Supplementary notes

General requirements for labels for medicines

The following Supplementary Notes are intended to explain various parts of the Order and are not part of the Order.

1 Scope of the Order

The requirements apply to medicines which come within the operation of the *Therapeutic Goods Act 1989* as provided in subsection 6(1) of the Act, as follows -

> '6(1) This Act applies to:
>
> (a) things done by corporations; and
>
> (b) things done by natural persons or corporations in so far as those things are done:
>
> (i) in the course of, or in preparation for, trade or commerce between Australia and a place outside Australia, among the States, between a State and a Territory or between 2 Territories; or
>
> (ii) under a law of the Commonwealth relating to the provision of pharmaceutical or repatriation benefits; or
>
> (iii) in relation to the Commonwealth or in relation to an authority of the Commonwealth.'

2 Provision for exemption for specific products

Subsection 14(1) of the Act requires therapeutic goods to comply with standards including standards for labelling and packaging as follows -

> 'Compliance with standards
>
> 14(1) Except with the consent in writing of the Secretary, a person must not:
> (a) import therapeutic goods into Australia; or
> (b) supply therapeutic goods for use in Australia;
>
> if the goods do not conform with a standard applicable to the goods.
>
> Maximum Penalty: 240 penalty units'

In effect, this subsection provides a mechanism for seeking an exemption for individual products from compliance with standards such as any of the labelling requirements specified in this Order except where the Order reproduces requirements from the Act or Regulations.

Subsection 14(2) of the Act states -

> '(2) Paragraph (1)(a) does not apply to goods that do not conform with a standard applicable to the goods by reason only of matters relating to labelling or packaging'

Subsection 14(2) of the Act therefore allows importation of therapeutic goods, the labels of which do not comply with the requirements of this Order. However, if imported goods or goods manufactured in Australia are intended for supply in Australia, the labels must comply with the requirements of this Order, except with the consent of the Secretary under subsection 14(1) of the Act.

Under subsection 14(3) of the Act, the labels of therapeutic goods intended only for export from Australia do not need to comply with the requirements of this Order.

Where exemption from any of the labelling requirements in this Order is sought for goods intended for supply in Australia, the sponsor is required to apply in writing to the Therapeutic Goods Administration (TGA) for a formal exemption stating precisely the exemption being sought from compliance with a particular requirement and providing a reason for seeking the exemption.

3 General exemptions

Certain classes of medicine are exempt from compliance with the labelling requirements specified in this Order and are referred to in clause 1 of this Order.

Subclause 1(1)(b) of this Order exempts medicines being imported into Australia or supplied in Australia which are neither exempt goods nor goods included in the Australian Register of Therapeutic Goods and are intended for Individual Patient Use or other Special Access Scheme purposes.

Subclause 1(1)(d) of this Order exempts starting materials, presently described in Item 9, Schedule 5 of the Regulations as a medicine used in the manufacture of therapeutic goods except when pre-packaged for supply for other therapeutic purposes or formulated as a dosage form. This means that active ingredients and excipients intended for use in the manufacture of medicines are exempt. However, if the same ingredients are prepackaged ready for sale they are not exempt; for example, an ingredient such as liquid paraffin can be used in manufacture of drug products in which case it is exempt from these requirements or can be pre-packaged for sale to the public in which case it is not exempt. Similarly, bulk finished tablets, for example, which are still to be packaged for supply, are exempt from the requirements in this Order.

Subclause 1(1)(f) of this Order exempts medicines which are Personal Imports for use in the treatment of the importer or his or her immediate family, as described in Item 1, Schedule 5 of the Regulations.

4 Reference to ‘name of the dosage form’

Appropriate names for the dosage form can be found in the Therapeutic Goods Administration publication ‘TGA Approved Terminology for Medicines’ and in the British Pharmacopoeia (BP). Synonyms or abbreviations for the names of dosage forms used in monographs of the BP may be used on labels.

It is recognised that the names of dosage forms for products such as sunscreens do not always conform with the usual names of dosage forms used for medicines and in such cases another name descriptive of the nature of the product can be used.

Subclause 3(2) could be interpreted to require the ‘name of the dosage form’ to appear up to four times on a label, as follows -

- under subclause 3(2)(a), as a part of the statement of the ‘non proprietary name’, such as ‘Aspirin Tablets BP’;
- under subclause 3(2)(c), as part of the statement of quantity or proportion of all active ingredients in the goods, such as ‘Each tablet contains Aspirin 300 mg’;
- under subclause 3(2)(e), as the name of the dosage form, such as ‘Tablets’; and

- under subclause 3(2)(f) as part of the quantity of the goods, such as ’25 Tablets’

Where the product name includes the name of the dosage form, a separate statement of the name of the dosage form can be omitted. Similarly, the statement of quantity or proportion of active ingredients in the goods could be combined with the statement of quantity of the goods, such as -

‘25 Tablets each containing Aspirin 300 mg’.

