26th July 2013
Comments by the Pharmacy Guild of Australia on:
Options for reform of the regulatory framework for pharmacy compounding

The Pharmacy Guild of Australia (Guild) welcomes the opportunity to comment on the Options for reform of the regulatory framework for pharmacy compounding prepared by the TGA.

1. Background

The Guild is an employers’ organisation servicing the needs of independent community pharmacies. It strives to promote, maintain and support community pharmacies as the most appropriate primary providers of health care to the community through optimum therapeutic use of medicines, medicines management and related services.

The Guild works closely with the TGA on many matters, and represents community pharmacy on a number of committees and panels. In addition, the Guild is an active participant in reviews and consultations on regulatory matters for therapeutic goods that relate to community pharmacy practice, providing submissions when appropriate and participating in relevant workshops and forums.

Extemporaneous dispensing is a core professional activity of pharmacists and ensures that patients are able to access essential medicines at a reasonable price when a commercially manufactured product is unsuitable or unavailable. Children and infants are examples of patients reliant on compounded medicines as many standard products are not available in a suitable dosage form or strength.

2. General Comments

The Guild supports the intent of the TGA to ensure appropriately enhanced regulatory oversight of certain compounding practices in specific circumstances. We acknowledge that the complexity and scale of some compounding practices in pharmacies are not adequately addressed under the current regulatory framework. We are also concerned about the reported non-compliances with quality and safety standards noted by State and Territory pharmacy inspectorates. The Guild is deeply concerned about the reported deaths in the USA in relation to below standard compounding practices, but, even under current arrangements considers the Australian system provides greater protection to the consumer. We reiterate our support of the TGA in undertaking this review, to ensure Australia’s high standards and reputation in relation to compounded therapies is upheld.
As noted in the consultation document, compounding is today a niche area for community pharmacy, with only a small number (6-10%) purported to advertise or claim some degree of specialisation in compounding. An even smaller number are ‘compounding only’ pharmacies.

While acknowledging the need for a reliable system which guarantees high standards of quality and safety, it is our preference that any change to the compounding regulatory framework does not result in a significant decline of an already small number of pharmacies specialising in compounding services. Such an outcome would likely have a detrimental impact on patients through diminished access and increased costs.

Professional Oversight

Pharmacist competencies covering compounding, including complex compounding, have been developed by the profession in the National Competency Standards Framework for Pharmacists in Australia 20101 (see Domain 5). The PSA covers compounding in Standards 10 and 11 in their Professional Practice Standards v42. In addition, the Professional Compounding Chemists of Australia (PCCA)3 provides training, guidelines, materials and resources to support pharmacists who wish to provide more extensive compounding services to the public through community pharmacy. PCCA is endorsed by the Pharmacy Guild of Australia.

The Guild’s Quality Care Pharmacy Program also includes requirements for community pharmacies to ensure simple compounding procedures are undertaken to an acceptable standard. Further information on the QCPP and opportunity to expand the role of QCPP in the areas of interest to the TGA, is discussed below.

Pharmacies specialising in compounding have demonstrated a flexibility to adhere to particular standards based on the demands of their customers. For example, many pharmacies that supply complex and sterile compounded products to hospitals are required by that hospital to sign a service agreement indicating they meet a minimum professional standard for the compounded product(s) they supply.

Quality Care Pharmacy Program (QCPI

The Guild’s Quality Care Pharmacy Program (QCPI) is a quality assurance program for community pharmacy that provides support and guidance on professional health services and pharmacy business operations. In 2011, the Quality Care Pharmacy Standard was recognised as Australian Standard AS85000:2011- quality management system for pharmacies in Australia. Over 90% of community pharmacies are now accredited against the Australian Standard and are subject to an external audit by licensed assessors every two years4.

Operating since 1998, QCPI became a complete pharmacy business operation model in 1999, with the inclusion of professional practice standards and the support of the Pharmaceutical Society of Australia (PSA). Now as an Australian Standard, the Quality Care Pharmacy Standard is reviewed and revised by a whole of profession Standards Committee. QCPI integrates the Australian Standard with tools, procedures and checklists.

3 Professional Compounding Chemists of Australia www.pccarx.com.au
4 www.qcpp.com/about-qcpp/what-is-qcpp
Under Action 2.6 of QCPP, a pharmacy must ‘maintain and follow a system for simple compounding (extemporaneous dispensing)’ for which there is an assessable procedure (P2C – see Attachment A) and a worksheet template (T2B – see Attachment B).

Currently, complex compounding is not assessed under the QCPP, but QCPP has long had the intention to strengthen requirements to cover additional compounding arrangements according to outcomes of these regulatory review processes. This may be through the addition of new Program procedures, checklists and templates and may also require changes to the Australian Standard and specific Actions within the Standard. Importantly, QCPP has existing administration and assessor infrastructure that gives it capacity to assess pharmacies against any new requirements, and this may include validating relevant licences and credentials as part of the audit and assessment process. The QCPP would charge an assessment fee and consider the application of an ongoing accreditation fee in relation to complex compounding services.

In developing new requirements for compounding within QCPP and the Quality Care Standard, the Guild would consult with the PSA, and PCCA (PSA is already a member of the Quality Care Standards Committee), and of course with the TGA. There may even be opportunities to work together with PCCA in implementing and assessing any new compounding requirements. The Australian College of Pharmacy (ACP) includes a Faculty of Compounding and ACP is also a member of the Quality Care Standards Committee. It is recognised that the Society of Hospital Pharmacists of Australia (SHPA) also has guidelines for manufacture of medicines in hospital pharmacy departments, but it is noted that the scope of this consultation RIS does not extend to manufacture of medicines in a public hospital or public institution.

The Guild’s proposed framework

To assist in distinguishing genuine compounders from manufacturers, the Guild has developed a flowchart (See Attachment C) that proposes key variables that make it clear to all stakeholders the circumstances in which a compounding pharmacy should be monitored and assessed under a self-regulatory framework, and where they are classified as a manufacturer and require a GMP licence from the TGA. Individual components of this flowchart will be referred to throughout our submission.

The Guild has also developed a regulatory framework for compounding in community pharmacy (See Attachment D). The framework outlines the mandatory training and professional standards a pharmacist must complete and adhere to in order to compound medicines. Proficiency in complex compounding requires additional training and accreditation under more advanced professional standards. It is proposed this proficiency would be assessed and audited under existing self-regulatory frameworks, namely QCPP. Under the Guild’s framework, pharmacies that repeatedly fail to meet the QCPP standards or are bona-fide manufacturers will be required to obtain a GMP licence from the TGA. There is capacity for this framework to be amalgamated with some of the regulatory options proposed in this consultation.
3. Comments on specific options
The Guild has considered the proposed options included in the consultation RIS, and provides the following comments:

3a) Option A- Status quo
The Guild is open to the retention of the current system. As mentioned, profession self-regulation in community pharmacy is managed through the QCPP. Complex compounding processes have been developed by specialised groups such as the PSA and PCCA. If a pharmacist undertakes complex compounding, they must ensure they develop and adhere to one of those standards.

The Pharmacy Board of Australia (PBA) is currently developing a revised set of guidelines for compounding medicines, particularly for complex formulations. The Guild will be responding to the PBA’s consultation when it is released.

Risks and benefits of the continuation of existing regulatory arrangements

Benefits
The main benefit of maintaining the existing regulatory arrangements is that compounding pharmacies will face no additional financial burdens. Such burdens may make many operations unviable and further reduce the already small number of pharmacists compounding services, to the likely detriment of patients.

As mentioned, maintaining the current framework also enables pharmacies to be flexible in adhering to specific standards requested by their customers as opposed to being required to comply with the same regulatory instrument, namely a GMP licence whose specific and associated costs would be prohibitive for many compounding pharmacies. Such a situation would reduce the number of compounding pharmacies with only marginal improvements in professional oversight. This also has the benefit of limiting the flow-on effect of such costs to consumers.

