Therapeutic Goods Act 1989

Therapeutic Goods Order Number 54A

AMENDMENT TO THE STANDARD FOR DISINFECTANTS AND STERILANTS (TGO 54)

I, John Cable, delegate of the Minister for Health and Family Services, for the purposes of the exercise of the Minister's powers under section 10 of the *Therapeutic Goods Act 1989* and acting under subsection 10(1), hereby **DETERMINE** that the matters specified in this Order shall constitute an amendment to Therapeutic Goods Order No. 54, the Standard for Composition, Packaging, Labelling and Performance of Disinfectants and Sterilants.

Therapeutic Goods Order No.54 is amended as follows:

Clause 1 - Application

(a) Delete paragraph 1(b).

Clause 2 - Interpretations

(b) Delete the first sentence in Clause 2 and replace with the following:

"Unless otherwise specified, the definitions contained in the *Therapeutic Goods Act 1989* and Therapeutic Goods Regulations will apply."

(c) Amend the following definitions in Clause 2:

(i) replace the definition for "Australian Approved Names List" with the following definition:

"Australian Approved Names List" means:

(A) the list of names or terms included in the document entitled "Australian Approved Names for Pharmaceutical Substances" published by the Therapeutic Goods Administration in the edition "TGA Approved Terminology for Drugs" dated July 1995, and

(B) the amendments to that list made by the document entitled "Amendments to TGA Approved Terminology for Drugs - Cumulative Amendment - additions from July 1995 to February 1997" dated 4 March, 1997;"

(ii) Replace the definition for "suitable" with the following definition:

" "suitable" means, when used in respect of a test to be passed, that the test is consistent with the recommendations and requirements in the document titled "Guidelines for the Evaluation of Sterilants and Disinfectants" published by the Therapeutic Goods Administration on 14 March, 1997;"

Clause 3 - Standards for performance of Disinfectants and Sterilants

(d) Delete subclause 3(7) and replace with the following:

"(7) Where different uses for a disinfectant or sterilant are specified in a label on the container or primary pack containing the disinfectant or sterilant and different conditions are recommended on the label for each use, each label claim should meet the prescribed test for that type of use. The test should be carried out at the highest dilution recommended on the label for that use and at the end of the shelf life of the disinfectant prepared for that use."

Clause 4 - Standards for Packaging and Labelling of Disinfectants and Sterilants

(e) Delete Clause 4.
(f) Insert the following new Clause 5:

"5. <u>Standards for Packaging and Labelling of Disinfectants and Sterilants</u>

<u>Packaging</u>

(1) A disinfectant or sterilant shall be enclosed in a container.

(2) The container shall be suitably designed to ensure the adequate protection and containment of the contents. If the disinfectant or sterilant is either a scheduled poison and/or classified as a dangerous good then the container shall comply with the Poisons Standard and/or the Australian Dangerous Goods Code.

<u>Labelling</u>

(3) Labelling for all goods covered by this Order shall comply with the requirements of the Poisons Standard except that where there is a conflict the requirement specified in this Order shall have precedence.

(4) The container and any primary pack containing a sterilant, disinfectant, sanitiser or sanitary product shall be labelled with the following particulars:

(a) except as provided in subparagraphs 5(5)(a)(i), (ii) and (iii), a *common name* of the disinfectant, sterilant, sanitiser or sanitary product as listed in Column 2 to Schedule 2 to this Order:

(i) for a sanitiser, the common name for an antibacterial clothes preparation may be also used instead of the common name for the sanitiser;

(ii) each of the following common names shall be used on its own and not in conjunction with any other common name:
sanitary fluid;
sanitary powder;

(iii) where a sterilant or instrument grade disinfectant is suitable for different levels of use, only the common name of the highest level of use is required to be shown as the common name.

(b) the Approved name of the ingredient active against pathogenic or food-spoilage micro-organisms or, in the case of a disinfectant or sterilant containing more than one such ingredient, the Approved name of each ingredient.

(c) the quantity or proportion of each ingredient active against pathogenic or food-spoilage micro-organisms, together with, where applicable, a statement of the proportion of available chlorine, bromine or iodine; this proportion shall be expressed as a percentage of the total mass or volume of the disinfectant or sterilant;

(d) the quantity of disinfectant or sterilant;

(e) the batch number of the disinfectant or sterilant immediately preceded by the words "Batch, " "Batch Number", "Batch No.", "Lot", Lot Number", "Lot No.", "Lot Code", or by words having a similar meaning or by the symbol " B ", "the Upper Case (Capital) letter B surrounded by a circle" or "(B)";

(f) the Expiry date or Use by date of the disinfectant, or sterilant immediately preceded by the words "Expiry date", "Expiry", "Exp." or "Use by" or words or an internationally recognisable symbol (such as the hour glass) having the same meaning;

NOTE: The provision for the use of a symbol does not include provision by way of a bar code at this time.

