Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Australian Regulatory Guidelines for Biologicals

Appendix 9 – Guidance on TGO 87 (General requirements for the labelling of biologicals)

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

The Labelling Order applies to all biologicals (encompassing biological starting materials and finished product) that come within the operation of Part 3-2A of the Therapeutic Goods Act 1989. The Labelling Order does not apply to biologicals that are exempt from the operation of Part 3-2A of the Therapeutic Goods Act 1989 under a Section 14, biologicals that are intended for export and not supplied in Australia or samples that are not intended for therapeutic use, i.e. blood or tissue samples for infectious disease or bioburden testing. If you are unsure if the Labelling order applies to a specific biological, the TGA should be contacted for clarification prior to the preparation of a dossier.

This guidance comprises notes on the interpretation of the various requirements of the Labelling Order, and a table aligning the requirements of the Order with the dossier preparation guidance. The table is designed to provide both guidance on where information may be placed in the dossier and evidence that the various requirements of the standard have been addressed. The requirement in question should be discussed in the indicated sections of the Dossier, and that information should be summarized above as evidence the requirement has been met. Please note that the TGA will evaluate the entire dossier, so only a brief summary is required. The completed table should be included with the submitted dossier as Appendix 1.

Commencement and updates

TGO 87 commences on the 31st May 2012. This will allow for a transition period for manufacturers to achieve compliance with the standards. All biologicals collected prior to 31st May 2012 will be exempt from this order.

TGO 87 will be subject to review on a regular basis, or as changes in technology, policy, or best practice requires. Ongoing stakeholder feedback in relation to any changes in practices or evolving technologies which may impact upon the Orders is desirable.

Definitions

In the labelling order a number of terms were not defined, rather referring the user to the definitions from the Therapeutic Goods Act 1989. For clarity these terms have been listed below with their definitions as defined in the Act. These were current at the time of writing, but should be confirmed before use.

bioburden, in relation to therapeutic goods, means the quality and characteristics of microorganisms present in the goods or to which the goods may be exposed in a manufacturing environment.

biological, has the meaning as given in section 32A

container, in relation to therapeutic goods, means the vessel, bottle, tube, ampoule, syringe, vial, sachet, strip pack, blister pack, wrapper, cover or other similar article that immediately covers the goods, but does not include an article intended for ingestion.

label, in relation to therapeutic goods, means a display of printed information: (a) on or attached to the goods; or (b) on or attached to a container or primary pack in which the goods are supplied; or (c) supplied with such a container or pack.

manufacture, in relation to therapeutic goods that are not medical devices, means: (a) to produce the goods; or (b) to engage in any part of the process of producing the goods or of bringing the goods to their final state, including engaging in the processing, assembling, packaging, labelling, storage, sterilising, testing or releasing for supply of the goods or of any component or ingredient of the goods as part of that process.

primary pack, in relation to therapeutic goods, means the complete pack in which the goods, or the goods and their container, are to be supplied to consumers.

product information, in relation to therapeutic goods, means information relating to the safe and effective use of the goods, including information regarding the usefulness and limitations of the goods.

Register, means the Australian Register of Therapeutic Goods maintained under section 9A.

TGO 87 Section 6 guidance

Subsection 6(1)

In order to ensure the safety and quality of biologicals it is imperative that they are labelled and traceable to the initial donor at every part of the manufacturing, storage and release process. The unique number/alphanumeric applied to the donor and the released product do not have to be identical, provided the final product can be traced to the donor.

Subsection 6(2)

The letter height of ≥ 1.5 mm is a requirement of all label particulars required by the Labelling Order. Hospital labels, which typically inform of donor details, will be required to be written with a label height of ≥ 1.5 mm. There is a proviso in subsections 6(5) and 6(8) for the inclusion of required information as accompanying documentation if the letter height of ≥ 1.5 mm means there is insufficient space for all required information on the container/primary pack label.

Subsection 6(3)

This subsection details the information required on the container that immediately covers the biological in question at the collection of the biological. The time of collection relates to the time at which the collection is completed, not commenced. The inclusion of the name of the collection facility and (if applicable) the name of the person collecting the starting material will facilitate complete traceability.

The 'person' collecting the starting material is considered the individual completing the documentation at collection and labelling of the container, rather than, for example, the surgeon in theatre performing the procedure. The identification of the person collecting the starting material must be sufficient to enable traceability to that individual. This may be a name, initials or a staff identification number, provided the systems are in place to enable traceability.

Subsection 6(4)

This subsection details the requirements when the outer surface of the container must remain sterile and unique identification is not supplied on the sterile packaging at starting material collection. When this situation applies, the information required by subsection 6(3) should be included on the first externally non-sterile layer of packaging.

Subsection 6(5)

This subsection applies when not all the information required by subsection 6(3), in the format required by subsection 6(2), can fit on the container label. At minimum, the unique number/alphanumeric identifier must be contained on the container label. The remaining information can be provided as accompanying documentation.

Subsection 6(6)

This subsection details the information required on both the container and primary pack in which the biological is packaged at the time of product release. The sponsor can include reference to a website with additional information, but this must be additional to, and not a substitute for the requirements of subsection 6(6). If the products are for export only, and will not be released in Australia, the Labelling order does not apply. However, product label examples must be supplied to TGA for assessment, in order to fulfil the requirement, under Section 26 of the Act, that 'the presentation of the goods is acceptable'.

Subsection 6(7)

This subsection details the requirements when the outer surface of the container must remain sterile and unique identification is not supplied on the sterile packaging at product release. When this situation applies, the information required by subsection 6(6) should be included on the first externally non-sterile layer of packaging.

Subsection 6(8)

This subsection applies when not all the information required by subsection 6(6), in the format required by subsection 6(2), can fit on the container label. In this situation, all information required by subsection 6(6) other than the unique identification number/alphanumeric (linked to donor), batch number (when applicable), product type and/or name and sponsor name can be provided as accompanying documentation. This may include release documents.

Location of requirements in dossier

Table 1 Summary table comparing TGO 87 requirements with the dossier sections in which it is suggested they are addressed

Please submit the completed table as Appendix 1 to the dossier.

Section	Summary of TGO 87 requirement	Relevant Dossier Section/s*	Summary of how requirement is met**	Reference Documents (SOPs etc)
6(1)	Labelled and traceable to donor at every part of the manufacturing process	4.7 (Labelling and release documentation)		
6(2)	Technical requirements for label content	4.7 (Labelling and release documentation)		
6(3)	Labelling requirements at collection	4.7 (Labelling and release documentation)		
6(4)	Labelling requirements at collection – sterile packaging	4.7 (Labelling and release documentation)		
6(5)	Labelling requirements at collection – accompanying documentation	4.7 (Labelling and release documentation)		
6(6)	Labelling requirements at release	4.7 (Labelling and release documentation)		
6(7)	Labelling requirements at release – sterile packaging	4.7 (Labelling and release documentation)		
6(8)	Labelling requirements at release – accompanying documentation	4.7 (Labelling and release documentation)		

* Suggested dossier location; actual location of information may vary depending on the nature of the product, but must be defined under this heading.

** Only a very brief summary is required, the entire dossier will be evaluated.

References

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

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