



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

EXPORTING MEDICINES FROM AUSTRALIA

OPERATIONAL GUIDELINES

Export Medicines Unit
TGA
September 2004

These guidelines should be read in conjunction with the document "*Policy for Export of medicines from Australia*" which outlines the objectives of the Australian regulatory system for export medicines and the relevant legislative framework. The aim of these guidelines is to enhance transparency in the operations of the Export Medicines Unit of the TGA and ensure consistency in the administrative processes which support the Therapeutic Goods legislation.

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1. COMMERCIAL EXPORT OF MEDICINES

Generally, any medicine which is being exported for commercial purposes must be either:

Goods not required to be in the ARTG are detailed in Schedule 5 to the Regulations

- listed in the ARTG for export only;
- listed or registered in the ARTG for supply in Australia; or
- have been granted an exemption by the TGA from the need to be in the ARTG under Section 19 of the *Therapeutic Goods Act 1989* (the Act), for example, goods for experimental uses.

Anyone who is intending to export a medicine from Australia for commercial supply which is not included in the Australian Register of Therapeutic Goods (ARTG), with the name of the exporter as the sponsor, can either:

- Submit an application to include the goods in the ARTG prior to export as the sponsor of the goods; or
- Arrange the exportation of the goods on behalf of the sponsor who already has the medicines included in the ARTG.

Exporters should also check that they meet any State or Federal laws regarding the procurement and storage of medicines, (eg. State poisons legislation) and other relevant legislation such as Trademarks, Patents, Wildlife Protection, Customs and Quarantine.

Special requirements exist for the export of drugs such as narcotics, psychotropic substances, or their precursors. These are listed in the various schedules of the *Customs (Prohibited Exports) Regulations*. Sponsors can also refer to the TGA website under Medicines going out of Australia at: <http://www.tga.gov.au/export/index.htm>.

2. EXPORT OF MEDICINES FOR DONATION OR HUMANITARIAN PURPOSES

Therapeutic goods can be exported without being on the ARTG if they are intended as donations or humanitarian aid, provided they have been obtained legally and they meet the criteria below.

To qualify for exemption they must not :

- be for commercial supply;
- contain a controlled substance under the *Customs (Prohibited Exports) Regulations* unless an export licence and permit are held; and
- be intended for clinical trials on humans.

The Australian Pharmaceutical Advisory Council has produced a publication entitled *Australian Guidelines for Drug Donations to Developing Countries*. Exporters can obtain a copy by calling (02) 6289 8023. The document is based on the *World Health Organization (WHO) Guidelines for Drug Donations*. It is strongly suggested that intending exporters of medicines for donation read and observe the nine articles of the guidelines.

Note: Donations should not include medicines with an expired 'use by' date. Donating medicines for which Pharmaceutical Benefits were paid is prohibited.

3. EXPORT OF HUMAN BODY FLUIDS / TISSUE

The exportation from Australia of human body fluids including blood, organs and substances derived from human blood is prohibited, unless:

- an export permit has been obtained from the Export Medicines Unit of the TGA; or
- the internal volume of the immediate container in which the material is packed exceeds 50ml (excluding blood products).

These requirements exist, *inter alia*, to ensure that blood and related products (eg, immunoglobulins, factor VIII), which are sourced from volunteer donations within Australia, are not exported without the knowledge and advice of the Australian Red Cross. This will help avoid the situation where these goods are in short supply in Australia.

The legislative basis for these requirements is found in Regulation 8 and Schedule 6 of the *Customs (Prohibited Exports) Regulations*.

4. ASSESSMENT PATHWAYS

Sections 26A and 26 of the Act

As soon as the Export Electronic Lodgement System (EEL) is operational, there will be two potential assessment pathways for medicines which are intended only for export and are not approved for supply in Australia. Export medicines which will be listed under Section 26A will follow the same assessment process as other medicines listed for supply in Australia (ie via ELF), whereas export medicines listed under Section 26 of the Act will undergo a manual assessment by TGA staff to ascertain their safety and quality. Currently all export medicines are listed under Section 26 of the Act and require submission of a paper application.

5. SEPARATE AND DISTINCT GOODS

Section 16 of the Act

The Therapeutic Goods Act defines how “different” a therapeutic good can be from a product already in the ARTG before it actually becomes a separate product for the purposes of the legislation. Each product in the ARTG is a “separate and distinct” good which has a separate entry. However, in some circumstances products can be “grouped” together and share the same AUST L or AUST R number. These circumstances are outlined in the Therapeutic Goods (Groups) Order No. 1 of 1992.

