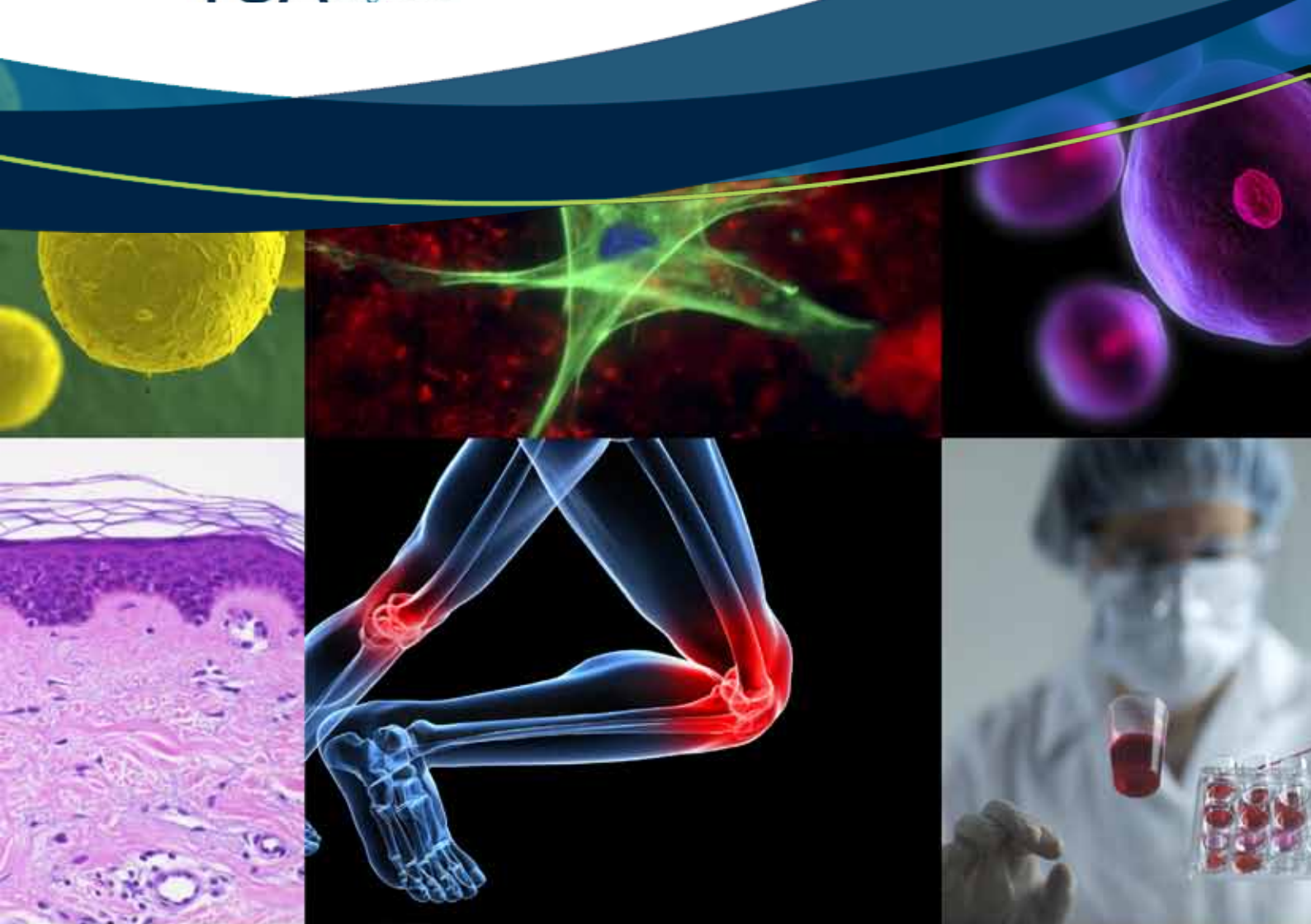
Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Australian Regulatory Guidelines for Biologicals

Appendix 12 – Transition arrangements

Version 1.0, June 2011

TGA Health Safety Regulation



About the Therapeutic Goods Administration (TGA)

