Webinar

Application for consent to import, supply, or export a medical device non-compliant with the Essential Principles

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Medical Device Surveillance Branch, TGA

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
- How to apply for consent for non-compliant medical devices
- Submitting the application form and applicable fees

Background

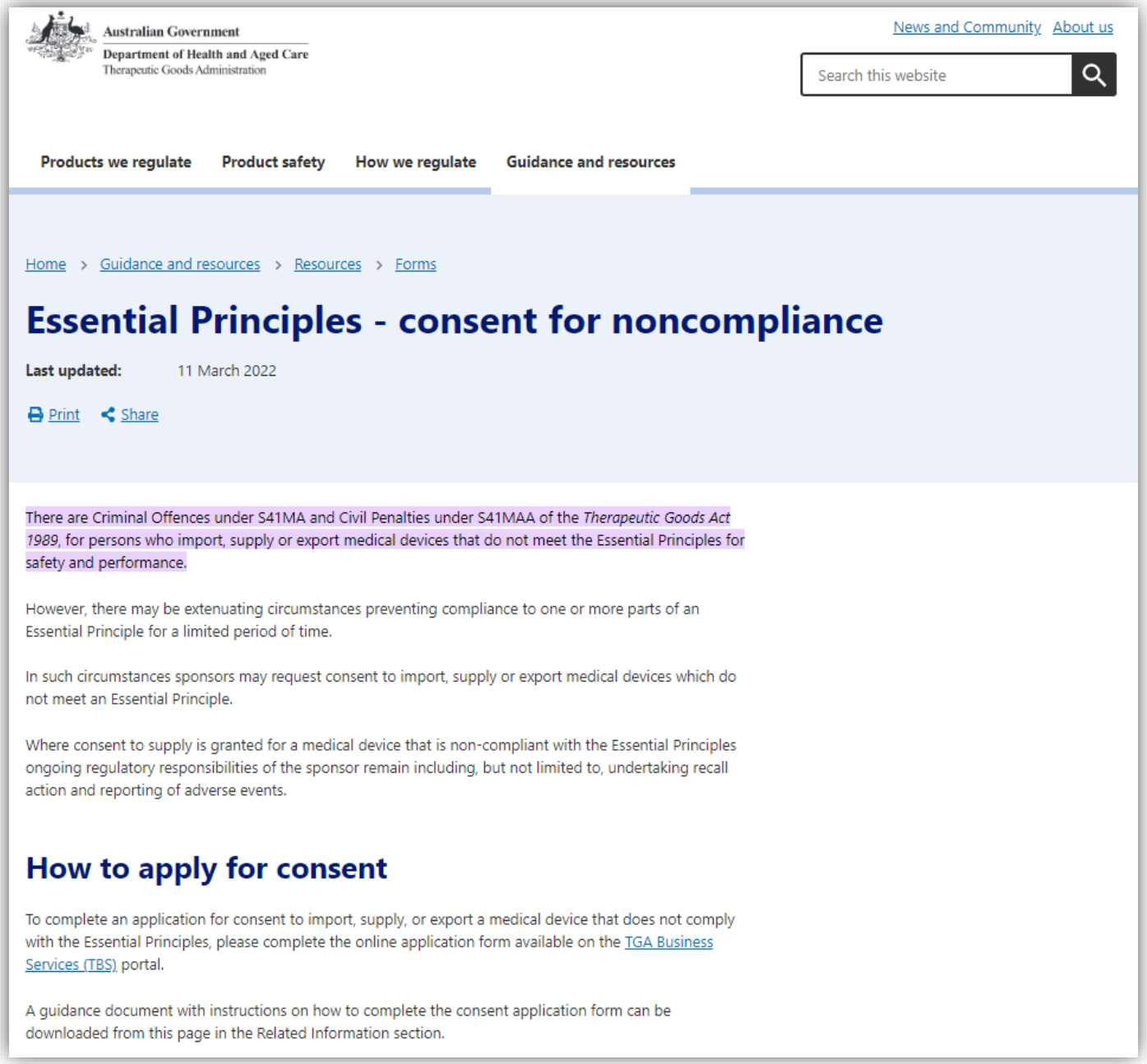
Criminal offences under section 41MA and civil penalties under section 41MAA of the *Therapeutic Goods Act 1989* (the Act), for importing, supplying, or exporting medical devices that do not meet the Essential Principles for safety and performance, unless consent has been granted by the Secretary of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



Australian Government
Department of Health and Aged Care
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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.

