Webinar

Viewing and responding to notifications on the Consent for Non-compliance Dashboard

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Acknowledgement of Country

I would like to acknowledge the Traditional Owners and Custodians of the lands on which we meet today and pay my respects to Elders past, present and emerging.

I would like to extend that acknowledgement and respect to any Aboriginal and Torres Strait Islander peoples here today.

Webinar overview

- Background on consent for non-compliance
- Notification types
- Viewing notifications
- Draft and submit a response to a notification
- Requesting an extension to a notification due date

Background

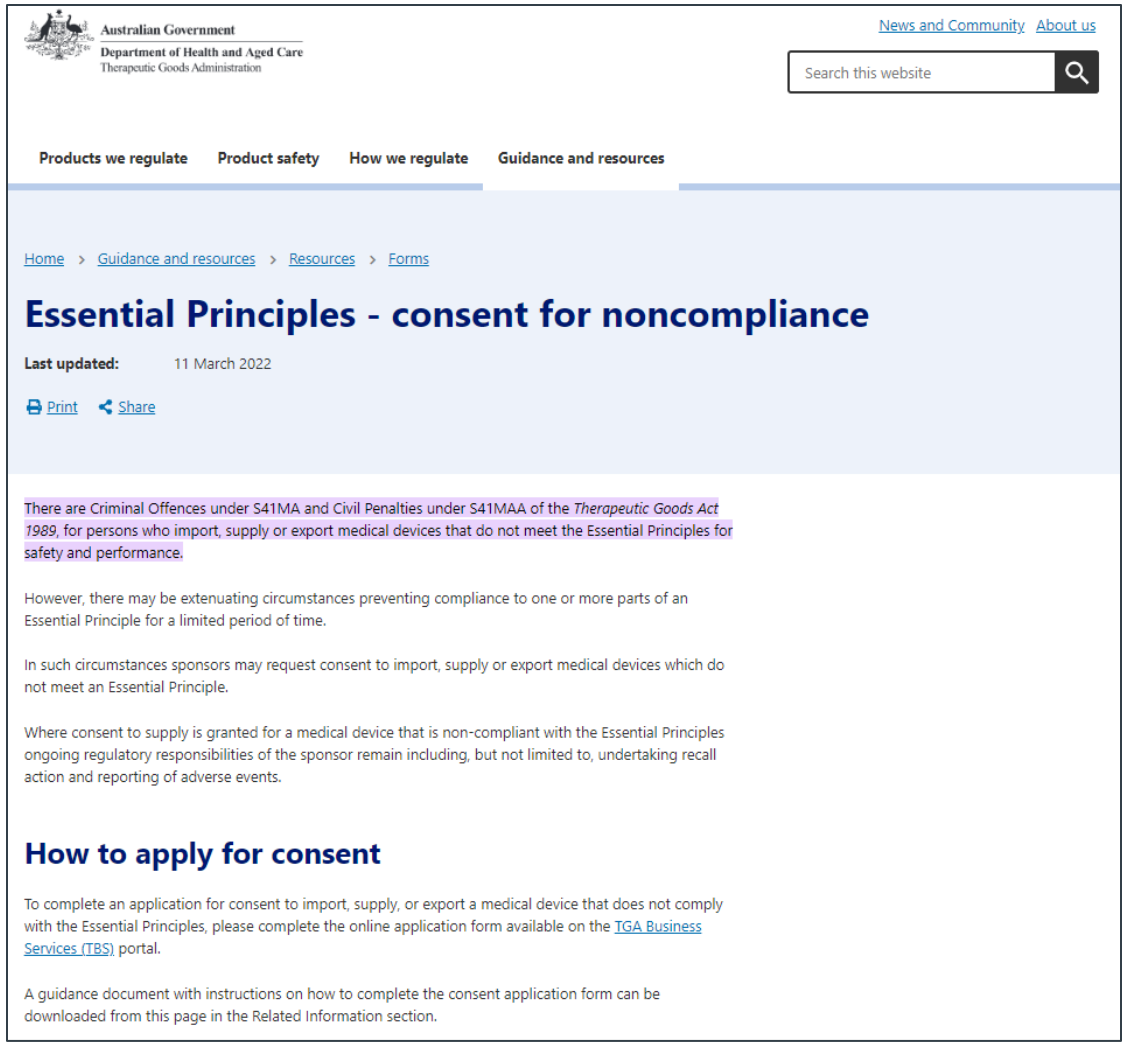
Criminal offences under section 41MA and civil penalties under section 41MAA of the *Therapeutic Goods Act 1989* (the Act), for importing, supplying, or exporting medical devices that do not meet the Essential Principles for safety and performance, unless consent has been granted by the Secretary of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

