A Discussion Paper on
Regulation of Extemporaneously Prepared Medicines in Non-Hospital Pharmacies

Issued by the
National Coordinating Committee on Therapeutic Goods (NCCTG)

10 April 2008
A Discussion Paper on Regulation of Extemporaneously Prepared Medicines in Non-Hospital Pharmacies

1. Introduction

Pharmacists formulate and prepare medicines for their customers. Over recent years, the scale of preparation and the variety of ingredients and formulations of such medicines has increased.

Medicines, and other therapeutic goods, are subject to regulation to provide acceptable quality, safety and efficacy of the products. The Commonwealth’s regulation is administered by the Therapeutic Goods Administration (TGA) through the application of the Therapeutic Goods Act 1989 and its Regulations.

When the Therapeutic Goods Act 1989 was enacted, exemptions to certain provisions of the legislation were given for extemporaneous compounding and dispensing. Extemporaneous compounding and dispensing is intended to be where a pharmacist prepares a medicine for an individual patient in response to an identified need of that patient. The medicine might be prepared in response to a diagnosis by the pharmacist or to a prescription by a medical practitioner. The exemptions recognised the one-off nature of such medicines and the professional training of the pharmacist to prepare a medicine extemporaneously.

Internationally, there has been a trend by some pharmacists to advertise themselves as compounding chemists where they promote their ability to prepare medicines in anticipation that there will be individual patients with a need for a product. Characteristically, these products are produced and dispensed within a single pharmacy and the products are not supplied by wholesale. The pharmacist would say that they are providing a service by providing to patients medicines which are not commercially available.

Some pharmacists have now moved past this stage to what is commercial manufacture where medicines are manufactured in large volumes and promoted and supplied by the internet or through a number of outlets.

The regulatory framework proposed in this discussion paper would not be applied to pharmacies operated by a public hospital or a public institution when the medicines are used for the treatment of patients in that hospital or institution or in another hospital or institution in the same State or Territory.

---

1 The NCCTG acknowledges the work of Oceania Health Consulting and its report “A Revised Regulatory Scheme for Compounded Products” (November 2005), commissioned by the TGA. The material in Section 4 of this paper is largely drawn from the consultant’s report.
2. Terminology

Accredited – means being successfully audited by a relevant and appropriately authorised body in that jurisdiction to undertake accreditation of compounding activities. Successful accreditation will require the pharmacist and the pharmacy to fully meet the relevant requirements specified in agreed standards (eg, standards established by the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme (PIC/S)).

Active ingredient – means the therapeutically active substance(s) included in the preparation, but does not refer to preservatives or other substances included for reasons other than therapeutic effect.

Adverse drug event – means the particular type of adverse drug event where an active ingredient or medicine is implicated as a causal factor in the adverse event. This encompasses both harm that results from the intrinsic nature of the medicine (an adverse drug reaction) as well as harm that results from medication errors or system failures associated with the manufacture, distribution or use of medicines.

Immediate use – means that supply for use by the patient occurs or is planned to occur within 24 hours of the preparation of the medicine.

New chemical entity – means a substance which has not been approved in Australia previously for a therapeutic use in humans, or has been cancelled from the Australian Register of Therapeutic Goods (ARTG) for reasons of public health or safety.

Pharmacy – means a (non-hospital) pharmacy operating under the relevant State or Territory laws that is open to the public. The term includes Friendly Society pharmacies.

Risk - means the probability that, in a certain timeframe, an adverse outcome will occur in a person or group of people who are exposed to a particular dose or concentration of a hazardous agent, that is, it depends on both the level of toxicity of the agent and the level of exposure.

Substantially similar – means that two or more preparations could be interchanged because they have the same dosage form and contain the same active ingredient(s) in similar or the same concentrations. However, a preservative-free formulation or a formulation with a different flavour, compared to a commercially available product, would not be regarded as ‘substantially similar’.

