



**Australian Government**

**Department of Health**

Therapeutic Goods Administration

# Guidance for completing an application for consent to import, supply or export a medical device that does not comply with the Essential Principles

TGA Consultation Hub

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**TGA** Health Safety  
Regulation

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# Introduction

This is a guidance document to provide advice on how to successfully submit an application for consent to import, supply, or export a medical device that does not comply with the Essential Principles. The TGA is currently undertaking a project to modernise the consent application process, moving from a paper form to an online, electronic digital form. The new form will streamline the application process and allow for greater functionality, including the ability for sponsors to view their current and previous applications for consent. The transition to the new form will occur in two phases, with the first phase complete and now ready to use. This interim electronic application form is currently located on the TGA's [Consultation Hub](#) and is the form that this guidance document refers to.

There are 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 (EPs) for safety and performance, unless consent has been granted by the Secretary of the Department of Health.

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

Please note that if your non-compliant device(s) is currently part of an application to vary the device or manufacturer's evidence, or have an Application for Inclusion in the ARTG, you will still need to apply for consent to be able to import, supply or export the device(s) if they are non-compliant with the EPs.

In seeking 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](#).

## Multiple devices included in one application

An application for consent can include entries included in the Australian Register of Therapeutic Goods (ARTG) or medical devices that are currently part of an Application for Inclusion in the ARTG that do not comply with the EPs.

**NOTE:** All ARTG entries/ Applications for Inclusion within a single consent application must be non-compliant with the same Essential Principles. Devices that are non-compliant with different parts of the Essential Principles cannot be submitted in the same application.

If you are seeking consent for more than 20 ARTG entries or Applications for Inclusion you will be required to complete multiple forms to complete your application, as each form can only accommodate up to 20 ARTG entries or Applications for Inclusions. For example, if your application for consent is for 80 ARTG entries, you will be required to complete four forms, which will be considered as one application for the purpose of fees. Multiple forms which are the part of the same application will be linked during processing using the response ID generated for each form. The response ID is sent in the receipt email upon completion and submission of the form.



### **Application for consent for non-compliant patient information materials.**

If you are a sponsor of implantable devices seeking consent to import, supply, or export medical devices with non-compliant patient information materials, there is a specific application form for this purpose which will accommodate more than 20 ARTG entries/Applications for Inclusion. Please refer to the [TGA Webpage](#) for more information.

## **Application / Processing Fees**

The processing fees apply to **each** ARTG entry/Application for Inclusion included in the application. The fees are \$500 for the first ARTG entry/Application for Inclusion, and then \$100 for each subsequent ARTG entry/Application for Inclusion.

### **How do I calculate my fees?**

Fees are calculated using the total number of ARTG entries/Applications for Inclusion in the consent application, regardless of the number of forms submitted as part of the application. For example, if your application for consent pertains to 45 ARTG entries, you will need to complete three forms as part of the application (20 ARTG entries on the first and second forms, and 5 ARTG entries on the third form). The fees are calculated as \$500 for the first ARTG entry plus \$100 for each of the remaining 44 ARTG entries [that is:  $(\$500 \times 1) + (\$100 \times 44) = \$4,900$ ].

If you are submitting multiple forms due to having more than 20 ARTG entries/Applications for Inclusion, please submit all forms within 24 hours, to avoid the initial \$500 fee for the first ARTG entry/Application for Inclusion being applied to subsequent applications for consent.

### **Reduced consent application fees for devices with non-compliant patient information materials**

On 29 October 2021, changes to the Therapeutic Goods (Medical Devices) Regulations 2002 came into effect to introduce a fee concession for sponsors of implantable devices seeking consent to import, supply, or export their devices where they do not have compliant patient information materials. The application fee has been reduced to a flat fee of \$30 for each ARTG entry and Application for Inclusion where the application is made solely in relation to non-compliance with EP 13A.2 and/or 13A.3.

The TGA will apply this fee concession retrospectively, refunding the difference in fees to eligible sponsors with consent in place on or after 1 January 2021. Sponsors with a consent in place who believe they are eligible for a fee refund should contact the TGA at [mdconsent@health.gov.au](mailto:mdconsent@health.gov.au) identifying the relevant consent application. If the refund request is validated, it will be forwarded to the Product Billing and Industry Assistance team who will contact you regarding the refund.

## **How to pay**

There are two ways to pay the processing fees for the consent application.

1. **IMMEDIATE PAYMENT** – You can pay the processing fees for your consent application immediately after completing and submitting the application. To do this:
  - a. Calculate the total fees for your application based on the number of ARTG entries or Applications for Inclusion, as per the example above.
  - b. Go to the [TGA payment page](https://www.bpoint.com.au/payments/TGA) (<https://www.bpoint.com.au/payments/TGA>)

- c. In the Biller Code field choose option 9 – “Exemption under S41MA device”
- d. Enter your client ID number in the box provided.
- e. Enter **one** ARTG or Application for Inclusion number from your application in the box provided.
- f. Enter the total amount of fees to be paid in AUD.
- g. Select the payment method.
- h. Follow the instructions to complete the credit card payment.

