



LABELLING REQUIREMENTS FOR IMPORTED MEDICINES

This fact sheet has been written in consultation with Medicines Australia and with the purpose of clarifying the labelling requirements for imported medicines as prescribed by the *Commerce (Trade Descriptions) Act 1905* (the Act) and the *Commerce (Imports) Regulations 1940* (the Regulations).

The Act and Regulations set out the labelling requirements for goods imported into Australia. Customs administers this legislation.

Imported medicines fall within the class of goods described in regulation 7(1)(b) of the Regulations. They therefore require a trade description with the name of the country in which the goods were made or produced and a true description of the goods.

The trade description must be in the form of a principal label or brand affixed in a prominent position and in as permanent a manner as practicable to the goods, for example, on the package that the items are customarily exposed or offered for sale. It is not necessary to mark both the packaging and the medicines.

While the term "true description" is not defined in the Commerce (Trade Descriptions) Act or the Commerce (Imports) Regulations, what is a true description will vary according to the goods. A general guide is to provide a factual description of the medicines in question, and could include brand names or scientific names, the constituent chemicals, or the method of investigation.

Additionally, Regulation 8 specifies that the trade description must be:

- in the English language;
- in prominent and legible characters;
- on a principal label or brand affixed in a prominent position and in as permanent a manner as practicable to the goods; and
- if affixture to the goods is impracticable, to the covering containing the goods.

Any other information included on the label, brand or packaging must not contradict or obscure the required trade description. This includes illustrations, wording or size of lettering.

In addition, the Act prohibits the importation of goods that bear a false trade description. A false trade description can be any description of goods that is false or misleading.

Examples of labelling requirements for import configurations

Imported Pack	Retail Pack	Requirements	Explanation
Retail Bottle of Tablets, Capsules, Liquid or Powder etc.	Same Retail Bottle	<ul style="list-style-type: none"> • Country of Origin • True Description • Label on Bottle 	The retail bottle to be exposed for sale is the <i>same</i> as that imported.
Bulk Drum or Bulk Bottle of Tablets, Capsules, Liquid or Powder etc.	Different Retail Bottles	<ul style="list-style-type: none"> • Country of Origin • True Description • Label on Bulk Drum or Bulk Bottle 	The retail bottles to be exposed for sale are <i>different</i> to that imported.
Retail Box of Blister Packs of Tablets or Capsules etc, or a Retail-boxed Bottle	Same Retail Box	<ul style="list-style-type: none"> • Country of Origin • True Description • Label on Box 	The retail box to be exposed for sale is the <i>same</i> as that imported.
Bulk Box of Blister Packs of Tablets or Capsules etc.	Different Retail Boxes	<ul style="list-style-type: none"> • Country of Origin • True Description • Label on Bulk Box 	The retail boxes to be exposed for sale are <i>different</i> to that imported

Country of Origin under the *Trade Practices Act 1974*

Establishing what is meant by the country or place of origin of goods is sometimes difficult. **Section 65AE** was added to the *Trade Practices Act 1974 (the TPA)* in 1998 to overcome this uncertainty concerning goods produced for the Australian market, and goods produced overseas and sold in Australia.

The scheme consists of a two-step test:

The primary test in section 65AE is a **qualitative measure** which considers that:

- (1) ...goods are **substantially transformed** in a country if they undergo a fundamental change in form, appearance or nature such that the goods existing after the change are new and different goods from those existing before the change.

The secondary test is a **quantitative measure** which refers to the costs of production or manufacture incurred in Australia and other countries.

For example, goods which claim to be 'Made in Australia', must have incurred 50 per cent or more of their total manufacturing costs in Australia.

Goods which claim to be a 'Product of Australia' or 'Produced in Australia' must have 'all or virtually all' Australian ingredients or inputs, and 'all or virtually all' of the steps in the production process must have occurred in Australia.

The costs of production are measured by a system based on the practice of the Australian Customs Service that includes the cost of labour and materials, overheads, and research and development.

Frequently asked questions

Q: Does the requirement to have a *trade description* on the label only apply to packed medicines, and not to in-process (e.g. bulk) medicines?

A: It needs to be on the label on the bulk product (e.g. drum) in which it is imported and on **pre-packed article**, but need not be on the product label ready for sale after being packaged in Australia.

Q: Does a *country of origin* statement need to be on the primary pack (e.g. carton), or can this appear on other packaging (e.g. shippers)?

A: If the product is imported in bulk (e.g. a drum of tablets), the **country of origin** statement must be on the drum or shipper. If it is imported packed in its final sales packaging, the **trade description** must be on the primary pack (e.g. carton).

Q: How do I determine the *country of origin* of medicines that are assembled in different countries?

A: The **country of origin** is the place where the **medicines are substantially transformed** (if they undergo a fundamental change in form, appearance or nature such that the goods existing after the change are new and different goods from those existing before the change), and/or the costs of production or manufacture are 50 per cent or more of their total manufacturing costs.

What if my goods have a false description?

The Commerce (Trade Descriptions) Act provides that goods imported in contravention of the Commerce (Imports) Regulations may be seized by Customs.

While Customs may permit the re-labelling of contravening goods where it is considered that the contravention was neither intentional nor reckless, we recommend that you ensure your goods comply with the legislation prior to their importation.

Where re-labelling is permitted, goods can only be released once the trade description is correct and all Customs formalities have been completed. You may also be asked to provide evidence that you have instructed your suppliers to correctly label goods in future.

Useful links

Commerce Markings on Imported Goods
[Australian Customs Notice No. 2006/39](#)
www.customs.gov.au

Medicines Australia
www.medicinesaustralia.com.au

Trade Practices Amendment (Country of Origin Representations) Bill 1998
www.aph.gov.au

Trade Practices Act 1974
[Section 65 AE\(1\)](#)
www.comlaw.gov.au

For more information

Further information regarding the labelling of imported goods can be found on the Customs website www.customs.gov.au in Australian Customs Notice 2006/39 or by emailing labelling@customs.gov.au

For more information on any Customs matter, contact the Customs Information and Support Centre on 1300 363 263 or email information@customs.gov.au or browse the website www.customs.gov.au