In addition, we consider that stronger professional oversight covers all pharmacists in all jurisdictions for all compounded medicines as compared to the limitations of federal regulatory control through the TGA which is not applicable to hospital pharmacists; not applicable in all jurisdictions; and not applicable to compounded animal products.

Risks
The Guild believes there is a reputational risk to community pharmacy under the status quo, as a rogue operator not adhering to professional standards would have the potential to damage the reputation of community pharmacy in the eyes of the regulator and consumers. A lack of regulatory oversight in specific circumstances also has the potential to undermine the currently high level of trust the general public has in community pharmacy.

3b) Option B: enhance co-regulation and update legislation
The Guild offers in-principle support to enhancing co-regulation and updating legislation, and makes the following comments in relation to specific elements of this proposal:

What are the risks and benefits of Option B?
The Guild believes the main benefit of this approach is that regulatory oversight of pharmacy compounding is enhanced through existing standards and the cost of compliance is therefore
minimised. It would also demonstrate to community pharmacy the TGA has confidence in the self-regulatory principle which gives the profession increased confidence in investing time and resources to strengthen its own framework and encourage more members to become accredited.

As highlighted above under Option A, it would effectively utilise professional oversight to manage practice that is not covered by the TGA requirements.

The major risk with this approach is that some of the proposed components of this option could lead to confusion and inadvertent breaches of the rules by pharmacies. This is elaborated upon under the Responses to Key Components of Option B part of our submission.

Do you have any views on how Option B could be improved?

The Pharmacy Board of Australia (PBA) is currently developing a revised set of guidelines for compounding complex formulations and the Guild will be responding to the PBA’s consultation.

The Guild intends to outline to the PBA our views regarding the distinction between a compounding pharmacy and a manufacturer (See Attachment C). Attachment C could then form the basis of a regulatory definition of a compounding pharmacy based on the following principles:

A compounding pharmacy,

- Compounds products in response to a direct request from a consumer or prescriber to address a specific identified need
- Supplies compounded products as a ‘single unit of issue’ for immediate use
- If applicable, batches compounded products within the limitations for which exemptions apply
- Does not supply compounded products by wholesale
- Meets an auditable Quality Assurance Standard
- Only compounds sterile products that are exempt from TGA regulation

If a compounding pharmacy does not meet all of these requirements, then they are required to obtain a GMP licence from the TGA. In order to make this framework an effective education tool for pharmacies, the Guild suggests it be presented in a flowchart (similar to Attachment C) so individual pharmacies are able to easily determine whether they fall into the category of compounder or manufacturer.

Batching

The Guild’s proposed framework also enables additional flexibility for pharmacies in relation to batching. Member feedback received by the Guild indicates it would be beneficial if compounding pharmacies could batch a limited number of products in anticipation of imminent and expected demand. Ideally this should be a time scale (e.g. maximum of ‘one week supply’). This would cover situations where it is more efficient for a pharmacy to produce products simultaneously, rather than having to constantly set up and pack away compounding equipment as expected individual requests are received. The scaled limit would vary according to average sales of individual pharmacies and would also take into account the ‘shelf life’ of the compounded medicine. A pharmacy would need to demonstrate through documentation that their batching was consistent with average demand and the products they were compounding remained stable over the relevant period of time. This would be monitored under the QCPP. QCPP already requires pharmacies to demonstrate retention of records and documentation proving records have been kept over a time period (e.g. daily fridge monitoring records). In our
view this would be an improvement on the current proposal for enhanced co-regulation as it would provide compounding pharmacies guidance and additional flexibility that is not available under the status quo, without compromising safety standards. We consider our approach to ‘batching’ as described above to be logical and practical and would encourage the TGA to include this allowance in the relevant regulation(s).