There is a different definition of separate and distinct good which applies to medicines which have been certified and validated as eligible for listing under Section 26A compared to those that are listed under Section 26 of the Act. Sponsors who have listed export medicines under Section 26A of the Act are able to make certain changes to the goods (eg container type, quantities of excipients) without the need for a new application to be submitted to the TGA. These differences are summarised in the table below.

Export medicines which are eligible to be listed for supply in Australia (Section 26A)	Export only medicines (Section 26)
<u>Section 16(1A) of the Act</u> <ul style="list-style-type: none"> ● different active ingredients ● different quantities of actives ● different dosage form 	<u>Section 16 (1) of the Act</u> <ul style="list-style-type: none"> ● different formulation ● different strength ● different dosage form ● different name ● different indications ● different directions for use ● different container
<u>Section 11(1) of the Regulations</u> <ul style="list-style-type: none"> ● different name ● different indications ● different excipients ● different quantity or concentration of a restricted ingredient 	

Directions
for use

Where different directions for use have been approved in the destination country (compared to those entered for the product in the ARTG) a new or grouping application is only required if these extended directions for use appear on the product label or in product information accompanying the goods as they are exported. Any additional information added after the product is actually exported from Australia is not relevant in determining whether the product is a separate and distinct good.

→ For an explanation of what constitutes a ‘different’ product name see Appendix 1.

6. STANDARDS

Export
goods must
comply with
applicable
standards

The sponsor [exporter] provides an assurance through a signed declaration that the medicine intended “solely for export” meets the required quality standards as set down by Chapter 3 Part 3-1 of the Therapeutic Goods Act and other prescribed quality criteria outlined below. Under Chapter 3 Part 3-1 of the Act, exported products must comply with relevant monographs of the British Pharmacopoeia (BP) or Therapeutic Goods Order (TGO) No. 70 for Export Only Medicines, where applicable (or amendments to TGO No. 70). The TGO for Export Only Medicines permits medicines to be exported which comply with standards other than the BP, including the current edition of the United States Pharmacopoeia (USP) and the Japanese Pharmacopoeia, provided that the sponsor holds evidence that these standards are accepted in the importing country.

Other Therapeutic Goods Orders (eg TGO No. 56 for capsules and tablets) may also apply unless an exemption under Section 14 of the Act has been granted by the TGA. If the product does not meet an applicable standard, a request for an exemption (including justification) must be provided as part of the application for listing of an export only medicine. The standard (TGO No. 69) relating to the labelling of the goods for supply in Australia does not apply to solely for export medicines. There is therefore no requirement for the AUST L number to be included on the label of a solely for export medicine.

7. THE ASSESSMENT PROCESS

Export medicines eligible for supply in Australia – assessed under Section 26A of the Act

Export
medicines
eligible for
listing in
Australia

In accordance with the model for listed medicines for supply in Australia, labelling will not be required to be submitted at the time of electronic lodgement of the application for solely for export medicines which would also be eligible for listing for supply in Australia. Sponsors will be required to declare as part of the electronic application that the finished product label includes all mandatory warnings relevant to the eligibility for listing of the good (for potential supply in Australia) and that the product complies with any relevant standards. Sponsors also need to declare that the product is not of an unacceptable presentation as part of the electronic application. For further information on unacceptable presentation refer to the TGA publication *Policy for the Export of Medicines from Australia*.

A random sample of solely for export medicines listed under Section 26A of the Therapeutic Goods Act will be selected for a full review post-listing. If selected for a review, the Export Medicines Unit will request the following material to be submitted to confirm “solely for export” product compliance with the necessary standards and criteria:

- certificates of analysis or product specifications (if certificates of analysis are not available); and/or
- product labels, product information, patient/consumer information and package inserts, if any.

Export only medicines – assessed under Section 26 of the Act

Medicines which are only listable because they are for export only

Products containing substances, quantities of substances or labels without mandatory warning statements required for listing for supply in Australia which would require registration for domestic supply [ie “registrable type medicines”] will be assessed under Section 26 of the Act. These applications will be subject to a product compliance assessment by the Export Medicines Unit before a decision is made to list the products. Individual active ingredients will generally not be evaluated, other than substances of human origin or certain substances of animal origin. For finished products, it is a condition of listing that the finished product label will include any warning statements required by the importing country.