NOTE: if you choose this payment option please ensure that you only pay the fees after the submission of your final form in the application. If you pay the fees prior to the submission of the final form in your application, any subsequent form submission may be charged as a new application.

Your application and payment will be linked during processing using the TBS Client ID number and the ARTG entry or Application for Inclusion provided in the payment details.

2. **PAYMENT AGAINST INVOICE** - If you require the TGA to raise an invoice for payment, simply complete and submit your application for consent, and the TGA will raise and send the submitter an invoice for the processing fees.

NOTE: Applications for consent will not be processed until all applicable fees have been paid in full.

# Application Form

## Overview Page

The overview page provides you with an overview of the consent to import, supply, or export medical devices that do not comply the EPs.

The page also points out that whilst this application form is being hosted on a consultation platform the information that is provided in the form will **not** be published. The information will be classified as 'For official use only'. For further information you can read [Treatment of information provided to the TGA](#).

**Step 1:** At the bottom of the '[Overview](#)' page, click on the link '[Application for consent to import, supply or export a medical device that does not comply with the Essential Principles](#)' to start the application. This will take you to the '[Contents](#)' page.

## Application Form

[Application for consent to import, supply or export a medical device that does not comply with the Essential Principles](#) >

## Contents Page

The Contents page contains links to all the different sections or 'pages' of the application form that you are required to complete as part of the application. When you complete a page, you will be returned the Contents page where you can select the next page to complete.

Click on the link '[Applicant Details](#)' to start the application.

### Application for consent to import, supply or export a medical device that does not comply with the Essential Principles

Closes 2 Dec 2021

This service needs [cookies enabled](#).

## Contents

Page	Response
<a href="#">Applicant Details</a> (Required)	<div><div></div><div>0 of 7 questions answered</div></div>
<a href="#">Information on non-compliance to the Essential Principles</a> (Required)	<div><div></div><div>0 of 4 questions answered</div></div>
<a href="#">ARTG/Application for Inclusion - 1</a> (Required)	<div><div></div><div>0 of 6 questions answered</div></div>
<a href="#">ARTG/Application for Inclusion - 2</a>	<div><div></div><div>0 of 6 questions answered</div></div>



## Applicant Details

This section of the form contains mandatory fields.

**1 -Submitter's name:** Fill in your first name and surname in the respective boxes. Only authorised representatives of the Sponsor should complete the application for consent form.

### Applicant Details

**1. Submitter's name:**

First Name (Required)

Surname (Required)

**2 -TBS Client ID Number:** provide your TGA electronic business systems (tBS) Client ID Number in the box provided.

**2. TBS Client ID number:**

TBS Client ID Number (Required)

**3 -Submitter's email address:** provide and confirm your email address in the boxes provided. This email address will be used to send a receipt and PDF copy of the application once it is submitted.

**3. Submitter's email address:**

Email (Required)

Confirm your email address (Required)

**4-Role of submitter:** select the option that best describes your role in relation to the medical device(s) for which the application for consent is being submitted. You can only select one option.

**4. Which of the following best describes your role in relation to the medical device(s) for which this application for consent to supply is being submitted?**

Please select most applicable option.

(Required)

- ☐ Sponsor
- ☐ Sponsor and Manufacturer
- ☐ Agent

**5-Sponsor details:** provide the sponsor details in the boxes provided including name, postal address, email address and phone number. When filling out the phone number, please ensure there are no spaces between numbers and do not include brackets.

**5. Sponsor details:**

Sponsor's Name (Required)

Sponsor's Postal Address (Required)

Sponsor's Email Address (Required)

Sponsor's Phone Number (Required)

**6-Consent (Import, export, Supply):** select the options for which you are seeking consent for in this application. You can select more than one option.

## 6. You are seeking consent for:

Please select all applicable options.

(Required)

- ☐ Importing the medical device(s)
- ☐ Exporting the medical device(s)
- ☐ Supplying the medical device(s)

**7-ARTG entries / Applications for Inclusion information:** provide the total number of ARTG entries or applications for inclusion in the ARTG for which you are requesting consent. This must be a whole number.

## 7. Information on ARTG entries or Applications for Inclusion for which you are requesting consent.

Total number of ARTG entries or Applications for Inclusion for which you are requesting consent. (Required)

If you are seeking consent for more than 20 ARTG entries or applications for inclusion you will be required to complete more than one form as each form can accommodate up to 20 ARTG entries or applications for inclusion in the ARTG. However, please include the total number of ARTG entries and applications for inclusion in the ARTG above, and not just how many will be in this form. For example, if your application for consent is for 80 ARTG entries, you will be required to complete four (4) forms which will be considered one application for the purpose of fees. Multiple forms will be linked during processing using the response ID generated for each form. The response ID is sent in the receipt email upon completion and submission of the form.