Another option for batch exemption could be that of a scaled limit that is similar to the United States Food and Drug Administration (FDA) approach i.e. a ten x factor scale-up of prescription units. The FDA, in their Guidance for Industry on Non-Sterile Solid and Semi-Solid Dosage Forms5 defines a scale-up factor of up to ten times a batch size as a change that does not require significant testing. This could be extended to preparation of small batches of solids and semi-solids with limited batch quantities of no more than ten prescription units at a time.

Guidelines relating to the monthly compounding limit will be discussed further under our response to Option C3.

Exemptions regarding sterile products will be discussed further under our response to Option C1.

What wording should be used on medicines labels to highlight that the medicine is compounded?
The Guild questions the need for such a requirement as important information regarding compounded medicines is conveyed verbally to the patient by a pharmacist. Generally, pharmacies prepare compounded products for a specific person for a specific identified need. A pharmacist will discuss the safe and appropriate use as well as the storage of these products with a patient, as part of the dispensing process. Under existing guidelines, pharmacies are required to label compounded products with information such as storage requirements and expiry dates and the addition of further labels could confuse patients. For example, QCPP Compounding Procedure P2C, Action 10 provides guidance on labelling compounded products, as does PSA’s Professional Practice Standards, Standard 10, Criterion 11. In relation to the proposed wordings put forward by the TGA we make the following comments:

- “This is a compounded medicine” is merely a truism that would require further details to provide any meaningful information to the patient. This wording alone is unlikely to be sufficient in making patients aware of the regulatory status of compounded medicines

- “Compounded medicine. Not TGA approved” is not supported as it implies compounded medicines are not safe or are being supplied illegally. We support compounding pharmacies meeting an auditable Quality Assurance Standard, thus ensuring the compounded products meet an acceptable level of safety and quality. The wording has the potential to create confusion amongst patients, increase medicine non-compliance and also be of detriment to compounding community pharmacies

- “Compounded medicine. Discuss with your pharmacist” is the preferred option as it encourages patient/pharmacist interaction without presenting ambiguous messages to patients. However, owing to the points raised above, a pharmacist will discuss a compounded medicine with a patient anyway, hence the need for a label suggesting the aforementioned appears redundant.

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Responses to Key Components of Option B

Where a pharmacist is not required to hold a manufacturing licence, a specified edition of the Pharmacy Board guidelines on compounding apply to pharmacists manufacturing medicines

The Guild supports this approach subject to the comments made above regarding improvements to Option B. As previously stated, the Pharmacy Board of Australia (PBA) is currently developing a revised set of guidelines for compounding complex formulations and the Guild will be responding to the PBA’s consultation.

The Guild intends to outline to the PBA our views regarding the distinction between a compounding pharmacy and a manufacturer (See Attachment C).

Exempt compounded medicines from inclusion in the ARTG only when there is no suitable and currently available medicine on the ARTG

The Guild has reservations with such a rule as there is currently no clear definition of ‘unavailable’ that can be accessed by pharmacies and it therefore may not be apparent whether a medicine is merely out of stock for a period of time, or has been discontinued. There is also no central database that would enable a pharmacist to determine the availability of a product. Such ambiguity is likely to create enormous confusion and could lead to pharmacies inadvertently breaching the rules. Furthermore, several products on the ARTG are for export only and hence are not for sale in Australia. Therefore the appearance or not of a product on the ARTG is not a definitive indicator regarding whether a compounded medicine would be exempt from inclusion under this approach and would require pharmacists to familiarise themselves with the finer details of the ARTG. The Guild considers that this issue is best managed through PBA guidelines.

Allow the Secretary to request information about exempt compounded medicines

The Guild has no objection to the proposal requiring pharmacists to collect records of compounded medicines, but believes requests from the secretary for such information should be limited to circumstances where a pharmacy is under formal investigation. The Guild considers this information as commercial-in-confidence and a pharmacy should not have to supply these sorts of records under normal conditions.

