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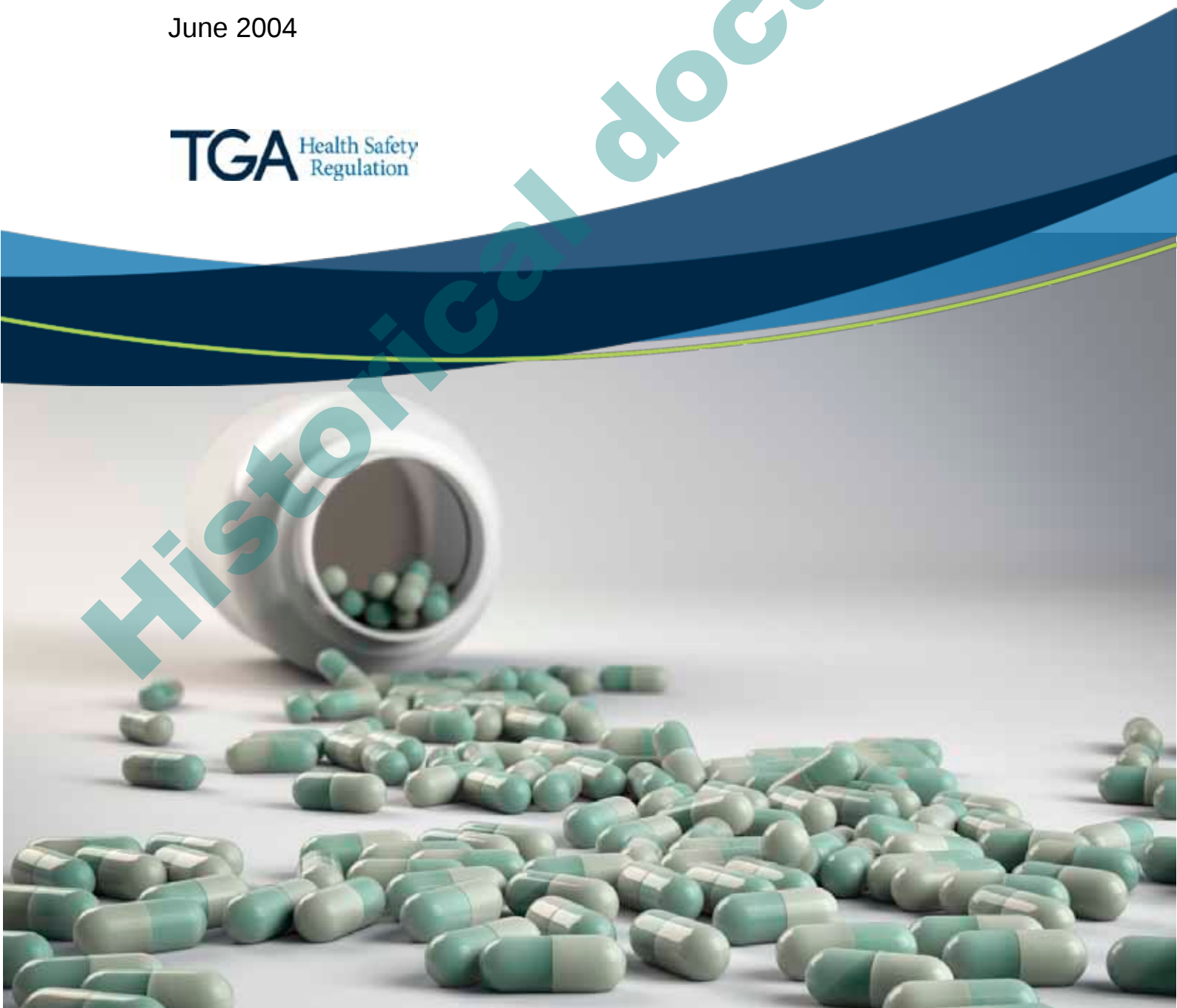
Department of Health and Ageing
Therapeutic Goods Administration

Australian regulatory guidelines for prescription medicines

Appendix 1: Glossary of terms

June 2004

TGA Health Safety
Regulation



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.
- 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. 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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Appendix 1: Glossary of terms

This document contains interpretations of terms commonly used by all Branches of the Therapeutic Goods Administration (TGA) and identifies terms which are defined in the *Therapeutic Goods Act 1989* and *Therapeutic Goods (Charges) Act 1989* and their regulations¹.