If this is the first form you have filled out as part of the application, please answer 'No' the question below. If this is the second or subsequent form you have filled out as part of the one application, please answer 'Yes' and then provide response IDs for the other forms you have submitted so far as part of your application. If this is the first form you have completed, or your application is for 20 or less ARTG entries or Applications for Inclusion, select 'No'.

Have you submitted more than one form as part of this application for consent? (Required)

-- Please Select -- ▾

If 'Yes' provide the response ID number for all the forms that you have submitted as part of this application so far. The Response ID number is listed in the Citizen Space acknowledgment email sent to your nominated address upon submission.

**Next page:** once you have completed this information you can either press 'save and come back later' to complete the rest of the application at another time, or you can press 'continue' to keep filling out the application.

Save and come back later...

Continue >

If you select the '[Save and come back later](#)' button you will be directed to a page that requires you to enter an email address. A link to the form with progress so far will be sent to that email address; to resume completing the form, click on the link.

If you select 'Continue', you will be returned the '[Contents](#)' page where you can select the link '[Information on non-compliance to the Essential Principles](#)' to continue the application.

## Application for consent to import, supply or export a medical device that does not comply with the Essential Principles

Closes 2 Dec 2021

This service needs  
[cookies enabled](#).

### Contents

Page	Response
<a href="#">Applicant Details</a> (Required)	0 of 7 questions answered
<a href="#">Information on non-compliance to the Essential Principles</a> (Required)	0 of 4 questions answered

## Information on non-compliance to the Essential Principles

The fields on this page are mandatory.

This page is where you need to select the EPs that the devices are non-compliant with, provide descriptions of how the devices do not comply to each of the selected EPs and sub-EPs, explain why they are non-compliant, and detail what risks are associated with the non-conformance.

### Application for consent to import, supply or export a medical device that does not comply with the Essential Principles

Closes 2 Dec 2021

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### Information on non-compliance to the Essential Principles

The Essential Principles for medical device safety and performance can be found here [Therapeutic Goods \(Medical Devices\) Regulations 2002](#), Schedule 1 - Essential Principles.

**1-Select the relevant Essential Principles or parts of an Essential Principle for which consent is requested:** select the EPs and sub-EPs that the device(s) are non-compliant with. Your application should be for devices that are non-compliant with the same parts of the EPs. However, you can choose more than one EP or sub-EP if the devices will be non-compliant with more than one EP. The EPs are listed in numerical order.

#### 1. Select the relevant Essential Principles or parts of an Essential Principle for which consent is requested:

This application can only be submitted for device(s) that are non-compliant with the same Essential Principles / sub-Essential Principles. Please submit a new application for device(s) that are non-compliant with different part(s) of the Essential Principles.

(Required)

- ☐ EP1: Use of medical devices not to compromise health and safety
- ☐ EP2: Design and construction of medical devices to conform with safety principles
- ☐ EP3: Medical devices to be suitable for intended purpose
- ☐ EP4: Long-term safety
- ☐ EP5: Medical devices not to be adversely affected by transport or storage
- ☐ EP6: Benefits of medical devices to outweigh any undesirable effects
- ☐ EP7.1: Choice of materials
- ☐ EP7.2: Minimisation of risks associated with contaminants and residues

**2-Describe how the device(s) do not conform to this/these selected Essential**

**Principle(s)?**: in the box provided, describe the particular aspect of how the device does not conform to each of the selected EPs. For example, if the Patient Implant Card does not contain the model of the device, this should be specified, rather than just stating that the Patient Implant Card is non-compliant with EP 13A.2.

**2. Describe how the device(s) do not conform to this/these selected Essential Principle(s)?**

Please describe against each Essential Principle(s) selected (Required)

**3-Are changes in the regulations a contributing factor for the non-compliance to the**

**Essential Principles?**: Due to implementation timeframes of changes in legislation being different across jurisdictions some manufacturers may be non-compliant with the EPs. If this is the case, select the most appropriate regulatory change that has impacted compliance with the EPs. For example, if your devices have non-compliant Patient Information Cards (PICs) or Patient Information Leaflets (PILs) due to manufacturers implementing changes in line with European regulations, please select 'Yes, change to EU MD Regulations'.

**3. Are changes in the regulation a contributing factor for the non-compliance to the Essential Principles?**

(Required)

- ☐ No
- ☐ Yes, change to Australian Regulations (please specify)
- ☐ Yes, change to EU MD Regulations (please specify)
- ☐ Yes, change to the EU IVD Regulations (please specify)
- ☐ Yes, other (please specify)

Please specify:

**4-Risks associated with the non-conformance, if the non-conforming device(s) were to be imported, exported, or supplied?** Describe the risks that have been identified due to the non-compliance. On the next page, you will be able to provide the risk mitigation strategy that you are proposing.

