# Australian Government

**Australian Customs and Border Protection Service**

# AUSTRALIAN CUSTOMS AND BORDER PROTECTION NOTICE NO. 2014/49

**Labelling Requirements for Pharmaceutical Goods** -

**Including Medicine**

The Australian Customs and Border Protection Service (ACBPS) administer the labelling requirements for imported goods under the *Commerce Trade Descriptions Act 1905* (the CTDA) and the *Commerce (Imports) Regulations 1940* (the Regulations) at the border.

The CTDA prohibits the importation of certain goods if a false trade description is applied. The Regulations outline labelling requirements in relation to different types of imported goods (for example, specifying that a country of origin and/or a true description must be displayed on certain goods).

The importation of therapeutic goods, as well as the subsequent domestic supply is also controlled under the *Therapeutic Goods Act 1989* (the TG Act) for which the Therapeutic Goods Administration (TGA) has policy responsibility.

Labelling requirements for pharmaceuticals are set out in *Therapeutic Goods Order No. 69* - *General Requirements for Labels for Medicines* (TGO 69), issued under the TG Act. Under TGO 69, country of origin information is not a matter that is required to be on the label.

The Regulations are currently scheduled for sunsetting in April 2016 under the sunsetting provisions of the *Legislative Instruments Act 2003,* unless re-negotiated and re-enacted.

At this time, ACBPS will ensure that any provisions subsequently re-enacted will be in line with the current Australian Government policy.

In the interim, ACBPS will cease to enforce the CTDA and the Regulations regarding country of origin labelling on imported pharmaceutical products.

Importers will still be expected to satisfy the requirements of the *Therapeutic Goods Act 1989* and TGO 69 when importing and supplying pharmaceutical products and, under the CTDA, will still be required to provide a true and accurate description of the goods on the packaging which will not mislead a consumer as to the nature of the goods.

If the importer chooses to include the country of origin on the goods, it must be accurate. Additionally words and imagery included on the label must not mislead the consumer as to the country of origin where this is not specified on the label (for example, a display of the Australian flag, or the use of a phrase such as "Australian owned").

The Intellectual Property and Consumer Goods team is the primary point of contact in ACBPS regarding the policy surrounding the labelling requirements for Pharmaceutical Goods including Medicine and enquiries can be forwarded to the labelling mailbox at [labelling@customs.gov.au](mailto:labelling@customs.gov.au) .

Enquiries concerning this notice may be directed to the Director Community Protection on telephone number (02) 6275 6642 or by email to [community.protection@customs.gov.au.](mailto:community.protection@customs.gov.au)



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December 2014