Policy for the export of medicines from Australia

August 2007
About the Therapeutic Goods Administration (TGA)

- The TGA is a division of the Australian Government Department of Health and Ageing, and is responsible for regulating medicines and medical devices.

- The TGA administers the Therapeutic Goods Act 1989 (the Act), applying a risk management approach designed to ensure therapeutic goods supplied in Australia meet acceptable standards of quality, safety and efficacy (performance), when necessary.

- The work of the TGA is based on applying scientific and clinical expertise to decision-making, to ensure that the benefits to consumers outweigh any risks associated with the use of medicines and medical devices.

- The TGA relies on the public, healthcare professionals and industry to report problems with medicines or medical devices. The TGA investigates reports received by it to determine any necessary regulatory action.

- To report a problem with a medicine or medical device, please see the information on the TGA website.
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Introduction

The export of medicines including prescription, OTC and complementary (e.g. vitamins, mineral supplements and herbal products) medicines from Australia is regulated by the Therapeutic Goods Administration (TGA) to protect human health and safety by ensuring that medicines originating from this country are of a similar quality and safety standard as those supplied domestically.

The TGA is first and foremost a regulator of medicines for supply in Australia. Exports are important to the future of the Australian medicines manufacturing sector. The TGA is committed to the development of streamlined and responsive regulatory and administrative processes that protect public health and safety and support the export of quality therapeutic goods from Australia.

The key purpose of this document is to delineate the role of the TGA in export regulation. Part A of the document comprises the policy framework or strategic commitments given by the TGA in relation to export regulation. These support and direct the TGA’s export-related actions outlined in Part B.

Background

Following the Industry Commission’s Report on the Pharmaceutical Industry¹ and the Review of the Therapeutic Goods Administration², the TGA commissioned an independent examination of the regulatory regime for the export of medicines.³ This lead to the introduction of new export procedures and initiatives, and re-aligned the then existing export processes, which formed the basis of the TGA Policy for the Export of Medicines that was formulated in 2002. The policy has since been revised on a regular basis.

The TGA Policy for the Export of Medicines from Australia 2007 supersedes the TGA Policy for the Export of Medicines from Australia 2002 and other TGA policy positions and statements on export regulation. The key objective of this policy is to confirm TGA’s commitment to protect public health and safety through the export of quality, safe medicines, and to help prevent the manufacture and sale of sub-standard and counterfeit medicines around the world.

The integrity of Australia’s export regulatory system - including export certification - relies on the quality of information provided to overseas authorities. The commitment of Australian sponsors to provide high quality factual information in applications supports the reputation of the TGA and the Australian medicine export industry.

An overview of the structure and operation of Australia’s medicine regulatory system is routinely included as part of export certification (refer attachment 3). Further operational information on the processes for exporting medicines is also located on the TGA website (www.tga.gov.au).

² KPMG, Review of the Therapeutic Goods Administration on behalf of the Department of Health & Family Services, The Department of Health and Family Services, Canberra, January 1997
Part A: Policy framework

The following strategic commitments are given in relation to export regulation:

A1. Quality and safety assurance for exports

Commitment to the implementation of an export certification system (issued under Section 58 of the Therapeutic Goods Act, 1989) that supports the international competitiveness of medicinal and other therapeutic products exported from Australia through the provision of a suitable standard of regulatory assurance regarding the quality and safety of export goods.

A2. Customer Service and Focus

Commitment to a professional and timely customer focussed service.

A3. Efficiency of domestic regulation

Recognition that:

• the majority of medicines exported from Australia are also authorised for supply to the domestic market;

• one of the most important factors for companies maintaining competitiveness in international export markets is response times to export opportunities; and,

• the timeliness of Australia’s domestic approval process and the efficient administration of our regulatory system are key factors in enhancing the competitiveness of exporters of therapeutic goods.

A4. International Obligations

Commitment to the protection of public health and safety through the export of safe medicines of an appropriate quality and continued participation in international arrangements that have the objective of preventing the manufacture and sale of sub-standard and counterfeit medicines around the world.

Australia is a participant in the World Health Organization (WHO) Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. The TGA has also assisted in the development of the WHO Guidelines for the Development of Measures to Combat Counterfeit Drugs (1999) and participates in training and surveillance programs to combat counterfeit medicines. Complementary medicines are included in the legislation governing export since the TGA recognises the role of complementary medicines in the general healthcare.
A5. Best Regulatory Practice

One of the goals of the regulation of export certification processes for therapeutic goods is to be consistent with Government regulatory best practice principles.4

Exports are considered one of the drivers of Australia’s economic growth. The Australian Government encourages the development of a sustainable manufacturing exports sector and is committed to enhancing the international competitiveness of this sector by reducing regulatory burdens and minimising business compliance costs.

Export regulation of medicines:
- is designed to ensure that medicines leaving Australia meet appropriate safety and quality standards in order to support public health internationally,
- promotes flexibility to encourage the development and manufacture of export product,
- is administered in a streamlined, responsive and timely manner; and
- supports market confidence in the quality of Australian products.

In the interest of supporting trade in quality and safe medicines and ensuring the appropriate understanding of Australia’s export certification, the TGA appropriately refers matters to, and liaises with other Australian Government agencies charged with responsibility for trade and industry facilitation.

A6. Risk-based regulation

The risk-based regulation of medicines:

6.1 The level of regulatory control of medicines in Australia is commensurate with the assessed risk posed by the product to public health and safety. Export medicines are assessed for general safety and must meet standards for quality equivalent to those for the domestic market5.

6.2 Australia recognises that most other countries have their own regulatory systems which take into account national clinical and cultural differences relating to the use of medicines by their community. The regulation of export medicines supports flexibility in working with industry to meet the requirements of other countries while maintaining market confidence in the quality and safety of the product.

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4 Principles and Guidelines for National Standard Setting and Regulatory Action by Ministerial Councils and Standard Setting Bodies/by Council of Australian Governments (COAG), Canberra: COAG, 2004

5 Therapeutic Goods Order No.70 B for export only medicines permits the export of medicines which meet specific alternate internationally recognised standards such as the United States Pharmacopoeia, European Pharmacopoeia and the Japanese Pharmacopoeia.
A7. Promotion of Australia’s quality export certification processes

Promotion of the quality and safety assurance provided by Australia’s therapeutic goods regulatory system in consultation with the local therapeutic goods industry.

7.1 The TGA will maintain ongoing contact and discussions with overseas regulatory authorities, the World Health Organization and other international agencies in order to:

- enhance the transparency and relevance of information provided on export certification exchanged between agencies;
- promote confidence in the quality and safety of medicines authorised for marketing in this country and/or intended for export; and
- as appropriate, reflect the outcomes of these processes in exchanges of letters and agreements on export certification.

7.2 One of the primary reasons for the initial adoption of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce was to ensure that all countries have equal access to information on the quality and safety of imported medicines. The TGA recognises that many countries are working progressively towards implementation of appropriate regulatory systems and that there are varying degrees of reliance placed on export certification from the exporting country. However, in support of the objectives of the WHO scheme, the TGA communicates appropriate additional information to overseas authorities, via export certificates. Australia respects the regulatory systems of other countries and regulatory agencies in export destinations have full discretion in the use of the information provided on certificates.
Part B: TGA Export-related regulatory and administrative processes

The TGA’s regulatory and administrative processes relating to the export of medicines are underpinned by the framework provided by the *Policy for the Export of Medicines from Australia.*

This section outlines the activities of the TGA in its role as:

a. the regulator for medicines for export, and

b. a point of support and referral for exporters of medicinal products regarding trade and industry issues relating to the export regulatory environment for medicinal products.

B1. Regulatory Role

The TGA:

- Requires that medicines exported from Australia comply with necessary quality and safety standards;
- Approves the supply of medicinal products in Australia and for export;
- Issues export certificates (including certificates issued under the WHO Scheme); and
- Communicates with other regulatory authorities to maintain awareness of any potential quality and safety issues.

1.2 Evidence based decision making

Documented evidence is considered in relation to the application of required product standards and manufacturing principles and product presentation and representations that may influence safe use. The TGA decision to approve medicines for export is based on whether this documented evidence in conjunction with certain assurances from the exporter are sufficient to support the quality and safety of the medicine.

1.3 Medicines approved for supply in Australia which are exported

Medicines *permitted for supply to the Australian domestic market* are automatically permitted for export by the sponsor or their agent, subject to other applicable export legislation such as Customs, Quarantine, and Environment Australia etc.

Many medicines exported from Australia fall into this category, that is, they have an authorisation to supply to the domestic market. The only allowable
differences between the product permitted for supply in Australia and the product being exported are:

- the name of the product;
- certain minor differences to the label of the product.

