Australian Government
Department of Health
Therapeutic Goods Administration

# ARGB Appendix 11 - Guidance on TGO 107: Standard for Biologicals – Labelling Requirements

## Australian Regulatory Guidelines for Biologicals (ARGB)

Version 2.0, February 2023

TGA Health Safety Regulation

# Contents

# About this guidance

This guidance is for manufacturers, sponsors and providers of biologicals and human cell and tissue (HCT) materials. It describes the mandatory labelling requirements set out in the Therapeutic Goods (Standard for Biologicals—Labelling Requirements) (TGO 107) Order 2021, which came into effect 30 September 2021.

Generally, Therapeutic Goods Orders (TGOs) are standards that determine the consistency of product quality, including label quality. As a provider of biologicals or HCT materials, you must comply with requirements that contribute to the quality and safety of the products, and that mitigate infectious disease risks.

TGO 107 replaces the Therapeutic Goods Order No. 87 - General requirements for the labelling of biologicals (TGO 87) 2011, which was in effect from 2011 and 'sunsetted' on 1 October 2021. Sunsetting is the process whereby legislative instruments undergo automatic repeal after 10 years following their registration.

This information is provided for guidance only and has been developed on the basis of current knowledge of the subject matter.

It should not be relied on to address every aspect of the relevant legislation. You should seek your own independent legal advice to ensure that all of the legislative requirements are met.

For clarification of a particular requirement, contact TGA's Biological Science Section (BSS).

Please read this guidance in conjunction with TGO 107.

# About TGO 107

The Therapeutic Goods (Standard for Biologicals—Labelling Requirements) (TGO 107) Order 2021 specifies the minimum requirements for the labelling of biologicals and HCT materials including;

- starting materials
- intermediates in the manufacturing process
- finished therapeutic goods.

**Definitions**

Biologicals – see section 32A of Therapeutic Goods Act 1989 (the Act)

HCT materials – see Therapeutic Goods (Standard for Biologicals—Labelling Requirements) (TGO 107) Order 2021

TGO 107 **applies to**:

- all biologicals and HCT materials that come within the operation of Part 3-2A of the Act

TGO 107 **does not apply to**:

- blood, stool or tissue samples that are taken for infectious disease or bioburden testing
- transparent coverings

If you are unsure whether TGO 107 applies to a specific biological, please contact TGA's Biological Science Section (BSS) for clarification.

## Commencement of TGO 107

TGO 107 commences on 30 September 2021. Prior to this date, this TGO applied:

- Therapeutic Goods Order No. 87 - General requirements for the labelling of biologicals (TGO 87) 2011

## Review of TGO 107

TGO 107 will be reviewed regularly as changes in legislation, emerging technology, and best practice occur. Sponsors and manufacturers are encouraged to discuss with TGA any proposed changes in practice or evolving technologies that may affect, or be affected by, the requirements of TGO 107.

As a provider of biologicals or HCT materials, you must comply with requirements that contribute to the quality and safety of the products, and that mitigate infectious disease transmission risks.

# Part 2 – Labelling requirements

Part 2 of TGO 107 outlines the labelling requirements for biological and HCT material containers.

These specifications were in part informed by requirements in the Council of Europe's 4th Edition of the Guide to the quality and safety of tissues and cells for human application (2019).

## Section 8 – General requirements

Section 8 outlines the general requirements that must be met in the labelling of all biologicals and HCT materials.

### Subsection 8(1) – Label particulars

**8 General requirements**

(1) The information that is displayed on the labels of a biological or HCT materials must be:

(a) in English; and

(b) clearly visible and not obscured; and

(c) in legible and durable characters, with a letter height of not less than 1.5 millimetres; and

(d) in metric units of measurement.

Use a letter height of not less than 1.5 millimetres for all label particulars. This requirement includes hospital labels, which typically inform of donor details.

Use plain English and write in an accessible, understandable way to clearly communicate key information about the origin of a biological or HCT materials to an audience with a range of scientific and medical knowledge, including consumers, patients and healthcare professionals.

Use metric units of measurement. Where metric units cannot be used, standard international units of measurement are acceptable.

Machine-written text is preferable but not essential.