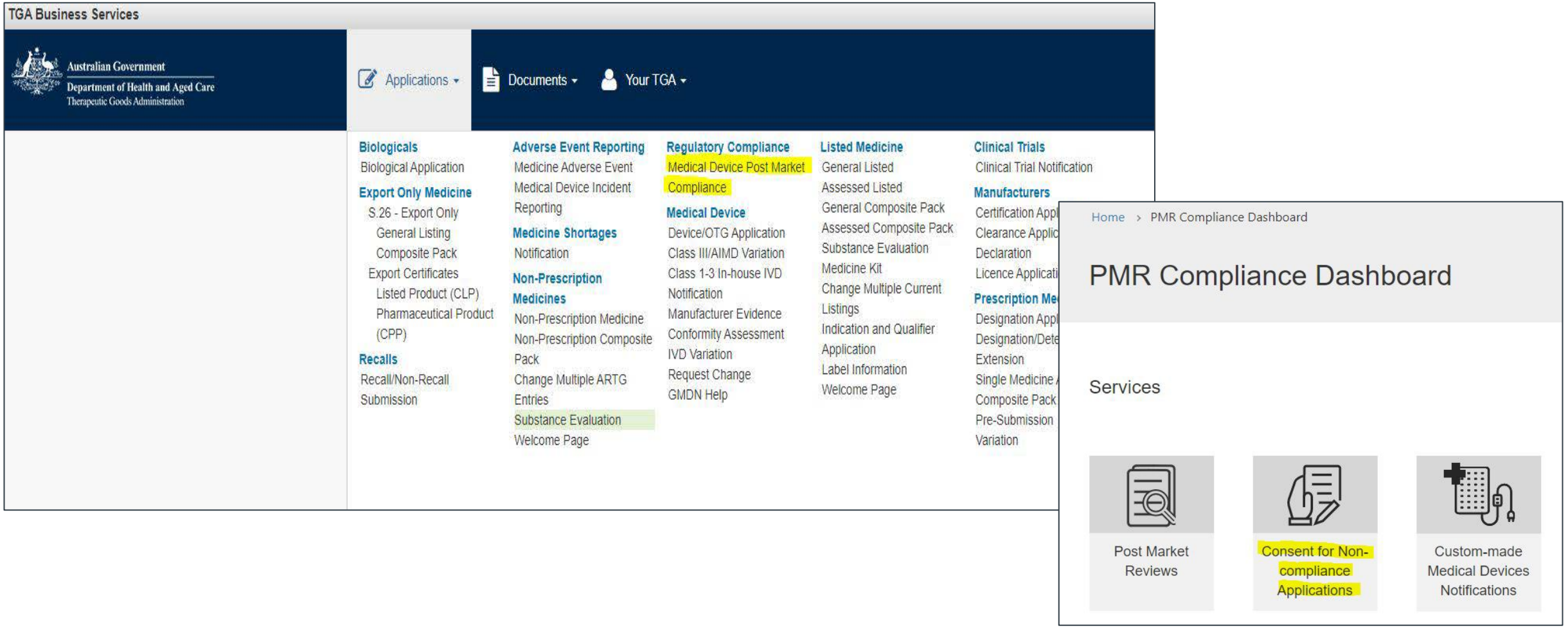
Where consent to supply is granted for a medical device that is non-compliant with the Essential Principles ongoing regulatory responsibilities of the sponsor remain including, but not limited to, undertaking recall action and reporting of adverse events.

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.

Consent for Non-compliance Application Form



Transitioning to the live demonstration

Application Fees

Currently, fees are $500 for the first ARTG entry/Application for Inclusion, and then $100 for each subsequent ARTG.

E.g., for 55 ARTG entries

$500 for the first ARTG entry plus $100 for each of the remaining 54 ARTG entries

($500 x 1) + ($100 x 54) = $5,900

Consent for non-compliance with EP13A

Fees are $30 for each ARTG entry/Application for Inclusion

E.g., for 55 ARTGs non-compliant EP 13A

$30 for each ARTG entry / App for inclusion

55 x $30 = $1,650

Consent for non-compliance with EP13 due to transitioning to EU MDR / IVDR

Fees are $30 for each ARTG entry

E.g., for 55 ARTGs non-compliant EP 13

$30 for each ARTG entry

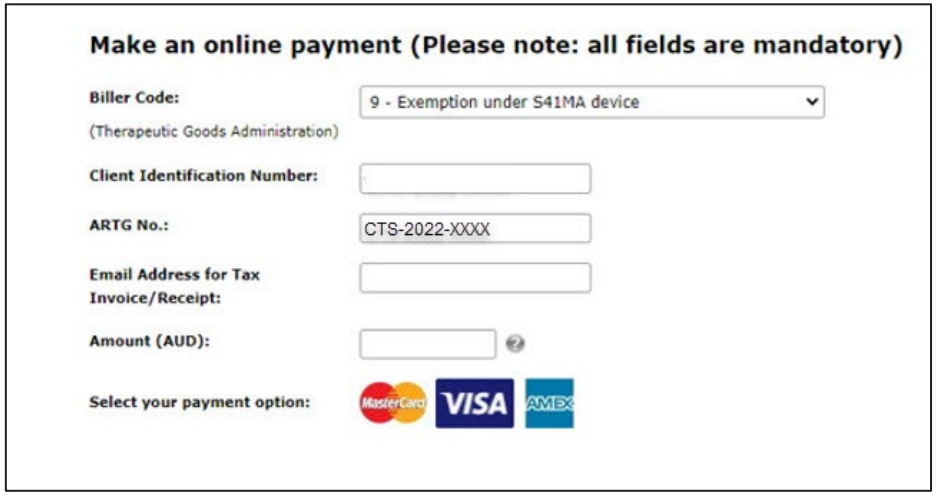
55 x $30 = $1,650

Application Fees

Two ways to pay the processing fees:

- **Immediate payment** - Calculate the total fees, and pay immediately after completing and submitting the application(s); and
- **Payment against invoice** – Complete and submit the application form, TGA to raise an invoice for payment, and send it to the submitter for paying the processing fees.

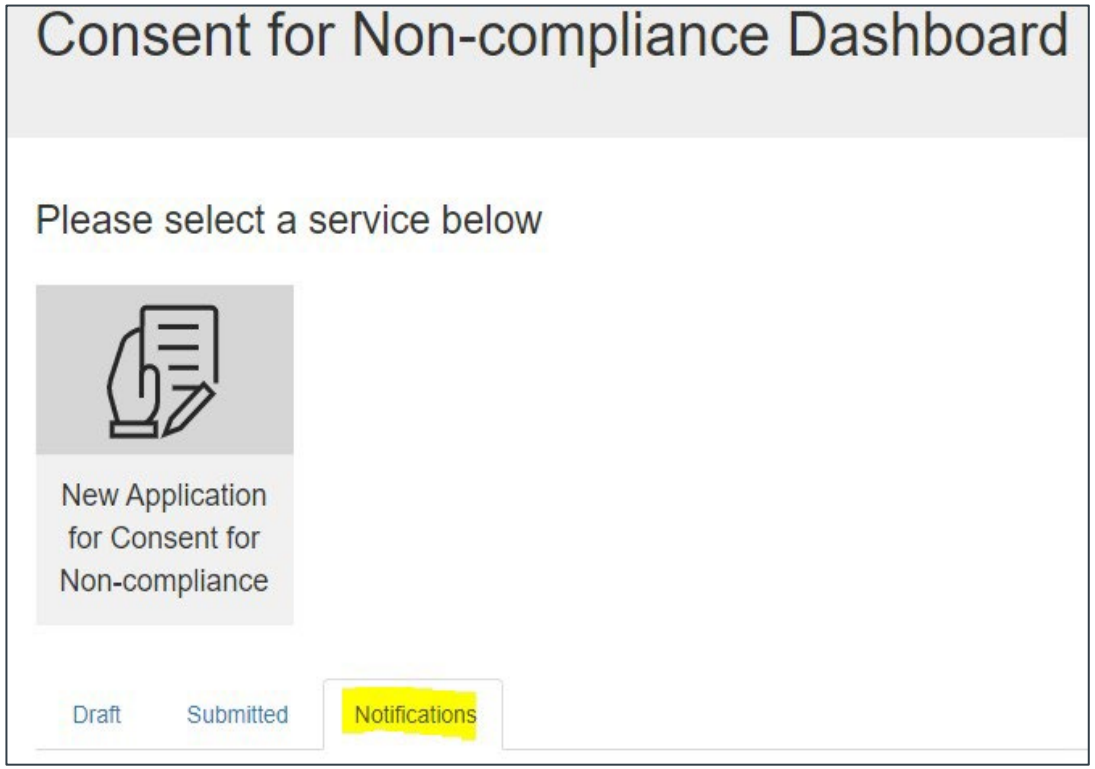
- **Immediate Payment**
- Use this link to make the payment https://www.bpoint.com.au/payments/TGA
- For ‘Biller Code’ field, select option 9: “Exemption under S41MA device”
- Enter your client ID number in the box provided.
- Enter the Consent Application ID number from your application in the ‘ARTG’ box provided.



Notification of decision

- If insufficient information/documents are provided you will be sent a notification to provide the missing information.
- A decision notification will be sent to the submitter.
- You may be required to demonstrate evidence of compliance with the mitigation strategy or implementation plan during the consent period.
- Consent may be revoked at any time if there is non-compliance with the approved mitigation strategy/implementation plan.
- You will be required to provide evidence of compliance at end of the consent period.

Notifications



Webinar:

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

Thursday 20 October 2022

11:00 am – 12:00 pm AEST

Contact us

Devices Post Market Reforms & Reviews

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More information

TGA website	www.tga.gov.au
TGA Facebook	www.facebook.com/TGAgovau/
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TGA YouTube	www.youtube.com/channel/UCem9INJbMSOeW1Ry9cNbucw
TGA topics blog	www.tga.gov.au/blogs/tga-topics
TGA Linkedin	www.linkedin.com/company/therapeutic-goods-administration/
TGA Instagram	www.instagram.com/tgagovau/?hl=en

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration