Australian Government
Department of Health
Therapeutic Goods Administration

Changing the sponsor of therapeutic goods

Version 4.0, October 2020

TGA Health Safety Regulation

Contents

Introduction

The 'sponsor' of therapeutic goods here refers to the person or company in relation to whom goods are registered, listed, or included in an entry in the Australian Register of Therapeutic Goods (ARTG).

Changes to the sponsorship of therapeutic goods in an entry in the ARTG occur where:

- the sponsor dies, is made bankrupt, or (if they are a company) the business is wound up, or
- the sponsor transfers or assigns its therapeutic goods business or their interest in inclusion of the goods in the Register to the person to whom the business or interest is transferred or assigned (the **new sponsor**).

As a result of such events, the **new sponsor** becomes responsible for the therapeutic goods in the ARTG entry, and must notify us of that event.

You, as the sponsor, are also required to notify us if you change your name, or amalgamates with another company under another name.

Changing the name of the registered therapeutic goods

If you are the new sponsor of registered therapeutic goods and you decide to change the name of the goods (perhaps because it contains the name of the former sponsor), you will need to make an application to register the product under its new name on the ARTG under section 23 of the *Therapeutic Goods Act 1989* (the Act). This is because once you rename the product, under subsection 16(1) of the Act, it will be taken to be separate and distinct goods from the one registered on the ARTG.

The same rule applies to listed goods.

When does a new sponsor become responsible for the ARTG entries?

We do not make that determination. It is determined by the timing of the relevant event (e.g. the transfer of the business) as set out in regulations 10AB, 10F and 10H of the *Therapeutic Goods Regulations 1990*.

Once a transfer or change occurs, the new sponsor is the person or business responsible for any relevant ARTG entries, **regardless of whether**:

- we have been notified of the transfer or change, or
- we have updated the ARTG entries of the relevant therapeutic goods.

Sponsors (and prospective new sponsors) should get their own advice about:

- the impact of regulations 10AB, 10AC (in relation to listed and registered therapeutic goods), regulations 10F and 10FA (in relation to medicinal devices) and regulations 10H and 10HA (in relation to biologicals) on their status; and
- their obligations under therapeutic goods legislation when sponsorship is transferred or the sponsor's name is changed.

Why is notifying us important?

- It allows us to continue the effective post-market monitoring of therapeutic goods that are marketed in Australia; in particular, the capacity to ensure recalls of products is effective.
- If information we hold about the identity of the current sponsor is not up to date, the new sponsor may not be aware of relevant information or documents that we require.
- Regulatory action may be taken by us that could result in goods being cancelled from the ARTG (for instance, if the new sponsor does not respond to a requirement to provide information).

What you need to do

When you become the new sponsor of an ARTG entry or entries, you:

- must inform us within 3 months of the event, and
- may need to provide evidence of the transfer / assignment.

When you, as the sponsor of therapeutic goods in an ARTG entry or ARTG entries:

- change your name or,
- as a company, amalgamate with another company and, as a result, change the company's name,

you:

- must inform us within 3 months of the event, and
- may need to provide evidence of the change of name.

Information about when evidence is required (including the type of evidence), can be found in the sections under 'How to notify us'.

How to notify us

Depending on the circumstances, a different form is used. The following pages explain each of these, and provide information about the relevant form:

- Change of sponsorship after death, bankruptcy, or winding up
- Change in business or product ownership
- Change of sponsor name

Submitting the form

Completed forms should be sent to the TGA TBS helpdesk:

- **Email:** sponsortransfers@tga.gov.au
- **Fax:** 02 6232 8581
- **Post:** TBS helpdesk, TGA, PO Box 100, Woden ACT 2606, Australia

Fees

There is no fee for notifying us about a change of sponsorship or change of name. However if as a result of either of those, the name of the therapeutic goods (such as a medicine) is also to be changed, an application for a new approval for the medicine may be required.