## Subsection 8(2) – Attachment and integrity of labels

**8 General requirements**

(2) The label of a biological or HCT materials must:

(a) be securely attached to the container and primary pack in which the biological or HCT materials are supplied; and

(b) maintain integrity and remain attached to the container and primary pack at the relevant storage conditions for the biological and HCT materials.

Attach labels using a reliable adhesive that has been validated to retain its functional properties under all anticipated storage and transport conditions. How the label is attached to the packaging will determine how information is displayed.

Labels must not be altered, obscured or removed from biological or HCT material primary packaging. This ensures accurate identification the contents within primary packaging. If there are instances where the labels are altered or changed, put in place an adequate Standard Operating Procedure (SOP) for the Good Manufacturing Practice (GMP) process.

## Subsection 8(3) – Container labelling and traceability

**8 General requirements**

(3) The container of a biological or HCT materials must be labelled to ensure traceability to the donor of the HCT materials at each step of manufacture.

(4) To avoid doubt, the requirements set out in this instrument do not apply in relation to transparent coverings, where those coverings enclose or wrap:

(a) a container containing HCT materials; or

(b) container or primary pack containing a biological; and

(c) the information required to be on or attached to the container or primary pack is clearly visible and not obscured by the covering.

Biologicals or HCT materials must be traceable to the donor of the materials at each step of manufacture (from potential donor identification to the application to patient or is discarded) and in relation to the released biological.

The concept of traceability is:

- the means to locate and identify the biological or HCT material during any step from collection through to processing, manufacture, testing and storage, and then to distribution to the recipient, or disposal

- the ability to identify the donor and the establishment receiving, processing or storing the biological, and the ability to identify the clinicians at the medical facility applying the biological to the recipient
- the ability to locate and identify all relevant data relating to products and materials coming in contact with those biologicals

Traceability is inseparable from, and in practice dependent on, the labelling system in place. Specify labelling operations in all relevant written procedures for procurement organisations and tissue establishment activities. Include labelling operations in the training of staff.

Label at every step of the process to ensure traceability and ensure the quality, safety and efficacy of biologicals or HCT materials. Use systems that allow for adequate biovigilance and follow-up procedures. Document each phase of the process.

Put in place a record keeping system for all data and activities associated with biologicals and HCT materials. Records should describe:

- donation procurement
- donor testing
- processing
- storage
- distribution
- destination
- clinical end use

Records should include details of:

- equipment used
- materials such as consumables that have come in contact with starting material
- the identity of the staff who were responsible for all critical activities from procurement until implantation/application or disposal

These record keeping systems need to ensure secure identification of:

- the donor and all records associated with the donor and their medical and behavioural history
- the donation (starting material collected from the donor)
- all records associated with processing, storage and distribution of the final biological products, and related events
- all samples taken from the donor or from the starting material for the purposes of testing for quality and safety
- the clinical application and recipient(s) of the biological

These requirements **do not apply** in relation to transparent coverings, where those coverings enclose or wrap a container or primary pack, and the information on or attached to the container or primary pack is clearly visible and not obscured by the covering.

# Section 9 – Labels of HCT materials

Section 9 outlines specific requirements that must be met in the labelling of HCT materials. It details the information required on the container that immediately covers the HCT material **at the time of collection and during processing**. The time of collection relates to the time at which the collection is completed rather than when it is commenced.

## Subsections 9(1) and 9(2) – Label particulars

**9 Labels of HCT materials**

(1) Subject to subsection (2) and (3), HCT materials must be labelled in accordance with the following:

(a) all information specified in the table in Schedule 1:

(i) must be on or attached to the container of the HCT materials; or

(ii) where the HCT materials are packaged in a sterile container—may instead be on or attached to the first externally non-sterile layer of packaging of the HCT materials.

(2) If there is not sufficient space on the container of the HCT materials to include all information specified in the table in Schedule 1, then:

(a) the information specified in item 1 of the table in Schedule 1 must be on or attached to the container; and

(b) the information specified in items 2 to 5 of the table in Schedule 1 must be supplied with the container.

(3) HCT materials exported from Australia must be labelled with information specified in item 1 of Schedule 1, that is on or attached:

(a) to the container of the HCT materials; or

(b) where the HCT materials are packaged in a sterile container—to the first externally non-sterile layer of packaging of the HCT materials.

This specification is partly adopted from the Council of Europe's 4th Edition of the Guide to the quality and safety of tissues and cells for human application (2019).

Schedule 1 outlines the information that must be included on the label or attached to the container of the HCT material. A sufficient area of the container must remain uncovered to permit inspection of the contents, whenever possible.

This subsection provides an important additional check of labelled HCT materials for identification purposes. It is not recommended for a label to be so large that it completely covers the container. A sufficient uncovered area is defined as one which allows for unobscured visual inspection of the contents within the primary packaging by an individual.

HCT materials used to manufacture biologicals that are not supplied in Australia must demonstrate donor to recipient traceability.

# Section 10 – Labels of biologicals

Section 10 specifies the information required on labels of both the container and the primary pack into which the biological is packaged **at the time of product release**.

## Subsections 10(1) and 10(2) – Label particulars

**10 Labels of biologicals**

(1) Subject to subsection (2), a biological must be labelled in accordance with the following:

(a) all Part 1 information:

(i) must be on or attached to the container and the primary pack of the biological; or

(ii) where the biological is packaged in a sterile container—may instead be on or attached to the first externally non-sterile layer of packaging and the primary pack of the biological; and

(b) all Part 2 information must be:

(i) on or attached to the primary pack of the biological; or

(ii) supplied with the primary pack of the biological, including where the information is contained in an electronic reference document, with a link or QR code to the document on or attached to the container or the primary pack of the biological.

(2) A biological exported from Australia must be labelled with information specified in item 1 of Part 1 of Schedule 2, that is on or attached:

(a) to the container or the primary pack of the biological; or

(b) where the biological is packaged in a sterile container—to the first externally non-sterile layer of packaging and the primary pack of the biological.

(3) In this section:

*Part 1 information*, in relation to a biological, means the information specified in an item of the table in Part 1 of Schedule 2 if:

(a) the expression "in all cases" is mentioned in column 3 of that item; or

(b) the circumstances mentioned in column 3 of that item exist in relation to the biological.

*Part 2 information*, in relation to a biological, means the information specified in an item of the table in Part 2 of Schedule 2 if:

(a) the expression "in all cases" is mentioned in column 3 of that item; or

(b) the circumstances mentioned in column 3 of that item exist in relation to the biological.

Schedule 2 outlines label information for biologicals:

- Part 1 is the information that must be included on or attached to containers and primary packs

- Part 2 is the information that must be supplied with primary packs or included on or attached to the primary pack or, where the information is contained in an electronic reference document, with a link or QR code to the document on or attached to the container or the primary pack of the biological

Reference to a website with additional information can be used.

Where relevant, the Australian Approved Name (AAN) of the therapeutically active ingredient should be used.

With a view to future-proofing TGO 107 for the emergence of new technologies, machine-readable codes may be used. The use of machine-readable barcode labels is primarily for donor traceability. It helps ensure the accuracy of records since such codes avoid the occurrence of manual transcription errors, and the machine output can easily be entered into electronic databases. The use of national or international standards such as bar code labelling systems utilised by the ISBT 128 (Information Standard for Blood and Transplant) labelling standard are encouraged.

New requirements of this subsection are broadly consistent with TGA labelling requirements for prescription medicines. These requirements seek to align important therapeutic goods information for the benefit of consumers, patients and healthcare professionals. The purpose is to allow the prescriber to properly consider the risk-benefit of the biological.

Biologicals that are not supplied in Australia must demonstrate donor to recipient traceability.

## Schedule 1 – Labels in relation to HCT materials

Schedule 1 of TGO 107 describes information that must be included on the label of HCT materials. This is relevant to the HCT material **at the time of collection and processing**.

Ensure you familiarise yourself with **all items listed in Schedule 1** and the associated requirements.

| Item | Information |
|---|---|
| 1 | either of the following in relation to the donor:<br>(a) unique identification number/alphanumeric; or<br>(b) machine-readable code linked to donor |
| 2 | the type of HCT materials |
| 3 | the date and time of collection of the HCT materials |
| 4 | the name and address of the collection facility |
| 5 | the name of the designated person (if any) collecting the HCT materials |

With a view to future-proofing TGO 107 for the emergence of new technologies, machine-readable codes may be used. The use of machine-readable barcode labels will ensure the accuracy of records since these avoid the occurrence of manual transcription errors. The machine output can also easily be entered into electronic databases. This specification is

inspired by bar code labelling systems utilised by the ISBT 128 (Information Standard for Blood and Transplant) labelling standard.