This glossary is not exhaustive and does not include many terms which are 'technically' specific to some areas of TGA, in particular, it does not interpret terms which are used exclusively for, or in connection with, the manufacture of medicinal products or therapeutic devices.

Terms which are defined in the Acts and their regulations may be defined slightly differently (for example, to expand or narrow a definition) in Orders made under the Act. References should be made to the definitions in the relevant Order when determining the requirements of a standard such as those for the labelling of medicines and devices.

Acceptable country: see Regulation 16C of the Therapeutic Goods Regulations (relates to medicines only).

Active pharmaceutical ingredient (API): Therapeutically active component in the final formulation of therapeutic goods.

Active raw material: The unformulated active chemical substance, usually a powder or a liquid, in the form in which it is used to manufacture a dosage form, usually in combination with excipients.

Advertisement: see Section 3(1) of the *Therapeutic Goods Act 1989*.

Agent: A person duly authorised in writing to act on behalf of the sponsor of the goods.

Analysis: see Regulation 2 of the *Therapeutic Goods Regulations*.

Antibiotic: A selective antimicrobial agent, other than disinfectants, antiseptics and substances solely used as antineoplastics, that, on application to living tissue or by systemic administration, kills or prevents growth of susceptible micro-organisms.

Antiseptic: see Regulation 2 of the *Therapeutic Goods Regulations*. Relates only to medicines.

Appellant: In the terms of the *Therapeutic Goods Act 1989* – a person seeking a review of a decision under the provisions of Section 60 of the *Therapeutic Goods Act 1989* or Regulation 48 of the *Therapeutic Goods Regulations*.

Application: An application made to the TGA under the following sections of the *Therapeutic Goods Act 1989* (note that where the section / regulation number is **highlighted**, the word 'application' is used in the legislation):

- Section 9C (request for copy of ARTG entry); or
- Section 9D (request to vary information about and ARTG entry); or
- Section 14 (exemption from compliance with a Standard); or
- **Section 19** (special and experimental uses); or

¹ <http://www.tga.gov.au/industry/legislation.htm>

- **Section 23** (registration or listing) [note that each application results in a single registration or listing or the inclusion of a separate and distinct product within a grouped registration or listing]; or
- **Section 37** (manufacturer's licence); or
- **Section 58** (export certification); or
- **Section 61(6)** (information from ARTG); or
- **Regulation 14** (transfer of goods registered/listed); or
- **Regulation 14A** (reassignment of registration / listing numbers).

(See also *submission*).

ARTG entry: Refers to a separate and distinct product included in the Australian Register of Therapeutic Goods (ARTG), as described by the criteria in Section 16(1) of the *Therapeutic Goods Act 1989*. Grouped products represent two or more ARTG entries under a single ARTG number.

ARTG purpose: Relates to the basis of the goods inclusion in the ARTG. Goods are included in the Register as a mechanism indicating approval for supply in Australia and/or approval for export from Australia. Goods listed for export only will have an ARTG purpose of 'export', all others will have a purpose of 'supply'.

ARTG status: A term which describes the registration /listing status of therapeutic goods in relation to their inclusion, or otherwise, in the ARTG. It includes registered, listed, cancelled by Secretary and cancelled by sponsor.

Australian Approved Name (AAN) for pharmaceutical substances: A name for an ingredient, or a plant or other organism included in the formulation of a medicine, which is included in the list of *TGA Approved Terminology for Medicines*² published by the Therapeutic Goods Administration. The list comprises three parts:

- Chemical substances AAN list
- Herbal substances AAN list
- Biological substances AAN list.

Authorised officer: see Regulation 23 of the *Therapeutic Goods Regulations*.

Note: may also refer to person authorised to examine records of the importation of therapeutic substances in accordance with Regulation 5A of the *Customs (Prohibited Imports) Regulations* or to person authorised to grant import permission for goods listed in Schedule 8 of the C(PI) Regulations.

Authorised person: see Section 3(1) of the *Therapeutic Goods Act 1989*.

Note: may also refer to person authorised to grant import permission for therapeutic substances under Regulation 5A of the C(PI) Regulations.

