Pharmaceutical Society of Australia

Options for reform of the regulatory framework for pharmacy compounding

Submission from the Pharmaceutical Society of Australia

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Purpose

The Pharmaceutical Society of Australia (PSA) makes this submission to the Therapeutic Goods Administration (TGA) in response to the *Consultation regulation impact statement* on *Options for reform of the regulatory framework for pharmacy compounding*.

About PSA

The Pharmaceutical Society of Australia (PSA) is the peak national professional pharmacy organisation representing Australia's pharmacists working in all sectors and locations. There are over 27,000 registered pharmacists,[1] of which approximately 80% work in the community sector.

PSA's core functions include: providing high quality continuing professional development, education and practice support to pharmacists; developing and advocating standards and guidelines to inform and enhance pharmacists' practice; and representing pharmacists' role as frontline health professionals.

As referred in the consultation paper, the competencies relevant to pharmacists undertaking extemporaneous dispensing or compounding are articulated in the *National competency standards framework for pharmacists in Australia 2010* (the 'Competency Standards').[2] PSA is the custodian and publisher of these standards on behalf of the pharmacy profession.

PSA is regarded as a professional standards-setting body and in this context, two key publications relevant to compounding, as referred in the consultation paper, are:

- Professional Practice Standards (PPS).[3] This publication provides a framework that defines and describes the qualities required by pharmacists to deliver a range of pharmacy services effectively and to an acceptable level.

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[1] Based on data published by the Pharmacy Board of Australia in April 2013.

[2] National Competency Standards Framework for Pharmacists in Australia 2010. Canberra: Pharmaceutical Society of Australia; 2010. Available at: *www.psa.org.au/download/standards/competency-standards-complete.pdf*

[3] Pharmaceutical Society of Australia. Professional Practice Standards. Version 4. Canberra: PSA; 2010. Available at: *www.psa.org.au/download/standards/professional-practice-standards-v4.pdf*

- Australian Pharmaceutical Formulary and Handbook (APF).[4] This publication provides guidance on a broad range of professional practice-related issues. It is one of the essential references prescribed by the Pharmacy Board of Australia (PBA) which should be accessed by pharmacists in their practice.

Further information on all of these standards is provided below.

Recommendations

With regards to the options presented, PSA provides the following recommendations:

1. *Regulatory reform of pharmacist compounding must be undertaken in the context of compounding-related activities by all health practitioners, in all health care settings and institutions, and with uniformity across all Australian jurisdictions.*
2. *In addition, further regulatory reform must not compromise the work already undertaken by the Pharmacy Board of Australia Compounding Working Party.*
3. *Reforms for pharmacist compounding must also be examined in the context of manufacturing activities of non-health practitioners, particularly where consumers are subjected to health claims about the products.*
4. *The risk-based focus embedded within existing standards of pharmacist competencies and professional practice must be supported and promoted when proposing any regulatory reforms.*
5. *As far as practicable, options for reform should be developed consistent with the definition of 'complex compounding' outlined in the Australian Pharmaceutical Formulary and Handbook.*

General comments

Advances in medical technology and therapeutics, greater consumer awareness of treatment options, and economic impact on pharmaceutical manufacturers have all contributed to the evolution around compounding activities. The review of compounding by pharmacists has been in progress for a considerable period of time. PSA is keen to help address any concerns about compounding practices of pharmacists but recognise due consideration is required around the complexities of the issues and the feasibility of any proposed solutions.

Standards for pharmacists

As referred above, PSA has carriage of three major publications which directly impact on and govern compounding practices by pharmacists. These are further detailed below.

[4] Pharmaceutical Society of Australia. Australian Pharmaceutical Formulary and Handbook. 22nd ed. Canberra: PSA; 2012.

Competency Standards

In the Competency Standards, one entire Domain (out of eight) is dedicated to the preparation of pharmaceutical products. In this Domain there are four standards articulating pharmacist competencies, viz.:

- Standard 5.1 – Consider product requirements
- Standard 5.2 – Prepare non-sterile drug products
- Standard 5.3 – Aseptically prepare sterile drug products
- Standard 5.4 – Prepare cytotoxic drug products

It is important to note that Standard 5.1 is the underpinning standard which must be regarded and applied in conjunction with each of the other three standards. Further it should be evident that Standards 5.2 – 5.4 relate to the type of product or formulation being prepared. Thus the Domain is inherently risk-based and comprehensive for the purposes of pharmacists undertaking extemporaneous preparation in the context of the regulatory exemption.