Reflect state and territory legislation on pharmacy premises, via amendments to Schedule 8 of the Therapeutic Goods Regulation 1990

The Guild would be supportive of this proposal if it clarifies existing legal and regulatory provisions.
3c) Option C-Manufacturing licence for specified manufacture in pharmacies

What are the risks and benefits of Option C?
The main risk the Guild sees in Option C is restrictions and increased licencing costs having a negative financial impact on pharmacies (and ultimately consumers). Feedback we have received from members indicates the costs involved in obtaining a licence and upgrading facilities to meet the GMP licence requirements would likely result in them being unable to maintain a competitive compounding service and would consequently force them to abandon their compounding services.

Such a situation would restrict patient access, increasing both the cost of the service and forcing some patients to rely on distance supply (including overseas) arrangements which the Guild believes is not ideal. It is likely this would have a greater impact on patients living in regional or remote locations. Therefore, we do not believe this option is feasible without considerable concessions to the GMP licence fee arrangements for these pharmacies.

Do you support sub-option C1, C2, C3 or a combination or hybrid of these options?

Option C1
The Guild notes that it is mentioned on page 6 of the consultation that the reconstitution of a TGA-approved medicine in accordance with the directions in the TGA-approved Product Information document is outside the scope of the consultation RIS. Nevertheless, the Guild seeks clarification whether reconstitution of ARTG registered products would also qualify for a manufacturing exemption under this option and if so, under what conditions. Clarification on this issue would improve the currently proposed exemption table and the Guild may then be open to supporting this option.

Option C2
The Guild recognises the rationale of the TGA’s proposal to require complex compounders to obtain a GMP licence. Under our framework proposal, complex compounders would have post-graduate training based on a PBA curriculum and assessed for professional competency through a self-regulatory framework such as QCPP, which would minimise the costs involved. As previously mentioned, the GMP licence fee and associated compliance costs would be prohibitive for many compounding community pharmacies. It is for these reasons the Guild does not support this option and instead proposes complex compounders are assessed under a self-regulatory framework.

Option C3
The Guild believes the use of quantity as a determinant for requiring a manufacturing licence is not appropriate as when compounded to meet quality assurance standards, the risk is the same regardless of the number of prescriptions compounded over a particular interval or the type of product prepared.

This approach may also inadvertently capture pharmacies that have invested in and developed specialised compounding services with responsible professional quality assurance processes for supply to individual patients to satisfy patient-specific needs.

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6 TGA consultation regulation impact statement- Options for reform of the regulatory framework for pharmacy compounding.
Furthermore, such an approach would be difficult to enforce and could lead to perverse health outcomes for patients as pharmacies may be inclined to turn away or refer patients to avoid reaching an arbitrary quota compounding limit that would subsequently require the pharmacies to obtain a GMP licence at great expense.

The Guild believes there is no scientific basis for requiring pharmacies to hold a GMP licence based on compound quotas and would create a legal and administrative burden on pharmacies with little to no improvement in safety.

**Do you have any views on how Option C could be improved?**

**Option C1**
As mentioned, the Guild believes Option C1 does have merit and the manufacturing exemptions listed under Appendix 3 are a good start. We seek clarification whether reconstitution of ARTG registered products would also require a manufacturing licence under this option and if so, under what conditions (e.g. unknown patient, non-immediate supply, providing to other pharmacies). The Guild believes exemptions need to balance safety and quality against affordable and easy access.

Clarification on this issue would improve the currently proposed exemption table and the Guild may then be open to supporting this option.

The proposed amendments to Appendix 3 would broadly reflect the Guild’s recommendations for sterile products exempt from TGA regulation mentioned in the Attachment C flowchart.

**Option C3**
As previously stated, the Guild does not believe pharmacies should have to automatically obtain a GMP licence if they exceed a certain quota in a given period of time. We instead propose in Attachment C that if a pharmacy regularly exceeds a reasonable monthly compounding quota limit to be determined in consultation with the profession, then they are required to provide to the TGA documentation that demonstrates why they should remain exempt from GMP licence requirements. The Guild proposes such justification could include high patient volume and adherence to professional standards. This would make this regulatory option more flexible to a pharmacy’s individual circumstances.