3. Background

The Therapeutic Goods Act 1989 uses the Commonwealth’s powers over imports, exports, interstate trade and corporations to regulate therapeutic goods to safeguard the public. The Commonwealth’s powers do not extend to unincorporated bodies operating solely within a State or Territory, so called sole traders. New South Wales, Tasmania and Victoria have enacted complementary legislation that adopts the terms of the Therapeutic Goods Act 1989 to cover persons who are not corporations and are operating solely intrastate. Other State and Territory jurisdictions had intended to achieve this same outcome via the implementation of the trans-Tasman joint regulatory scheme. With the postponement of negotiations towards the trans-Tasman joint regulatory scheme in July 2007, these States and Territories have now
undertaken to introduce legislation complementary to Commonwealth legislation dealing with therapeutic products.

Under the Therapeutic Goods Act 1989, the current exemptions for extemporaneous dispensing apply to both the need for products to be entered on the ARTG for supply and the need for pharmacists to have a licence to manufacture therapeutic goods:

Schedule 5, Item 6 of the Therapeutic Goods Regulations 1990 provides that medicines which are extemporaneously prepared are not required to be included on the ARTG. The wording of the exemption is:

Medicines (other than medicines used for gene therapy) that are dispensed, or extemporaneously compounded, for a particular person for therapeutic application to that person.

Schedule 8(2) of the Therapeutic Goods Regulations 1990 provides an exemption from the operation of Part 3-3 of the Therapeutic Goods Act 1989, pursuant to Regulation 18. Part 3-3 of the Act deals with the manufacture of therapeutic goods (other than goods that are exempt) for supply for use in humans unless the person is the holder of a licence that authorises the carrying out of that step in relation to the goods at those premises. The Regulations provide an exemption for pharmacists as follows:

The manufacture of therapeutic goods produced by the pharmacist:
   a) in a pharmacy where the pharmacist practices and the pharmacy is open to the public; or
   b) on the premises of a dispensary conducted by a Friendly Society; or
   c) on the premises of a private hospital;
for supply (other than by wholesale) on or from those premises.

The manufacture of therapeutic goods by a pharmacist in a public hospital or a public institution and their supply in hospitals or public institutions in the same State or Territory are also activities that are exempt under the Therapeutic Goods Regulations. These exemptions would not be affected by the proposals below. Further comment on compounding in hospital pharmacies is included in Section 7.

4. Risk

4.1 Potential risks

The risk of harm from medicines increases with the potency of the active ingredient, the dosage form, the quantity of product and as the overall public exposure is increased. The potential for poor compounding, cross-contamination and human errors increases when multiple products are made. Some typical hazards and risks in compounding are outlined in Table 1.
### Table 1 - Outline of some typical hazards and risks in compounding

<table>
<thead>
<tr>
<th>Risks from ingredients</th>
<th>Hazard</th>
<th>Risk</th>
<th>Means of addressing risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Substances that are not included in products on the ARTG because:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• they are likely to be misused (see Schedule 9 of the SUSDP); or they are so dangerous that they should not be permitted to be supplied or used in Australia (see Appendix C of the SUSDP, eg, clioquinol for internal use); or they are herbs prohibited by the Therapeutic Goods Regulations.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• the toxicity and other negative effects as well as the benefits are unknown as the ingredient has not been assessed in Australia (eg DHEA).</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• the ingredient may carry prion disease despite normal processing of the material.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Very high risk of injury or death (eg, through respiratory failure or stroke), and in some cases risk of addiction.</td>
<td>Supply is prohibited because of the risks.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Potentially high risk because no assessment of the risks and benefits of these substances has been undertaken to identify the level of risk.</td>
<td>Require premarket approval by TGA.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Prion diseases (eg, variant CJD) are not eliminated by normal processing.</td>
<td>TGA requirements for therapeutic goods to apply.</td>
<td></td>
</tr>
<tr>
<td>Active ingredient or other starting material (including containers and labels) may be defective or substandard.</td>
<td>Active ingredient may contain harmful impurities, or be subpotent, or may not be the right material.</td>
<td>Require active ingredients and other starting materials to meet pharmacopoeial or other standards, or a standard to be developed. Testing of the material against that standard to be undertaken routinely.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Misidentification of materials, printing errors on labels, etc.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Calculation and weighing errors.</td>
<td>Errors may lead to a person receiving an overdose which could lead to death or injury, or underdosing where death or injury could result, eg, in an asthmatic.</td>
<td>Requirement to follow good compounding practices.</td>
<td></td>
</tr>
</tbody>
</table>
### Risks from failure in the pharmaceutical technology – the dosage form fails or the product is not homogeneous

<table>
<thead>
<tr>
<th>Hazard</th>
<th>Risk</th>
<th>Means of addressing risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Poorly formulated or prepared product may result in too little or too much active ingredient being released, or no release at all.</td>
<td>Complex formulations such as aerosols, patches, and modified (delayed) release formulations may cause injury, illness or death from overdosage or underdosage.</td>
<td>Restrictions on the range of dosage forms.</td>
</tr>
<tr>
<td>Active ingredient may not be evenly distributed through all dosage units. Poor dispersal of active ingredients is a key source of potential hazard in extemporaneous compounding.</td>
<td>Variations in dosage, with one dose being overpotent and the next lacking potency, leading to toxicity or lack of effective therapy, which can be serious, eg, in asthma.</td>
<td>Restrictions on the range of dosage forms and requirements for good compounding practices.</td>
</tr>
</tbody>
</table>

### 4.2 Actual Experience

There are a number of examples which support the need for greater regulation of the practice of pharmacy compounding.

#### 4.2.1 Overseas reports of concerns with the quality, safety and efficacy of extemporaneous products

In the United States, where extemporaneous compounding is relatively widespread, there have been a number of serious cases of error which have led to death and disability. The most serious have been with injectable preparations, but there have also been deaths from poorly formulated and prepared non-sterile products.

In relation to injection products, some of the better known cases are summarised below:

- **2001 California**
  - Contaminated compounded betamethasone suspension injections resulted in the deaths of three hospitalised patients from meningitis\(^2\)

- **2002 South Carolina**
  - Five patients identified as acquiring fungal infection from contaminated methylprednisolone injections. One died. The medicine was recalled and further action taken\(^3\)

- **2005 Minnesota**
  - Two reports of loss of vision associated with contaminated ophthalmic solution used in surgery\(^4\)

- **2007 Texas**
  - Three deaths due to an overpotent batch of colchicine injection\(^5\)


\(^3\) “Exophilia infection from contaminated injectable steroids prepared by a compounding pharmacy.” MMWR, 51(49):1109-1112. [http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5149a1.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5149a1.htm) (accessed April 2008)

\(^4\) “Custom-Rx Compounding Pharmacy Issues Nationwide Recall of Trypan Blue 0.06% Ophthalmic Solution” [http://www.fda.gov/oc/po/firmrecalls/customrx08_05.html](http://www.fda.gov/oc/po/firmrecalls/customrx08_05.html) (accessed April 2008)


Some events involving non-injectable products include:

- **2001 California**
  - Pharmacy compounded inhalation solutions were recalled due to contamination with *Serratia*.

- **2003 Missouri**
  - Inadequate pharmacy procedures regarding the recall of contaminated batches of inhalation solution.

- **2005 North Carolina**
  - A 22 year old woman died from brain anoxia after using a poorly formulated local anaesthetic gel.

The United States FDA conducted a small survey of medicines manufactured by 12 pharmacies that sold over the internet. The survey disclosed a number of quality problems. A representative of the FDA said of this survey:

> The 29 products sampled included hormonal products, antibiotics, steroids, anesthetics and drugs to treat glaucoma, asthma, iron deficiency anemia, and erectile disfunction. Five different dosage forms (i.e. sterile injectables, ophthalmic products, pellet implants, inhalation products, and oral dosage forms) were sampled.

Ten (34 percent) of the 29 sampled products failed one or more standard quality tests performed. Nine with failing analytical results failed assay (potency) testing, with a range of 59 percent to 89 percent of expected potency.

Since 2003 the Missouri Board of Pharmacy has conducted a random testing program of extemporaneously prepared products from community pharmacies. Nearly 900 medicines have been tested, of which 22% have failed to be within the limits of ± 10% for the active ingredient; this is the limit commonly required for United States Pharmacopoeia formulations. Failing results for the content of active ingredient in the tested extemporaneously prepared medicines have ranged from 0.0% to 553%. There have been no sterility failures in medicines required to be sterile.

### 4.2.2 Recent Australian reports of concerns with the quality, safety and efficacy of extemporaneous products

Much of the public commentary on the Australian experience of the safety, efficacy and/or quality of extemporaneously compounded medicines has concerned ‘bioidentical’ or ‘natural’ hormone replacement therapy (HRT) provided by compounding chemists. A recent publication by Eden *et al* describes case reports of three women who developed endometrial cancer after taking ‘bioidentical’ HRT.

---


See also [http://www.fda.gov/foi.warning_letters/archive/g3527d.htm](http://www.fda.gov/foi.warning_letters/archive/g3527d.htm) (accessed April 2008).


The authors suggested “the possibility that the oestrogen component of the troche was significantly absorbed but the dose of progesterone was inadequate”.

Sponsors of medicines listed or registered on the ARTG are required by Commonwealth legislation to report to the TGA information that indicates that the use of a medicine in accordance with the recommendations for use has had unintended harmful effects, and information that indicates that the quality, safety or efficacy of the medicine is unacceptable. Pharmacists are not required to report such information in respect of extemporaneously compounded medicines.

### 4.2.3 Potent products which have not been evaluated and which are promoted to the public in Australia

<table>
<thead>
<tr>
<th>Indication</th>
<th>Product</th>
<th>Possible Concerns</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ageing, Impotence</td>
<td>DHEA</td>
<td>Prohibited import; lack of data on quality of raw material and effectiveness.</td>
</tr>
<tr>
<td>Ageing</td>
<td>Pregnenolone products, procaine (KH3)</td>
<td>Quality, safety and efficacy.</td>
</tr>
<tr>
<td>Brain Health</td>
<td>Melatonin</td>
<td>Lack of data on quality of raw material and effectiveness.</td>
</tr>
<tr>
<td>Endocrine</td>
<td>Thyroid extract; Triiodothyronine and Thyroxine Combination Capsules</td>
<td>Quality, safety and efficacy. Alternatives on the ARTG.</td>
</tr>
<tr>
<td>Hormonal replacement</td>
<td>Creams containing Estradiol, Estriol, ‘Natural’ Progesterone, Pregnenolone</td>
<td>Quality, safety and efficacy.</td>
</tr>
</tbody>
</table>

### 5. Proposed regulatory framework

The regulation of therapeutic goods is based on the level of risk where the level of regulation is commensurate with the risk represented by the products. In line with this, it is proposed to redefine the existing exemptions for extemporaneous dispensing and compounding to introduce a three class structure for pharmacies and pharmacists:

**Class 1** a pharmacy prepares individual products for immediate supply to meet the identified needs of an individual patient. In this case, the pharmacist would use the existing professional practice of self assessment to determine their capability to carry out extemporaneous dispensing.

**Class 2** a pharmacy prepares sufficient quantities of product to meet the anticipated needs of patients, with supply from that pharmacy. An accreditation process for extemporaneous compounding, consisting of accreditation of the premises and practices and credentialing of the pharmacist would be developed in consultation between the NCCTG, Pharmacy Boards, the profession and the TGA.