Professional Practice Standards

A risk-based approach is also embedded in the PPS and those standards relevant to compounding, viz.:

- Standard 10 – Compounding (Extemporaneous dispensing)
- Standard 11 – Compounding sterile preparations

These quality standards apply to service delivery (rather than practitioner competencies). Within these Standards, PSA also cites other reference sources (e.g. the TGA and the Society of Hospital Pharmacists of Australia) for service delivery areas which are not covered by these standards such as extemporaneous manufacturing and the preparation of cytotoxic products.

Australian Pharmaceutical Formulary and Handbook

Through its extensive history, the APF has been regarded as the essential reference for extemporaneous dispensing. It maintains a formulary section and a general section which outlines product considerations, product preparation, packaging, counselling and quality assurance.

The risk-assessment process is, once again, outlined in the APF as a high priority for pharmacists. The concerns of regulators around ‘complex compounding’ are certainly acknowledged by PSA. This is reflected in the inclusion of a definition of “complex compounding” in the current edition of the APF which we note, has been referenced in the consultation paper.

Board activities

It is our understanding that the PBA's Compounding Working Party has been progressing work since 2011 to review legislation, standards and relevant information with a view to revising its current guideline on extemporaneous dispensing (compounding). It has been reported through various PBA Communiqués that the Working Party activities have included the following.

- Proposal to align the PBA's definition for 'complex compounding' to that published in the APF.
- Clarification of activities or circumstances which are considered to be 'manufacturing'.
- Liaised with officers of the TGA and the Australian Pesticides and Veterinary Manufacturing Authority. It has been reported that the liaison with the TGA has been in relation to the "proposed regulation of manufacturing as it relates to pharmacists". However PSA is unaware of whether this has impacted on this TGA consultation paper.
- Development of core competencies for complex compounding and a 'professional practice profile' of pharmacists undertaking this activity which will inform a proposal of minimum training requirements for complex compounding.
- Preparation of an indicative curriculum for compounding courses and mapping of the Competency Standards against identified competencies for complex compounding.
- Development of an accreditation process for compounding courses.

The PBA has indicated that revised guidelines for complex compounding "will be released for general consultation shortly".[5]

Fundamental principles

It is PSA's firm view that any proposed solutions must have regard for several fundamental principles. Without the following core underpinnings, we believe the outcomes are not likely to be sustained long-term.

- A comprehensive and rigorous framework must apply to all health practitioners undertaking extemporaneous compounding, and not implemented solely in the context of the exemption granted to pharmacists under the *Therapeutic Goods Regulations 1990*.
- An overarching framework underpinning extemporaneous preparation of medicines must apply equally to public and private hospitals.
- The regulatory framework must also be applicable to the same extent in all jurisdictions of Australia.
- Any regulatory framework that applies to pharmacists (and other health professionals) must also be canvassed in the context of other manufacturing activities of non-health

[5] Pharmacy Board of Australia. Communiqué. 25 Jan 2013.

practitioners. Some pharmacists have alerted PSA with their concerns around these types of activities, in particular, where they also appear to make therapeutic claims for their products.

While some of the issues above may be regarded to be outside the scope of the current consultation, we believe that reforms to "compounding" generally, or "pharmacy compounding" specifically, would not be comprehensive unless these matters are considered and/or addressed. The matters listed above are essential for achieving consistent standards for compounding and is fundamental to public safety.

Comments on proposed options

Given the contents of this consultation paper are likely to be directly impacted by the outcomes of the work of the PBA Compounding Working Party, PSA finds it somewhat difficult to select preferred options from the paper in the absence of details of the PBA's imminent proposals. We have therefore made several broad comments on the options in the consultation paper.

Option A – status quo

- PSA acknowledges that Option A is not supportable in terms of "maintaining the status quo".