**Additional suggestions for Option C improvement**
It is noteworthy that while the Guide to Good Manufacturing Practice For Medicinal Products is a comprehensive document, many of the elements assessed are unlikely to apply to a community pharmacist compounding complex formulations purely for a specific person, for a specific need. Therefore if this option is to be implemented, the Guild recommends a truncated version of the current guide should be developed that specifically discusses topics of relevance to these community pharmacies. This would enable these pharmacies to gain a better understanding of their obligations in obtaining and retaining a GMP licence and reduce the likelihood of them being confused or overwhelmed by material they do not need to consider (such as Contract Manufacture and Analysis and Complaints and Product Recall).

**If your business would be affected by this proposal, what would be the financial impact on your business and flow-on impact on consumers, if any?**
The Guild has received feedback from members that the potential financial impact from these changes would be significant. Several members plan to make individual submissions and are best placed to detail the full extent of any impacts.
In sub-option C3, which means of controlling quantity do you support?
The Guild does not offer specific comments on this issue at this time. Please refer to previous comments regarding Option C3.

Are there other mechanisms that can discriminate using quantities between traditional and commercial scale compounding?
As noted in Attachment C, wholesale supply should be the determining factor for requiring a GMP licence, not quantity.

At the commencement of any new requirement for requiring a manufacturing licence, would a two year transition be sufficient?
The Guild believes a two year transition period may be insufficient.

3d) Additional Comments
It has been well documented through a recent Senate Community Affairs Reference Committee inquiry that a significant shortfall exists in current funding for chemotherapy preparation. Any changes to regulatory arrangements relating to compounding are likely to increase costs on pharmacies that maintain their own chemotherapy reconstitution facilities. Some pharmacies have established these facilities in order to ensure continuity of supply within their local area, particularly for drugs with a short time to expiry once prepared. It will be important that the cost impacts of any changes to the regulatory framework are examined and that corresponding adjustments to remuneration are applied, without affecting remuneration for other areas of pharmacy activity. Without such consideration the viability of chemotherapy supply may again diminish, even if the existing remuneration shortfall is addressed, as expected, through the current review into funding of chemotherapy.

4. Conclusion
The Guild welcomes this consultation and appreciates the previous and ongoing dialogue the TGA has had with us on compounding. The Guild supports the intent of the TGA to increase regulatory oversight of certain compounding practices in specific circumstances. We have put forward our own suggestions for a regulatory framework that proposes further oversight under QCPP and distinguishes between a genuine compounding pharmacy and a manufacturer. The Guild encourages the TGA to consider this approach. The Guild supports Option A and the general principle of enhancing co-regulation and updating legislation (Option B) but has some concerns regarding specific proposals contained within both these options, as outlined in this submission. We have reservations regarding Option C, mainly relating to restrictions and increased licencing costs having a negative financial impact on pharmacies which in-turn would force the closure of these compounding services. The Guild would welcome the opportunity for further discussions with the TGA on the regulatory framework for pharmacy compounding.
## Attachment A- QCPP Simple Compounding Procedure (P2C)

### Simple Compounding

Actions marked with an asterisk are mandatory and will be assessed. Any modified procedure must include those actions marked with an asterisk.