**Class 3** the nature, quantities or distribution of products represent manufacture, and such products and pharmacies (sponsors) would come under the requirements of the *Therapeutic Goods Act 1989* (extemporaneous manufacture).

All activities would need to comply with the relevant State and Territory laws.
For Class 1 and Class 2 pharmacies it is proposed that there will be risk mitigation through restrictions on the dosage forms, active ingredients and advertising, as discussed under 5.1, 5.2 and 5.3 below. For all pharmacies, further requirements regarding the reporting of adverse drug event are proposed, as discussed under 5.4.

**5.1 Dosage forms**

Table 3 – List of dosage forms that may be compounded by a pharmacist in a Class 1 pharmacy.

<table>
<thead>
<tr>
<th>Applications</th>
<th>Nasal drops and sprays</th>
</tr>
</thead>
<tbody>
<tr>
<td>Collodions</td>
<td>Ointments</td>
</tr>
<tr>
<td>Creams</td>
<td>Oral applications</td>
</tr>
<tr>
<td>Diluents</td>
<td>Oral liquids</td>
</tr>
<tr>
<td>Dressings, medicated</td>
<td>Paints</td>
</tr>
<tr>
<td>Ear drops</td>
<td>Pastes</td>
</tr>
<tr>
<td>Ear ointments</td>
<td>Pessaries (but not modified release)</td>
</tr>
<tr>
<td>Elixirs</td>
<td>Powders, including powders for use as oral liquids or suspensions</td>
</tr>
<tr>
<td>Enemas</td>
<td>Soaps</td>
</tr>
<tr>
<td>Extracts, including concentrated, dry, soft and liquid extracts</td>
<td>Solutions, unless otherwise proscribed</td>
</tr>
<tr>
<td>Gels (but not modified release)</td>
<td>Solutions for injection (by sterile reconstitution only)</td>
</tr>
<tr>
<td>Gum, chewing</td>
<td>Sprays (but not pressurised sprays)</td>
</tr>
<tr>
<td>Herbal preparations</td>
<td>Sticks, including lipsticks and urethral inserts</td>
</tr>
<tr>
<td>Inhalations (but not aerosols)</td>
<td>Suppositories (but not modified release)</td>
</tr>
<tr>
<td>Insufflations</td>
<td>Suspensions</td>
</tr>
<tr>
<td>Liniments</td>
<td>Teas</td>
</tr>
<tr>
<td>Liquids, unless otherwise proscribed</td>
<td>Tinctures</td>
</tr>
<tr>
<td>Lotions</td>
<td></td>
</tr>
<tr>
<td>Mouthwashes</td>
<td></td>
</tr>
</tbody>
</table>

Table 4 – List of dosage forms that may be compounded by a pharmacist in a Class 2 pharmacy.

| All dosage forms that can be compounded in a Class 1 pharmacy, plus Capsules (but not enteric coated; limited modified release) |
| Eye Drops |
| Eye Ointments |
| Injections for single use |
| Lozenges |
| Pastilles (but not highly flavoured) |
| Pills (but not enteric coated; limited modified release) |
| Tablets (but not enteric coated; limited modified release) |
| Troches |

There would be provision that an individual extemporaneous compounder at a specific pharmacy could seek accreditation for a specific dosage form such as a modified release product where the accreditation body can be convinced that the prepared preparation will meet relevant mandated standards.
5.2 Ingredients
Extemporaneously prepared products will not contain:
- ingredients in Schedule 9 or Appendix C of the SUSDP
- ingredients proscribed for therapeutic use under the *Therapeutic Goods Act 1989* or the Regulations.

In addition, extemporaneously prepared products will not:
- contain a new chemical entity for the Australian market
- be substantially similar to an existing product that is on the ARTG and is commercially available.