The unique identification number/alphanumeric or machine-readable code applied to the donor of the starting material does not have to be identical-provided the final biological product can be traced to the donor.

The inclusion of the name of the collection facility and (if applicable) the name of the person collecting the starting material will facilitate reliable traceability.

The 'person' collecting the starting material is considered to be 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 specific individual. This may include the use of a name, initials, or a staff identification number.

Standard nomenclature should be used to describe the cells and tissues, and potentially any processing they have undergone.

# Schedule 2 – Labels in relation to biologicals

Schedule 2 of TGO 107 outlines label information for biologicals and is relevant to both the container and the primary pack into which the biological is packaged **at the time of product release**:

- Part 1 is the information that must be included on or attached to containers and primary packs
- Part 2 is the information that must be supplied with primary packs or on or attached to the primary pack

Ensure you familiarise yourself with **all items listed in Schedule 2** and the associated requirements.

## Part 1 – Information included on or attached to containers and primary packs

| Item | Information | Circumstances |
|---|---|---|
| 1 | either of the following in relation to the donor:<br>(a) unique identification number or alphanumeric; or<br>(b) machine-readable code | in all cases |
| 2 | the batch number | there is a batch number in relation to the biological |
| 3 | the product type or name | in all cases |

| Item | Information | Circumstances |
|---|---|---|
| 4 | both of the following:<br>(a) the words “autologous use only”; and<br>(b) the name of the intended recipient | the biological is for autologous use |
| 5 | the name or identifier of the designated patient | the biological is for directed allogeneic use |
| 6 | the name of the sponsor of the biological | in all cases |

The intention of this subsection is to provide an important additional check of labelled biologicals for identification purposes, to clearly link product with recipient, and prevent errors in administration to the intended recipient. This requirement may be satisfied with a unique identifier number rather than a name on or attached to containers or primary packs.

## Part 2 – Information supplied with primary packs

This part contains requirements that are broadly consistent with TGA labelling requirements for prescription medicines. It seeks to align important therapeutic goods information for the benefit of consumers, patients and healthcare professionals. The purpose is to allow the prescriber to properly consider the risk-benefit of the biological.

This part details the information that must be supplied on or attached to or with the primary pack of all biologicals. This can be provided as a physical copy or electronically, including in the form of the product information (PI).

| Item | Information | Circumstances |
|---|---|---|
| 1 | **Information**<br>both of the following:<br>(a) the words “autologous use only”;<br>(b) the name of the intended recipient | the biological is for autologous use |
| 2 | the name or identifier of the designated patient | the biological is for directed allogeneic use |

This subsection aims to provide an additional check of labelled biologicals for identification purposes to clearly link product with recipient and prevent errors in administration to the intended recipient. This requirement may be satisfied with a unique identifier number, rather than a name, supplied with primary pack.

| Item | Information | Circumstances |
|---|---|---|
| 3 | the name of the sponsor of the biological | in all cases |

| Item | Information | Circumstances |
|---|---|---|
| 4 | all of the following in relation to the sponsor's principal place of business in Australia:<br>(a) the address;<br>(b) the phone number;<br>(c) the email address | in all cases |
| 5 | a description of the biological | in all cases |

Item 5 is a description of the formulation(s) including quantity, proportion or strength of each therapeutically active ingredient, visual description of the product appearance, and a description of clinically-relevant biological characteristics of each therapeutically active ingredient. For products that are to be reconstituted before use, a reference to the appearance before reconstitution should be included.

Standard nomenclature should be used to describe the biological.

| Item | Information | Circumstances |
|---|---|---|
| 6 | the approved indications of the biological | the biological is included in the Register as a Class 3 biological or Class 4 biological |
| 7 | the approved intended clinical use of the biological | the biological is included in the Register as a Class 1 biological or Class 2 biological |
| 8 | a description of the therapeutic uses of the biological | the biological is not included in the Register |

The approved indications (Item 6) or intended clinical use (Item 7) or description of the therapeutic uses (Item 8) should be stated clearly and concisely. It should define the target disease or condition, distinguishing between treatment (symptomatic, curative or modifying the evolution or progression of the disease), prevention (primary or secondary), and diagnostic indications. Mandatory conditions of product usage, where relevant, should be included.

