

Webinar



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

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 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



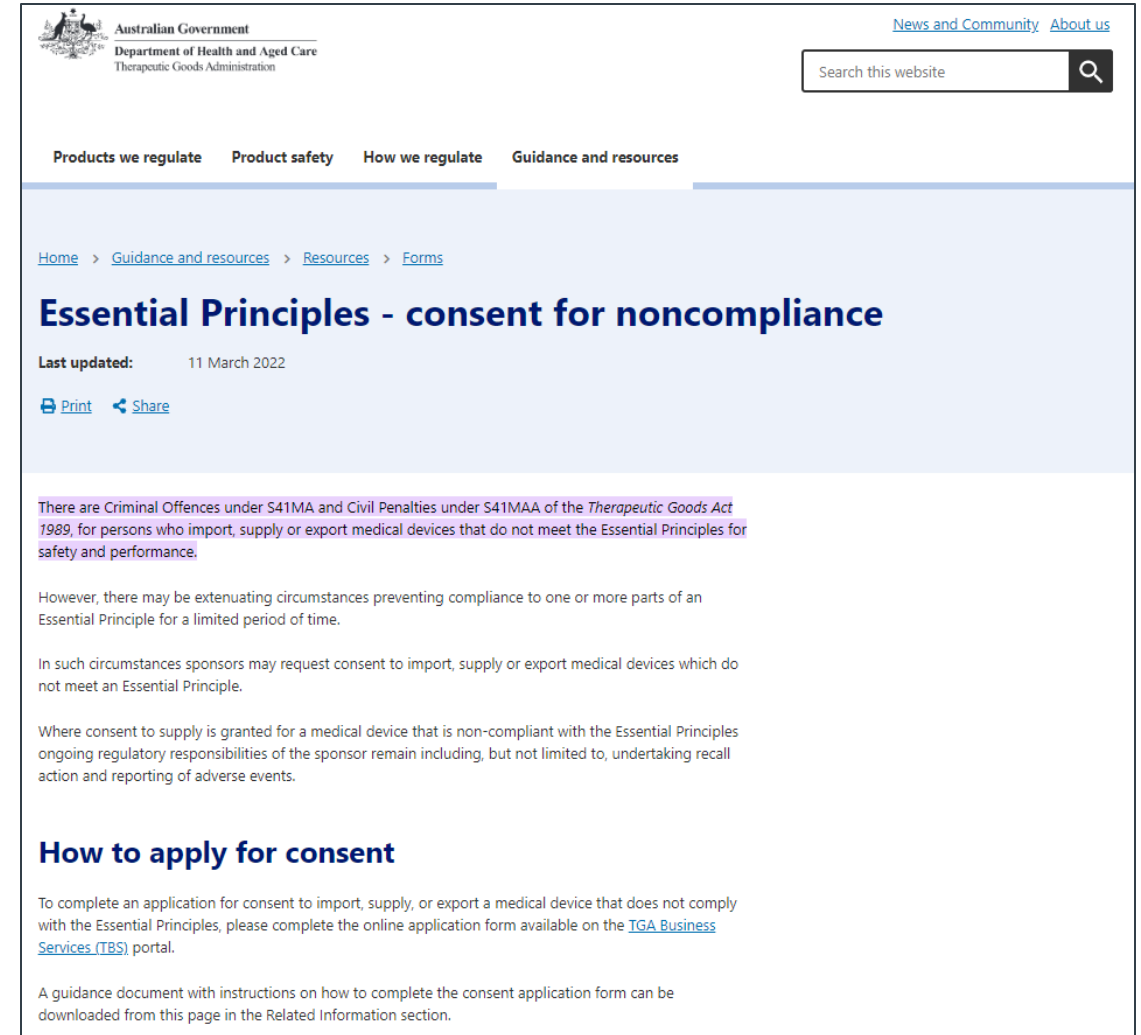
Criminal offences under section 41MA and civil penalties under section 41MAA of the *Therapeutic Goods Act 1989* (the Act), for importing, supplying, or exporting medical devices that do not meet the Essential Principles for safety and performance, unless consent has been granted by the Secretary of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

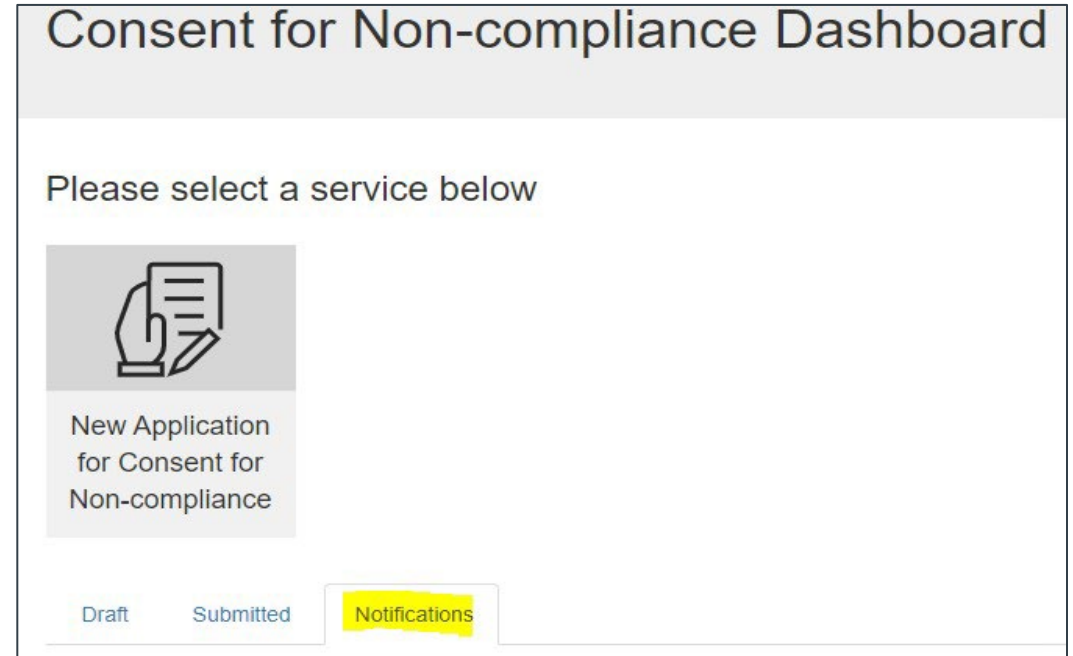
- complete and submit the application for ‘consent to import, supply or export a medical device that does not comply with the Essential Principles’;
- attach all relevant documentation; and
- pay the applicable processing fees in full.



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". It includes a search bar, navigation links, and a breadcrumb trail: Home > Guidance and resources > Resources > Forms. The page is dated "Last updated: 11 March 2022" and has "Print" and "Share" options. The main content states: "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." It further explains that extenuating circumstances may prevent compliance and that sponsors may request consent for non-compliant devices. It also notes that regulatory responsibilities remain for sponsors, including recall actions. A section titled "How to apply for consent" provides instructions to complete an online application form via the TGA Business Services (TBS) portal. A guidance document for completing the form is available 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

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 Pack
 - 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/Declaration 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



Questions



Kathryn Fuller
Devices Post Market Reforms and Reviews
Medical Device Surveillance Branch, TGA



Q&A

Contact us

Devices Post Market
Reforms & Reviews

mdconsent@health.gov.au

More information



TGA website www.tga.gov.au



TGA Facebook www.facebook.com/TGAgovau/



TGA Twitter www.twitter.com/TGAgovau



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