(g) the name and address of the manufacturer or sponsor of the disinfectant or sterilant;

(h) clear and adequate instructions for all intended uses of the disinfectant or sterilant, including:

(i) the method of use of the disinfectant or sterilant and a clear warning in any case where a danger exists if an incorrect method of use is employed:

(ii) except as provided in subclauses 5(8) and 5(9) the words "Do not mix with detergents or other chemicals";

(iii) subject to subclause 5(10), a statement of the dilution or dilutions of the disinfectant or sterilant in water or other diluent to be employed or the words "Use undiluted"; and

(iv) in the case of a disinfectant or sterilant requiring preparation before use, instructions for correct preparation, use and storage conditions of the preparation should be supplied.

Specifications, Modifications and Exceptions

(5) The words required by paragraphs 5(5)(h) and (i) will, in the case of a sterilant or instrument grade - high level disinfectant, clearly show the time, temperature and strength or dilution required for the intended purpose. Where multiple intended uses exist, the requirements for each use will be clearly identified.

(6) The words required by paragraphs 5(5)(h) and (i) will, in the case of a hospital grade disinfectant, indicate that it is not intended to be used on therapeutic devices.

(7) The words required by paragraphs 5(5)(h) and (ii) may be followed by the word "except", the name of a specific substance or product and the words "as directed below".

(8) Paragraphs 5(5)(h)(ii) and (iii) do not apply in the case of a surface spray

disinfectant.

(9) For a liquid disinfectant or sterilant, the statement of dilution (if applicable), referred to in paragraphs 5(5)(h)(iii) to be employed shall be either:

(a) "1 in N" meaning that 1 part of the disinfectant or sterilant is made up with water or other diluent to a total volume of N parts, or

(b) "1: N" meaning that 1 part of the disinfectant or sterilant is added to N parts of water or other diluent.

(10) In the case of a hospital grade or instrument grade disinfectant, or sterilant, the statement of dilution referred to in paragraphs 5(5)(h)(iii) shall not contain directions for the preparation of a dilution of the disinfectant from another such dilution.

(11) The particulars referred to in paragraphs 5(5)(a), (b), (c) and (d) shall be written on the main label.

(12) The particulars referred to in subclause 5(5) shall be written:

(a) in the English language;

(b) on the outer face of the label;

(c) in durable and legible characters having a letter height of not less than 1.0 millimetre;

(d) in a metric unit of measurement and

(e) in a colour or colours that will afford a distinct contrast to the background colour and be clearly visible.

(13) A common name referred to in subclause 5(5) shall be:
(a) written immediately above, below or adjacent to the trade name of the disinfectant or sterilant, or in the case of a disinfectant or sterilant with no trade name, immediately below any statement required by any other regulation to be on the first line or lines of the main label, and
(b) shall be in a font size that is similar for all parts of the common name.

(14) Notwithstanding subclause 5(13)(e) the product shall be labelled with:

(a) the words "Batch No.", the symbol "B" , "the Upper Case (Capital) letter B surrounded by a circle" or "(B)", or words having a similar meaning, and the batch number of a sterilant or disinfectant required by clause 4(5)(e); or
(b) the words "Expiry date" or "Use by" and the date required by clause 4(5)(f) to follow those words

may be embossed on a label attached to or appearing on the container or any primary pack containing a disinfectant or sterilant.

(15) Where a disinfectant is demonstrated to pass as a hospital grade disinfectant under Option A of the prescribed test, the labelling shall explicitly, clearly and in a way that highlights the requirement, indicate that the surface must be pre cleaned before disinfection for the process to be effective."

Commencement Dates

Except for paragraph (f) of this Order, this Order comes into effect on the day of notification in the Commonwealth of Australia Gazette.

Paragraph (f) of this Order shall commence to operate:

(a) In relation to all the goods specified under subparagraphs 1(a)(i) to (vii) inclusive of TGO 54 that are already being supplied in Australia on the date of the making of this Order - from 25 October 1998.

(b) In relation to all the goods specified under subparagraphs 1(a)(i) to (vii) inclusive of TGO 54 that have not yet been supplied in Australia on the date of the making of this Order - from the date of commencement of this Order.

Dated this 26 day of March 1997

John Cable
Delegate of the Minister for Health and Family Services