In some cases approval to supply the product in Australia is subject to inclusion of specific label warning statements. If the product is also to be exported, these warning statements must remain on the label in order for the Australian approval to extend to the exported product. Warning statements may only be omitted where the product is solely for export.

1.4 Quality and safety requirements for export medicines

Medicinal products for export from Australia that are manufactured exclusively for export and can not be supplied in Australia including Australian duty free outlets, and that have to be listed “as export-only medicines or solely for export medicines”, must:

- comply with required quality standards and prescribed quality and safety standards;
- be manufactured according to Good Manufacturing Practice (GMP) principles;
- be of acceptable presentation and not make false or misleading representations;
- be safe for their intended purposes; and
- not have been imported without an appropriate import licence or permit where required under Australian Customs legislation.

Medicinal products which are not finished products as they are exported in bulk and then packaged/labelled and released for sale overseas are required to be approved by the TGA for export.

Many export products are similar to products sold on the Australian market (for instance, they may have minor variations to formulation, different presentation or are transported in bulk). Some higher risk products (which would require a full evaluation for approval for supply in Australia) may have exactly the same formulation but are not considered to be the same product if they are packed in different container types (eg bottles, blister pack, bulk pack etc).

Label warning statements

Often warning statements are associated with the types of indications permitted for the product within the regulatory framework of the destination.

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7 Label claims must be consistent with the indications included for the product in the Australian Register of Therapeutic Goods.
8 Export-only medicines are listed on the Australian Register of Therapeutic Goods under Section 26 of the Therapeutic Goods Act 1989 (the Act), whereas Solely for Export medicines are listed under Section 26 A of the Act (Refer Section 26 and Section 26 A of the Therapeutic Goods Act 1989).
9 GMP evidence is not required for the manufacture of active raw materials.
country (e.g., depending on whether the product is regulated as a food or drug on the export market). While product labels must be submitted for medicines assessed under Section 26 of the Act, these labels are not assessed for the presence of appropriate warning statements. And, if a product is assessed under Section 26A, labels are not required at the time of listing. However, considering the growing number of warning statements that are required in Australia for non-prescription medicines, it is expected that sponsors will act responsibly and include appropriate warning statements which are relevant to the safe use of the product for the intended overseas market. The following condition of listing applies to export medicines approved under Section 26 or Section 26A of the Act: “It is the responsibility of the sponsor to ensure that any necessary warning statements are included on the product label as required by the destination countries”.

The Australian standard (i.e., the Therapeutic Goods Order No. 69) for labelling of goods for supply in Australia is not applicable to labels for export medicines.

**Material of human/animal origin**

The TGA approach to minimising the potential risk of exposure to Transmissible Spongiform Encephalopathies (TSEs) through the use of medicines also encompasses export medicines. Products which contain any human material or materials identified in Category 1 or 2 of the European Guidelines (i.e., high and medium infectivity risk) require a pre-clearance through the Therapeutic Goods Administration Laboratories (prior to submission of the listing application).

If the product contains certain ingredients of human/animal origin that may potentially transmit TSEs, sponsors will be asked to provide details of the specific species/tissues and the country of origin in the electronic listing application. These and other details such as the source of feed for the animals and the health status of the animals as certified by a veterinarian should also be provided to the TGA Laboratories as part of the process of obtaining a Pre-clearance for the use of the animal origin ingredient in the export product formulation.

If the country of origin is not a known BSE-free country, the application will be referred to TGAL for further assessment. A statement of compliance with the joint Committee For Veterinary Medicinal Products (CVMP) guideline for minimising exposure to TSE agents may be submitted to support the application.

The guideline, *Note for guidance for minimising the risk of transmitting spongiform encephalopathy agents via human and veterinary medicinal products* was issued by The European Agency for the Evaluation of Medicinal Products (EMEA/410/01 – FINAL). It is available on [http://www.emea.eu.int/pdfs/vet/regaffair/041001en.pdf](http://www.emea.eu.int/pdfs/vet/regaffair/041001en.pdf).

If the product contains material of animal origin which has been assessed as having a low risk of possible transmission of TSEs or has not yet been
assessed by the TGA the sponsor must hold details on the species of animal, tissue and country of origin.

Presentation

Presentation of the product includes the product’s name, packaging, labelling (content not format) and design of the dosage form. The TGA assesses this material to make a decision on the acceptability of the medicine’s presentation and safety for intended purpose of use.