5 Label requirements for product name where English and non-English names are present [subclause 3(1)(a)]

Subclause 3(1)(a) requires that label particulars be written in the English language. As many Chinese and other forms of traditional medicines have the product name also expressed in non-Anglicised characters eg Pinyin and Chinese characters, it is unlikely that many of these names can be translated into a meaningful English name. It is therefore sufficient for the sponsor to provide a certified English translation of the non- English characters to the TGA to verify that the name does not include prohibited claims.

6 Expression of ‘microgram’

The TGA requirements for the expression of microgram are that wherever possible, ‘microgram’ should be stated in full to minimise the possibility of confusion with ‘milligram’. When it is not practicable to use the word ‘microgram’ in full, the preferred abbreviation is ‘µg’. However, the term ‘mcg’ is acceptable for use in other than prescription medicines.

7 Expression of quantity or proportion of vitamins and minerals [subclause 4(13)]

As a general principle, the quantity or proportions of vitamins have, in the past, been expressed in biological units of potency until such time as their purity and assay procedure allows quantitative expression in terms of mass.

Currently, only Vitamin A has an international standard expressed in biological units. Other vitamins are generally expressed in terms of mass.

Vitamin A can be expressed on the label solely in International Units. For all other vitamins, the expression of amount should be in terms of mass (such as milligrams or micrograms, as appropriate). It is recognised that various optical isomers and salts of alpha tocopherol (Vitamin E) are in use, which have different activity depending on their source, i.e. synthetic or naturally occurring. To allow the consumer to compare the activity of these tocopherols from different sources in various products, companies may also include their activity in International Units.

For cholecalciferol and ergocalciferol (Vitamin D), the expression of strength on the label is required to be in terms of mass. Companies may also include a potency statement in International Units.

For Betacarotene, (a Precursor of Vitamin A), the statement of strength of Betacarotene is required to be expressed in terms of mass (such as milligrams) rather than international units of Vitamin A activity. It is known that the amount of Betacarotene which is converted in the body to Vitamin A depends to some extent on reserves of Vitamin A in the body. It is therefore considered inaccurate to express the content of Betacarotene in International Units.

For preparations containing trace elements of salts intended as mineral supplements - as the quantity of the element with the name of the salt being indicated.

8 Names of large volume injections [subclause 3(6)]

The naming of large volume injections is described at subclause 3(6) of this Order. This note provides further guidance to manufacturers in the naming of large volume injections. The ‘non-proprietary name’ should include the name or names of the active ingredient(s), together with a word(s) denoting the name of the dosage form.

The majority of large volume injections contain one, two or three active ingredients and the use of the non-proprietary name which specifies the identity and amount of each active ingredient together with the usual name of the dosage form should not present any difficulty.

However, it would be impractical to include the name of each individual active ingredient in the non-proprietary name for the medicine containing, for example, multiple amino acids. For such products the non-proprietary name can be a general name which categorises the types of active ingredient present.

For example:

‘Amino Acid and Electrolyte Intravenous Infusion’

‘Triglyceride, Phospholipid and Glycerol x% Intravenous Infusion’

The use of a general term such as ‘electrolyte’, ‘carbohydrate’, ‘amino acid’, etc. will be permitted where the product contains more than three active ingredients in one category.

9 Osmolality [subclause 3(6)(h)]

Subclause 3(6)(h) of this Order requires a statement of the ‘osmolality’ on the label of all large volume injections.

Osmolality represents the number of osmols (usually expressed as milliosmols or mOsm) of the solute in a kilogram of water.

The method usually used to determine osmolality is the depression of freezing point which can be readily measured with a fair degree of accuracy.

10 Herbal preparations [subclause 4(11)]

Reference should be made to the TGA publication ‘Guidelines to the Expression of Herbal Ingredients in ARTG Applications and on Labels’ for:

(a) guidance in naming and quantifying herbal substances on labels;

(b) definitions of herbal preparations including ‘extract’ and ‘tincture’; and

(c) abbreviations for names of preparations for use on labels where space is a limiting factor.

11 Homoeopathic preparations [subclause 3(15)]

There are currently no names approved specifically for homoeopathic ingredients. However, sponsors are encouraged to use the equivalent Australian Approved Name wherever possible to provide consumers with consistent terminology for chemical, herbal or biological names.

Similarly to other medicines, the expression of content of the active ingredient on the label should provide information on the final concentration of the active ingredient in the preparation. If the homoeopathic product contains more than one active ingredient, the relative quantities should be stated, for example:

Each 1 mL contains:
ingredient A 5X 300 microgram/L
ingredient B 4X 500 microgram/L
etc.

Or

Contains equal parts of
ingredient A 5x
ingredient B 4x
etc.

12 Dispensing labels

It is recognised that the particulars required to be included on a dispensing label must comply with the relevant State’s or Territory’s legislation relating to dispensing of medicines. Under subclause 1(1)(i), this Order exempts the label of these dispensed goods from the requirements of the Order.

Subclause 1(1)(k) is intended to apply to the situation where a doctor, dentist or veterinary surgeon supplies an individual patient or animal with a dose of a medicine to be taken immediately and/or repacks a small number of doses to be taken away. It is not intended to apply to sample packs supplied by a sponsor to a doctor, dentist or veterinary surgeon and these sample packs are required to comply fully with the requirements of this Order.