Batch: see Section 3(1) of the *Therapeutic Goods Act 1989*.

Bioburden: see Section 3(1) of the *Therapeutic Goods Act 1989*.

Biological entity: As used in Schedule 10 of the *Therapeutic Goods Regulations* - refer to *biological substance*.

² <http://www.tga.gov.au/medicines-approved-terminology.htm>

Biological products: Products in which the active ingredient is a biological substance including antisera, antivenins, monoclonal antibodies and products of recombinant technology.

Biological substance: Substances of biological origin which are frequently chemically complex and of a molecular weight over 1,000, such as hormones, enzymes and related substances, but not including herbal substances and antibiotics.

Biological substances are not uniquely defined by a chemical name and their purity, strength and composition cannot readily be determined by chemical analysis. Substances which can be isolated as a low molecular weight pure substance, such as purified steroids, digoxin, ergotamine are considered to be chemical substances.

Biopharmaceutics: The study of the ways that the physical and chemical properties of drug substances, drug products and routes of administration affect bioavailability (the rate and extent of drug absorption). Biopharmaceutic studies of new medicines typically include the investigation of bioavailability, relative bioavailability and bioequivalence of different dosage forms or formulations, and the effect of food or antacids on their bioavailability.

British Pharmacopoeia (BP): see Section 3(1) of the *Therapeutic Goods Act 1989*. Sponsors should make reference to the latest edition of the BP that has been adopted by the TGA and published as such in the Commonwealth Gazette³.

Business name: The name of the person or corporation for which particulars are being supplied or which is making an application. It may be either the name registered with the Australian Securities Investments Commission, or the name of the person or persons who conduct the business. Trading names are not usually included in the business name for Australian applicants, but may be supplied in particular for overseas companies. Also referred to as the Client name / ID. (See also *client*.)

Category A patient: see Regulation 12A of the *Therapeutic Goods Regulations*. Relates only to medicines.

Certificate of a Pharmaceutical Product: For medicinal products, the issue of a certificate by the TGA under the World Health Organisation (WHO) Certification Scheme on the Quality of Pharmaceutical Products moving in International Commerce. It is issued only for therapeutic goods that are medicines. It allows the country of import to ascertain the product's marketing status in Australia and whether it has been manufactured in compliance with GMP.

Certified product details (CPD): A statement of product details, specifications and test methods generated by the sponsor at the request of the TGA.

Charge: The sum payable annually for activities identified under the *Therapeutic Goods (Charges) Act 1989* (for example, registration, listing and manufacturing licence).

Client: A person or organisation having an involvement in the import, export, manufacture or supply of therapeutic goods. An enterprise can include sponsors, manufacturers and agents.

Client identification code (client ID): Identification code assigned by the TGA to a client.

Clinical trial: A planned study in humans designed to investigate or report upon the effectiveness and/or safety of a therapeutic good or treatment. (See *experimental purposes in humans*).

Clock: Refers to recording of working days by TGA.

Codes of Good Manufacturing Practice (GMP): Good principles and practices to be followed in the manufacture of therapeutic goods to provide assurance of product quality and compliance with product ARTG registration or listing.

³ <http://www.comlaw.gov.au/Details/F2007B00704>

Composite pack: A medicinal product where the primary pack or the container includes at least two kinds of medicinal products and does not contain any therapeutic devices. The medicinal products must be for use as a single treatment regimen. Examples include: a strip or blister pack containing tablets or capsules with differing formulations to be taken in a specified order, or a primary pack containing an active ingredient in one vial and a diluent in another vial, or a primary pack containing separate containers of different formulations for use as part of a single regimen of treatment.

Consumer Medicine Information (CMI): A medicine information document as described in Schedule 12 to the *Therapeutic Goods Regulations*, for supply to patients; required to be available for certain medicines as specified in Regulation 9A. The document is required to be provided to patients with prescription medicines. It provides patients with a 'plain English' explanation of the product.

Container: see Section 3(1) of the *Therapeutic Goods Act 1989*. Refers to the immediate covering of the goods. (see also *primary pack*).

Container type: The Act describes a container as a 'vessel, bottle, tube, ampoule...or other similar article that immediately covers the goods...'. Types of containers are defined in the TGA list *Types of Containers* published in the latest edition of *TGA Approved Terminology for Medicines*². It describes container types for the purposes of Section 16(1)(g) of the *Therapeutic Goods Act*. Container types are independent of the material used to fabricate them.

Contract manufacture: Where all or part of the manufacturing process of therapeutic goods is carried out by a person other than the sponsor on a contract basis. Can include principal manufacturers and other (sub)manufacturers.

Corporation: see Section 3(1) of the *Therapeutic Goods Act 1989*.

Corresponding State law: see Section 3(1) of the *Therapeutic Goods Act 1989*.

Data processing device: see Section 3(1) of the *Therapeutic Goods Act 1989*.

Decision: see Section 60 of the *Therapeutic Goods Act 1989*. Refers to *Administrative Appeals Tribunal Act 1975* (AAT Act).

Decision: see Regulation 48 of the *Therapeutic Goods Regulations*. Refers to *Administrative Appeals Tribunal Act 1975* (AAT Act).

Delegate: An officer who has been given authority by the Minister or Secretary to exercise a power, which the *Therapeutic Goods Act* or *Regulations* confer on the Minister/Secretary. Refer to Section 57 and *Regulations 47 and 47A*.

Diagnostic goods for in vitro use: see Regulation 2 of the *Therapeutic Goods Regulations*. Relates only to therapeutic devices.

Directions for use: see Section 3(1) of the *Therapeutic Goods Act 1989*.

Disinfectant: see Regulation 2 of the *Therapeutic Goods Regulations*.

Dosage form: The pharmaceutical form in which a product is presented for therapeutic administration for example, tablet, cream. A list of dosage forms and their definitions for the purpose of recording information in the ARTG database is included in the *TGA Approved Terminology for Medicines*².

Drug: See medicine (Section 3(1) of the *Therapeutic Goods Act 1989*).

Note that legislative definitions apply in both singular and plural forms.

ECRI classification system (UMDNS/IMDC): The system devised by the Emergency Care Research Institute of the USA that consists of assigned nomenclature and corresponding 5 digit codes for an extensive range of medical equipment. This system has been renamed by ECRI as the Universal

Medical Device Nomenclature System (UMDNS) with codes being called International Medical Device Classifications.

Ethics committee: Section 3(1) of the *Therapeutic Goods Act 1989*.

Excipient: Any component of a finished dosage form other than an active ingredient (in some cases the distinction between an active ingredient and an excipient may not be clear cut, for example, sodium chloride used to adjust tonicity of an injection is an excipient).

Excluded goods: Goods which might be considered to be therapeutic goods but which are specifically declared not to be by an Order of the Secretary (and therefore not subject to any requirements of the *Therapeutic Goods Act 1989*). Refer Section 7 of the *Therapeutic Goods Act 1989*.

Exempt goods: see Section 3(1) of the *Therapeutic Goods Act 1989*. Relates to provisions of Part 3 or 4 of the Therapeutic Goods Act, and covers therapeutic goods that are exempted from the requirements to be registered or listed or are exempted from licensing requirements.

Exempt person: see Section 3(1) of the *Therapeutic Goods Act 1989*.

Experimental purposes in humans: As used in the Therapeutic Goods Act and Regulations, refers to use of medicines or devices in clinical trials subject to approval under Section 19(1)(b) of the Therapeutic Goods Act or to notification under item 3 of Schedule 5A of the Regulations.

Export certificate (Devices): A certificate issued for therapeutic devices equivalent to the WHO Certificate of a Pharmaceutical Product.

Export certification: see Section 58 of the *Therapeutic Goods Act*. Can include a WHO Certificate of a Pharmaceutical Product for medicines, a Certificate of Free Sale (Devices) or an Export Certificate (Devices).

Export name: The proprietary name used for the goods for supply in another country where that name is different from the proprietary name used for the goods for supply in Australia.

Fee: A sum payable for activities or events identified in Schedule 9 of the Regulations to the *Therapeutic Goods Act 1989* (for example, evaluation fee).

Financial corporation: see Section 3(1) of the *Therapeutic Goods Act 1989*.

Finished goods: The finished or final dosage form of the therapeutic good when all stages of manufacture, other than release for sale, have been completed.

FOI Act: The *Freedom of Information Act 1982*.

