Australian Government
Department of Health
Therapeutic Goods Administration

Guidance on quality requirements for medicinal cannabis products

Conforming with Therapeutic Goods (Standard for Medicinal Cannabis) (TGO 93) Order 2017 - including 2022 Amendments

Version 1.5, March 2022

TGA Health Safety Regulation

Contents

Unapproved medicinal cannabis products imported into and supplied/manufactured in Australia must conform with *Therapeutic Goods (Standard for Medicinal Cannabis) (TGO 93) Order 2017* (TGO 93). TGO 93 is a standard that specifies minimum quality requirements for medicinal cannabis products.

This guidance is for manufacturers and sponsors, to assist in ensuring medicinal cannabis products conform with TGO 93.

Responsibility for products conforming with TGO 93 rests with the sponsor. It is an offence under the *Therapeutic Goods Act 1989*, to import, export, or supply therapeutic goods that do not conform to an applicable standard.

Please note that although the cannabis plant used in the manufacture of the medicinal cannabis product must meet the requirements of Schedule 1 of TGO 93, reduced or rotational testing of the cannabis plant used in the manufacture of the product can be carried out provided that this is justified on good manufacturing practice (GMP) grounds. For example, a manufacturer may be able to justify reducing or not conducting pesticide testing if no pesticides are used in the cultivation of the cannabis plant. Medicinal cannabis products, like any therapeutic good may be subject to testing by the TGA at any time to ensure compliance with relevant standards.

What TGO 93 applies to

TGO 93 applies to:

- ü any medicinal cannabis product imported into or supplied in Australia
- ü cannabis plant used in the manufacture of medicinal cannabis products (e.g. as an ingredient or as a starting material for an extract used as an ingredient)
- ü any other ingredients used in the manufacture of medicinal cannabis products, such as excipients
- ü steps and procedures carried out in the manufacture of medicinal cannabis products

TGO 93 does not apply to medicinal cannabis products:

- û manufactured in Australia solely for export ('export only medicines')
- û imported by a person for their own use or for use by their immediate family, as described in item 1 of Schedule 5 to the *Therapeutic Goods Regulations 1990*
- û imported by a member of a group of persons visiting Australia to participate in a national or international sporting event, as described in item 4 of Schedule 5A to the *Therapeutic Goods Regulations 1990*
- û imported by a member of the military forces of another country visiting Australia for military training, as described in item 8 of Schedule 5A to the *Therapeutic Goods Regulations 1990*
- û imported by a medical practitioner or member of a medical team accompanying a critically ill patient, as described in item 10 of Schedule 5A to the *Therapeutic Goods Regulations 1990*
- û imported by a member of a group of persons that includes the Head of Government or Head of State of a foreign country and senior Government officials of that country, who are visiting Australia on official business, as described in item 11 of Schedule 5A to the *Therapeutic Goods Regulations 1990*

- that are part of the medical supplies of a marine vessel or an aircraft visiting Australia for use in treatment of a passenger or crew member, as described in item 12 of Schedule 5A to the *Therapeutic Goods Regulations 1990*

What TGO 93 applies to is defined in Section 6 of TGO 93.

Commencement

TGO 93 commences the day after it is registered on the Federal Register of Legislation (section 2 of TGO 93). All medicinal cannabis products imported or supplied in Australia must conform with TGO 93 from its commencement, unless you have been given a consent by the Secretary.

Transition period

Amendments to the version of TGO 93 registered in 2019 were made in March 2022. These amendments are subject to transition periods to allow industry to make changes to their products.

Sections 13, 14, 15 and 16 are subject to a transition period. All medicinal cannabis products released for supply in Australia on or after 1 July 2023 must comply with these requirements.

Interpretation

The terms used in TGO 93 are consistent with therapeutic goods legislation, and may differ in meaning from the terminology in narcotic drugs legislation (*Narcotic Drugs Act 1967* and *Narcotic Drugs Regulation 2016*).

'Act' is defined in section 4 of TGO 93 as the *Therapeutic Goods Act 1989* and 'Regulations' as the *Therapeutic Goods Regulations 1990*. Any term not defined in TGO 93 will usually take its ordinary English meaning.

European Pharmacopoeia monographs

Section 7 of TGO 93 incorporates the requirements of the following general monograph of the European Pharmacopoeia as being applicable to medicinal cannabis products and ingredients:

- *Pharmaceutical Preparations (2619)*

This general monograph encompasses the requirements of specific monographs of the European Pharmacopoeia for pharmaceutical raw materials (e.g. active ingredients, excipients) as well as the requirements of general texts (e.g. *Residual Solvents (5.4)*) and other general monographs of the European Pharmacopoeia, including:

- *Herbal Drugs (1433)*
- *Herbal Drug Preparations (765)*
- *Herbal Drug Extracts (765)*
- *Substances for Pharmaceutical Use (2034)*
- dosage form monographs such as *Oromucosal Preparations (1807)*

Source of active ingredients and cannabinoids

All active ingredients and cannabinoids in medicinal cannabis products must be manufactured from the cannabis plant **only** (section 8 of TGO 93).

This means that no other substances can be used to alter the chemical characteristics of the cannabinoids naturally occurring in the cannabis plant used as the starting material.

This requirement does NOT capture chemical changes that occur because of natural or environmental factors, such as drying, heating or burning. Medicinal cannabis products that contain neutral cannabidiol (CBD) and tetrahydrocannabinol (THC) after conversion from their acid forms would comply with section 8 of TGO 93.

To comply with TGO 93, medicinal cannabis products cannot contain:

- the synthetic form of any cannabinoid (including, for example, the synthetic form of THC, known as dronabinol)
- active ingredients from any source other than the cannabis plant
- cannabinoids synthesised by chemical conversion, such as delta-8 THC derived from CBD.

Decontamination

If you decontaminate the cannabis plant—for example, by using gamma irradiation to reduce the microbial load—you must **ensure** that this does not adversely affect the quality of the medicinal cannabis product (section 9(a) of TGO 93).

Do not use ethylene oxide to decontaminate the cannabis plant (section 9(b) of TGO 93). This is in line with current guidance on the quality of herbal medicinal products. For more information, see:

- *Guideline on quality of herbal medicinal products1/traditional herbal medicinal products (EMA/CPMP/QWP/2819/00 Rev. 2)*

Identification

You must positively identify the cannabis plant used in the manufacture of medicinal cannabis products and differentiate it from potential adulterants and substitutes using each of the following identification methods (section 10 of TGO 93):

- macroscopic examination
- microscopic examination
- chromatographic procedures

These identification methods must be suitably validated and performed on every batch of the cannabis plant.

TGA guidance Identification of herbal materials and extracts relates to the identification of plant materials, such as cannabis plant, that do not have a monograph in a pharmacopoeia recognised by the TGA. This guidance specifies that the macroscopic, microscopic, and chemical characteristics of the plant should be compared against either:

- an authenticated reference specimen

OR

- the descriptions given in an authoritative literature source such as:
  - the United Nations Office of Drugs and Crime website: Recommended methods for the identification and analysis of cannabis and cannabis products
  - the American Herbal Pharmacopoeia monograph *Cannabis inflorescence*

Further guidance on identification testing is given in United States Pharmacopeia-National Formulary General Chapter <563> *Identification of articles of botanical origin.*

Chromatographic procedures

Chromatographic procedures are chemical tests that determine whether the characteristic chemical constituents of the plant are present in the plant.

Examples of chromatographic procedures include:

- high-performance liquid chromatography
- thin-layer chromatography
- gas chromatography

Tests may involve one or more chromatographic procedures. For example, the British Pharmacopoeia monograph for *Holy Basil Leaf* (the dried leaves of *Ocimum tenuiflorum*) stipulates the use of macroscopic and microscopic examination as well as two thin-layer chromatography test procedures for the identification of the plant.

Chemical constituents of cannabis plant

Recognised chemical constituents of the cannabis plant include cannabinoids, such as tetrahydrocannabinols, and terpenes.

Examples of tetrahydrocannabinols include:

- delta-9-tetrahydrocannabinol (also commonly referred to as tetrahydrocannabinol, delta-9-THC, or THC)
- tetrahydrocannabinolic acid (THC-acid)
- delta-8-THC
- tetrahydrocannabivarin (THCV or THV)
- 11-hydroxy-delta-9-THC

Examples of other cannabinoids include:

- cannabidiol (CBD)
- cannabidiolic acid (CBD-acid)
- cannabichromene (CBC)
- cannabinol (CBN)

Examples of terpenes include:

- beta-caryophyllene
- geraniol

- alpha-humulene
- limonene
- linalool
- myrcene

Some cannabinoids, such as THC and CBD, are unique to the *Cannabis* genus.

Adulteration

Do not adulterate the formulated medicine or any of its ingredients with undeclared substances (section 11 of TGO 93). Tobacco, calamus and synthetic cannabinoids are notable examples of adulterants.

The motivation for adulterating a product is irrelevant - the presence of any substance extraneous to the formulation (such as undeclared substances) - will be considered to amount to adulteration for the purposes of TGO 93.

Processing aids used in the manufacture of medicinal cannabis products are not considered adulterants. These are defined in section 4 of TGO 93 as:

- a substance used in the manufacture of a medicine that is not intended to remain in the final formulation of the medicine (although trace amounts may remain in the medicine).

Tests

Section 12 of TGO 93 specifies tests and assay limits for medicinal cannabis products.

How to validate tests

For guidance on the principles and practice of validating tests:

- *ICH Harmonised Tripartite Guideline Validation of Analytical Procedures: Text andMethodology Q2 (R1)*.

Cannabis plant tests

The cannabis plant you use must comply with the limits specified in Schedule 1, in addition to being positively identified as described in section 10 of TGO 93. The limits for the parameters apply **on a dried basis**, with the exception of the test for foreign matter. It may be appropriate to carry out additional tests to those specified in TGO 93 in certain circumstances.

Sample size and preparation guidance

Choose a sample size that is representative of the batch. For guidance on sample sizes and how to prepare herbal plant material for analysis, see:

European Pharmacopoeia method of analysis *Herbal Drugs: Sampling and Sample Preparation (2.8.20)*

Specified tests

You must determine whether the cannabis plants used to manufacture the medicinal cannabis products meet the requirements of Schedule 1.

The following parameters are specified in Schedule 1:

1. aflatoxins
2. ochratoxin A
3. foreign matter
4. heavy metals (arsenic, cadmium, lead and mercury)
5. pesticides
6. total ash

The tests in Schedule 1 are standard pharmacopoeial tests applied to the cannabis plant used in the manufacture of medicinal products. For more information, see:

- European Pharmacopoeia general monograph *Herbal Drugs (1433)*
- *Guidance on Specifications: Test Procedures and Acceptance Criteria for Herbal Substances, Herbal Preparations and Herbal Medicinal Products/Traditional Herbal Medicinal Products(CPMP/QWP/2820/00 Rev 2)*.
- Note that heavy metals must be reported in mg/kg, rather than ppm. Parts per million (ppm) is not sufficiently specific as it can be interpreted as mg/kg or mg/L.

Every batch must comply

Every batch of your medicinal cannabis product must be manufactured from cannabis plants that meet the requirements of Schedule 1. Generally, we expect all tests to be carried out on a routine basis to ensure that if a sample was tested by the TGA it would meet TGO 93 requirements.

However, in accordance with good manufacturing practice (GMP) considerations, you may perform reduced or rotational testing for non-critical tests provided that you are able to justify this reduced or rotational testing. For example, you may be able to justify reducing or not conducting pesticide testing if no pesticides are used in the cultivation of the cannabis plant.

Alternative tests

You do not have to use the methods specified in Schedule 1 to test the cannabis plant. You could use:

- equivalent methods in established pharmacopoeia, including the United States Pharmacopeia-National Formulary
- suitably validated in-house or literature (non-pharmacopoeial) tests that are suitable for the intended purpose

However, in the event of a dispute, the methods of analysis specified in TGO 93 are the official methods.

Additional tests

In addition to testing the parameters specified in Schedule 1, consider performing additional tests on the cannabis plant from the general monograph on *Herbal Drugs (1433)*, where such tests are warranted.

For example:

- Water or loss on drying
  - Consider performing tests for the cannabis plant in relation to water or loss on drying with appropriate limits to ensure that the cannabis plant does not contain excessive moisture that could facilitate the growth of microorganisms
- Radioactivity
  - Consider performing tests for the cannabis plant in relation to radioactive contamination if the plant is grown in an area with potential for radioactive contamination, e.g. the Chernobyl region.

Assay of active ingredients in the product

You need to measure the concentration of the active ingredients in the finished product. The actual quantity of active ingredients must be within a specified range of the stated quantity [section 12(2) of TGO 93]. You may wish to apply tighter limits for release, to ensure the product still complies at the end of its shelf-life.

Active ingredient definition

An active ingredient is a therapeutically active component in the medicine's final formulation that is responsible for its physiological or pharmacological action (section 4 of TGO 93). In addition, the following ingredients are active ingredients in section 4(2) of TGO 93 for the purposes of TGO 93:

- any tetrahydrocannabinol (including any corresponding acid) greater than or equal to 1.0% w/w or w/v of the product
- any other cannabinoids (including any corresponding acid) greater than or equal to 2.0% w/w or w/v of the product

Corresponding acids

The term 'corresponding acid' is used because some cannabinoids such as THC and CBD ordinarily exist in the cannabis plant in the form of their corresponding acid, namely THC-acid and CBD-acid respectively. These acids form THC and CBD as a result of decarboxylation during storage or heating.

It is common practice to express the contents of cannabinoids in the cannabis plant as the total of cannabinoid and corresponding acid. For example, total THC is the sum of THC and THC-acid and total CBD is the sum of CBD and CBD-acid. The assay should be performed with reference to these total sums.

Assay method

No particular test method is prescribed for calculating the average content of each active ingredient in accordance with section 12(2) of TGO 93. The assay method you use will depend on the active ingredient, the dosage form and the formulation of the product. You can use any suitably validated test method.

Examples of literature assay methods can be found in:

- Monograph Cannabis Flos Version 7.1 (November 28, 2014) _40953, Dutch Office of Medicinal Cannabis
- Recommended methods for the identification and analysis of cannabis and cannabis products, United Nations Office on Drugs and Crime.

Stated content

The assay limits are specified in relation to the stated content of each active ingredient. 'Stated content' is defined in section 4 of TGO 93. 'Stated content' means the quantity or proportion of each active ingredient:

- specified on the label
- disclosed in an application made under section 19 of the *Therapeutic Goods Act 1989*, whether or not the quantity or proportion is specified on the label
- disclosed in an application made under regulation 12A of the Regulations, whether or not the quantity or proportion is specified on the label
- purported to be present in a medicinal cannabis product that is dispensed, or extemporaneously compounded, for a particular person for therapeutic application to that person, in the manner mentioned in item 6 of Schedule 5 to the *Therapeutic Goods Regulations 1990*
- notified to be present for the purpose of clinical trials as described in item 3 of Schedule 5Ato the *Therapeutic Goods Regulations 1990*

Assay limits for various dosage forms

You need to test the concentration of the active ingredients in medicinal cannabis products. The assay limits for these tests are specified at section 12(2) of TGO 93 and will differ depending on the dosage form of products, specifically:

- herbal final form
- tablets and capsules
- other dosage forms

Herbal dosage form

When the product is in herbal final form (section 12(2)(a) of TGO 93), such as sachets of cannabis leaf material, each active ingredient, together with any corresponding acid, in a representative sample must be in the range of 80.0–120.0% of the stated content of that active ingredient.

Tablets or capsules

When the product is in tablet or capsule form (section 12(2)(b) of TGO 93), the average content of each active ingredient, together with any corresponding acid, as determined from a pooled sample of not fewer than 20 tablets or capsules, must be in the range of 90.0–110.0% of the stated content of that active ingredient.

Tablets or capsules on the ARTG

Medicinal cannabis products in tablet or capsule form that are registered on the ARTG must comply with the assay limits in TGO 101, which are tighter than those in TGO 93 (section 12 note).

Other dosage forms

For any other dosage form (for example, oromucosal spray) (section 12(2)(c) of TGO 93), the content of each active ingredient, together with any corresponding acid, in a representative sample must be in the range of 90.0–110.0% of the stated content of the active ingredient.

Manufacturing quality

Domestic manufacturers of medicinal cannabis products must have a TGA manufacturing licence, demonstrating compliance with Australian Good Manufacturing Principles (GMP). Section 13 sets out equivalent GMP requirements for medicinal cannabis products manufactured overseas.

Sponsors must ensure each batch of product imported into Australian is manufactured at a site that meets one of a number of 'equivalent' GMP codes. Sponsors must also ensure they have evidence of compliance that is valid at the time each batch was manufactured.

- Overseas manufacturing of medicinal cannabis must occur on sites that comply with one of the Good Manufacturing Practice (GMP) standards set out in section 13(2) and
- the Australian sponsor (the importer) of the medicinal cannabis product must hold evidence of GMP compliance, as specified in section 13(3).

These new requirements apply to medicinal cannabis products released for supply in Australia after 1 July 2023 (see section 17 of TGO 93).

Exemptions for Australian and overseas manufacturing sites

It is important to note that Section 13 does not apply to herbal material or oil (extracted directly from the cannabis plant) if that material or oil is used as starting material in the manufacture of another medicinal cannabis product.

This is equivalent to the exemptions applying to Australian sites, see Item 2 in Schedule 7 to the *Therapeutic Goods Regulations 1990*.

Applicable standards and required evidence

The relevant GMP standard that needs to be followed, and the evidence to be kept, will depend on the country of manufacture, as follows:

- United Kingdom - must be manufactured at a site that meets the specified European Union GMP standard. The required evidence is a Certificate of Good Manufacturing Practice issued to the manufacturer of the product by either the UK regulator (the Medicines and Healthcare products Regulatory Agency / MHRA) or a licensing authority of one of the EU member states.

- European Union member state – must be manufactured at a site that meets the specified European Union GMP standard. The required evidence is a Certificate of Good Manufacturing Practice issued to the manufacturer of the product by a licensing authority of one of the EU member states.
- Canada – There are three options available for sponsors of products made in Canada.

    (1) If the product is manufactured at a site that meets Canadian Good Manufacturing Practices, the required evidence is a copy of the Drug Establishment Licence issued by Health Canada.

    (2) If the product is manufactured in accordance with the European Union GMP standard, the required evidence is **both** a Certificate of Good Manufacturing Practice issued to the manufacturer of the product by a licensing authority of one of the EU member states **and** written confirmation from Health Canada that the manufacturing site operates in accordance with Part 5: Good Production Practices of the Cannabis Regulations SOR/2018-144 (Canada).

    (3) If the product is manufactured in accordance with the PIC/S Guide to GMP but the importer cannot obtain the evidence referred to in options (1) or (2), the importer or sponsor can request that the TGA conduct an inspection of the manufacturing facility. The required evidence would then be written confirmation from the TGA that the manufacturing site operates in accordance with the PIC/S Guide to GMP **and** a written confirmation from Health Canada that the manufacturing site operates in accordance with Part 5: Good Production Practices of the Cannabis Regulations SOR/2018-144 (Canada).

- South Africa – must be manufactured at a site that meets the requirements set out in the South African Guide to GMP. The required evidence is written confirmation from the South African Health Products Regulatory Authority that the manufacturing site operates in accordance with the South African Guide to GMP.
- Israel – must be manufactured at a site that meets the specified European Union GMP standard. The required evidence is a Certificate of Good Manufacturing Practice issued to the manufacturer of the product by the Israel Ministry of Health.

TGA GMP inspections

If the medicinal cannabis product is to be manufactured in a country other than those specified in TGO 93, an application can be made to the TGA requesting an inspection of the manufacturing facility. The full cost of doing an inspection is payable by the sponsor. The TGA will inspect for compliance with the PIC/S Code of GMP, as adopted by Australia, and provide written confirmation of the results of the inspection. A successful inspection outcome will satisfy the requirements under sections 13(2) and 13(3).

Acceptable certificate and/or ‘written confirmation’

Section 13(4) sets out the basic requirements for the written confirmation or certificate.

‘Written confirmation’ must be in the form that is typically used in the particular jurisdiction. For instance, where a certificate of compliance is normally issued, the ‘written confirmation’ must be the certificate.

If the jurisdiction only issues the confirmation in the form of a letter, then that will be sufficient.

In all cases, the ‘written confirmation’ must be:

- issued by the relevant government authority
- be clear and legible
- in English
- readily verifiable by the TGA.

Evidence to be kept on file

The sponsor must hold the relevant evidence for **at least** until the end of the shelf-life of the batch of product. It does not need to be presented to the TGA prior to the product being supplied in Australia. However, it must be available for presentation to the TGA on request.

Child-resistant packaging

To minimise the risk of toxicity if accidentally ingested by a child, most medicinal cannabis products need to be packaged using child-resistant closures. The exceptions are medicinal products in the form of plant material and those products described in section 6(2) of TGO 93.

The packaging is not child-proof - it should be difficult for young children to open but should not be difficult for adults to use properly. It is intended to provide a delay in the time taken by a child to open a package, thereby increasing the probability of adult intervention before the contents are fully accessible.

The requirements parallel those that apply to other medicinal products in Australia and are specified in sections 8, 9 and 10 of the separate *Therapeutic Goods Order No. 95 - Child-resistant packaging requirements for medicines 2017*.

Labelling

Section 15 of TGO 93 outlines key information that must be included on the label to ensure the safe use of the medicinal cannabis product.

All products

Section 15 sets out the information that must be included on the labels of all medicinal cannabis products that are covered by TGO 93. These requirements are designed to provide prescribers and consumers sufficient information to properly identify the goods and know how to use and store them safely. This information also supports efficient recall processes if a recall is necessary.

Labels should clearly differentiate between medicinal cannabis products that are based on plant material, broad spectrum extracts, full spectrum extracts and isolates (of the active ingredient). Different information is required in each case - more information is required for active ingredients that are not present as isolates. These requirements are set out in section 15 of TGO 93.

Isolates

Where the active ingredient has been refined from the plant preparations to a single cannabinoid only minimal information is required. The name of the cannabinoid and its quantity must be stated on the label.

Plant materials

The cannabinoids that are active ingredients in some medicinal cannabis products are present in plant material that has not undergone any refinement. This does not include physical processing such as cutting or grinding.

The labels of these products must include the following additional information to accurately identify the plant material, see 15(2)(a)-(f) of TGO 93:

- the minimum dry weight or minimum fresh weight of plant material (including the word 'minimum')
- the plant species
- the plant part.

Example: "Cannabis sativa flower dry 500 mg minimum, containing tetrahydrocannabinol 30 mg".

Plant preparations

The cannabinoids that are active ingredients in some medicinal cannabis products are present in plant preparations. These are plant materials that have undergone refinement but not those where the outcome is a single cannabinoid. Plant preparations do include broad and full spectrum extracts, oils, decoctions, and suspensions.

The labels of these products must include the following additional information to accurately identify the plant preparation, see 15(2)(g) of TGO 93:

- the weight of the plant preparation and the minimum dry weight or fresh weight of the plant material from which it was prepared, **except if the plant preparation is an essential oil**
- the plant species
- the plant part
- the preparation type.

Example: "Cannabis sativa leaf extract 5 mg, derived from Cannabis sativa leaf dry 500 mg minimum, containing tetrahydrocannabinol 30 mg".

Mixtures/blends

Where the finished medicinal cannabis product is a blend of two plant preparations, each component needs to be identified accurately.

Example 1: an extract prepared from cannabis leaf containing a high concentration of THC, blended with a second extract prepared from cannabis flowers containing a high concentration of CBD. The labels on this product would state:

> *Cannabis sativa* leaf extract 50 mg, derived from *Cannabis sativa* leaf dry 500 mg minimum, containing tetrahydrocannabinol 30 mg
>
> *Cannabis sativa* flower extract 50mg, derived from *Cannabis sativa* flower dry 600mg minimum, containing cannabidiol 10mg

Example 2: CBD isolate extracted from *Cannabis sativa* leaves, blended with leaf resin with stated content of THC. The labels on this product would state:

> Cannabidiol 10 mg and *Cannabis sativa* leaf extract 50 mg, derived from *Cannabis sativa* leaf dry 500 mg minimum, containing tetrahydrocannabinol 3 mg.

Microbiological attributes

TGO 93 includes microbiological requirements to provide sponsors with a more complete set of quality requirements in a single TGO.

Sponsors or manufacturers should identify which of the nominated monographs apply to their products. Products are only expected to meet **one** of the specified monographs.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Laboratories Branch; Pharmacovigilance and Special Access Branch; Regulatory Guidance Team	March 2017
V1.1	Updated to clarify content	Pharmacovigilance and Special Access Branch	July 2018
V1.2	Updated to amend name	Pharmacovigilance and Special Access Branch	May 2019
V1.3	Minor updates to reflect CTA name change	Biological Science Section	November 2020
V1.4	Updates to reflect removal of TGO 93 declaration form requirement	Experimental Products Section	November 2021
V1.5	Updates to take into account the revised TGO 93 (Amendment Order March 2022)	Manufacturing Quality Branch	March 2022

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