#### 4. Risks associated with the non-conformance, if the non-conforming device(s) were to be imported, exported or supplied?

(Required)

**Next page:** once you have completed this information you can either press 'save and come back later' to complete the rest of the application at another time, or you can press 'continue' to keep filling out the application.

Save and come back later...

Continue >

If you select the 'Save and come back later' button you will be directed to a page that will require you to enter an email address. A link to the form with progress so far will be sent to that email address; to resume completing the form, click on the link.

If you select 'Continue', you will be returned the 'Contents' page where you can select the link 'ARTG/Application for Inclusion - 1' to continue the application.

### Application for consent to import, supply or export a medical device that does not comply with the Essential Principles

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<a href="#">ARTG/Application for Inclusion - 1</a> (Required)	0 of 6 questions answered
<a href="#">ARTG/Application for Inclusion - 2</a>	0 of 6 questions answered

## ARTG / Application for Inclusion – 1

This is where you provide the details for the first ARTG entry or application for inclusion in the ARTG that you want included in this consent application. The information that you complete in this section can be used for subsequent ARTG entries or applications for inclusion in the ARTG without the need to re-enter it.

Only some of these fields are mandatory.

### Application for consent to import, supply or export a medical device that does not comply with the Essential Principles

Closes 2 Dec 2021

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#### ARTG/Application for Inclusion - 1

Complete the information below for the first ARTG entry, or medical device with current valid application for inclusion, which is non-compliant with the Essential Principle(s).

**1-ARTG entry or Application for Inclusion number:** this is a mandatory field.

Select whether this first device has an existing ARTG entry or if it is part of an application for inclusion in the ARTG, and then provide the relevant identifying number in the appropriate box. That is, if this is an existing ARTG entry, provide the ARTG number in 'ARTG entry number -1', or if it is in an application for inclusion, provide the full application number (including any letters e.g. DA-XXX) in 'Application for Inclusion number -1'.

#### 1. ARTG entry or Application for Inclusion number:

(Required)

- ☐ ARTG Entry
- ☐ Application for Inclusion number

This application form will be considered for processing only if you provide a valid ARTG number or Application for Inclusion number.

ARTG entry number - 1

Application for Inclusion number - 1



**2-Proposed duration of the consent to supply for this ARTG/Application for Inclusion:** this is a mandatory field.

Select a proposed start and end date for consent and include a reason in the text box provided for why those dates have been selected.

For example, if you are seeking consent for device(s) with non-compliant Patient Information Cards (PICs) or Patient Information Leaflets (PILs) due to manufacturers implementing changes in line with European regulations, you may choose to enter your start date as 01-12-2021 and the end date as 25-05-2024.

**2. Proposed duration of the consent to supply for this ARTG/Application for Inclusion -1**

Start Date of the proposed duration of consent to supply: (Required)

Day (dd)      Month (mm)      Year (yyyy)

-  -

End Date of the proposed duration of consent to supply: (Required)

Day (dd)      Month (mm)      Year (yyyy)

-  -

Give reason for proposed duration of the consent to supply. (Required)

**3-Batches affected:** this is not a mandatory field. However, if your application is for a very limited time and/or only affects specific batches, it is expected that details on the number of affected batches and details on which batches are affected and why or how they are affected.

**3. Batches affected:**

Number of batches affected

Provide any additional information, if necessary.

**4-Information of estimated stock levels:** there are several components to this question, and these are not mandatory fields. However, if your application is for a very limited time and/or only affects only specific batches, it is expected that details on the current stock level and foreseeable stock to be included. A drop-down list is included for when the device is provided in boxes or cartons.

**4. Information on estimated stock levels:**

Current stock level

Future stock level (affected supply for proposed period of non-compliance)

Unit of measurement

-- Please Select -- ▾

If unit/box/carton has been selected, specify the number of devices included in each unit/box/carton.

If this application relates to specific batches, please provide an estimate (if known) of the expected depletion date of all affected stock.

**Expected depletion date of stock, including current and future stock**

Day (dd)      Month (mm)      Year (yyyy)

dd

-

mm

-

yyyy

If you think there will be any supply shortages on this device if consent is not granted, please select 'Yes' and in the text box provide an explanation.

Will there be any supply shortage of devices on this ARTG/Application for Inclusion, if the consent to supply is not granted?

-- Please Select -- ▾

Please explain:

**5-Any additional impact(s) to Australian consumers if the consent is not approved?:**

This is not a mandatory field.

This field provides the opportunity to convey any additional impacts that you are aware of, such as there being no other devices of this kind included in the ARTG, or that this device is for a particular patient group.