Formulated therapeutic device: A therapeutic good presented in a dosage form and recognised as a therapeutic device for the principal purpose of its use (for example, artificial tears).

Formulation: A list of the ingredients used in the manufacture of a dosage form and a statement of the quantity of each ingredient in a defined weight, volume, unit or batch.

For the ARTG computerised database only, the recorded formulation excludes ingredients not present in the finished goods (for example, water in lyophilised powders), and excludes overages. Where ingredients used in the manufacture of a dosage form react chemically with one another, the ingredient formed as a result of this reaction is recorded, not the original ingredients.

Foreign corporation: see Section 3(1) of the *Therapeutic Goods Act 1989*.

Gazetted kits group: see Section 3(1) of the *Therapeutic Goods Act 1989*.

Gazetted therapeutic devices group: see Section 3(1) of the *Therapeutic Goods Act 1989*.

Gazetted therapeutic goods group: see Section 3(1) of the *Therapeutic Goods Act 1989*. Note that this only refers to medicines.

Generic medicine: see Regulation 2 of the *Therapeutic Goods Regulations*. Known in New Zealand as a multi-source medicine.

Goods for home use: see Regulation 2 of the *Therapeutic Goods Regulations*. Relates only to therapeutic devices.

Grouped therapeutic goods: see Section 3(1) of the *Therapeutic Goods Act 1989*. Refers to medicines, devices or kits grouped under the one ARTG number. Not to be confused with gazetted therapeutic goods group which only refers to medicines.

Grouping: The mechanism whereby goods, which would normally be required to be included in the ARTG under different ARTG registration or listing numbers (because they are separate and distinct by virtue of S 16(1) of the *Therapeutic Goods Act 1989*, may be included in the ARTG under the one ARTG registration or listing number, thereby attracting a single annual charge for the group of goods. Each product (as defined by S 16(1)) is still regarded as a separate ARTG entry and all controls under the *Therapeutic Goods Act 1989* apply discretely to each separate and distinct product (for example, application fees; conditions; cancellation).

Herbal substance: see Regulation 2 of the *Therapeutic Goods Regulations*. Relates only to medicines.

Homoeopathic preparation: see Regulation 2 of the *Therapeutic Goods Regulations*. Relates only to medicines.

Immediate family: see Regulation 2 of the *Therapeutic Goods Regulations*.

Implantable: see Regulation 2 of the *Therapeutic Goods Regulations*. Relates only to therapeutic devices.

Indications: see Section 3(1) of the *Therapeutic Goods Act 1989*. In relation to therapeutic goods, means the specific therapeutic uses of the goods.

Individual patient data: see Section 24 of the *Therapeutic Goods Act 1989*.

Informed consent: see Regulation 12A of the *Therapeutic Goods Regulations*. Relates only to medicines.

Initial decision: see Section 60 of the *Therapeutic Goods Act 1989* and Regulation 48 of the *Therapeutic Goods Regulations*. Refers to decisions of the Secretary (or delegate) under various sections.

Kit: see Section 7B(1) of the *Therapeutic Goods Act 1989*. Kits are listed as either medicine or device kits.

Label: see Section 3(1) of the *Therapeutic Goods Act 1989*. In relation to therapeutic goods, means a display of printed information on or attached to the goods; or on or attached to a container or primary pack in which the goods are supplied; or supplied with such a container or pack.

Licence: see Section 3(1) of the *Therapeutic Goods Act 1989*.

Licence number: The number of the licence issued by the TGA to a manufacturer of therapeutic goods for use in humans under Part 4 of the *Therapeutic Goods Act*.

Listable devices: see Section 3(1) of the *Therapeutic Goods Act 1989*. Relates only to therapeutic devices.

Listable goods: Goods that are required under Part 3 of the *Therapeutic Goods Act 1989*, as specified in Schedule 4 of the *Regulations*, to be included in that part of the Register for listed goods.

Listed goods: see Section 3(1) of the *Therapeutic Goods Act 1989*.

Listing number: see Section 3(1) of the *Therapeutic Goods Act 1989*. When printed on a label must be positioned in accordance with the requirements of Regulation 15 and preceded by AUST L.

Manufacture: see Section 3(1) of the *Therapeutic Goods Act 1989*. In relation to therapeutic goods, means to: to produce the goods; or to engage in any part of the process of bringing the goods to their final state, including engaging in the processing, assembling, packaging, labelling, storage, sterilising, testing or releasing for supply of the goods or of any component or ingredient of the goods as part of the process.