The TGA expects compliance with the Essential Principles, however there may be some extenuating circumstances preventing compliance to one or more parts of an Essential Principle for a limited period of time.

How to apply for consent

An authorised representative of the sponsor needs to:

- complete and submit the application for ‘consent to import, supply or export a medical device that does not comply with the Essential Principles’;
- attach all relevant documentation; and
- pay the applicable processing fees in full.



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Essential Principles - consent for noncompliance

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There are Criminal Offences under S41MA and Civil Penalties under S41MAA of the *Therapeutic Goods Act 1989*, for persons who import, supply or export medical devices that do not meet the Essential Principles for safety and performance.

However, there may be extenuating circumstances preventing compliance to one or more parts of an Essential Principle for a limited period of time.

In such circumstances sponsors may request consent to import, supply or export medical devices which do not meet an Essential Principle.

Where consent to supply is granted for a medical device that is non-compliant with the Essential Principles ongoing regulatory responsibilities of the sponsor remain including, but not limited to, undertaking recall action and reporting of adverse events.

How to apply for consent

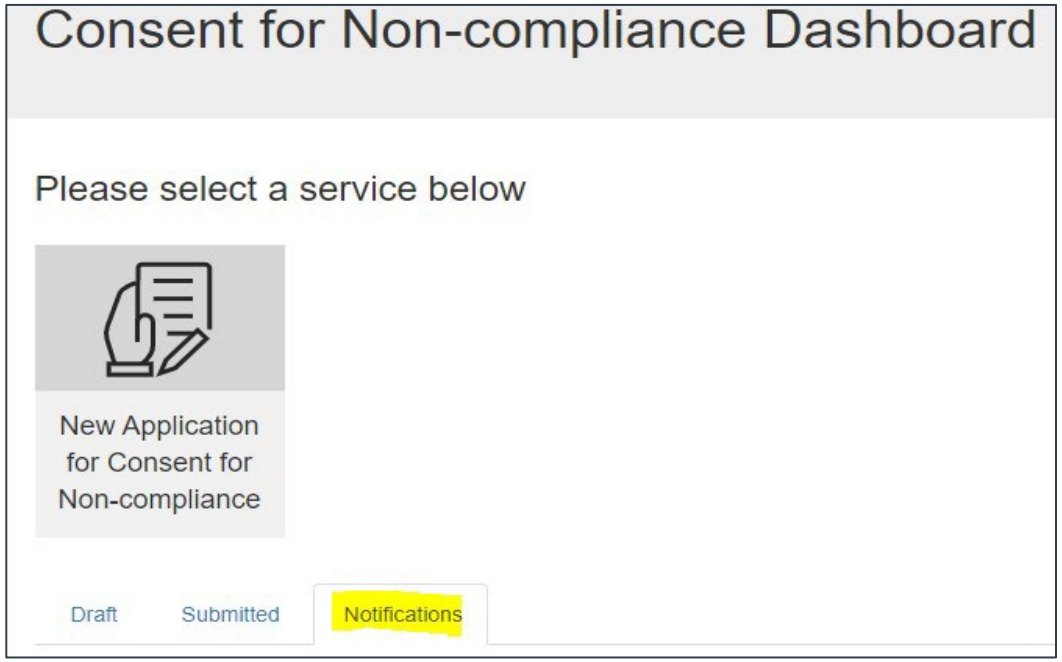
To complete an application for consent to import, supply, or export a medical device that does not comply with the Essential Principles, please complete the online application form available on the TGA Business Services (TBS) portal.