However, these limitations on ingredients would not apply to the extemporaneous preparation of products under a clinical trials protocol notified to or approved by the TGA.

5.3 Advertising
Products prepared at Class 1 and 2 pharmacies will not be advertised.

Products made by Class 3 pharmacies that are not on the ARTG will not be advertised.

Products made by Class 3 pharmacies that are included on the ARTG will come under the provisions of the Therapeutic Goods Advertising Code for non prescription medicines or, where relevant, the Medicines Australia Code of Conduct for prescription medicines.

5.4 Adverse drug events
All pharmacists would be expected to report clinically significant adverse drug reactions to the Adverse Drug Reactions Unit of the TGA where appropriate. Class 2 and Class 3 pharmacies would be expected to maintain a register of adverse drug events relating to extemporaneously prepared medicines.

6. Proposed provisions
Class 1 involves extemporaneous dispensing which covers compounded preparations prepared within a pharmacy for immediate supply in response to the identified needs of an individual for use by that patient where:

a. for a non sterile preparation:
   i) the preparation is a permitted dosage form and does not contain active ingredients which are not permitted; and
   ii) the preparation is prepared in a single lot all of which is supplied as a single supply to the one patient for immediate use; and
   iii) the preparation is not substantially similar to a product on the ARTG and commercially available.

b. for a sterile preparation:
   i) the preparation is a registered therapeutic good which is reconstituted in accordance with the product sponsor's instructions.
Pharmacists undertaking extemporaneous dispensing would be required to self-certify against agreed professional standards.

**Class 2 involves extemporaneous compounding** which covers compounded preparations prepared within a pharmacy in anticipation of the needs of a patient attending that pharmacy where:

a. for a non sterile preparation:
   i) the preparation is a permitted dosage form and does not contain active ingredients which are not permitted;
   ii) the average monthly quantity of an individual formulation of a solid dose preparation does not exceed 20 000 dosage units (eg, capsules) and the average monthly quantity of all solid dose preparations does not exceed 150 000 dosage units, or other quantitative limits (as discussed below). Comparable limits would be established for semi-solid and liquid dosage forms based on typical prescribing patterns;
   iii) the preparation is not substantially similar to a product on the ARTG and commercially available; and
   iv) the preparation is not sold by wholesale, promoted or advertised.

b. for a sterile preparation:
   i) the preparation is a topical preparation including eye preparations, or an injection for single use, and does not contain active ingredients which are not permitted;
   ii) the preparation is not substantially similar to a product on the ARTG and commercially available; and
   iii) the preparation is not sold by wholesale, promoted or advertised.

Pharmacies and the pharmacist undertaking extemporaneous compounding will be externally accredited by the accreditation body against professional standards for extemporaneous compounding. The accreditation process should include the requirement to keep a staffing ratio of no more than 1:2 pharmacist to technicians in the pharmacy.

**Class 3 involves extemporaneous manufacture** and covers compounded preparations prepared in a pharmacy that does not meet the limitations that are applied to Class 1 or Class 2 pharmacies.

Extemporaneous manufacture, as defined, carries a higher risk of harm from preparations due to:

- the nature of the active ingredients (where this is a new chemical entity);
- the dosage form (where verification of the performance or quality of the product is required such as for a modified release formulation or a sterile infusion);
- the quantity of product prepared is not for immediate use or anticipated supply; or
- the overall public exposure is increased (where the product is promoted, advertised or supplied by wholesale).
The quantitative parameter(s) and the numeric limit(s) that would be used to distinguish between Class 2 and Class 3 pharmacies could take various forms:

- limits on the quantity of an individual formulation, and also on total dosage units of each dosage form per month, e.g., the average monthly quantity of a solid dose preparation is not to exceed 20,000 dosage units and the average monthly quantity of all solid dose preparations is not to exceed 150,000 dosage units; or
- a batch size limit of ten ‘prescription units’ (e.g., 10 x 100 capsules or 10 x 100 g cream); or
- arrangements based solely on professional staffing levels and ratios to technicians.