Fees **are** payable if the change requires any additional updates to ARTG entries. For example:

- a transfer which includes a prescription medicine will usually require:
  - approval of new labels (under section 9D of the *Therapeutic Goods Act 1989*)
  - changes to the approved Product Information
- a transfer which includes a medical device may require:
  - provision to the TGA of Manufacturers' Evidence

What happens after notification?

Once we receive a fully completed and signed notification form (including additional information if required), or other acceptable form of notification, we will update the relevant ARTG entries, usually within 10 working days.

Approximately 24 hours after the change(s) are completed, new ARTG certificates for the entries will be available to the new sponsor through our online portal - TGA Business Services (TBS).

If you don't have TBS access

See TGA Business services: getting started with the TGA for information on how to apply for access.

Relevant legislation

The *Therapeutic Goods Regulations 1990* provides the basis for transfer of sponsorship:

- **Listed and registered therapeutic goods** - regulation 10A (sponsor transfer)
- **Medical devices** - regulation 10F (sponsor transfer)
- **Biologicals** - regulation 10H (sponsor transfer).

Change of sponsorship after death, bankruptcy or winding up

Who becomes the new sponsor?

Following the death or bankruptcy of a person, or winding up of a company, the new sponsor is the person (or company) described in the table below. This person becomes responsible for any relevant ARTG entries, **regardless of whether we have been notified of the event**.

The following table outlines who is the new sponsor for particular events.

Sponsor event	New sponsor
Death	Legal representative of the sponsor who died
Bankruptcy	Trustee in bankruptcy of the sponsor that has become bankrupt
Winding up of body corporate	Liquidator of the body corporate

Requirements for new sponsors

We urge new sponsors to advise us of a change of sponsorship **as soon as possible**. This ensures we know who they are if we need information from them or any action needs to be taken in relation to the products in the ARTG.

Under regulations 10AB, 10F and 10H, the new sponsor must:

- notify us within 3 months of the event (even if 3 months has passed, notify us as soon as possible in any event)
- provide us with evidence of the relevant event (preferably by completing and lodging a notification form)

See also: Obligations of new sponsor

How do I notify the TGA?

Please use the following form to notify the TGA: Notification: transfer of sponsorship following death, bankruptcy or winding up.

You can include ARTG entries for different therapeutic good types in the one form (e.g. medicines, medical devices, etc.), provided the relevant change comes from the same event (e.g. bankruptcy).

When you complete the form, ensure that you:

- make the relevant declarations about the nature of the relevant event, including the date on which it occurred
- include a list of the relevant therapeutic goods (for each, ensure you include its ARTG entry number, and the type of therapeutic good).

Who signs the form?

The person to sign the form must be either:

- the new sponsor (i.e. the legal representative, trustee in bankruptcy or the liquidator); or
- a person who has the authority of the new sponsor to sign the form (e.g. a partner of a law or accountancy firm, or a person authorised to sign the form on that person's behalf).

Please note

If you choose not to use the form, you must:

- identify which regulation (10AB, 10F or 10H) you are notifying us under, **and**
- provide sufficient documentary material to verify the event stated in the notification (e.g. bankruptcy).

Important

We may ask you, as the person giving us the notification to provide more information before we make updates to the ARTG. This may include additional evidence about the event that triggered the transfer (or its date), and the additional information required may depend on the circumstances of the particular case.

You should be aware that, under the Criminal Code, it is an offence to:

- knowingly provide information to the Commonwealth (including the TGA) that is false or misleading in a material particular, or
- omit any information, without which the information is misleading in a material particular.

Change in business or product ownership

Who becomes the new sponsor?

Following a change in business or product ownership, the new sponsor is the person (or company) described in the table below. This person becomes responsible for any relevant ARTG entries, **regardless of whether we have been notified of the change**.

The following table outlines who is the new sponsor for particular events:

Sponsor event	New sponsor
Transfer or assignment by a person of: • the business to which listed or registered therapeutic goods relate, or • the person's interest in the therapeutic goods and, who also agrees to transfer or assign the registration or listing in the Register of the goods.	Person to whom the business or interest is transferred or assigned.
Transfer or assignment by a person of: • the business to which a kind of medical devices relates, or • the person's interest in the kind of medical device and, who also agrees to transfer or assign the inclusion of the medical devices in the Register.	Person to whom the business or interest is transferred or assigned.
Transfer or assignment by a person of: • the business to which a biological relates, or • the person's interest in the biological and, who also agrees to transfer or assign the inclusion of the biological in the Register.	Person to whom the business or interest is transferred or assigned.

Requirements for new sponsors

We urge new sponsors to advise us of a change of sponsorship **as soon as possible**. This ensures we know who they are if we need information from them.

Under regulations 10AB, 10F, or 10H, the new sponsor must:

- notify us within 3 months of the event (even if 3 months has passed, notify us as soon as possible), and

- provide us with evidence of the relevant event (preferably by completing and lodging a notification form).

See also: Obligations of new sponsor

How do I notify TGA?

Please use the following form to notify the TGA: Notification: transfer of sponsorship following transfer/assignment of business or interest in therapeutic good.

You can include ARTG entries for different therapeutic good types in the one form (e.g. medicines, medical devices, etc.), provided the relevant change comes from the same transfer or sale of business.

When you complete the form, ensure that you:

- make the relevant declarations about the nature of the relevant event, including the date on which it occurred, and
- include a list of the relevant therapeutic goods (for each, ensure you include its ARTG entry number, and the type of therapeutic good).

Who signs the form?

Both the new and former sponsor should sign this form, for example:

- **New sponsor**
  - the new owner, managing director, etc.; **or**
  - a person who is authorised to sign the form on behalf of the new sponsor.
- **Former sponsor**
  - the previous owner, managing director, etc.; **or**
  - a person who is authorised to sign on behalf of the former sponsor.

This provides us with additional evidence (as required by the relevant regulations) to establish that the transfer or assignment has occurred.

If the former sponsor can't complete the form

In exceptional circumstances, we will accept a notification that has not been signed by the former sponsor. If you are a new sponsor and are unable to get the signature of the old sponsor, please contact us.

In such a case we may require the new sponsor to provide both:

- an explanation for why it is not possible for the former sponsor to complete the form; **and**
- additional evidence to verify that the sponsor transfer has taken place.

We will consider contacting the former sponsor if there are any doubts about the status of the relevant entries in such a case.

Contact the TGA Business Services (TBS) Helpdesk of the TGA at sponsortransfers@tga.gov.au or 1800 010 624.

Please note

If you choose not to use the form, you must ensure that:

- you identify which regulation (10AB, 10F or 10H) you are notifying us under, and
- provide sufficient documentary evidence to verify the event stated in the notification (e.g. sale of the business to the new sponsor)

Important

We may ask the person giving us the notification to provide more information before updating the entries in the ARTG. This may include additional evidence about the event that triggered the transfer or its date, and the additional information required may depend on the circumstances of the particular case.

You should be aware that, under the Criminal Code, it is an offence to:

- knowingly provide information to the Commonwealth (including the TGA) that is false or misleading in a material particular, or
- omit any information, without which the information is misleading in a material particular.

What should former sponsors do?

If you are proposing to transfer the sponsorship of goods in the ARTG, for instance through the sale of your business, you may be asked by the new sponsor to sign the TGA notification form in relation to the transfer.

To help ensure that the ARTG is updated as soon as possible, you may consider requiring the purchaser (i.e. the prospective new sponsor) as part of the contractual obligations to:

- provide you with a notification form to sign within X days of the sale; and
- provide it to us as soon as possible after the sale takes place.

This will help to ensure:

- we do not unnecessarily involve you (as the former sponsor) in any regulatory matters that may occur after the sale takes place, and
- there is minimal delay between the change in sponsorship, and updating the ARTG with the new sponsors' details.

Change of sponsor name

You also need to tell us where you as a sponsor (whether an individual or a company):

- change your name, or
- if a company, you amalgamate with another company (and as a result change your name).

This does not result in a change of sponsor, but it does require us to update any relevant ARTG entries to ensure they remain accurate.

This is done within our secure online business portal, TBS. If you have TBS access, you can make changes to the client name using your user account details.

If you do not have TBS access, either:

- apply for access by following the instructions at TGA Business services: getting started with the TGA
- contact us on 1800 010 624 or at ebs@tga.gov.au.

Changing sponsor details in the Product Information and labels

When there is a change in sponsor name and details, you must also apply to change the details in the Product Information (PI) and labels.

For more information refer to Changing sponsor details in Product Information (PI) and labels of prescription medicines.

If the ABN or ACN is also changing

If changing the business name involves changing the Australian Business Number (ABN) or Australian Company Number (ACN), this constitutes forming a new business entity and therefore a change of sponsorship.

This is considered to be a transfer of business, and therefore needs to follow the process for a Change in business ownership.

Relevant legislation

The Therapeutic Goods Regulations 1990 provides the basis for change of name:

- **Listed and registered therapeutic goods** - regulation 10AC (change of name)
- **Medical devices** - regulation 10FA (change of name)
- **Biologicals** - regulation 10HA (change of name).

Obligations of new sponsor

If you become (or are considering becoming) a new sponsor as the result of any of the events described in regulations 10A, 10F and 10H (i.e. Change in sponsorship **after death, bankruptcy or winding up** or Change in business ownership), a number of legal obligations will then apply to you.

Depending on the type of therapeutic good, the legal obligations of sponsors are imposed by the:

- *Therapeutic Goods Act 1989*
- *Therapeutic Goods Regulations 1990*
- *Therapeutic Goods (Medical Devices) Regulations 2002*

The obligation to pay annual charges also applies, and is imposed by the:

- *Therapeutic Goods (Charges) Act 1989*
- *Therapeutic Goods (Charges) Regulations 1990*

Please note

These obligations arise:

- as soon as the relevant event occurs; and
- even if we have not been notified of that event; and
- even if we have not updated the relevant entries in the ARTG.

What should I, as a new sponsor, be aware of?

Information about the role and responsibilities of sponsors, as well as information on how to apply for an entry on the ARTG, can be found at: Role of the Sponsor.

Sponsors of all therapeutic goods in the ARTG are required to comply with a range of regulatory obligations, including the conditions of approval that are imposed on the goods while they remain in the ARTG.

All potential sponsors are advised to acquaint themselves with these requirements, which vary depending on the therapeutic good type.

For example:

- The sponsor of a medical device is required to:
  - have access to sufficient information to substantiate that a medical device complies with the relevant Essential Principles; and
  - be able to substantiate that the relevant conformity assessment procedures have been applied to the device.
- It may be a condition of registration for a prescription medicine that the sponsor:
  - comply with requirements in a Risk Management Plan, and/or prepare and submit post-market studies to the TGA, or
  - for a specified period, provide samples of a medicine and data to us for assessment prior to release of the medicine for sale.

- It is often a condition of ARTG inclusion for high-risk medical devices that annual reports be provided to us (for a specific period) about complaints and adverse reports relating to the device.
- A condition of inclusion for all types of medical devices is the requirement to retain all distribution records.

Requests for information

We can ask for information at any time to establish that certifications made by the sponsor (at the time of ARTG entry) for listed medicines, and all medical devices and biologicals remain correct and any conditions applicable to the entry are being complied with. We can take action to suspend or cancel the products from the ARTG if the certifications are no longer correct or conditions are not being complied with.

This includes:

- for medical devices - compliance with the essential principles and the application of conformity assessment procedures
- for all other types of therapeutic goods - compliance with standards
- compliance with advertising requirements (all therapeutic goods).

We recommend that any person (or company) proposing to take on responsibility for ARTG entries ensure it has access to any information that will allow it to respond to such requests, as it is reasonable to assume that the new sponsor will have access to data (and other information about a therapeutic good) submitted to us by the former sponsor.

Post market safety requirements for registered and listed medicines

Sponsors are obliged to notify us (within 15 calendar days) of **any** change in the details of the person nominated to be responsible for fulfilling the sponsor's pharmacovigilance obligations for ARTG entries. See: *Australian requirements and recommendations for pharmacovigilance responsibilities of sponsors of medicines* (Version 1.3)

Manufacturing clearances

Any new sponsor will need to transfer (or renew) any manufacturing (GMP) clearance held by the former sponsor for any overseas manufacturer in relation to any listed or registered medicine, or biological, which is part of a transfer of sponsorship.

Both the former sponsor and the new sponsor will need to authorise the transfer of the GMP clearance to the new sponsor. If only some of the goods covered by the GMP clearance have been transferred, the new sponsor will need to submit a new application to us for GMP clearance.

Contact the Manufacturing Quality Branch of the TGA: gmpclearance@tga.gov.au.

Outstanding annual charges for the current financial year

Unless a low value exemption is in place, annual charges are payable for any entry that is in the ARTG for any part of a financial year.

Failure to pay annual charges payable in relation to an entry in the ARTG is a ground for suspension or cancellation of the entry from the ARTG.

We recommend that any person (or company) proposing to take on responsibility for therapeutic goods that are in the ARTG seek an assurance (or evidence) from the sponsor that any annual charges for the current financial year have been paid.

Low value exemptions for the current financial year

Sponsors are exempt from paying annual charges for goods in an ARTG entry if the goods qualify for an annual charge exemption.

Outstanding requests for variations to ARTG entries

We recommend any person or company proposing to take on responsibility for therapeutic goods in the ARTG to inquire about any outstanding applications we have for variations to the entry in relation to the goods (see FAQ section).

TGA regulatory action

We recommend any person or company proposing to take on responsibility for therapeutic goods in the ARTG to check with the current sponsor if any regulatory compliance action has been, or is being, proposed by us in relation to the goods.

Sponsors of therapeutic goods certify a range of matters about the good(s) as part of their entry in the ARTG. We can request information and/or documents from the sponsor at any time, and failure to respond, or to provide sufficient material for the TGA to be satisfied as to the matters and/or to the correctness of those certifications, may result in us proposing to suspend or cancel the product from the ARTG.

We may also:

- propose to suspend or cancel products in the ARTG because of matters that have arisen since a product was entered in the ARTG (usually after requesting information and/or documents from the sponsor)
- be proposing other post-market action relating to a product in the ARTG, for example, imposing additional conditions or change(s) to the Product Information document for a registered medicine because of a potential safety concern.

Record keeping

Sponsors are required to keep various records for all their goods in the ARTG. The most important of these is information about:

- adverse events, and
- supply in Australia of the goods.

We can ask the sponsor to provide information about these matters at any time, and the relevant sections in the Act under which this information can be sought are:

- registered and listed goods (including prescription, OTC and complementary medicines) - section 31
- biologicals - section 32JA
- medical devices - section 41JA.

We recommend that any person or company proposing to take on responsibility for therapeutic goods in the ARTG ensure that it has access to:

- information about adverse events and supply in Australia, and
- documents that have been provided to, or by, the TGA about those therapeutic goods.

Failure by a sponsor to provide requested information about products in the ARTG can result in suspension or cancellation of the products from the ARTG.

Frequently asked questions

Can I nominate a future date to transfer my products?

No.

Under the Therapeutic Goods Regulations, the obligation to notify us happens **after the relevant event has occurred**.

We will only process notification forms or other notifications of a transfer etc. that:

- have been provided to us after the event; **and**
- indicate that the event has already occurred.

Can the TGA object to the new sponsor?

No.

Regulations 10AB, 10F and 10H of the Therapeutic Goods Regulations set out the circumstances where a person is taken to be the new sponsor.

This is not affected by whether the products covered by the relevant entries are or are not compliant with regulatory requirements. If goods supplied by any sponsor are not compliant (for instance with labelling standards that apply under the Therapeutic Goods Act) or a sponsor is not complying with conditions or other regulatory requirements in relation to the goods (for instance, does not respond to a request to provide information about the goods), we may take regulatory action.