A guidance document with instructions on how to complete the consent application form can be downloaded from this page in the Related Information section.

Notifications

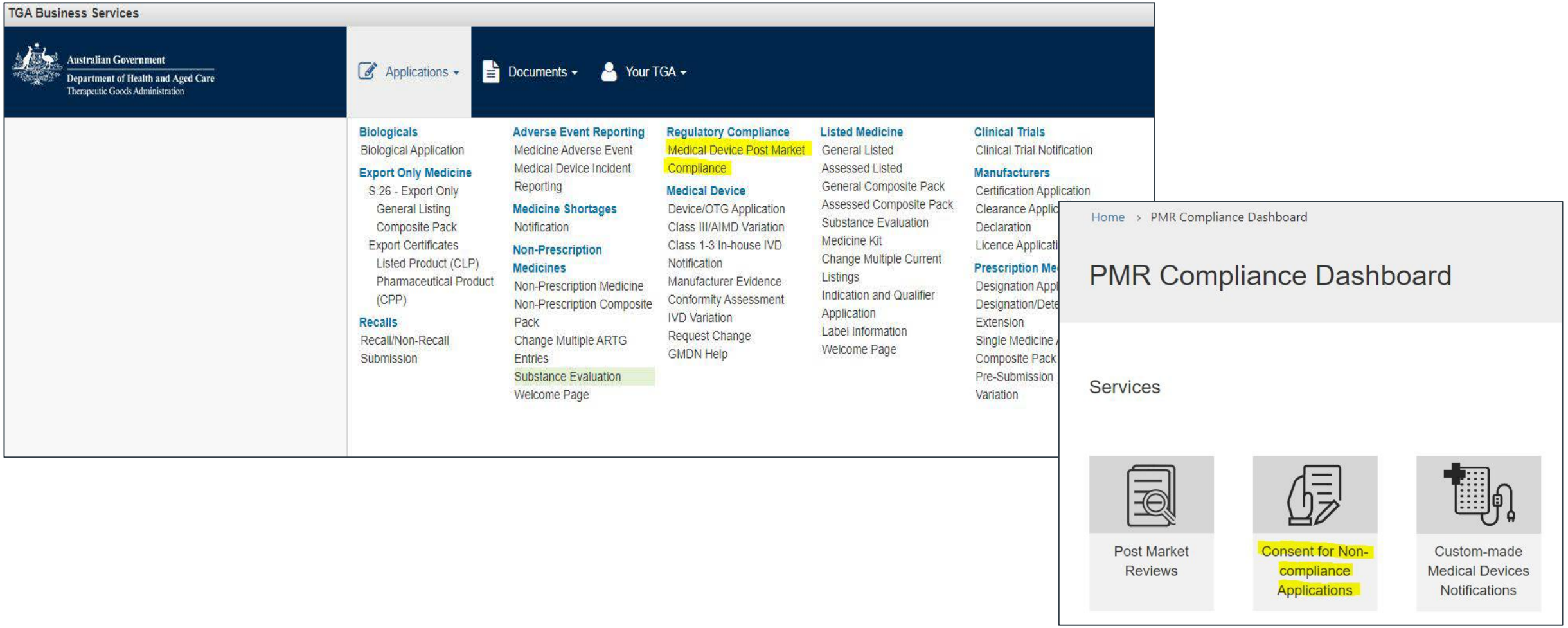
- **Informal request for information**
  - Additional information notification

- **Notification of the outcome of application:**
  - Application withdrawn
  - Application approved
  - Application not approved
  - Application revoked
  - Application expired



- **Regulatory letters** related to devices in a consent application such as:
  - s41JA request for information
  - Proposal to suspend or cancel
  - Suspensions or cancellations
  - Conditions of inclusion

TBS Application Form



Transitioning to the live demonstration

Questions

Kathryn Fuller
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Q&A

Contact us

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More information

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Department of Health and Aged Care

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