- The TGA is a division of the Australian Government Department of Health and Ageing, and is responsible for regulating biologicals, medicines and medical devices.
- TGA administers the *Therapeutic Goods Act 1989* (the Act), applying a risk management approach designed to ensure therapeutic goods supplied in Australia meet acceptable standards of quality, safety and efficacy (performance), when necessary.
- The work of the TGA is based on applying scientific and clinical expertise to decision-making, to ensure that the benefits to consumers outweigh any risks associated with the use of biologicals, medicines and medical devices.
- The TGA relies on the public, healthcare professionals and industry to report problems with biologicals, medicines or medical devices. TGA investigates reports received by it to determine any necessary regulatory action.
- To report a problem with a biological, medicine or medical device, please see the information on the TGA website.

Version history

Version	Description of change	Author	Effective date
V1.0	Original	BSS	June 2011

Contents

Introduction

Transition provisions have been set out in the TG Act to provide sufficient time for the industry to make any changes necessary to comply with the new requirements of the Biologicals Regulatory Framework ('the framework'). All new biological products that were not supplied before the start date of the framework must meet the new requirements before they can be legally imported, exported, supplied or used.

The start date of the framework was 31 May 2011.

Formerly approved biological products

The amended TG Act includes transitional provisions for biologicals that are currently entered in the ARTG as a registered good, a listed good or as a medical device. Following the start date of the framework, the TGA will cancel the inclusion of the registered good, listed good or medical device and include the good as a biological in the biologicals section of the ARTG. The TGA will write to the sponsor informing them of the transfer of the biological and providing the new unique biological ARTG number. Supply of the product can continue throughout this process and no fees are payable for transferring products to the biologicals part of the ARTG. The TGA will also ensure that only one set of annual fees will be imposed for that product during the year of transfer.

Formerly exempted or excluded biological products

Biologicals exempted before the start date of the framework, will be covered by a transitional exemption from ARTG inclusion for a period of three years from the start date of the framework. This will allow ongoing supply while applications for ARTG inclusion are processed. If the sponsor applies to include the exempted biological in the ARTG within 18 months of the start date of the framework, and a decision on the application is not made within three years, the transitional period will be extended until a decision on the application is made and notified to the person.

If a sponsor makes an application more than 18 months after the start date of the framework and a decision on the application is not made within the three-year transitional exemption period, then the biological ceases to be able to be imported, exported or supplied until such time as the biological is included in the ARTG (if the decision is to include the biological). If the application is not approved, all importation, exportation, manufacture and supply of the biological will need to cease unless an alternative exemption, approval or authorisation is granted.

In order to be included in the ARTG the TG Act requires that the manufacturer(s) of a Class 2, 3 or 4 biological must be either licensed under Part 3-3 of the TG Act if they are in Australia (unless they are exempted) or be certified as approved.

Biologicals formerly exempt from ARTG entry but approved by the TGA through a cGMP licence

Biologicals formerly regulated through a manufacturing licence alone will also need to be entered onto the ARTG within the three-year transition period. Licensed manufacturers can continue to manufacture under their existing licence after the start of the framework.

Biologicals formerly exempted or excluded from both ARTG inclusion and cGMP licencing requirements

Formerly exempted or excluded biologicals will be covered by a transitional exemption for a period of three years from the start of the framework. The sponsor is required to lodge an application for inclusion of the biologicals in the ARTG during the transition period.

Applications in progress (new product or variation application)

The amended TG Act also sets out transitional provisions for applications that are pending at the start date of the framework. Applicants for a biological to be or included in the ARTG (as a medicine, therapeutic device or medical device) for which the application is still in progress have two options:

- Have their application finally determined in accordance with the legislation under which the application was made. If successful, the product will be included in the part of the ARTG for which the application was made (e.g. included in the ARTG as a medical device). The TGA will then cancel that entry and include the product as a biological in the ARTG.
- Withdraw their original application and make a new application for inclusion of a biological in the ARTG in accordance with the new requirements.

References

Resource	URL
TGA website	http://www.tga.gov.au

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