Any material which is supplied with medicines which would require registration to be supplied to the Australian market (including product information and package inserts included as part of the exported product), must be attached to the listing application.

The TGA uses the submitted material to make a decision on the acceptability of the medicine’s presentation and safety for intended purpose of use. Issuing of an ARTG “solely for export” listing certificate does not mean (nor imply) that the TGA has approved or endorsed any of the submitted material and this information will not be certified by the TGA as part of export certification.

Any product material (eg packages inserts) which is physically added after the product is exported from Australia is not subject to control by the TGA. Similarly, the TGA does not have any regulatory controls over the overseas packaging and labeling of a finished product which has been exported as bulk from Australia.

8. GOODS EXPORTED AS BULK PRODUCT

Refer Section 16 of the Act “separate and distinct goods”

Often goods which have been approved for supply in Australia are also exported in bulk for further packaging and/or labeling overseas. Where the goods to be exported are registered in the ARTG for supply in Australia, the export bulk product is generally a separate and distinct good as the container type is different or the product name is different or the indications for use and/or directions for use are missing. A separate export only listing application must therefore be submitted for the bulk product. Where the finished good is a listed product for supply in Australia, the same considerations do not apply other than the product name. However, certain types of goods are only listable for supply in Australia if the product label contains certain statements or warnings. If this is a requirement for listing and the label of the bulk product to be exported does not include these statements then the product no longer meets the criteria for eligibility for listing for supply in Australia and an application for an export only listing must be submitted.

Labels of bulk goods may be requested, as the details included in the label are relevant to the safety and quality of the product when it reaches its destination. The information on a bulk label is the primary identifier for the goods and would be subject to normal GMP requirements in respect of inclusion of a unique product name identifier, batch number, storage conditions and identification of the exporter or manufacturer. If the product is exported in bulk, it is not mandatory to include therapeutic indications in the listing application form.

9. STABILITY STUDIES AND SHELF LIFE

The stability of a product is relevant to the safety and quality of a product as noted in the 32nd report of the *WHO Expert Committee on Specifications for Pharmaceutical Preparations*. The *Australian Code of GMP for Medicinal Products (2002)* also requires that data is available to support the claimed shelf life of the product. While the existence of a stability program may be checked by the Manufacturer Assessment Section (MAS) during audits of Australian manufacturers, the Export Medicines Unit would only request stability data to be provided by sponsors where safety concerns are identified which relate to the stability of the product. It is the responsibility of the sponsor to be in possession or to have ready access to stability data in accordance with the declaration in the application for listing of solely for export medicines.

Stability data must be based on stability studies for each product. Where a shelf life is unusually lengthy in comparison with like products, evidence may be requested that the expiry date is acceptable to authorities in the export destination.

In order to clarify the responsibility of sponsors in this matter, the following condition of listing applies:

Condition
of listing

The sponsor shall hold stability data to support the claimed shelf life of the listed medicine according to the labelled storage conditions. The sponsor will provide stability data to the Director, Non-Prescription Medicines Branch, Therapeutic Goods Administration, upon request, except where the overseas importer accepts responsibility for stability studies. When an overseas importer accepts responsibility for providing stability data for this product, it is the sponsor's responsibility to ensure that they have a written agreement to this effect from the overseas importer. The sponsor will provide a copy of this agreement to the Director, Non-Prescription Medicines Branch, Therapeutic Goods Administration, upon request.

(note: the Manufacturer Assessment Section expects that the GMP agreement between the manufacturer and the overseas purchaser should clearly reflect this arrangement).

Where the product is registered for supply in Australia and the sponsor wishes to nominate a different shelf life for export of the product, a solely for export application must be submitted. If the product is already listed for export and the sponsor wishes to increase the nominated shelf life an application to vary the details held in the ARTG must be submitted (see changes table).

Following approval of a solely for export medicine, a *Certificate of Listing for Export Only* is issued by the Export Medicines Unit which specifies any conditions which the sponsor is required to meet. Failure to comply with these conditions is grounds for cancellation of the product from the Australian Register of Therapeutic Goods.