What if I don't have a Client ID with the TGA?

The notification forms ask the new sponsor to provide its Client ID (if any).

If you are a new sponsor and do not have a Client ID, make an application by completing the Organisation details form, which can be found at: Organisation details.

New sponsors who contact us will be advised of the process for applying for a new Client ID, and other available options, such as completing a paper-based form.

For sponsors without eBS access, information is available on our website at TGA Business services: getting started with the TGA.

Can I still sell stock once my products have been transferred to another company and, if so, for how long?

It may be an offence under the Therapeutic Goods Act for the former sponsor to supply therapeutic goods once a sponsor transfer has taken place, even though the product was in stock when the transfer became effective.

This is because the disposal of the business resulted in the new owner becoming the person legally responsible for the goods in the ARTG, **even if we have not been notified of the transfer and/or the ARTG entry has not been updated**.

The change of sponsorship occurs by operation of law, i.e. it is triggered by the one of events referred to in regulations 10AB, 10F and 10H, and **not** by the TGA updating the ARTG entries **after** we have been notified.

The new owner (new sponsor) does not commit an offence by supplying the goods.

Relevant offences in the Act

Supplying therapeutic goods (that are not biologicals or medical devices) such as medicines, that you have imported, or that have been manufactured on your behalf, when you are not the sponsor is and offence:

- section 19B of the Act.

Supplying biologicals that you have imported or that have been manufactured on your behalf when you are not the sponsor is an offence:

- section 32BD of the Act.

Supplying medical devices that you have imported, or that have been manufactured on your behalf, when you are not the sponsor is an offence:

- section 41MI of the Act.

Can the new sponsor supply stock containing labels that refer to the former sponsor?

It is the responsibility of the new sponsor to ensure that therapeutic goods they supply include their name and address where required to do so.

- Medicines may be supplied with the existing sponsor details for up to 12 months while you are waiting for TGA approval of your variation application. Your product must comply with Therapeutic Goods Order No. 91 (TGO 91) - Standard for labels of prescription and related medicines.
- Biologicals must have the name of the current sponsor on the container in which the biological is packed (this is a requirement of the standard in Therapeutic Goods Order 87 – General requirements for the labelling of biologicals).
- It is an offence not to provide the name and address of the sponsor with a medical device (Regulation 10.2 of the *Therapeutic Goods (Medical Devices) Regulations 2002*).

Unless the Secretary has consented under section 14 of the Act, it is an offence for a person to supply a product that does not meet applicable standards (the Therapeutic Goods Orders are standards). Failure to comply is a ground for suspension or cancellation of the goods from the ARTG, as well as being an offence under the Act.

Changes to labels for medicines also have to be approved under section 9D of the Act.

What happens with the PI/CMI documentation - are they transferred also?

No.

Changes to the approved Product Information for a medicine requires approval by the TGA under section 9D of the Act for which a fee is payable.

For more information refer to Changing sponsor details in Product Information (PI) and labels of prescription medicines.

As the legal representative of a sponsor who died, I forgot to notify TGA of the death and I am now proposing to transfer the former sponsor's business to a new sponsor. What should I do?

You are legally the new sponsor.

If you are now proposing to transfer the business to a third party, you should notify us of the change by which you became the sponsor as soon as possible and **before** transferring the business to a third party.

Then, if and when you transfer the business to the third party, it will be their responsibility as the new sponsor to notify us of that transfer.

What if there is an application with the TGA for a new ARTG entry when the transfer occurs?

Any application for the inclusion, registration or listing of new therapeutic goods in the ARTG at the time a sponsor transfer occurs is not affected by regulations 10AB, 10F or 10H. This is because those regulations only change the sponsorship in relation to entries that are already in the ARTG at the time of the relevant event.

If:

- an application by a company for approval of therapeutic goods (that would result in a new entry in the ARTG) is under consideration by us at the time that another person becomes the new sponsor of that company' products, and
- it is intended by the company that the responsibility for the application is to be the transferred to the new sponsor,

the new sponsor should contact the relevant TGA Branch about the next steps in relation to the application.