<table>
<thead>
<tr>
<th>Action</th>
<th>Related procedure or template</th>
<th>Responsibility for the action</th>
</tr>
</thead>
<tbody>
<tr>
<td>* 1. Ensure any compounding is undertaken by a pharmacist (if possible) or a suitably qualified and supervised staff member.</td>
<td>Nil</td>
<td></td>
</tr>
<tr>
<td>* 2. Ensure ingredients are available, have been stored appropriately, are visibly uncontaminated, are of pharmacopoeial standard and the containers are suitable and clean (e.g. light resistant containers). Do not conduct the compounding if you have concerns about these issues.</td>
<td>Nil</td>
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<tr>
<td>* 3. Prepare a compounding area, which is away from other dispensing activities within the area in which dispensing occurs.</td>
<td>Nil</td>
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<td>* 4. Clean all equipment and surfaces prior to the compounding activity.</td>
<td>Nil</td>
<td></td>
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<tr>
<td>* 5. Confirm all equipment has been calibrated. If equipment is uncalibrated, do not undertake the compounding activity until the equipment is calibrated. Make alternative arrangements if necessary.</td>
<td>T5B Equipment Calibration/ Maintenance Schedule and Record</td>
<td></td>
</tr>
<tr>
<td>6. Develop a compounding worksheet for documenting the ingredients and procedure used for compounding products, where no product compounding worksheet exists. Add the new worksheet to the folder of standard worksheets.</td>
<td>Nil</td>
<td></td>
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<tr>
<td>7. Refer to the compounding worksheets that have the formulae and procedure for products compounded on a regular basis.</td>
<td>T2B Compounding Worksheet</td>
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<tr>
<td>8. Ensure notes and calculations are recorded on the compounding worksheet.</td>
<td>Nil</td>
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<tr>
<td>9. Conduct the compounding in accordance with the product compounding worksheet, recording the source, batch numbers and expiry dates where appropriate.</td>
<td>T2B Compounding Worksheet</td>
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<tr>
<td>* 10. Ensure the compounded medicine label includes the approved pharmacopoeial name (when available). When no pharmacopoeial name exists, the label must contain all therapeutic ingredients and their amounts/proportions. All labels must include appropriate ancillary warnings as recommended in the APF, and the expiry date. Consider advising the patient about any preservatives used.</td>
<td>Nil</td>
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<tr>
<td>* 11. Provide instructions to patients about the appropriate use and storage of the compounded medicine.</td>
<td>Nil</td>
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<td>* 12. Clean the compounding area and equipment. Return any unused and unadulterated portions to storage.</td>
<td>Nil</td>
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### Attachment B-QCPP Compounding Worksheet (T2B)

**COMPOUNGING WORKSHEET**

Data fields marked with an asterisk are mandatory and will be assessed. Any modified template must include those data fields marked with an asterisk.

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>*Formula quantity</th>
<th>*Quantity used</th>
<th>*Source</th>
<th>*Batch no.</th>
<th>*Expiry date</th>
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<tbody>
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<td>10.</td>
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Procedure and notes:

Prescriber Name:

Copy of label:

* Signature:  
  Date:  
Attachment C- Proposed regulatory framework to determine Compounder or Manufacturer
Explanatory Notes

1. **PREPARATION FOR AN INDIVIDUAL PATIENT?**
   Compounded product is in response to a patient-specific request from consumer or prescriber for an identified therapeutic need
   a) Prescription Only medicines via a prescription that is consistent with State/Territory/Commonwealth legislation
   b) Vet products on the written order (usually a prescription) of a veterinarian
   c) Non-prescription products on the direct request of the consumer

2. **BATCH PREPARATION?**
   Answer ‘Yes’ if the pharmacy only prepares a single supply for immediate use. Answer ‘No’ if the pharmacy prepares ‘batches’ for use by patients at different time intervals or where stock is kept on hand in the pharmacy to meet anticipated future need by the same patient or different patients.

3. **BATCH EXEMPTION?**
   The regulations should exempt ‘batch’ supply within a scaled limit. Ideally this should be a time scale (e.g. maximum of ‘one week supply’) in anticipation of demand. The scaled limit would vary according to average sales of individual pharmacies and would also take into account the ‘shelf life’ of the compounded medicine.