**5. Any additional impact(s) to Australian consumers if the consent is not approved?**

(Required)

- ☐ Yes, there is additional impact (please explain)
- ☐ No, there is no additional impact
- ☐ Unsure about additional impact (please explain)

If you have selected 'Yes' or 'Unsure', please explain

**6-Strategy to mitigate non-conformance for ARTG/Application for Inclusion - 1?:** this is a mandatory field. The information on how the non-conformance is being mitigated can be provided here as free text or by uploading documents. If you are only uploading a document, then in the free text box refer to the uploaded documents.

**6. Strategy to mitigate non-conformance for ARTG/Application for Inclusion - 1?**

Response can be submitted by typing in the text box or by uploading a PDF/Word/Excel document. Refer to the guidance document for further information on how to respond to this question and required information for PIC/PIL implementation plan.

Strategies to be implemented, or proposed to be implemented (Required)

Documents uploaded may include an implementation plan, which should include information such as the proposed risk mitigation strategy, how it will be implemented, and when the mitigation will commence.

If the non-compliance relates to patient implant cards or patient information leaflets, there are fields to upload the interim non-compliant patient information to support the information provided in the implementation plan. Please ensure the documents uploaded are either in Adobe PDF, Microsoft Word or Excel formats. Further information on the requirements for patient implant cards and patient information leaflets can be found in the guidance <https://www.tga.gov.au/book-page/patient-implant-cards>.

#### Upload implementation plan:

##### Implementation Plan

Please make sure your file is under 25MB

No file chosen

If non-compliant with Essential Principle 13A.2, you can upload a copy of the interim PIC that will be provided, if applicable.

##### Interim PIC

Please make sure your file is under 25MB

No file chosen

If non-compliant with EP13A.3, you can upload a copy of the interim PIL that will be provided, if applicable.

##### Interim PIL

Please make sure your file is under 25MB

No file chosen

## Implementation Plans

### Example 1 – Non-compliant Patient Implant Card (PIC)

If the consent relates to non-compliant patient implant cards due to missing device information, it would be expected that the implementation plan would include:

- what information is missing from the card (i.e. the card is missing the device model and batch number);
- how the missing information is going to be provided to the patient or healthcare facility and when will this be provided (e.g., there are stickers provided with the device that can be adhered to the card);
- how the non-compliant card will be provided to the patient or healthcare facility and when will this be provided (e.g., a template card will be provided in bulk prior to device

being supplied or with the device. Extra cards can be requested from the sponsor or downloaded from the manufacturer's web site);

- what the expectation is of the healthcare facility (if any) to facilitate the convergence of the missing information with the non-compliant card (e.g., the healthcare facility will need to adhere the device sticker on the template card);
- will there be education sessions provided to the healthcare facility or patient, and if so, when will these be provided (e.g., the sponsor will provide support to the healthcare facilities when products are ordered or supplied); and
- when can the healthcare facility or patient expect to receive a compliant patient implant card and how will this change be relayed (e.g., the compliant cards will be introduced for products manufactured from 20 May 2022. Healthcare facilities will be advised by email when the new cards are being included with the device and they are no longer required to add stickers to template cards).
- Copy of interim non-compliant card.



### Electronic Patient Information Cards and Leaflets

On 29 October 2021, amendments to the Therapeutic Goods (Medical Devices) Regulations 2002 came into effect to allow patient information materials for implantable and active implantable devices to be supplied in more flexible (principally electronic) formats. The Regulation changes mean that patient information cards and patient information leaflets can be supplied electronically rather than in hard copy format, as long as they contain all required information and are made available in a way that is readily accessible by the patient concerned. Where this is the case, electronic PICs and/or PILs made available in a way that is readily accessible by the patient concerned will be considered compliant and consent will not be required for these devices.

**Next page:** once you have completed this information you can either press 'save and come back later' to complete the rest of the application at another time, or you can press 'continue' to keep filling out the application.

Save and come back later...

Continue >

If you select the 'Save and come back later' button you will be directed to a page that will require you to enter an email address. A link to the form with progress so far will be sent to that email address; to resume completing the form, click on the link.

If you select 'Continue', you will be returned the '[Contents](#)' page where you can select the link '[ARTG/Application for Inclusion - 2](#)' if you have more ARTG entries or applications for inclusion in the ARTG to be included in this application.

If you do not have any other ARTG entries or applications for inclusion in the ARTG, the you can select the link 'Declarations and acknowledgement' to finalise and submit the application.

**Application for consent to import, supply or export a medical device that does not comply with the Essential Principles**

Closes 2 Dec 2021

This service needs [cookies enabled](#).

