

## Webinar



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

**Kathryn Fuller**

Devices Post Market Reforms and Reviews  
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.](#)

The screenshot shows the Australian Government Department of Health and Aged Care Therapeutic Goods Administration website. The page title is "Essential Principles - consent for noncompliance". The page is dated "Last updated: 11 March 2022". The page content includes a warning about criminal offences under S41MA and S41MAA of the Therapeutic Goods Act 1989 for non-compliance with the Essential Principles for safety and performance. It also mentions that 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. The page also includes a section titled "How to apply for consent" which states that 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.

Australian Government  
Department of Health and Aged Care  
Therapeutic Goods Administration

News and Community [About us](#)

Search this website

Products we regulate Product safety How we regulate Guidance and resources

[Home](#) > [Guidance and resources](#) > [Resources](#) > [Forms](#)

## Essential Principles - consent for noncompliance

Last updated: 11 March 2022

[Print](#) [Share](#)

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

TGA Business Services

Australian Government  
Department of Health and Aged Care  
Therapeutic Goods Administration

Applications Documents Your TGA

- Biologicals**
  - Biological Application
- Export Only Medicine**
  - S.26 - Export Only
  - General Listing
  - Composite Pack
  - Export Certificates
  - Listed Product (CLP)
  - Pharmaceutical Product (CPP)
- Recalls**
  - Recall/Non-Recall Submission
- Adverse Event Reporting**
  - Medicine Adverse Event Reporting
  - Medical Device Incident Reporting
- Medicine Shortages Notification**
- Non-Prescription Medicines**
  - Non-Prescription Medicine
  - Non-Prescription Composite Pack
  - Change Multiple ARTG Entries
  - Substance Evaluation
  - Welcome Page
- Regulatory Compliance**
  - Medical Device Post Market Compliance
- Medical Device**
  - Device/OTG Application
  - Class III/AIMD Variation
  - Class 1-3 In-house IVD Notification
  - Manufacturer Evidence
  - Conformity Assessment
  - IVD Variation
  - Request Change
  - GMDN Help
- Listed Medicine**
  - General Listed
  - Assessed Listed
  - General Composite Pack
  - Assessed Composite Pack
  - Substance Evaluation
  - Medicine Kit
  - Change Multiple Current Listings
  - Indication and Qualifier Application
  - Label Information
  - Welcome Page
- Clinical Trials**
  - Clinical Trial Notification
- Manufacturers**
  - Certification Application
  - Clearance Application
  - Declaration
  - Licence Application
- Prescription Medicines**
  - Designation Application
  - Designation/Deletion
  - Extension
  - Single Medicine Application
  - Composite Pack
  - Pre-Submission
  - Variation

Home > PMR Compliance Dashboard

## PMR Compliance Dashboard

Services

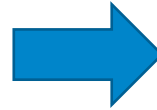
- Post Market Reviews
- Consent for Non-compliance Applications**
- Custom-made Medical Devices Notifications

# Transitioning to the live demonstration



# Application Fees

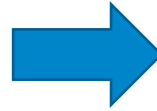
Currently, fees are \$500 for the first ARTG entry/Application for Inclusion, and then \$100 for each subsequent ARTG.



E.g., for 55 ARTG entries  
\$500 for the first ARTG entry plus \$100 for each of the remaining 54 ARTG entries  
 $(\$500 \times 1) + (\$100 \times 54) = \$5,900$

## **Consent for non-compliance with EP13A**

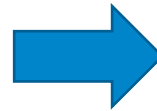
Fees are \$30 for each ARTG entry/Application for Inclusion



E.g., for 55 ARTGs non-compliant EP 13A  
\$30 for each ARTG entry / App for inclusion  
 $55 \times \$30 = \$1,650$

## **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  
 $55 \times \$30 = \$1,650$



# 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.

**Make an online payment (Please note: all fields are mandatory)**




**Biller Code:**  (Therapeutic Goods Administration)

**Client Identification Number:**

**ARTG No.:**

**Email Address for Tax Invoice/Receipt:**

**Amount (AUD):**  ⓘ

**Select your payment option:**   


# 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

Consent for Non-compliance Dashboard

Please select a service below



New Application  
for Consent for  
Non-compliance

Draft Submitted **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

[mdconsent@health.gov.au](mailto:mdconsent@health.gov.au)



# More information



TGA website [www.tga.gov.au](http://www.tga.gov.au)



TGA Facebook [www.facebook.com/TGAgovau/](http://www.facebook.com/TGAgovau/)



TGA Twitter [www.twitter.com/TGAgovau](http://www.twitter.com/TGAgovau)



TGA YouTube [www.youtube.com/channel/UCem9INJbMSOeW1Ry9cNbucw](http://www.youtube.com/channel/UCem9INJbMSOeW1Ry9cNbucw)



TGA topics blog [www.tga.gov.au/blogs/tga-topics](http://www.tga.gov.au/blogs/tga-topics)



TGA LinkedIn [www.linkedin.com/company/therapeutic-goods-administration/](http://www.linkedin.com/company/therapeutic-goods-administration/)



TGA Instagram [www.instagram.com/tgagovau/?hl=en](http://www.instagram.com/tgagovau/?hl=en)





**Australian Government**

---

**Department of Health and Aged Care**  
Therapeutic Goods Administration