Manufacturer: Corporation or person carrying out one or more of the steps specified in the definition of manufacture.

Manufacturing premises: see Section 3(1) of the *Therapeutic Goods Act 1989*.

Manufacturing principles: see Section 36 of the *Therapeutic Goods Act 1989*. Includes GMP codes.

Medical practitioner: see Section 19(9) of the *Therapeutic Goods Act 1989*.

Medicated therapeutic device: A therapeutic device that is represented to achieve, or is likely to achieve, one or some of its purposes of use, but not the principal purpose of its use, as a result of chemical action in or on the body of a person.

Medicinal component: The name applied by the ARTG to any one item within a composite pack.

Medicinal product: An alternative term to medicine for the finished, packaged goods.

Medicine: Therapeutic goods that are represented to achieve, or are likely to achieve, their principal intended action by pharmacological, chemical, immunological or metabolic means in or on the body of a human or animal. Previously referred to as drug.

Mother tincture: see Regulation 2 of the *Therapeutic Goods Regulations*. Relates only to medicines.

Mutual Recognition Convention: see Section 3(1) of the *Therapeutic Goods Act 1989*.

Name: As used in relation to differentiation between therapeutic goods in Section 16 of the *Therapeutic Goods Act 1989*. May include the brand name, a descriptor of the goods or generic name together with a sponsor name or logo or banner name of a product range, that is, all elements which, together, serve to make the product recognisable as a particular item of commerce or supply.

Name of the goods: The nonproprietary name including the name of the dosage form or a synonym for the name of the dosage form, used to describe the goods in a specific standard. Listing and registration names include the name of the goods but may include further information to differentiate between forms of presentation.

Non-clinical: The preclinical, pharmaco-toxicological and pharmacological or toxicological studies.

Nonproprietary name: The name used to describe the goods (particularly medicines) in a specific standard. It includes the name of the dosage form. If no standard exists, a name comprising of the AAN of the active ingredient and the name of the dosage form.

Notification: Advice to the TGA in accordance with the requirements of:

- Section 29A (information about registered goods different from previously given);
- Section 29B (adverse effects of goods -registration application withdrawn);
- Section 9D (variation to goods which may be notified as specified in guidelines);
- Schedule 5A item 3 (clinical trial);
- Regulation 13 (change in sponsorship);

- Regulation 21 (change in QC manager -licensed promises);
- Regulation 22 (change of licence holder).

Official analyst: see Regulation 2 of the *Therapeutic Goods Regulations*.

Official sample: A sample of goods taken under the provisions of Part 5 of the *Therapeutic Goods Regulations*. A certificate of official analyst is issued.

Orphan drug: see Section 16(H) of the *Therapeutic Goods Regulations*.

Pack size: Size of the goods in terms of the quantity contained in the container (for example, volume in a multi-use container) and / or the number of items in the primary / unit pack (for example, number of tablets in a bottle).

Partially processed goods: Therapeutic goods whose manufacture has not been completed to the stage of final packaging and labelling.

Patient information document: see Consumer Medicine Information.

Pharmaceutical benefit: see Regulation 2 of the *Therapeutic Goods Regulations*.

Poison: see Regulation 2 of the *Therapeutic Goods Regulations*.

Poisons Schedule: A schedule of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP).

Poisons Standard: see Regulation 2 of the *Therapeutic Goods Regulations* and Regulation 2 of the *Therapeutic Goods (Charges) Regulations*.

Premises: see Section 3(1) of the *Therapeutic Goods Act 1989*.

Prescribed quality and safety criteria: see Section 26(1)(k) of the *Therapeutic Goods Act 1989*. Quality and safety requirements prescribed in the Regulations for particular listable goods or categories of listable goods.

Presentation: see Section 3(1) of the *Therapeutic Goods Act 1989*. The way in which the goods are presented for supply, and includes matters relating to the name of the goods, the labelling and packaging of the goods and any advertising or other informational material associated with the goods.

Primary pack: The complete pack in which the goods, or the goods and their container, are to be supplied to consumers.

Problem report: Report of a suspected deficiency of quality, safety or efficacy in a therapeutic good.