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<a href="#">ARTG/Application for Inclusion - 2</a>	<div><div></div><div>0 of 6 questions answered</div></div>

## ARTG / Application for Inclusion – 2

This is where details for the second ARTG entry or Application for Inclusion can be filled. The remaining ARTG / Application for Inclusion pages are a similar format to this page. These pages allow you to select the response from a previous ARTG entry or Application for Inclusion, if the response is the same, or you can provide different information if necessary.

Application for consent to import, supply or export a medical device that does not comply with the Essential Principles

Closes 2 Dec 2021

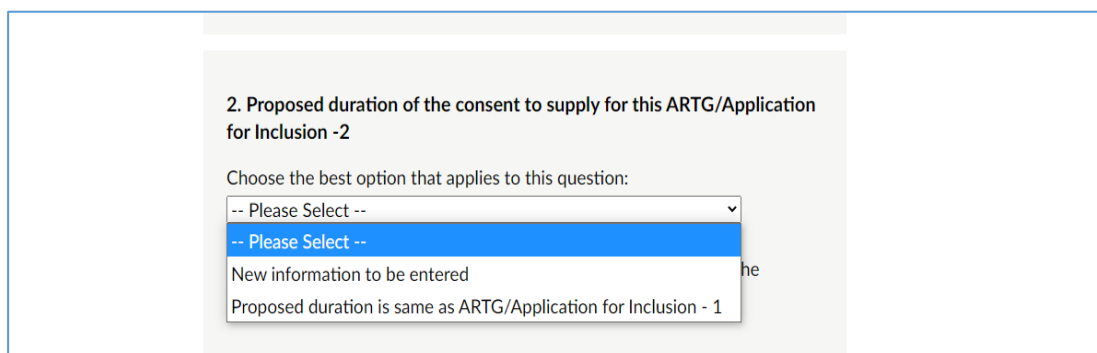
This service needs  
[cookies enabled](#).

### ARTG/Application for Inclusion - 2

Complete the information below for the second ARTG entry, or medical device with current valid application for inclusion, which is non-compliant with the Essential Principle(s).

### Replicating information for subsequent ARTG entries or Applications for Inclusion

Some ARTG entries or Applications for Inclusion may have identical information for some questions, such as proposed duration of the consent to supply, additional impacts to Australian consumers, and strategies to mitigate non-conformance. For these questions, there is the option to either enter new information, or select a previous ARTG entry or Application for Inclusion from which you can replicate the information.



2. Proposed duration of the consent to supply for this ARTG/Application for Inclusion - 2

Choose the best option that applies to this question:

-- Please Select --


-- Please Select --

New information to be entered

Proposed duration is same as ARTG/Application for Inclusion - 1

If you select 'New information to be entered', then you need to respond to the subsequent related questions regarding this ARTG entry or Application for Inclusion. If the information is identical to a previous ARTG entry or Application for Inclusion, then you can select the relevant ARTG entry or Application for Inclusion from which you would like to replicate the information for that question.

**Next page:** once you have completed this information you can either press 'save and come back later' to complete the rest of the application at another time, or you can press 'continue' to keep filling out the application.



Save and come back later...

Continue >

If you select the 'Save and come back later' button you will be directed to a page that will require you to enter an email address. A link to the form with progress so far will be sent to that email address; to resume completing the form, click on the link.

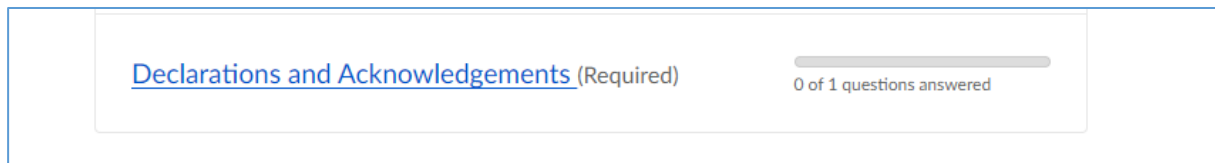
If you select 'Continue', you will be returned the '[Contents](#)' page where you can select the link '[ARTG/Application for Inclusion - 3](#)' if you have more ARTG entries or Applications for Inclusion in the ARTG to be included in this application.

If you do not have any other ARTG entries or Applications for Inclusion in the ARTG, the you can select the link 'Declarations and Acknowledgements' to finalise and submit the application.