4. **COMPOUNDING FOR WHOLESALE SUPPLY?**
   Answer ‘Yes’ if supplying to other agents (e.g. other pharmacies, vets, surgeries) for on-selling with a mark-up. Answer ‘No’ if:
   a) Supplying to another pharmacy that acts as a ‘depot’ for the compounding pharmacy where the compounding pharmacy is the pharmacy professionally responsible for managing supply and preparation against a direct request (e.g. prescription) for the compounded product (NB the ‘depot pharmacy’ may collect the payment from the patient on behalf of the compounding pharmacy but may not add any mark-up or commission)
   b) Supplying to other health care professionals (e.g. vets, dentists or doctors) so long as the compounded product is for use on a specified patient within the health care professional’s place of practice.

5. **AUDITED AGAINST PHARMACY QUALITY ASSURANCE STANDARD?**
   Compounding pharmacies must meet a quality assurance standard that is auditable and reflects current professional pharmacy practice standards recognised by the Pharmacy Board of Australia.

6. **NON-ACCREDITED PHARMACY**
   Pharmacies that do not meet the quality assurance Standard for compounding should not provide the service. In the event of any non-compliance with the quality assurance audit, the compounding pharmacy must demonstrate to the auditing body within a specified time frame that all remedial actions are addressed. If this is not done to the satisfaction of the auditing body, the pharmacy will not be accredited to provide that service.
7. **STERILE COMPOUNDING**
   The regulations should exempt identified low-risk sterile products (to be determined) from manufacturing requirements so long as the pharmacy can adequately demonstrate that it is equipped and capable to compound these products to the professional standard endorsed by the Pharmacy Board of Australia.

8. **STERILE COMPOUNDING (CONT)**
   SEE POINT 7

9. **MONTHLY QUOTA**
   Answer ‘Yes’ if the pharmacy’s average monthly compounded products for the past X months is below the quota limit (to be determined) for which exemptions apply.

10. **MANUFACTURING EXEMPTION**
    In the event that the pharmacy does not directly meet the regulatory exemptions but believes it is still a compounding pharmacy that meets all the previous requirements, the pharmacy can apply to the TGA for an exemption to practice as a ‘compounding pharmacy’. In such circumstances, the pharmacy must:
        a. provide the TGA with an outline of its specific circumstances
        b. demonstrate to the TGA that it meets the necessary QA standard reflecting professional practice requirements (e.g. provides positive assessment outcomes from QA audit)
        c. receive restricted (e.g. time-limited until next assessment) authorisation from the TGA to practice as a compounding pharmacy

11. **MANUFACTURER** - requires pharmacy to have GMP license

12. **COMPOUNDER** - meets regulatory exemptions to practice as a ‘compounding pharmacy’
Explanatory Notes

Pharmacist Education- A ‘Simple Compounding Pharmacist’ has undergone training to become a registered pharmacist through an internship as part of their pharmacy undergraduate training based on Pharmacy Board of Australia (PBA) curriculum. Simple compounding pharmacists can work to a standard formulary (e.g. APF).

A ‘Complex Compounding Pharmacist’ has expertise based on experience and post-graduate training based on PBA curriculum. The complex compounding expertise is recognised by the PBA.

A complex compounding pharmacist is capable of working away from standard formulary providing it is:

- Evidence-based
- Quality assured

Premises and Practices

Pharmacy must comply with revised Australian Standard (currently 85000:2011), supported by quality improvement protocols and procedures and biennially audited via Quality Care Pharmacy Program (QCPP)

Compounding pharmacists work to professional protocols & procedures consistent with PBA guidelines and professional practice standards:

Simple & Complex Compounding - PSA Professional Practice Standard 10 (Compounding)
Complex compounding - PSA Professional Practice Standard 11 (Compounding Sterile Preparations)

Assessment
QCPP assessors are trained to audit against a revised Australian Standard in which criteria are set for simple and complex compounding in consultation with the PBA.

Regulatory Control
Pharmacies that fail to adhere to self-regulatory controls are not accredited under QCPP to provide compounding services. Non-QCPP-accredited pharmacies may be subject to inspection by PBA or TGA. If a pharmacy’s compounding practices are considered to be manufacturing under the guidelines or legislation, the TGA will provide regulatory oversight through GMP licensing requirements.