10. MANUFACTURE – GOOD MANUFACTURING PRACTICE

Manufacturers
are assessed
for GMP

Australian manufacturers must be appropriately licensed for the steps of manufacture involved. If an application is being made under Section 26A of the Act, pre-clearance of all overseas manufacturers from the Manufacturer Assessment Section is mandatory prior to lodging the application. While pre-clearance of overseas manufacturers is not mandatory for other solely for export applications, it is strongly encouraged. GMP evidence is not required for manufacturers of active raw materials. However, the Export Medicines Unit cannot certify manufacturing details as part of export certification if they are not held in the ARTG.

Often a pre-clearance can be obtained which applies across a range of products or activities and it can then be submitted with any relevant application to the TGA provided that the product and manufacturing step falls within the scope of the pre-clearance. Where a pre-clearance has not been obtained, the covering letter to the application should clearly identify if evidence of GMP for the manufacturer/s and type of product has previously been reviewed in relation to another application. The enterprise number of the manufacturer should also be provided to facilitate confirmation of the specific record in the GMP Audit & Licensing overseas database.

Certificates of Pharmaceutical Product or Listed Product include a statement that “For overseas manufacturers evidence of satisfactory GMP compliance has been supplied”.

11. EXPORTING MEDICINES WHICH HAVE BEEN APPROVED FOR SUPPLY IN AUSTRALIA.

Currently under Section 16 of the Act, the only allowable differences between the product permitted for supply in Australia and the product being exported are:

- the name of the product (a product may have a number of different export names included in the Australian marketing authorisation but misleading names or names that may lead to unsafe use are not permitted);

- certain minor differences to the label of the product. Relatively minor changes may be made to labels when the product is being exported (eg colour, font size, direct translation to allow for local language requirements etc) but the differences must not fundamentally change the content of the labels. While the wording of the label claims may vary slightly to account for cultural differences, they must be consistent with the approved indications for the product in the ARTG.

If the export “version” of a product which is listed or registered for supply in Australian includes differences in formulation, container, shelf life, indications, directions for use, label warning statements etc then either:

Export
'versions'
of
Australian
approved
medicines

- a new application / grouping or variation application must be submitted through the appropriate processing area of TGA for approval of this change to also apply to the Australian approved product; or
- an export only listing application (new or grouping) needs to be lodged.

If a sponsor wishes to export a medicine with a different product name to the product which is approved for supply in Australia, an export grouping application must be submitted unless the alternative name is already specified in the ARTG (eg it was included in the original application for listing or registration). Product names are not linked to a specific country and may be used for any destination country other than where a specific condition of listing or registration restricts export to nominated countries.

Where it is a condition of listing that export is permitted only to specified countries, sponsors may request in writing that this condition be removed or amended at any time. The Export Medicines Unit will review such requests on a case by case basis, taking into consideration the reasons for the restriction and any further documentation provided by the sponsor relevant to the overseas availability of the product.

Refer to the changes table for further details on specific changes to existing products and the need for an application to be submitted.

Export certification

Export
clone of an
Australian
approved
product

The TGA recognises that overseas authorities in the importing country often require changes to an Australian approved product label which can then lead to the creation of a separate and distinct good from the Australian approved product. For the purposes of export certification, where the product to be exported differs from the product listed in the ARTG for supply in Australia only in respect of packaging (including different indications, different directions for use or label warning statements), sponsor should also complete the *Supplementary form for Applying for Export Certification* identifying the “Australian” approved product. Where the AUST L or AUST R number is not known sufficient information must be provided to allow the Export Medicines Unit to confirm the identity of the Australia approved product in the ARTG.

Provided that the TGA is satisfied that the formulation of the export medicine is identical to the medicine approved for supply in Australia, the following standard TGA statement will be included on the export certificate:

“This product has been approved by the TGA and may be freely sold (in that it can be legally supplied) in Australia provided that it is labeled to meet Australian requirements. The label of the product for export has been modified to meet the requirements of the importing countries”.

Obviously, the requirements of governments overseas will vary greatly with regard to registration of medicine. These requirements should be thoroughly checked by the sponsor of the goods before

applying for approval, as generally the TGA is not in a position to give advice on the policies of other countries. However, exporters may contact the Export Medicines Unit if difficulties are encountered in accessing overseas markets due to export certification concerns. This will assist in identifying foreign regulatory agencies, which the TGA may need to contact to clarify aspects of the Australian regulatory system.