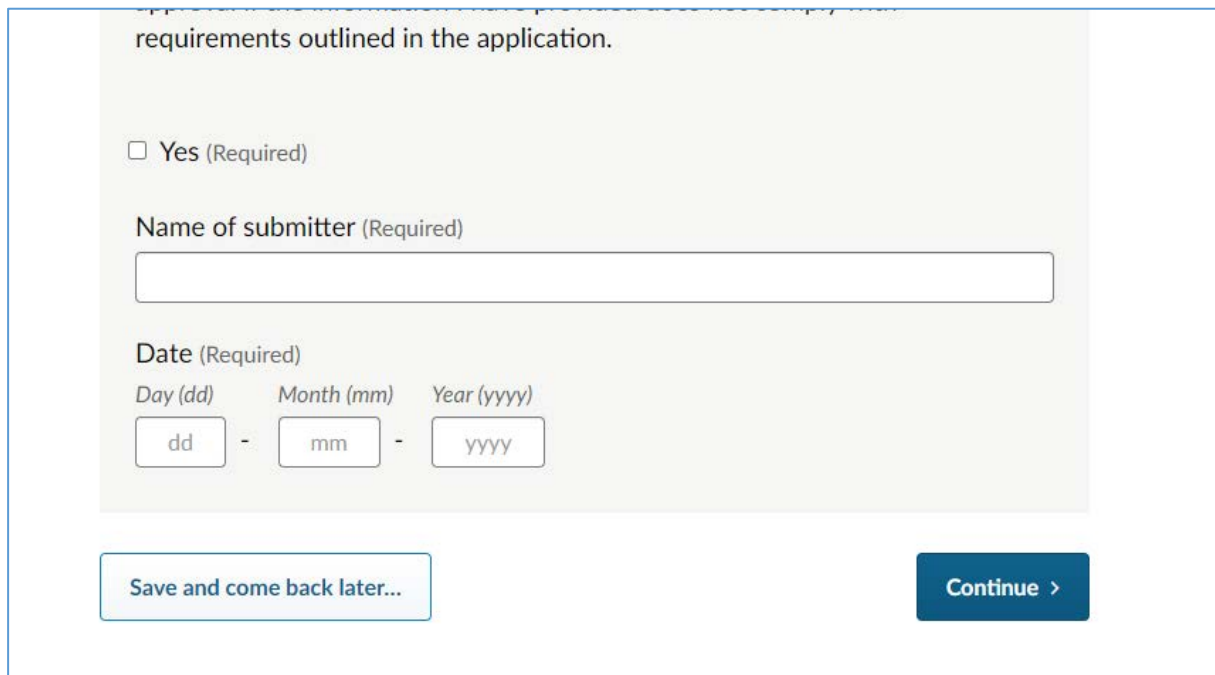
## Declarations and Acknowledgements

Once you have finished entering details of all or up to 20 ARTG entries or Application for Inclusions, select the 'Declarations and Acknowledgements page'. All fields on this page are mandatory.



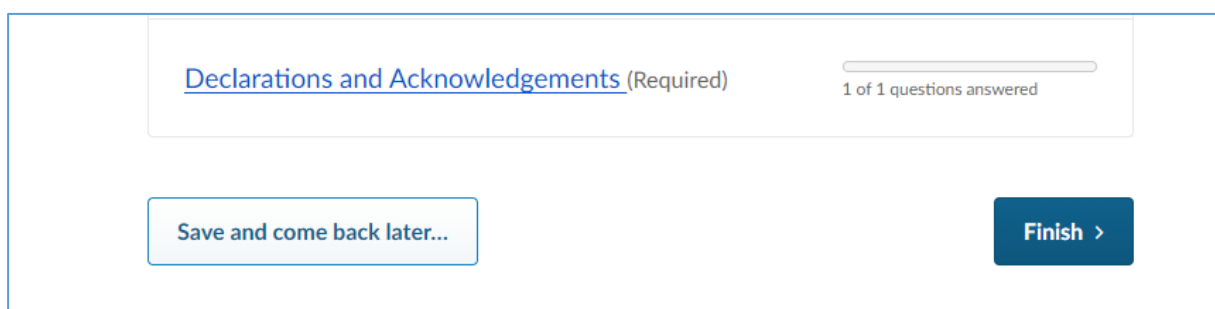
This screenshot shows the top section of the 'Declarations and Acknowledgements' page. It features a blue header bar with the page title 'Declarations and Acknowledgements (Required)' on the left and a progress indicator '0 of 1 questions answered' on the right, accompanied by a horizontal progress bar.

At the bottom of this page, check the 'Yes' box, to approve the declarations and acknowledgements, enter your name and date in the spaces provided.



This screenshot shows the main content area of the 'Declarations and Acknowledgements' page. It includes a light green box with the text 'requirements outlined in the application.' Below this is a checkbox labeled 'Yes (Required)'. Further down is a text input field for 'Name of submitter (Required)'. Below that is a date selection section labeled 'Date (Required)' with three input fields for 'Day (dd)', 'Month (mm)', and 'Year (yyyy)', separated by hyphens. At the bottom of the page are two buttons: 'Save and come back later...' and 'Continue >'.

Once you have completed this information you can either press 'save and come back later' to complete the rest of the application at another time, or you can press 'continue' to keep filling out the application. Selecting 'Continue' will take you to the 'Contents' page, where you can select 'Finish', located at the bottom of the page, to submit your application.