We strongly advise any person or company proposing to acquire a business or an interest involving therapeutic goods to check whether:

- there are any such applications in progress with the TGA, and
- the original applicant proposes to continue with the application in the event that the business or interest is transferred.

It is up to the relevant parties to come to appropriate arrangements about the transfer of any relevant intellectual property, information, and data that would (or may) be relevant to the application where:

- there is an application in process that was submitted by the former sponsor, **and**
- the product (which is the subject of the application) is part of the business that is intended to be transferred.

Applications for prescription medicines made under Streamlined Submission Process (SSP)

We will accommodate the transfer of these applications to a new applicant up until Milestone 5 of the SSP provided we receive appropriate information and authorisations from both the former and new applicant.

If the application is past this stage, contact us about other options.

Applications to vary a prescription medicine under section 9D of the Act

It is preferable that the sponsor transfer does not occur until we make a decision on the variation application.

If the transfer cannot be delayed, ensure you inform our Application Entry Team (AET) of the transfer, so we can avoid sending the decision letter to the former sponsor.

The AET is in our Medicines Authorisation Branch, and the email address is aet.application.entry.team@tga.gov.au.

Do the regulations also apply to manufacturers that transfer their businesses?

No. They do not affect any responsibilities of the person as a manufacturer under therapeutic goods legislation.

Regulations 10AB, 10AC, 10F, 10FA, 10H and 10HA only apply to the transfer of the sponsorship from, or the change of name of, persons in relation to whom goods are included in the ARTG. This person is described as the "sponsor".

Where the "sponsor" of therapeutic goods is also the manufacturer of the goods, and the sponsor sells the business (but remains the manufacturer), then those regulations apply only to the extent that they transfer the responsibilities of "sponsor".

If you are proposing to transfer a manufacturing business to another manufacturer, different procedures will apply, and you should contact the TGA. For instance, if you have a conformity assessment certificate, the provisions in Division 4.3 of the Therapeutic Goods (Medical Devices) Regulations 2002 will be relevant.

What if I propose to change the name of a product on the ARTG as a result of a sponsor transfer?

If you are the new sponsor of registered therapeutic goods and you decide to change the name of the product (perhaps because it contains the name of the former sponsor), you will need to make an application to register the product under its new name on the ARTG under section 23 of the *Therapeutic Goods Act 1989* (the Act). This is because once you rename the good, under subsection 16(1) of the Act, it will be taken to be separate and distinct goods from the product registered on the ARTG.

The same rule applies to listed goods.

What happens to manufacturer evidence – are they transferred also?

No, sponsor transfer does not include transfer of the Manufacturer Evidence.

To ensure that appropriate manufacturer evidence is referenced in the ARTG entry the new sponsor must:

1. Submit Manufacturer Evidence application as per the standard process.
2. Once the evidence has been accepted submit a change request application to have the evidence linked to the ARTG entry or entries. Please refer to the Varying entries in the ARTG - medical devices and IVDs document for more information.

If the manufacturer evidence is appropriate for the kinds of devices included in the ARTG entry the change will be approved under section 9D of the Act. Further information on submitting manufacturer evidence can be found in Section 7 of the ARGMD - What a sponsor needs to know about conformity assessment.

Sponsors should note that it is a condition of the ARTG inclusion for all medical devices that they have available sufficient information to substantiate the application of the conformity assessment procedures or requirements, comparable to the conformity assessment procedures, to their kind of medical device, or has a procedure in place, including a written agreement with the manufacturer of the device to obtain such information.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Therapeutic Goods Administration	20/04/2015
V2.0	Updated	Therapeutic Goods Administration	17/08/2016
V3.0	FAQ updated to include information on manufacturer evidence	Therapeutic Goods Administration	04/07/2019
V4.0	Updated to include information on changing sponsor details in PI/labels	Therapeutic Goods Administration	8/10/2020

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6203 1605
https://www.tga.gov.au

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