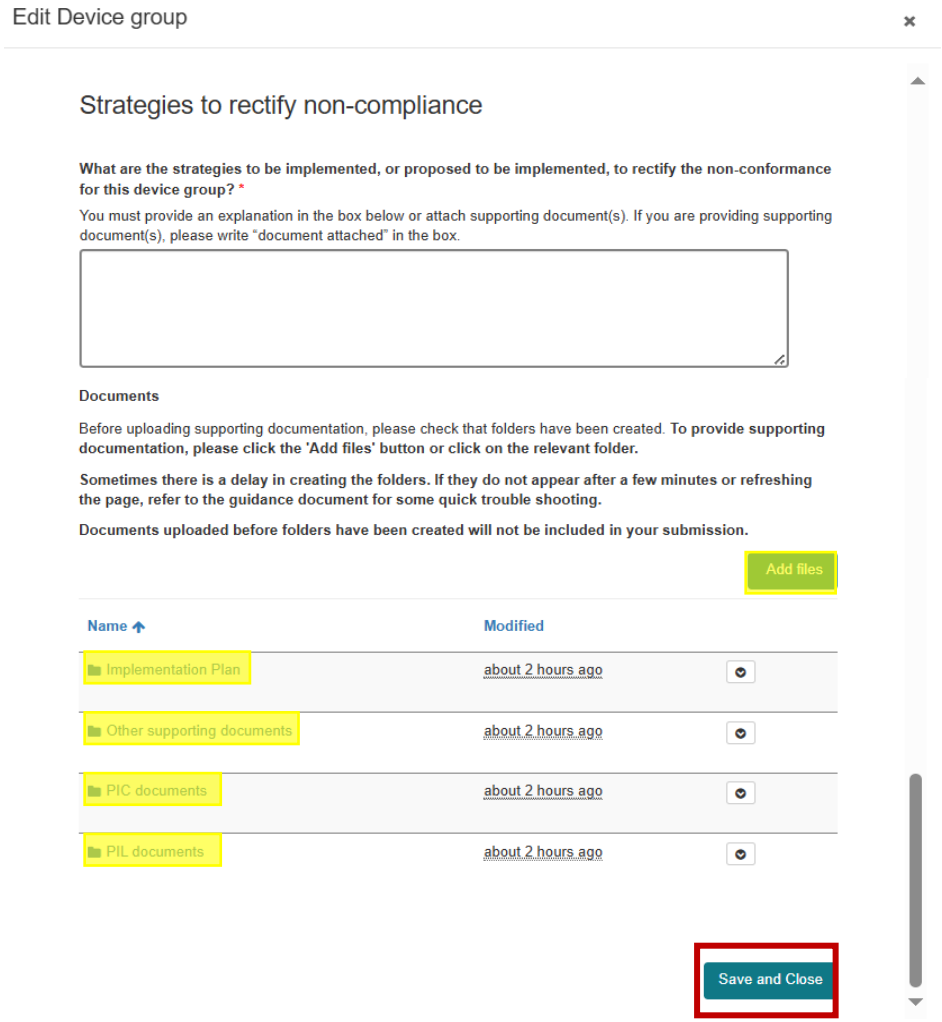
# Edit device group

Add devices to the device group

## Proposed consent duration



## Device groups

**You can group the devices with the same proposed start and end dates, and the same implementation plan for this consent application.**

Add Device group

| Group name | Device(s) linked to the Group | Proposed start date | Proposed end date | Group data completed | Created On | |
|---|---|---|---|---|---|---|
| Application 01 - Group 1 | BBB,ABC | 08/03/2025 | 23/07/2026 | Yes | 25/02/2025 11:33 AM | |
| Application 01 - Group 2 | | | | No | 25/02/2025 3:19 PM | Edit Delete |

## Declaration !

☐ I declare that the information provided in this application is true and correct. I understand that providing false or misleading information is an offence. *

Back Save Submit

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# Application 01

For guidance on how your information will be treated by the TGA see:
Treatment of the information provided to the TGA at https://www.tga.gov.au/privacy

**Are your correspondence details up to date?**
To update your correspondence details (postal, email, phone or mobile), please email the Therapeutic Business Service (TBS) at ebs@health.gov.au or contact your account administrator. Please see Questions and Answers for Administrators for more information.