The TGA will not accept presentation of a medicinal product that:

- is misleading, confusing or false, that is, it suggests it has ingredients or characteristics which it does not; and/or
- promotes itself as a treatment for a serious disease such as cancer, asthma or HIV where the TGA is of the view that there is insufficient evidence of efficacy for these conditions; and/or
- is likely to be confused with toys, food or confectionary; and/or
- does not reveal all the active therapeutic ingredients it contains.

If the presentation of the product is unacceptable in the Australian context, the overseas authority will be informed of any concerns via the Export Advisory Procedure (see Section 1.5.1 below).

Intellectual property

Intellectual property right issues are the responsibility of the patent holder and the agencies charged with administration of patent legislation. However, sponsors of new listings are required to submit with their application a declaration notifying either a patent is not wilfully being infringed upon or that such a declaration is not required. Further information in this regard including the necessary forms is available at <http://www.tga.gov.au/about/international-usa-fta.htm>.

1.5 Notification of additional information to overseas destinations

Where the TGA makes a decision that the relevant authority in the destination country should be advised on specific issues with regard to an export medicine the Export Advisory Procedure or Safety Approval Process will be used.

1.5.1 Export Advisory Procedure

The Export Advisory Procedure is a mechanism for communication between the TGA and the country of receipt of the goods via conditions of listing which may be imposed on the supply of the product or as a statement in the export certificate. Under this procedure the responsibilities of the sponsor are outlined as a condition of listing on the Export Listing Certificate (Certificate of Medicine Listing for Export Only) and details of specific issues included in any Certificate of Pharmaceutical Product issued for the product under the auspices of the World Health organisation. The Export Advisory Procedure will generally be used where there is:
In determining the safety of products containing substances which have not been evaluated by the TGA for use in therapeutic goods in Australia, the following factors will be considered:

- the availability of the substance in other countries with comparable regulatory systems (e.g., USA, UK, Canada, Switzerland, The Netherlands, Sweden, and New Zealand); and/or
- any concerns identified in a limited search of scientific literature databases; and/or
- any other information relevant to the substance.

Where the substance is available in other countries and there are no safety concerns (e.g., toxicity, adverse monitoring reports) related to the substance, identified through online searches of well-recognised scientific references (such as the US FDA website, Micromedex / Toxnet / Complementary & Alternative Medicine Databases) the following condition of listing applies:

"Where the product is considered to be a food in the destination country, the sponsor must ensure that the product meets any relevant food standards. Where the product is considered to be a medicine in the destination country, the sponsor must advise the regulatory authorities that the product contains a substance which has not been evaluated for therapeutic use in Australia."

The availability of the substance in the country to which the product is being exported will also be considered in determining whether application follows the Export Advisory Procedure or the Safety Approval Process.

### 1.5.2 Safety Approval Process or refusal to list

The TGA reserves the right to refuse export authorisation outright where the safety of a medicine is of sufficient concern, or to require either:

1. evidence provided by the sponsor from proper authorities in the export destination that it will allow import of the medicine in question; or
2. written confirmation to the TGA from the authority in the export destination that it will allow the import of the medicinal product (known as the Safety Approval Process)

TGA concern regarding the safety and quality of a product will be based on one or more of the following factors:

- the product contains an entity which has not been assessed for therapeutic use in Australia and there is well-documented evidence of serious toxicity or adverse reactions; or
• domestic supply/registration of the product has been rejected in Australia due to (specified) safety concerns; or

• lower risk medicines are making claims for the treatment of serious conditions (e.g., diabetes, heart disease, HIV); or

• the risk of toxicity to the target group indicated on the label (pregnant women, children etc) is unacceptable as supported by well documented evidence; or

• the Good Manufacturing Practice of the manufacturer/s has not been established or is unacceptable; or

• the TGA has other serious safety concerns with the product as supported by well documented scientific references.

Any evidence which is submitted indicating that the country of receipt is prepared to accept the goods or to justify the appropriateness of the quantity of active for the target group (in the context of the overseas market) will be considered prior to deciding to use the Safety Approval Process. Where this information can be submitted it is likely that the Export Advisory Procedure would be used instead. If the TGA is of the view that the product is not safe for the intended purpose of the product or the importing country has not indicated their willingness to accept the goods under the Safety Approval Process, the application for listing will be refused.

Sponsors will be formally notified of any intended course of action and have an opportunity to comment before a final decision is made.

Attachment 2 outlines the decision process in considering approval for the export of medicines which contain a substance that has not been evaluated for therapeutic use in Australia.