Product: The commercial presentation or marketed entity of therapeutic goods, excluding pack size. Where a therapeutic device, it excludes such fine details as size or gauge; and, where a kit / tray or pack containing one or more medicines, it is an individual medicinal entity within the kit.

Product information: see Section 9D(5) of the *Therapeutic Goods Act 1989*. Also referred to as PI. Known in New Zealand as *Data Sheet*.

Product material: This term is used in ARTG application forms and guides when asking for copies of information provided about the goods for medical practitioners and / or patients / users. It includes Consumer Medicine Information (CMI), Product Information (PI) and promotional material.

Product name - medicines: The proprietary name as shown on the label or where there is no proprietary name, the registration/listing name.

Product name - therapeutic devices: The name required by the ARTG to describe individual products within a registration or listing. It will be the name under which the product is supplied, and may be the brand name or registered trademark of the product, or other commercial identification.

Product name - therapeutic device kit /tray/ pack containing medicines: The proprietary or non-proprietary name of a medicine within the kit. Each medicine in a therapeutic device kit/tray/pack has a different product name.

Product number: Reference number assigned by ARTG to each product grouped under one registration or listing.

Prohibited representation: see Regulation 2 of the *Therapeutic Goods Regulations*.

Proprietary ingredient: Formulated ingredients, usually commercially obtained, for which the formulation may not be available to the sponsor of the final product. Examples are perfumes and flavourings. Some active ingredients may be supplied as proprietary ingredients.

Proprietary name: The registered trademark of the therapeutic goods or the unique name assigned to the goods by the sponsor and appearing on the label.

Quality: see Section 3(1) of the *Therapeutic Goods Act 1989*. Includes the composition, strength, potency, stability, sterility, purity, bioburden, design, construction and performance characteristics of the goods.

Recall: The permanent removal of therapeutic goods from supply or use for reasons relating to deficiencies in the quality, safety or efficacy of the goods.

Recall for product correction: The repair, modification, adjustment or relabelling of therapeutic goods for reasons relating to deficiencies in the quality, safety or efficacy of the goods.

Record of ARTG entry: see Section 32(a) of the *Therapeutic Goods Act, 1989* re copy of entry. A printout of the information which has been entered in the ARTG computer database about a product.

Register: see Section 3(1) of the *Therapeutic Goods Act 1989*.

Registered goods: see Section 3(1) of the *Therapeutic Goods Act 1989*.

Registrable goods: Goods that are required under Part 3 of the *Therapeutic Goods Act 1989* and specified in Schedule 3 of the *Therapeutic Goods Regulations* to be included in that part of the ARTG for registered goods.

Registration/listing name - medicines: The name which will appear on the Certificate of Registration/Listing. The Registration/ Listing name is a fully descriptive name which enables clear identification of the goods as they are presented for supply. Where goods have a name which applies to more than one product, the name must be followed by sufficient details to enable unique identification. It includes: the proprietary name (if any); and the nonproprietary name; or a descriptive name which includes a commercial identifier such as sponsor name; and must include the dosage form, and where appropriate, the strength and container type.

Registration/listing name – therapeutic devices: The name which will appear on the Certificate of Registration/Listing. The Registration/Listing name is a fully descriptive name which enables clear identification of the goods as they are presented for supply. It may include the proprietary name or be a descriptive name which includes a commercial identifier such as sponsor name. It may embrace the unique characteristics of its inclusion in the ARTG - the Australian Device Group, and identify products which are sterile. Where goods have a name which applies to more than one product, the name must be followed by sufficient details to enable unique identification.

Registration number: see Section 3(1) of the *Therapeutic Goods Act 1989*. When printed on a label must be positioned in accordance with Regulation 15 and preceded by AUST R.

Relevant test: see Regulation 23 of the *Therapeutic Goods Regulations*.

Required representation: see Regulation 2 of the *Therapeutic Goods Regulations*.

Responsible analyst: see Regulation 23 of the *Therapeutic Goods Regulations*.

Restricted goods: see Regulation 2 of the *Therapeutic Goods Regulations*.

Reviewable decision: see Section 60 of the *Therapeutic Goods Act 1989* and Regulation 48 of the *Therapeutic Goods Regulations*. Refers to decisions of Minister (delegate) about reviews of initial decisions.