The Class 3 pharmacy would be required to have a Good Manufacturing Practice (GMP) licence to manufacture, issued by the TGA and assessed against a code of GMP specific to extemporaneous manufacture by pharmacies.

The following products made by a Class 3 pharmacy would be required to be included on the ARTG:

a. a dosage form that is not permitted to be prepared by a Class 1 and Class 2 pharmacy, or
b. a product that contains a new chemical entity, or
c. a product that is substantially similar to a product on the ARTG, or
d. a product that is supplied by wholesale or otherwise promoted or advertised.

7. Compounding in public hospitals

It is not intended that the above proposed regulatory controls on extemporaneously prepared products will apply to pharmacies operated by a public hospital or a public institution when the products are used for the treatment of patients in that hospital or institution or another hospital or institution in the same State or Territory.

A pharmacist in a public hospital or institution is exempt from the requirements for GMP licensing for the manufacture of therapeutic goods for supply in hospitals or public institutions in the same State or Territory. However, where the pharmacist engages in interstate trade this activity is not covered by the exemption in Schedule 8, Item 3 of the Therapeutic Goods Regulations.

The Society of Hospital Pharmacists of Australia (SHPA) has been asked by the TGA to undertake a review of the standards for the preparation of pharmaceuticals in hospital pharmacies.

An exemption from entry on the ARTG of certain products prepared for use by patients of public and private hospitals is provided by Schedule 5A, Item 5 of the Therapeutic Goods Regulations. This exemption is conditional on, among other matters, the manufacturer being licensed by the TGA and the formulation being specified by the hospital and supplied for use by a hospital patient.

8. Standards

Usual professional practice and competence would be sufficient controls for self-certification against professional standards of extemporaneous dispensing in Class 1 pharmacies.
Successful accreditation will require the Class 2 pharmacy to fully meet the relevant requirements specified in agreed standards.

The TGA has convened the Pharmacy Manufacturing Technical Expert Reference Group to consider the good manufacturing practice issues relating to pharmacy manufacturing, that is, to Class 3 pharmacies. The Group has members drawn from peak pharmacy bodies and industry associations, as well as the TGA's Manufacturers Assessment Branch.

Quality standards should be applied to starting ingredients and finished products consistent with usual professional practice and competence. Medicines supplied under the PBS are required to conform to standards of composition or purity prescribed in the *Therapeutic Goods Act 1989*. In practice, this requires that ingredients (including water) and dosage forms comply with the standards of the British Pharmacopoeia. Requirements applicable under other Commonwealth, State or Territory legislation, such as those concerning weights and measures may also apply.
### Overview of Regulation of Compounding Chemists

<table>
<thead>
<tr>
<th>Class</th>
<th>Regulatory Framework</th>
<th>Moderation of risk factors</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>activity</td>
<td>non sterile products</td>
</tr>
<tr>
<td>3</td>
<td>extemporaneous manufacture</td>
<td>all other products</td>
</tr>
<tr>
<td>2</td>
<td>extemporaneous compounding</td>
<td>up to quantity limit **</td>
</tr>
<tr>
<td>1</td>
<td>extemporaneous dispensing</td>
<td>made for defined patient only in a single lot</td>
</tr>
</tbody>
</table>

*not permitted if:
- Schedule 9 or Appendix C of the SUSDP
- new chemical entity (unless product included on the ARTG)
- proscribed under therapeutic goods regulations
- substantially similar to an existing product that is commercially available

**Class 2 limit: for example, the average monthly quantity of a solid dose preparation is not to exceed 20 000 dosage units and the average monthly quantity of all solid dose preparations is not to exceed 150 000 dosage units, or other quantitative parameter(s) and/or numeric limit(s).

Class 1 and 2 preparations would not be substantially similar to products on the ARTG and which are commercially available.