1.6 Export Certification

The TGA issues three types of export certificates for medicinal products:

• a World Health Organization (WHO) Certificate of Pharmaceutical Product (CPP) (for products permitted to be supplied in Australia or for products authorised for export – refer to example attachment 3);

• a TGA Export Certificate of a Listed Product (for lower-risk products permitted to be supplied in Australia – refer to example at attachment 4); and

• a TGA Export Certificate of an Exempt Product (for products not required to be entered in the Australian Register of Therapeutic Goods but still subject to therapeutic goods legislation). This certificate is generally designed for exempt medicines which are manufactured in a GMP licensed manufacturing facility. In this situation, the standard of manufacture may be certified in accordance with the WHO model.

1.6.1 Purposes of export certification issued by the TGA

The purpose of export certification is to:

• enable the international monitoring of trade in medicines to ensure that the safety and reliability of products is maintained;

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TGA Export Certificates (as opposed to a WHO Certificates of Pharmaceutical Product) are not and do not purport to be WHO CPPs. TGA Export Certificates have been designed for medicinal products for which a WHO CPP is not necessarily appropriate as they are not conventionally classed as “pharmaceutical products” e.g. complementary medicines.
provide appropriate and useful regulatory support to overseas health authorities. (Information may be included in certificates to assist authorities to properly determine the safety/quality status of a medicine in the context of their own market);

enhance the confidence of overseas regulatory authorities in the quality and safety of Australian medicines permitted for export; and

be relevant in the international market place and acceptable to authorities in export destinations.

1.6.2 Information able to be certified

The WHO Export Certification Scheme was put in place to provide assurance regarding the quality and safety of pharmaceuticals being traded internationally for countries that do not have regulatory arrangements to undertake assessments themselves. The basis of the Scheme is formed by WHO endorsed requirements for Good Practices in the Manufacture and Quality Control of Drugs.

The Scheme is an administrative instrument that requires a participating country, on application from a product sponsor, to certify to another country that:

- a specific product is authorised to be placed on the market within its jurisdiction or, if it is not, the reason why; and

- the plant in which it is produced is periodically subject to GMP inspections; and,

- that all aspects of the manufacture of the product are satisfactory.

If the GMP status of any manufacturers nominated in the export certificate is 'Unacceptable', a CPP or CLP cannot be issued until these matters have been resolved and a Certificate of GMP for the manufacturer has been forwarded to the Export Medicines Unit.


In accordance with the WHO Scheme, the following information will be certified by the TGA:

- (export) name and dosage form of product;
- formulation composition;
- regulatory status of the medicine in Australia, including AUSTL/AUST R number and date entered in the Australian Register;
- name and address of sponsor;
- name and address of manufacturer(s) involved in all steps of manufacture; and
- GMP compliance for all manufacturers as requested by certificates
shelf life and storage conditions for registered products, where these
details are held as part of the ARTG record; and

the product label as currently authorised for the Australian market.

If a sponsor wishes to attach a TGA approved product information (PI) for a
registered medicine, the TGA will indicate on the certificate that a notarised
copy of the TGA approved PI is provided by the sponsor.11

While certification is limited to the above documents, in accordance with
the WHO Scheme, the TGA recognises that some countries require the
competent authority in the exporting country to stamp additional
documentation. These additional documents may be submitted for
stamping as "Seen by TGA" but will be clearly identified as not being part of
certification under the WHO Scheme. These documents may include:

- product specifications
- product information which has not been approved by the TGA (eg for
  products listed for supply in Australia)
- Certificates of Analysis
- test methods
- shelf life and storage conditions (for products other than as described
  above)

At the same time, the TGA will also enter into discussions with these
countries to gain a better understanding of the need for such
documentation. Documentation which does not directly relate to the
regulation of the product by the TGA (eg trademarks, pricing, subsidiary
addresses etc) cannot be included as an attachment to a CPP.

To assist communication with overseas regulators regarding the
circumstances of the product, the TGA has included the option for
exporters to, within the electronic certificate application, select a codified
statement12 on CPPs for export products.

Sponsors are required to sign a declaration at the time of application
submission that information in applications for export certificates is
truthful and accurate.

**Certification of product labels**

If sponsors wish the TGA to certify product labels for products approved
for supply in Australia, the Australian approved product label must be
submitted. However, a second label may also be submitted specifically for
the destination country which includes the statement, "label for [name of
country]". This label will be attached to the CPP but not certified by the
TGA.