- However, Option A also includes reference to "professional practice standards and guidelines". It is conceivable that any arrangements that may be implemented by the PBA around complex compounding could be considered to be adequate to guide appropriate compounding practice by pharmacists and to ensure the safety and quality of compounded products for consumers.

Option B – enhance co-regulation and update legislation

- In principle, co-regulation seems a feasible option. However Option B in the consultation paper appears to contain weaknesses. For example, we would contend that "continue TGA liaison with pharmacy inspectors in states and territories, using available communication channels" is not a satisfactory 'solution' and lacks any real progress.

- The proposal to distinguish between products which are 'dispensed' and 'extemporaneously compounded' has a degree of in principle support by PSA but requires further detailed consideration. While we believe this is consistent with promoting the underlying purpose and rationale for using compounded products, we believe the way in which such information is presented and communicated to consumers will be critical.

- The consultation paper (p. 17) provides possible wording for labels that would be applied to extemporaneously compounded medicines. This is one example area where we believe consumer needs and health literacy will require careful consideration and consultation.

- PSA also strongly believes that any system to distinguish between dispensed and extemporaneously compounded products must be implemented in the context of strengthening the health care team, specifically, the relationship between the prescriber, the consumer/patient and the pharmacist.

Option C – manufacturing licence for specified manufacture in pharmacies

- While acknowledging the TGA's desire to address the higher risks resulting from the sterility or complexity of the medicine or scale of manufacturing activity, PSA's assessment of Option C, based on feedback from pharmacists, is that it would impose significant cost burdens and would not be sustainable by the majority of compounding pharmacists.

- Pharmacists may attempt to address any cost burden through increased costs being passed on to consumers. On the other hand, the lack of sustainability may mean that compounding pharmacists cease the provision of this service. Either way, the most concerning aspect of this Option is the potential impact on consumers i.e. the cost impost and/or the difficulty in accessing compounded products.

- PSA is also concerned that Option C (and its sub-options) would not necessarily be applicable to all pharmacists, nor to all settings.

- PSA also has concerns, based on feedback we have received from members, that obtaining a TGA licence can be challenging for small business operators (pharmacies). Lack of transparency, and limited communication and support by the TGA have been cited as barriers for pharmacies, other than the large pharmacy operators, in attaining a manufacturing licence. The pharmacists have suggested that limited resources of the TGA may be contributing to the limited access to support and guidance.

Option C1: Sterile medicines; and
Option C2: Other complex formulations

- As referred in the consultation paper, the definition in the APF for 'complex compounding' includes "sterile products" and other complex formulations such as "modified release preparations". Given reports from the PBA that the necessary standards for complex compounding are being developed, PSA does not support the sub-options C1 and C2 which separate these two aspects. We believe there should be consideration of consistent standards for the preparation of all products requiring or involving special competencies, equipment, processes or facilities.

Option C3: Quantity limits

- PSA remains opposed to quantity limits as we believe they are arbitrary markers in the context of safety and quality of compounded products. Quantity limits cannot adequately or consistently accommodate genuine therapeutic needs of consumers, reasonable therapeutic quantities or trends in prescribing practice.

Conclusion

As a recognised core competency at initial registration, pharmacists have the scientific knowledge base and skills underpinning the practice of extemporaneous compounding. All pharmacists undertaking compounding activities must have the appropriate training commensurate with the

level and type of compounding they undertake. They must also meet their obligations through professional practice which is consistent with the expectations of their peers and the public.

PSA, the professional body for pharmacists, strongly supports a partnership approach to addressing concerns surrounding compounding activities by pharmacists and is committed to working with regulators, including the TGA and PBA, to ensure compounded medicines are available to Australian health consumers who require this alternative as safe, high quality therapeutic products.

PSA strongly advocates for regulatory reforms in pharmacist compounding to be considered in the context of compounding activities by all health practitioners, in all health care settings and institutions, and with uniformity across all Australian jurisdictions, as well as activities of non-health practitioners engaged in manufacturing and often making health claims for their products.

Submitted by:

Pharmaceutical Society of Australia
PO Box 42
Deakin West ACT 2600
Tel: 02 6283 4777
www.psa.org.au

Contacts:

[redacted]

[redacted]

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