Australian Government
Department of Health
Therapeutic Goods Administration

Post-market responsibilities (biologicals)

Australian Regulatory Guidelines for Biologicals (ARGB)

Version 1.0, July 2018

TGA Health Safety Regulation

Contents

If you supply biologicals in Australia then you need to know your responsibilities. This page will help you understand your responsibilities after your product is included on the Register.

Maintaining your ARTG entries

Being the sponsor of an entry in the ARTG, you need to:

- Continue to satisfy the conditions that were part of the approval for inclusion on the ARTG
- provide information to us about your product, if requested
- notify us of notifiable changes
- request a variation, when applicable

You may also want to:

- reinstate an entry on the ARTG
- change the sponsor of therapeutic goods

Paying your fees & charges

When you have a biological included on the ARTG, you will need to pay an **annual charge**.

Applications for notification and variation have a fee or fees attached. Sometimes there is both an **application** and an **evaluation** fee.

Fees and payments provides an overview and summary of fees and charges for biologicals outlines the fees and annual charges for both manufacturing and sponsoring biologicals.

Manufacturing responsibilities

Following approval of your manufacturing sites, there are a number of ongoing activities that you are responsible for, including maintaining the GMP conditions and accreditation and notifying TGA of any changes to the site or any overseas regulatory action for that site:

- Sponsor responsibilities related to GMP clearance and certification

Biovigilance responsibilities

Biovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse events or any other problem related to biologicals.

Biovigilance responsibilities include:

- adverse event reporting requirements
- record-keeping requirements

To meet legislated requirements, you need a biovigilance system, which is used to fulfil the tasks and responsibilities associated with the detection, assessment, understanding and prevention of adverse effects of biologicals.

Some additional responsibilities for higher risk biologicals:

- A Risk Management Plan (RMP) is required for Class 3 and 4 biologicals.
- A Periodic Safety Update Report (PSUR) is required for Class 3 and 4 biologicals and when imposed for a particular Class 2 biological.

Recall responsibilities

As a sponsor of a therapeutic good, you have ongoing responsibilities to ensure you are prepared for a recall and able to respond appropriately to complaints and problem reports:

- Roles in recalling therapeutic goods

Advertising biologicals

Biologicals are not allowed to be advertised to the public:

- Australian Regulatory Guidelines for Advertising Therapeutic Goods

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication incorporating new legislative changes and information previously published on the TGA website.	Biological Science Section Regulatory Guidance Team	July 2018

Therapeutic Goods Administration

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