Australian Government
Department of Health
Therapeutic Goods Administration

Consultation: Therapeutic Goods Order 54 - Standard for Disinfectants (TGO 54)

Proposed improvements including reduced regulation for hard surface disinfectants

December 2018

TGA Health Safety Regulation

Confidentiality
All submissions received will be placed on the TGA's Internet site, unless marked confidential. Any confidential material contained within your submission should be provided under a separate cover and clearly marked "IN CONFIDENCE". Reasons for a claim to confidentiality must be included in the space provided on the TGA submission form. For submission made by individuals, all personal details, other than your name, will be removed from your submission before it is published on the TGA's Internet site. In addition, a list of parties making submissions will be published. If you do not wish to be identified with your submission you must specifically request this in the space provided on the submission form.

Contents

Introduction

The Therapeutic Goods Administration (TGA) is responsible for regulating the supply, import, export, manufacturing and advertising of therapeutic goods. Hard surface disinfectants are regulated by the TGA and form part of the category of therapeutic goods known as 'other therapeutic goods'. The regulatory requirements for the supply of hard surface disinfectants to the public are currently set out in the:

- *Therapeutic Goods Act 1989* (the Act)
- *Therapeutic Goods Regulations 1990* (the Regulations)
- Therapeutic Goods Advertising Code
- Therapeutic Goods (Single Therapeutic Goods) Order No.1 of 1991
- Therapeutic Goods Order 54 - Standards for Disinfectants and Sterilants (TGO 54), and
- Therapeutic Goods Order 37: General Requirements for Labels for Therapeutic Devices (TGO 37).

This consultation seeks comments on the expansion and amendment of TGO 54.

NOTE

Sponsors are encouraged to invite any organisation that you supply to, to comment on this consultation.

Review of Medicines and Medical Devices Regulation and the Government's response

The Review recommended that the TGA examine whether the regulatory oversight applied to a range of products that represent a very low safety risk to consumers was consistent with the principles of best practice regulation, and whether there were any opportunities for streamlining or simplifying current regulatory requirements for affected stakeholders.

The Government accepted recommendations 14, 23 and 48 from the Review of Medicines and Medical Devices Regulation (MMDR review) to carry out further reviews of the regulation of 'low risk' products to ensure that the level of regulation is appropriate and consistent with the Government's Deregulation Agenda. A range of potential options for the future regulation of 'low risk' products were developed into a public consultation paper. The consultation paper was published on the TGA website from 31 March 2017 until 12 May 2017, and 1028 submissions were received.

Following review of the consultation submissions, a series of specific policy proposals for regulatory reforms were developed for consideration by Government, with a view to implementing reforms in 2018. More information can be found within the Review recommendations and the Government response document.

In order to address the recommendations from the Review, TGA is streamlining the current regulatory pathway for hard surface disinfectants to more appropriately reflect the risks to the Australian public. The Regulations relevant to disinfectants have been re-made down-regulating

registered to listed, and listed to exempt. As a component of this change pre-market review of listed disinfectants will only be conducted on new ingredients and/or new specific claims.

Despite the down-regulation, hard surface disinfectants will need to continue to meet all regulatory requirements as set out in TGO 54 and the associated guidance. Sponsors have previously expressed in-principle support for improved clarification of the requirements. Accordingly, TGO 54 has been rewritten to incorporate all relevant regulatory requirements.

Proposed Therapeutic Goods Order

The arrangements for disinfectants were historically set out across three documents:

- TGO 54
- 'Guidelines for the evaluation of disinfectants' that describe the information to be supplied for the listing of disinfectants, and
- TGO 37 (which sunset on 1 October 2018).

The new Therapeutic Goods Order will be a standard for hard surface disinfectants comprised of:

- Updated sections of TGO 54 that clarify existing requirements for hard surface disinfectants
- The labelling requirements of TGO 37, and
- Standards and requirements contained within the 'Guidelines for the evaluation of disinfectants'.

As a result, all relevant regulatory requirements relating to hard surface disinfectants will be contained within one Therapeutic Goods Order.

NOTE

All hard surface disinfectants must meet the requirements of the proposed Therapeutic Goods Order, whether or not they make specific claims.

It is proposed that the updated Therapeutic Goods Order will include:

- Clearer definitions
- A mechanism for providing relevant testing certificates
- Clearer performance requirements to demonstrate efficacy for specific claims for listed products, and
- Clearer labelling requirements.

Clearer definitions

Hard surface disinfectants now explicitly include disinfectant cloth wipes and surface sprays.

Sterilants have been removed as they are now regulated as medical devices.

Relevant testing certificates

The new Therapeutic Goods Order allows for equivalent testing from a GMP licensed laboratory or laboratory accredited to ISO/IEC 17025 or equivalent e.g., NATA, TGA, US FDA, PIC/S, US EPA, NAMAS UK etc. Testing to the recognised standard that was in place at the time testing took place is also acceptable.

Clearer performance requirements to demonstrate efficacy for specific claims for listed products

When products claim new ingredients and/or new specific claims, pre-market review is conducted. Information to be submitted for review includes:

- performance requirements to demonstrate microbial efficacy, stability and toxicity for specific claims
- instructions for use
- promotional material
- labels and packaging, and
- test certificates.

Sponsors must comply with, and retain data to support compliance with:

- Schedule 1 – The TGA disinfectant test, and
- Schedule 2 – Physical Stability, Chemical Stability, Microbial Efficacy Testing and Shelf Life of Disinfectants.

Clearer labelling requirements

The requirement for household grade disinfectants and commercial grade disinfectants to not be labelled as “hospital grade” has been explicitly stated in the revised Therapeutic Goods Order.

The physical form of the disinfectant must be appropriate for its intended application.

- For example, hard surface disinfectants should not be provided in a pump action bottle, to minimise the risk of these products being used on skin.

Content of submissions

Submissions must be relevant to the proposed Therapeutic Goods Order and associated guidance documents. Submissions must be received by the closing date. Submissions must be in English and legible.

In addition, submissions may include information on:

- The suitability of the test requirements and limits specified in the new Therapeutic Goods Order.
- Suggested improvements.

- Whether or not you support the proposal. If you do not support the proposal, you may make suggestions for an alternative acceptable to you.
- An assessment of how the proposal will impact on you.

Enquiries

Any questions relating to submissions should be directed to the LowRiskDevices@health.gov.au, or by telephone to 02 6232 8748. Please include *'Proposal to remake standards for disinfectants'* in the subject line of the email.

What will happen

All submissions will be placed on this website unless marked confidential or indicated otherwise in the submission form (see Privacy information).

Submissions will be reviewed by the TGA and feedback on submissions will be provided through this website.

Privacy information

The TGA collects your personal information in this submission in order to:

- Contact you if the TGA wants to seek clarification of issues raised in your submission or to check whether you consent to certain information that you have provided being made publicly available.
- Help provide context about your submission (e.g. to determine whether you are an individual or a director of a company or representing an interest group).
- Seek feedback about how the consultation was undertaken.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Therapeutic Goods Administration, Medical Devices Branch	18/12/2018

Therapeutic Goods Administration

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Reference/Publication # D18-11337479