| Item | Information | Circumstances |
|---|---|---|
| 9 | the expiry date of the biological | in all cases |

Include information on the in-use shelf life, if relevant, in the expiry date section. The following optional standard text may be used in place of the shelf life information:

> *In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging.*

| Item | *Information* | *Circumstances* |
|---|---|---|
| 10 | the storage conditions applicable to the biological | in all cases |
| 11 | the size, volume, weight or concentration of the biological, as applicable | there is a size, volume, weight or concentration associated with the biological |
| 12 | the words "single patient use" | the biological is for single patient use |
| 13 | the word "sterile" or words to that effect | the biological is sterile |
| 14 | the name of the additives or antimicrobial agents, as applicable | the biological has been treated with additives or antimicrobial agents |

For Item 11, where metric units of measurement cannot be used, standard international units of measurement are acceptable.

For Item 14, AANs should be used for any excipients.

| **Item** | **Information** | **Circumstances** |
|---|---|---|
| 15 | the name of the sterilisation or bioburden reduction process, as applicable | the biological has been subject to a sterilisation or bioburden reduction process |
| 16 | the name of the suspending solution | the biological is stored in a suspending solution |
| 17 | the instructions for preparation | the biological requires specific instructions for preparation |

For Item 17, the instructions for preparation include manipulation, reconstitution, thawing, mixing, or other preparation methods. Details regarding the in-use storage and shelf life of the reconstituted product should be included, if applicable.

| **Item** | **Information** | **Circumstances** |
|---|---|---|
| 18 | the instructions for use | in all cases |

Item 18 includes information about dosage adjustment (if applicable) in renal impairment, hepatic impairment, dialysis or concomitant disease. This includes the time of day to take dose, the maximum tolerated daily dose and maximum dose for an entire course of therapy, monitoring advice, what to do in case of overdose, and any other relevant information such as compatibility with other biologicals.

| Item | Information | Circumstances |
|---|---|---|
| 19 | the precautions for use and special warnings | in all cases |

Item 19 includes, but is not limited to:

- any circumstances where caution is required (for example, use in hepatic impairment, use in renal impairment, use in the elderly, use in children, the effects on laboratory tests)
- the actions of healthcare professionals to specify particular investigations that may need to be carried out
- particular population groups or clinical situations where dosage adjustment is required

| Item | Information | Circumstances |
|---|---|---|
| 20 | the contraindications | in all cases |

Item 20 includes a description of situations in which persons should never be treated with the biological, and situations where life threatening or fatal adverse reactions may occur.

| Item | Information | Circumstances |
|---|---|---|
| 21 | a description of the kinds of interactions | the biological may have interactions with other biologicals, medicines, or a physiological process of the intended recipient |

Interactions with other biologicals and medicines include interactions that increase or decrease the action of the product.

Other interactions include interactions with food or fluids, along with known clinically relevant interactions and other potentially serious interactions. These should be grouped according to outcome, for example, potentiation or reduction of effect. The mechanism of action should be explained where this is known.

| Item | Information | Circumstances |
|---|---|---|
| 22 | a description of the incompatibilities | the biological may have incompatibilities |

Item 22 refers to information on incompatibilities of the biological with other products with which it is likely to be mixed or co-administered.

| Item | Information | Circumstances |
|---|---|---|
| 23 | a warning of the potential impact on fertility, pregnancy, or breastfeeding, as applicable | the biological may have an impact on fertility, pregnancy, or breastfeeding |

The impact on pregnancy refers to a general description, and includes any effects on labour and delivery. Note that Australian Pregnancy Categorisation is not required.

| Item | Information | Circumstances |
|---|---|---|
| 24 | a warning of the potential impact on allergies | the biological may have a potential impact on allergies |

This refers to both known and potential allergens.

| Item | Information | Circumstances |
|---|---|---|
| 25 | a warning of the personal behaviours and a description of the effect of those behaviours | the biological may affect the personal behaviours of the intended recipient |

Relevant personal behaviours include driving a vehicle, operating machinery, or drinking alcohol. This may include a sedation warning, where relevant.

| Item | Information | Circumstances |
|---|---|---|
| 26 | a warning of the adverse or undesirable effects | the biological may have adverse or undesirable effects |

For adverse or undesirable effects, report the severity, clinical importance, and frequency of such effects according to MedDRA system organ class (SOC). Preferably provide in a table format with numbers and frequencies, with each frequency grouping presented in order of decreasing seriousness (for example, very common, common, uncommon, rare, very rare) according to Council for International Organizations of Medical Sciences (CIOMS) frequencies.

| Item | Information | Circumstances |
|---|---|---|
| 27 | the instructions for reporting adverse events | in all cases |

The reporting of adverse reactions after registration of a biological is important. It allows continued monitoring of the benefit-risk balance of the biological. An adverse reaction is an unwanted or harmful reaction experienced following the administration of a biological under normal conditions of use and is suspected to be related to the biological.