12. UPDATING THE ARTG RECORD

⚡ Fees

\$490
New or
grouping

\$240
Variation

Generally, any amendments to details which are held for the product in the ARTG or other information that was relevant to the decision to list the goods requires an application form to be submitted. The type of form to be submitted depends on what details are being changed. Changes to product details specified in Attachment 1 require either a new listing application, a grouping application or a variation application to be submitted to the TGA. If you wish to make a change which is not specified in the list please contact the Export Medicines Unit to confirm whether an application is required.

Currently only one fee is payable where a grouping and a variation are applied for simultaneously as a single application. For example if there are changes to indications or directions for use in addition to a change to manufacturer details, the sponsor may apply for a grouping and a variation in the same application with only one fee of \$490. However, if the grouping and variation application are submitted as separate items, two fees will apply (eg \$490 and \$240 respectively). There is no annual charge to maintain the export listing in the ARTG.

Formulation or manufacturing details, which are included as part of a Certificate of Pharmaceutical Product or Certificate of Listed Product, must be consistent with the ARTG record. If sponsors have previously submitted an application to change these details and the ARTG has not been updated, or the entry is incorrect, the relevant processing area (eg Australian Listed Medicines Unit, OTC Evaluation Section, Drug Safety and Evaluation Branch or the Export Medicines Unit) must be contacted to make the changes. The Export Medicines Unit is only authorised to make changes to solely for export listings. The CPP cannot be issued until the ARTG record has been amended accordingly. It is therefore strongly recommended that sponsors do not apply for export certification until notification has been received that the ARTG details have been updated.

If the product details have otherwise changed, a new application, grouping or variation may be required. Contact the relevant processing area of the TGA for further information.

13. LABEL WARNING STATEMENTS, MATERIAL OF HUMAN/ANIMAL ORIGIN, NEW SUBSTANCES AND PRESENTATION OF THE PRODUCT

Further guidance on these specific issues is in the TGA publication *Policy for the Export of Medicines from Australia*.

14. APPLICATION FORMS and GUIDES TO COMPLETING THE FORMS

Copies of the most current version of the following application forms can be downloaded from the TGA website: <http://www.tga.gov.au/export/index.htm#forms>.

TGA
Internet
address

- Application for a new listing of an export only medicine in the ARTG
- Application for grouping or variation to an existing export only medicine
- Application for new listing of non-sterile bulk medicine for export only
- Application for Certificate of Pharmaceutical Product
- Supplementary form for applying for export certification

15. TARGET TIMEFRAMES - MAKING SURE THAT YOUR APPLICATION IS NOT REFUSED OR DELAYED UNNECESSARILY

The target timeframes for processing of listing applications is 30 working days and for export certification (CPPs) the target is 15 working days. In order for the Export Medicines Unit to meet these relatively tight timelines, sponsors are urged to take care with completing application forms to ensure that all of the details are current and correct. Applications for export certification which are resubmitted following initial advice from the Export Medicines Unit and still contain errors will be refused.

While there are detailed guidelines to completing the application forms available, it is in the interest of sponsors to ensure that several key criteria are met in order for applications to be processed efficiently. These criteria include:

- typing mistakes in the application or schedules
- missing schedules
- incorrect information in the application or schedules (different sponsor's name, information in the schedules referring to a different product, AUST R/L, formulation or label submitted for a different product)
- incorrect manufacturing details in schedules
- inconsistent numbers of schedules supplied for the number of Certificates requested
- incorrect boxes ticked
- application signed by an unauthorised person (instrument of appointment not submitted when requested)
- application or declaration missing signature, date, name and position in relation to sponsor
- invalid instrument of appointment submitted
- application not filled in according to the Guides (information submitted not presented in the correct format)
- ingredients in the formulation not in the approved terminology (ingredients not in AANs, units and other information not according to the Approved Terminology for Medicines book).

Timeframes are linked to the standard of the application

Please also refer to *Avoiding rejections in requests for Certificates of Pharmaceutical Product (CPP)* on the TGA website – <http://www.tga.gov.au/export/index.htm>.

The number of applications which are submitted with the above types of discrepancies, directly impacts on the ability of the Export Medicines Unit to achieve target timeframes.

