



Options for reform of the regulatory framework for pharmacy compounding

Submission by the Pharmacy Board of Australia to the Consultation Regulation Impact Statement

The Pharmacy Board of Australia (“the Board”) is the registering authority established under the Health Practitioner Regulation National Law Act 2009 (“the National Law”) and its roles are stated on page 9 of the Consultation Paper.

The Board has noted the increasing level of compounding by pharmacists, the types of products being prepared and associated risks.

The Board has published guidelines including in its *Guidelines on dispensing of medicines*, a section on compounding otherwise known as extemporaneous dispensing.

Pharmacists are permitted to extemporaneously prepare medicines for patients in accordance with the provisions of the therapeutic goods legislation. Pharmacists are also permitted to extemporaneously prepare veterinary pharmaceutical products provided that a written order or prescription has been received from a veterinary practitioner as outlined in the Agricultural and Veterinary Chemicals Code (AgVet Code) which is outside the scope of this consultation.

This guideline must be read in conjunction with:

- relevant state, territory and Commonwealth legislation
- codes and guidelines published by jurisdictional Pharmacy Registering Authorities
- the section *Extemporaneous dispensing* in the current edition of the *Australian Pharmaceutical Formulary and Handbook*
- the following practice standards:
 - The Pharmaceutical Society of Australia Professional Practice Standards - Standard 10: Compounding (also known as Extemporaneous Dispensing)
 - The Pharmaceutical Society of Australia Professional Practice Standards - Standard 11: Compounding sterile preparations
 - Society of Hospital Pharmacists of Australia. SHPA Standards of Practice for the Safe Handling of Cytotoxic Drugs in Pharmacy Departments
 - Society of Hospital Pharmacists of Australia. SHPA Standards of Practice for the Transportation of Cytotoxic Drugs from Pharmacy Departments
 - Society of Hospital Pharmacists of Australia, SHPA Guidelines for Medicines Prepared in Australian Hospital Pharmacy Departments
 - Occupational, Health and Safety Standards, and Australian Standards for Cleanrooms

Failure to practise in accordance with these requirements may give rise to action by one or more responsible authorities. These matters may then be referred to the Board for appropriate action under the National Law.

Noncompliance with this guideline may also be notified directly to the Board for appropriate action under the National Law. Notification may be by an individual lodging a notification form or through other means such as notification of details of audits carried out by a pharmacy registering authority.

An extemporaneous product should be prepared only in circumstances where an appropriate commercial product is unavailable or unsuitable.

In preparing an extemporaneous product, a corresponding formulation in a standard reference should be used by the pharmacist when available.

The Board has recently completed work through a pharmacy stakeholder working party to prepare new guidelines which will shortly be published for consultation.

The development of this new guideline has considered the following:

- Pharmacists competence to undertake compounding (extemporaneous dispensing)
- Pharmacists Competence to undertake 'complex compounding'
- A Professional Practice Profile for pharmacists undertaking complex compounding
- Training courses in complex compounding
- Formulation considerations
- Risk assessment process for extemporaneously prepared products
- Facilities, working environments and equipment
- Raw materials
- Documentation
- Labelling requirements
- References

The Board proposes to incorporate the following definitions:

Approved and / or registered premises – a pharmacy premises established and operating under relevant state and territory legislation.

Complex compounding – the preparation and supply of a single 'unit of issue' of a therapeutic product that is intended for immediate use by a specific patient and that requires or involves specific competencies, equipment, processes or facilities. Examples include sterile preparations and preparations containing ingredients which pose an occupational health and safety hazard (such as cytotoxics or hormones), micro-dose single unit dosage forms, and sustained release or other modified-release preparations.

Compounding (extemporaneous dispensing) – the preparation and supply of a single 'unit of issue' of a therapeutic product intended for immediate use by a specific person in response to an identified need.

Consultation Paper Scope

The Board notes the matters which the consultation regulation impact statement does not include registered health practitioners other than pharmacists or allied health and alternative and complementary health care practitioners.

The Board submits that the risk may be considerably larger for those who also extemporaneously prepare products for human therapeutic use with little or no formal training.

The issues

The Board notes the issues and risks outlined in the consultation paper which include many of the matters considered by the Board's working party and also considered the changing nature of practice with some highly specialised pharmacies preparing products for use in private hospitals and clinics.

Options

Option A – status quo

The Board submits that this option does not provide for the risks presented by complex compounding and may not have appropriate regulatory provisions to control these activities.

Option B – enhanced co-regulation and update legislation

The Board submits that this is the most viable option and would provide for appropriate controls through Therapeutic Goods legislation, the National Law and State and Territory pharmacy premises legislation.

Most jurisdictions have legislation regulating pharmacy premises which includes layout, equipment, security and hygiene. The State and Territory pharmacy premises authorities have established a cooperative process to work towards consistency and also to cooperate with the Board.

This system provides a cost effective level of approvals, inspection programs and complaints management.

This option could be enhanced through further consideration of the possible amendments to Schedule 8 of the Therapeutic Goods Regulations 1990, for example, community pharmacies preparing compounded products on prescription for individual patients in private hospitals.

The Board would be pleased to participate in such further consultation.

Option C – manufacturing licence for specified manufacture in pharmacies

The Board does not support this option as a control measure where preparations are made on prescription for individual patients in accordance with the Board's proposed guidelines and professional practice standards. The additional cost burden would result in all likelihood with increased costs to consumers, a possible reduction in the number of pharmacies which do meet required standards but are unable to bear the costs of licences and inspections as proposed.

Option C1: Sterile medicines

Current practices of compounding sterile medicines that are topical products and single use injections for immediate supply and immediate use without a manufacturing licence should continue given the range and nature of supply to private hospitals and clinics which currently occurs.

Option C2: Other complex formulations

The Board's guidelines will cover some of these circumstances and in others such as radiopharmaceuticals and cytotoxic products there is other specific legislation and/or standards. These products are prepared in some community pharmacies for day procedure centres and

private hospitals now and licensing may make these products more difficult to obtain including to rural patients and more expensive.

Such activities are identified in the Board's proposed professional practice profile.

Option C3: Quantity limits

The Board is opposed to quantity limits as this may not provide for appropriate risk management in the public interest. The Board supports the current requirements in relation to batch preparation, individual patient treatment on individual prescription being retained.

Conclusion

The Board supports Option B with the inclusion of parts of Option C2 and Option C3 and recommends that inclusion of the Board's guidelines on compounding be considered in a co-regulatory scheme.