Route of administration: Route by which a therapeutic good is applied on or introduced to the body.

Sample: see Regulation 48 of the *Therapeutic Goods Regulations*.

Samples officer: see Regulation 23 of the *Therapeutic Goods Regulations*.

Schedule 10 medicines: A medicinal product of a type described in Schedule 10 of the *Therapeutic Goods Regulations*. Medicines in Part 1 of Schedule 10 are evaluated by the Drug Safety and Evaluation Branch of TGA.

Secretary: see Section 3(1) of the *Therapeutic Goods Act 1989*.

Service goods: Therapeutic goods which are required in the public interest but whose supply does not offer financial incentive for the sponsor.

Single step of manufacture: For the purpose of annual licence charge classification only - for example one of the following: tablet coating; capsule filling from bulk; aerosol filling from bulk; storage other than for sale; packaging including labelling; sterilisation; testing including analysis; assembling devices from components, testing or batch testing of therapeutic devices; releasing for sale (by a person not involved with actually preparing the goods).

Site identification: Identification code assigned by the Manufacturer Assessment Section (MAS) to a manufacturing site(s) for an enterprise which is involved with the manufacture of therapeutic goods.

Sponsor: see Section 3(1) of the *Therapeutic Goods Act 1989*. A person who exports, or arranges the exportation of, the goods from Australia; or a person who imports, or arranges the importation of, the goods into Australia; or a person who, in Australia, manufactures the goods, or arranges for another person to manufacture the goods, for supply (whether in Australia or elsewhere); but does not include a person who: exports, imports or manufactures the goods; or arranges the exportation, importation or manufacture of the goods; on behalf of another person who, at the time of the exportation, importation, manufacture or arrangements, is a resident of, or is carrying on business in, Australia.

Standard: see Section 3(1) of the *Therapeutic Goods Act 1989*. Must be specified in a TGO or the BP. A general standard that applies to all products of a particular dosage form. A specific standard of medicines refers to a particular dosage form of particular active ingredient(s).

State law: see Section 3(1) of the *Therapeutic Goods Act 1989*.

Step in manufacture: Any part of the process of bringing goods to their final state which may be completed separately from other parts of the process.

Strength: The quantity of an active pharmaceutical ingredient in a medicine or a formulated or medicated device.

Sub-manufacturer: A manufacturer who completes part of the manufacturing process of therapeutic goods on behalf of the principal manufacturer (no longer used in the ARTG system - replaced by manufacturer with an identified step in manufacture).

Submission: A series of related applications (as defined) made under Section 23 of the Therapeutic Goods Act on the same day and under the same covering letter.

Summary of Product Characteristics (SmPC): European equivalent to the Australian Product Information (PI).

Supply: see Section 3(1) of the *Therapeutic Goods Act 1989*.

TGA Approved Terminology for Medicines²: A compendium document which (in the main) identifies terms to be used when making an application to the TGA for registration of medicines.

TGA Identification Number (TGAIN): Number assigned by the TGA Business Management Group to each transaction or event.

The Act: see Regulation 2 of the *Therapeutic Goods Regulations*.

Therapeutic device: see Section 3(1) of the *Therapeutic Goods Act 1989*.

Therapeutic medicine - device combination: A therapeutic good in which the presentation of the medicinal product(s) includes therapeutic device(s). These goods are classified as drugs for registration/listing in the ARTG but details of both the drug and device component are required for inclusion in the ARTG.

Therapeutic goods: see Section 3(1) of the *Therapeutic Goods Act 1989*.

Therapeutic Goods Advertising Code: see Regulation 2 of the *Therapeutic Goods Regulations*.

Therapeutic goods information: see Section 61 of the *Therapeutic Goods Act 1989*.

Therapeutic Goods Order (TGO): Sponsors should refer to the Publications page on the TGA website for information in regard to current TGO's.

Therapeutic use: see Section 3(1) of the *Therapeutic Goods Act 1989*.

Trade name: see Regulation 2 of the *Therapeutic Goods Regulations*.

Trading corporation: see Section 3(1) of the *Therapeutic Goods Act 1989*.

Working day: see Regulation 16A of the *Therapeutic Goods Regulations*. Relates only to medicine

Historical document

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www.tga.gov.au

Reference/Publication #