Where the product is listed for supply in Australia and an “Australian” label
does not exist, a draft label which includes relevant warning statements

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11 As priority in the design of the electronic lodgement system has been given to streamlined and responsive handling of
export certification applications, the TGA will not certify the PI documents.
12 A list of the codified statements is included at attachment 1
may be submitted for certification which includes the statement “draft label for Australia”. Alternatively, where the overseas label has not been finalised, a statement may be included above the Australian approved label as per below:

*The label for the importing country will be based on this label, amended as necessary to meet local commercial and regulatory requirements.*

**Records in the Australian Register of Therapeutic Goods (ARTG)**

The TGA recognises that maintaining the quality of the data in the ARTG is a shared responsibility of the TGA and sponsors. The TGA is committed to assisting sponsors with the resolution of problems with ARTG records. To facilitate speedy processing of export certificate applications, sponsors are requested to correct discrepancies between their records and the ARTG, with the Register and/or relevant areas in the TGA prior to requesting an export certificate.

**Additional information**

If an overseas destination requests additional information from the TGA:

- the sponsor may obtain it directly from the relevant area of the TGA, or
- the overseas agency is welcome to obtain it directly from the TGA with the written consent of the sponsor.

Such information and any other information the sponsor wishes to submit to the overseas authorities is considered to be separate from the export certificate.
B2. Support Role

2.1 Communication and Consultation

2.1.1 International

The TGA is committed to consistent interaction with other regulatory authorities on issues of export regulation through an active program promoting Australia’s export certification system.

Export certification matters will also be discussed, with overseas visitors to the TGA.

The TGA will develop material explaining Australia’s export certification processes for distribution to overseas regulators. The TGA website will provide up-to-date information on export certification policies and processes.

2.2 Advice and Referral

The TGA will assist sponsors, wherever possible, by providing advice and referral for Australian exporters of therapeutic goods in relation to the export regulatory environment for therapeutic goods.

In relation to market entry matters the TGA will:

- refer cases to Australian trade and industry officials (including Department of Foreign Affairs and Trade and Austrade) for resolution; and/or
- undertake discussions directly with overseas authorities on regulatory matters.

For issues with wider regulatory implications, the TGA will consider raising a matter in bilateral and multilateral forums and the negotiation of formal arrangements with regulatory authorities.

2.3 Local

The TGA will work with industry associations and government agencies to ensure the provision of education and training programs for industry that enhance their knowledge and expertise in export regulatory issues.
Attachment 1: Codified sponsor statements

CPP for Export products

The statements below appear on the CPP electronic certificate application forms for export products that are manufactured only for export purpose and can not be supplied in Australia. Sponsors/agents of sponsors may only select one statement, which is in most agreement with the market situation of their export product. If none of the statements suits to the product situation, sponsor or agent of sponsor may select “other” option and provide their own statement. The TGA will include this statement on the CPP if it agrees with the statement. The statements are:

- This product has been developed exclusively for the treatment of conditions, not endemic in Australia, and as such listing/registration for the Australian market is not requested.
- This product has been developed exclusively for the importing country and as such listing/registration for the Australian market is not required.
- This product has been repackaged to meet the importing country’s requirements.
- The product approved for supply in Australia has been reformulated to exclude excipients not approved in the importing country.
- This product has the same formulation as another product on the Australian market (AUST L / R ..... ) which is supplied in a different container or packaging.
- This product does not require marketing approval in Australia as it has been manufactured for an overseas principal. It is being transported in bulk.
- Listing/registration for the Australian market has not yet been requested for commercial reasons.
- This product is approved for supply in the following markets (insert countries).

CPP for products registered for supply in Australia that are intended to export

- This product is approved for supply in Australia but is not marketed at present for commercial reasons.
Attachment 2:

Assessment path for export medicine containing a new substance not evaluated for therapeutic use in Australia

- **Evaluated for therapeutic use in Australia?**
  - **NO**
  - **YES**

  - **Approved in USA / UK / Canada / Switzerland / New Zealand / The Netherlands / Sweden**
    - **YES**
      - Export Advisory Procedure
        - condition of listing to inform authorities in importing countries
        - TGA comment “not evaluated for therapeutic use in Aust” on CPP
    - **NO**
      - Export Advisory Procedure
        - condition of listing to inform authorities in importing countries
        - TGA comment “not evaluated for therapeutic use in Aust” on CPP
        - Only for export to this country
        - If there are safety concerns