Your application has been saved successfully x

Expand All | Collapse All

**Application details** +

**Non-compliant Essential Principles** +

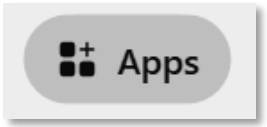
**Device groups** +

**Declaration** +

Back | Save | Submit

# How did we go?

Take a moment to complete our survey, and we'll be back with your shortly for Q&A




**Use the app in Webex**

**Use the QR code**

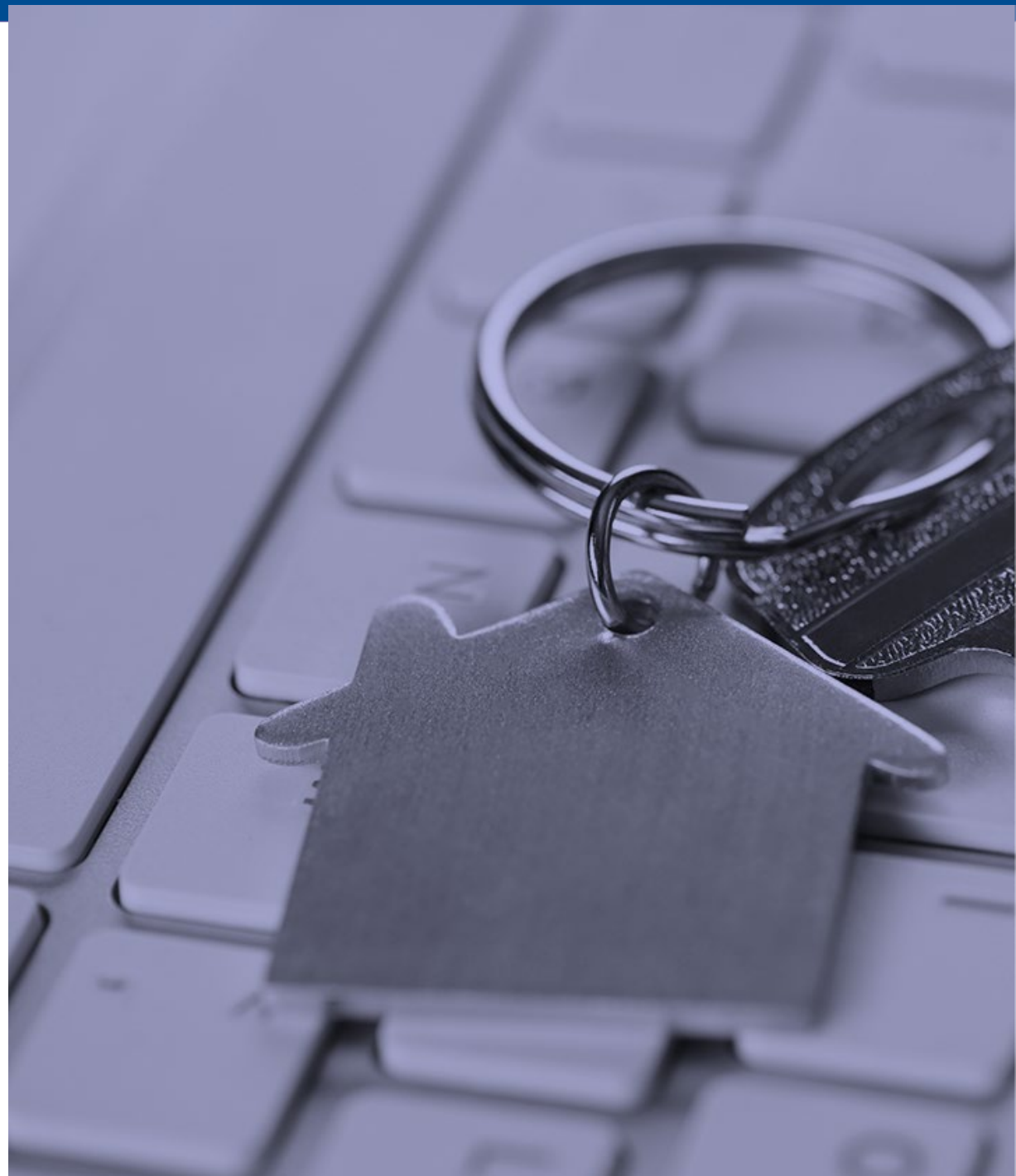
# Website and Reference links

| | |
|---|---|
| Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023 | https://www.legislation.gov.au/F2023L01686/latest/text<br><br>Requirements for unapproved therapeutic vaping devices and accessories in Australia |
| Essential Principles | https://www.tga.gov.au/how-we-regulate/manufacturing/manufacture-medical-device/quality-safety-and-performance-requirements-medical-devices-essential-principles<br><br>https://www.tga.gov.au/sites/default/files/2024-03/standards-therapeutic-vaping-devices-checklist.docx |
| Consent under section 14/14A | https://www.tga.gov.au/resources/resource/forms/application-consent-import-supply-or-export-goods-do-not-comply-standards-section-1414av |
| Consent for non-compliance with the Essential principles | https://www.tga.gov.au/resources/resource/forms/essential-principles-consent-non-compliance |

# Contact us

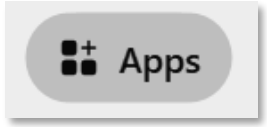
**Email**

mdconsent@health.gov.au



# Questions?

## Ask us through Slido

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**Use the QR code**

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Medical Devices Surveillance Branch

Department of Health and Aged Care, TGA

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Therapeutic Goods Administration