Healthcare professionals are asked to report any suspected adverse reactions to TGA.

| Item | Information | Circumstances |
|---|---|---|
| 28 | the instructions for return of the biological | the biological may be returned to the sponsor |

If there are no special precautions for return/disposal, then either of the following standard text options may be used:

> *In Australia, any unused biological or waste material should be disposed of by taking to your local pharmacy.*

*In Australia, any unused biological or waste material should be disposed of in accordance with local requirements.*

| Item | Information | Circumstances |
|---|---|---|
| 29 | the information on biochemical, biodynamic or biokinetic properties, as applicable | the biological is a Class 3 or Class 4 biological and there is information in relation to the biochemical, biodynamic or biokinetic properties of the biological |
| 30 | the information and outcomes of the clinical trials | the biological is a Class 3 or Class 4 biological in relation to which clinical trials have been undertaken |
| 31 | the information and outcomes from the preclinical safety studies about the risks relating to:<br>(a) effects on fertility;<br>(b) use in pregnancy;<br>(c) genotoxicity; and<br>(d) carcinogenicity | the biological is a Class 3 or Class 4 biological in relation to which preclinical safety studies have been undertaken |

Items 29-31 requirements are broadly consistent with TGA labelling requirements for prescription medicines and seeks to align important therapeutic goods information for the benefit of consumers, patients and healthcare professionals.

These additional information requirements for Class 3 and 4 biologicals are for those biologicals that are classified as medium to high risk.

Item 29 includes details of mechanism of action, biodynamic effects, absorption, distribution, metabolism and excretion. Where defined, a schematic representation of the biological's structure or mode of action should be included.

Item 30 includes clinical trial data related to the therapeutic indications and/or intended use, and includes data that is both positive and negative with a view to transparency in the trial outcomes.

Item 31 includes study data which allow the prescriber to properly consider the risk-benefit of the biological.

# Annex 1: Location of requirements in dossier

**Table 1 Summary table of TGO 107 requirements and suggested dossier sections in which they can be addressed.** This may be completed and submitted as Appendix 1 to the dossier.

| Subsection | Summary of TGO 107 requirement | Relevant dossier section/s[1] | Summary of how requirement is met[2] | Referenced documents |
|---|---|---|---|---|
| 8(1) | General requirements for labels | 4.6/4.7. Labelling and release documentation | | |
| 8(2) | Label integrity validation | 4.6/4.7. Labelling and release documentation | | |
| 8(3) | Donor to recipient traceability | 4.6/4.7. Labelling and release documentation | | |
| 8(4) | Transparent coverings and wraps | 4.6/4.7. Labelling and release documentation | | |
| 9(1) | Labels of HCT materials at collection | 4.6/4.7. Labelling and release documentation | | |
| 9(2) | Labels of HCT materials at collection | 4.6/4.7. Labelling and release documentation | | |
| 9(3) | Labels of HCT materials at collection – exported products | 4.6/4.7. Labelling and release documentation | | |
| 10(1) | Labels of biological (final product) | 4.6/4.7. Labelling and release documentation | | |
| 10(2) | Labels of biological (final product) | 4.6/4.7. Labelling and release documentation | | |
| 10(3) | Labels of HCT materials and biologicals – specific requirements in Schedules 1 and 2 | 4.6/4.7. Labelling and release documentation | | |

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

[2] Only a very brief summary is required, the entire dossier will be evaluated.

# Version history

| Version | Description of change | Author | Effective date |
|---|---|---|---|
| V1.0 | Original publication | Biological Science Section, Scientific Evaluation Branch | September 2021 |
| V2.0 | Addition of Annex 1 | Biological Science Section, Scientific Evaluation Branch | February 2023 |

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Reference/Publication #