16. FUTURE DIRECTIONS FOR THE REGULATION OF EXPORT MEDICINES

These guidelines reflect the current practices and interpretation of TGA policy and the therapeutic goods legislation. It is acknowledged that improvements can always be made and a number of steps have been taken to ensure the continuation of effective, flexible export controls through the co-operative efforts of the key Industry Associations and the TGA. An electronic lodgment system which will allow sponsors to submit applications for listing of export only medicines and export certificate online is being developed as part of this commitment. However, significant changes can generally only be brought about through legislative reform. This document will be updated progressively to reflect these changes.

Interpretation of ‘name’ for goods in the ARTG

Under Section 16 of the Act goods are regarded as “separate and distinct” if they have a different product name from other goods in the ARTG. For the purposes of determining whether medicines have a different product name, the information which appears on the label(s) attached to the goods (eg printed on the package or container) when the goods are exported is considered. The ‘name’ is regarded as including one or more of the following:

- ➔ Specific registered trademark given to the product (‘proprietary name’);
- ➔ A unique word or code given to the product;
- ➔ A description of unique characteristics of the product (‘non-proprietary name’);
- ➔ A registered trademark or other unique name, mark or logo belonging to the manufacturer or supplier (eg company trading name), which appears prominently on the label other than as an integral part of the information giving name and address of the exporter/manufacturer/distributor;
- ➔ A registered trademark or other unique name, mark or logo belonging to the manufacturer or supplier (eg trading name) which as an integral part of the information giving name and address of the exporter/manufacturer/distributor in a prominent location on the main label in letters of equal or greater size than is used for the name of the active substances in the goods.

Changes table for solely for export medicines

A notifiable change may be implemented before formal approval is received of the change, following submission of an application.

Product detail changes	Application type	Details
Change to product name	Grouping	Grouping to replace existing listed or registered medicine
Export only name – change or addition	Grouping	Grouping to add a different export only name to an existing listed or registered medicine - notifiable
New therapeutic claims/ indications	Grouping / new*	Grouping to add different indications to an existing export only listing else new application
Therapeutic claims/indications – change of wording or removal of some or all indications	No application required	If a change of wording the intent must remain the same
Directions for use	Grouping / new*	Grouping to add different directions for use to an existing export only listing else new application
Dosage form	New	
Change in source of animal ingredient	Variation	
Visual identification	Variation	notifiable
Shelf life – increase or decrease	Variation	Required only for <u>sterile</u> products (notifiable if in accordance with stability testing protocol)

* Note : if the new label is not available when these changes are made, the revised label may be submitted within 6 months of the date of submission of the application provided that this information remains consistent with that entered in the ARTG.

Formulation changes - Actives	Application type	Details
Addition of an active ingredient	New	
Deletion of an active ingredient	New	
Change in the amount of an active ingredient	New	
Formulation changes - excipients	Application type	Details
Removal or addition of fragrance, flavour or colouring	Grouping	Grouping to replace an existing listed or registered medicine
Addition or deletion of an excipient other than above	New	
Change in the amount of an excipient	Grouping	Except export only listings approved under Section 26A of the Act
Type of starch	Variation	notifiable

Packaging changes	Application type	Details
Change from Bulk product to finished product	Variation	For export only listings processed under Section 26A of the Act
	New	For export only listings processed under Section 26 of the Act (refer also container type)
Change from finished product to bulk product	No application required	
Immediate container size	Variation	For export only listings of <u>sterile</u> products processed under Section 26 of the Act
	No application required	For export only listings approved under Section 26A of the Act no application is required
Secondary pack size	No application required	Provided that the only change to the outer carton label is the change in pack size
Container type	New	For export only listings processed under Section 26 of the Act
	No application required	For export only listings processed under Section 26A of the Act other than a change from bulk product to finished good

Manufacturer changes – finished product	Application type	Details
Manufacturer – Australian or overseas	Variation	If adding an overseas manufacturer evidence of GMP required or GMP preclearance number. If change relates to an Australian licensed manufacturer then notifiable. Not required for manufacturer of active raw material.
Steps in manufacture – Australian or overseas manufacturer	Variation	If change relates to an Australian licensed manufacturer then notifiable.
Label changes (including package insert)	Application type	Details
Manufacturer, supplier, sponsor details on label	None	Forward copy of label to Export Medicines Unit
Colour, font, type size only (no change in label copy)	None	
Addition of more restrictive safety related statements	None	Forward copy of label to Export Medicines Unit
Changes on label: warning, caution	Variation	Notifiable