  - **Approved in country of receipt?**
    - **YES**
      - Export Advisory Procedure
        - condition of listing to inform authorities in importing countries
        - TGA comment “not evaluated for therapeutic use in Aust” on CPP
    - **NO**
      - Export Advisory Procedure
        - condition of listing to inform authorities in importing countries
        - TGA comment “not evaluated for therapeutic use in Aust” on CPP
        - Only for export to this country
        - If there are safety concerns

  - **Adverse reactions / Toxicity reports?**
    - **YES**
      - Safety Approval Procedure applies
        - Serious safety concerns (eg Hazardous chemical rating, associated with death, illnesses)
        - Listing is refused.
1. Name and dosage form of product:
   ABC adrenaline 1mg/5mL (as acid tartrate) injectin BP ampoule
   To be exported as: CBA injection ampoule

1.1 Active ingredient(s) and amount(s) per unit dose (if applicable):
   (for complete composition including excipients see Schedule 1, attached to this Certificate)

1.2 Is this product licensed to be placed on the market for use in the exporting country? YES

1.3 Is this product on the market in the exporting country? YES

TGA comments: This product has been approved by the TGA and is permitted to be supplied in Australia

Sponsor’s comments: Not Applicable

2. Listing/Registration No: AUST R xxxxx 32 January 1990
   Name and address of applicant: Wonder Pharmaceuticals Pty Ltd 100 Smith Road SPRINGVALE VIC 3171 AUSTRALIA
   Status of applicant (categories as defined in note 5): (a)
   For categories (b) and (c) the name and address of the manufacturer producing the dosage form is:

   Is officially approved product information, complete and consonant with the licence, attached? Yes

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced? YES, IF APPLICABLE*
   *For manufacturing steps carried out in Australia. For overseas manufacturers evidence of satisfactory GMP compliance has been supplied.

3.1 Periodicity of routine inspections (years): NOT LESS THAN EVERY TWO YEARS

3.2 Has the manufacture of this type of dosage form been inspected? YES

3.3 Do the facilities and operations conform to GMP as recommended by the World Health Organization? YES

4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product? YES
Certificate of a Listed Product

Exporting (certifying) country: Australia
Importing (requesting) country: Kuwait

1. Name and dosage form of product:
   XYZ Active Power Capsules

1.1 Active ingredient(s) and amount(s) per unit dose (if applicable):
   (for complete composition including excipients see Schedule 1, attached to this Certificate)

1.2 Is this product licensed to be placed on the market for use in the exporting country? YES
   TGA comments: This product has been approved by the TGA and is permitted for free sale (in that it can be legally supplied) in Australia

2. Listing No: AUST L xxxxxx 32 January 1990
   Name and address of applicant: Wonder Pharmaceuticals Pty Ltd 100 Smith Road SPRINGVALE VIC 3171 AUSTRALIA
   Status of applicant: (b)
   For categories (b) and (c) the name and address of the manufacturer producing the dosage form is:

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced? YES*
   *For manufacturing steps carried out in Australia. For overseas manufacturers evidence of satisfactory GMP compliance has been supplied.

3.1 Periodicity of routine inspections (years): NOT LESS THAN EVERY TWO YEARS

3.2 Has the manufacture of this type of dosage form been inspected? YES

3.3 Do the facilities and operations conform to GMP as recommended by the World Health Organization? YES

4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product? YES
Explanatory Notes