This screenshot shows the bottom section of the 'Declarations and Acknowledgements' page. It features a blue header bar with the page title 'Declarations and Acknowledgements (Required)' on the left and a progress indicator '1 of 1 questions answered' on the right, accompanied by a horizontal progress bar. Below the header are two buttons: 'Save and come back later...' and 'Finish >'.

## Final Step

After you select 'Finish' you will be directed to the 'Almost done...' page. On this page you can select 'Submit Response' to submit the application or select 'Back' to amend the application. Selecting 'Back' will take you to the ['Contents'](#) page.

### Almost done...

You are about to submit your response. By clicking 'Submit Response' you give us permission to analyse and include your response in our results. After you click Submit, you will no longer be able to go back and change any of your answers.

When you submit your response, you will be sent a receipt and a link to a PDF copy of your response.

[< Back](#)[Submit Response](#)

After you submit the application, an acknowledgement email will be sent to your nominated email address with a copy of your submission, including the response ID number of this application form. Please ensure that you keep a record of this response ID for future reference.

If you are seeking consent for more than 20 ARTG entries / Applications for Inclusion, you will need to complete a new form(s) for the additional devices.

# Frequently Asked Questions

## How long will the application form take to complete?

Typically, the form takes 15-30 minutes to complete depending on how many ARTG entries or Application for Inclusions you are including in your application.

## Is it mandatory to answer all the sections of the form?

Most of the questions on the 'Applicant Details' page, 'Information on non-compliance to the Essential Principles' page, and 'Declarations and Acknowledgements' page are mandatory, and require a response. The 'ARTG/Application for Inclusion – 1' page has a mixture of non-mandatory and mandatory questions. All mandatory questions must be answered to allow you to submit the application.

## Are there any special considerations that I should keep in mind while answering a question?

Please follow the instructions while answering a question (e.g. *'If you selected 'New information to be entered', please respond to the questions below. Otherwise, skip to question 4'.*). This is important for processing your application.

Some questions will have additional elements or sub questions (e.g. *'Please specify'*). Please answer those elements wherever possible, as it will give you an opportunity to provide further information.

## What should I do after I finish answering all questions on the page?

Once you finish answering questions on a page, please click on the '[Continue](#)' button located at the bottom of that page. Doing so will take you to the next page of the form.

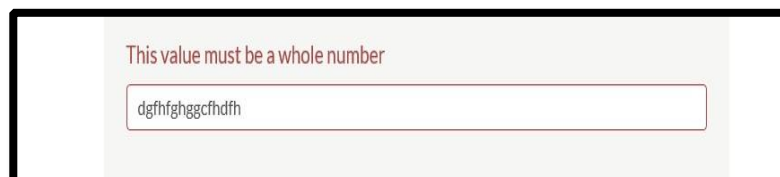
## Can I partially complete form and come back to it later?

If you are not able to complete the form in one sitting, you can click the '[Save and come back later](#)' button. This will save your progress and allow you to complete the form later (before the due date). Doing so will direct you to a page that will require you to enter an email address. A link to the form with progress so far will be sent to that email address. Please click on the link provided to resume the form.

## Why am I seeing an error message when I click 'Continue' after answering all the questions?

The error message indicates that you have submitted a response in a format that is not acceptable for that question.

**For example:**

A screenshot of a web form field. Above the input box, there is a red error message that reads "This value must be a whole number". The input box itself contains the text "dgfhfghggcfhdfh". The entire form field is enclosed in a black rectangular border.

## Can I copy and paste text into the form?

You can copy and paste text into the form wherever the form permits free text answers.

## Can I attach a supporting document to the form?

You can attach a supporting document into the form wherever the format allows you to do so.

## What should I do to save my progress on each page?

To save the progress on a page, you need to click a button such as 'Continue', 'Save and come back later', 'Finish' located at the end of the page. This ensures that the data you have entered will be saved. You will lose your progress if you navigate away without clicking on a button.

The portal does not receive and register the data entered on a page unless you click on a button.

## Can I make changes to my response after I have submitted the form?

Your responses cannot be edited once you have clicked the 'Submit Response' button. However, a request to make changes to the application can be considered by the TGA on a case-by case basis by email [mdconsent@health.gov.au](mailto:mdconsent@health.gov.au) and quoting the response ID number.



### Further information:

For more information or further question on how to submit your application online, please contact [mdconsent@health.gov.au](mailto:mdconsent@health.gov.au) or call us on 1800 141 144.

## Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Medical Devices Surveillance Branch	October 2021
V1.1	Updated to include information on fee reduction for sponsors seeking consent for non-compliant patient information, and regulation changes for electronic patient information materials	Medical Devices Surveillance Branch	October 2021

## **Therapeutic Goods Administration**

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Reference/Publication #