1. This certificate, is not issued under the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. However, the format is essentially the same as that recommended by the WHO. It is for a single product only, since manufacturing arrangements for different dosage forms and strengths can vary.
2. Use, whenever possible, international nonproprietary names (INNs) or national nonproprietary names.
3. The formula (complete composition) of the dosage form should be given on the certificate or appended.
4. When applicable, append details of any restriction applied to the sale, distribution or administration of the product that is entered into the product licence.
5. Specify whether the person responsible for placing the product on the market:
   (a) manufactures the dosage form;
   (b) packages and/or labels a dosage form manufactured by an independent company; or
   (c) is involved in none of the above.
6. This information can only be provided with the consent of the product licence holder or, in the case of non-registered products, the applicant. Non-completion of this section indicates that the party concerned has not agreed to inclusion of this information. It should be noted that information concerning the site of production is part of the product licence. If the production site is changed, the licence has to be updated or it is no longer valid.
7. Not applicable means the manufacture is taking place in a country other than that issuing the product certificate and inspection is conducted under the aegis of the country of manufacture.
8. The requirements for good practices in the manufacture and quality control of drugs referred to in the certificate are those included in the report of the Thirty-second Expert Committee on Specifications for Pharmaceutical Preparations, WHO Technical Report Series No 823, 1992. Recommendations specifically applicable to biological products have been formulated by the WHO Expert Committee on Biological Standardization and are published in the WHO Technical Report Series.
9. Subject to any applicable conditions under Commonwealth, State or Territory legislation.
The Commonwealth Therapeutic Goods Act 1989 ("the Act") establishes and maintains a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods used in Australia or exported from Australia. Therapeutic goods are products used in the prevention, diagnosis, cure or alleviation of a disease, ailment, defect or injury and include those goods which are likely to be taken to be for therapeutic use because of the way they are presented or advertised. Therapeutic goods which have been accepted by the Therapeutic Goods Administration are included in the Australian Register of Therapeutic Goods (ARTG), which is a computer database holding details of therapeutic goods supplied in, or exported from, Australia. Some therapeutic goods are subject to the Act but exempt from listing on the ARTG.

There are three categories of medicinal products within the ARTG:

1. **Listed medicines (including complementary medicines) approved for supply in Australia**
   These are therapeutic goods which are formulated from a restricted list of active ingredients for which there are minimal safety concerns. They are indicated for self-limiting conditions and are of acceptable presentation (including labelling). These products, containing active substances whose quality and safety have been accepted, include vitamin & mineral supplements, most herbal medicines, homoeopathic products and sunscreens. While stability data is required to be available, or being generated to support the claimed shelf life, this is not verified by the TGA. Sponsors are also required to hold evidence to support any label claims, however this evidence is not evaluated by the TGA prior to entry in the ARTG. Once listed in the ARTG, these goods may then also be exported without further regulation. Exporters may request the TGA to issue Certificates of Pharmaceutical Product or Certificates of Listed Product for these products (see note below).

2. **Registered medicines**
   These are therapeutic goods other than those that may be listed and are evaluated with regard to their quality, safety and efficacy before being approved for supply. They include the conventional pharmaceutical products, traditional remedies which include animal parts and medicines for the treatment of more serious diseases. Once included in the ARTG, these goods may also be exported without further regulation. Exporters may request the TGA to issue Certificates of Pharmaceutical Product for these products.

3. **Medicines intended solely for export**
   These are goods that may be manufactured to satisfy an overseas supplier's requirement. They are subject to similar standards as apply to other listed therapeutic goods that are supplied in Australia. Where the product is exported in the final packaging, the TGA does not assess label indications or whether label warning statements required for approval in Australia have been included. Sponsors are required to declare that the label will meet the requirements of the importing country. Product labels cannot contain information which is false or misleading. Exporters may request the TGA to issue Certificates of Pharmaceutical Product for these products.

Where an application to register or list a product has been rejected for supply in Australia for safety or quality reasons and it is proposed to export such a product, or there are other concerns with a product manufactured solely for export, the TGA will contact the importing regulatory authority to confirm there is no objection to the export of the goods.

**Export Certificates**
The TGA provides two types of export certificates, a Certificate of Pharmaceutical Product (CPP) and a Certificate of Listed Product (CLP). While both certificates are based on principles of the WHO Scheme for export certification, only the CPP is formally issued under this scheme. The CLP is a modified certificate provided only for medicines listed for supply in Australia. While a CPP can be provided for both listed and registered medicines, a CLP can only be provided for listed medicines which may be supplied in Australia.

**Standards** - All therapeutic goods that are exported from, imported into or supplied in Australia must comply with internationally recognised standards that are of a comparable standard to those that apply to such goods in Australia. The only exception is that labelling of goods manufactured solely for export does not need to conform to labelling requirements applicable to goods supplied in Australia.

**Licensing of manufacturers** - The Act provides for the licensing in Australia of manufacturers of therapeutic goods for human use. In order to obtain a licence a manufacturer is inspected to confirm compliance with the codes of good manufacturing practice. Overseas manufacturers must be able to demonstrate that their standards of manufacture and quality assurance are equivalent to that of Australian manufacturers.

This page is intended as a summary of the main features of the national regulatory scheme. Specific queries or requests for clarification should be directed to:

**The Export Medicines Unit, Therapeutic Goods Administration, PO Box 100, Woden ACT 2606, Australia**