

Pharmacy Board of Australia
GPO Box 9958
Melbourne VIC 3001

Via email to pharmacyconsultation@ahpra.gov.au

Dear Pharmacy Board of Australia,

Re: Public Consultation on the draft Guidelines on compounding medicines

Introduction

Thank you for the opportunity to provide feedback on the draft *Guidelines on compounding of medicines*. Medicines Australia represents the research-based pharmaceutical industry in Australia, which brings new medicines, vaccines and health services to the Australian market. Medicines Australia's members are responsible for the discovery, research, development and commercialisation of up to 86% by value of medicines currently available on the Pharmaceutical Benefits Scheme (PBS).

Medicines Australia has been a strong advocate of the need for reforms to the regulation of medicines compounding and to the guidelines for many years. More information regarding our position on regulatory reform for compounding medicines can be found in our submission to the TGA Consultation Regulation Impact Statement: Options for reform of the regulatory framework for pharmacy compounding available on the TGA website at www.tga.gov.au. We note that the outcomes of this consultation have not been finalised and we are expecting further consultation from the TGA on this issue.

Definition of compounding

Medicines Australia has reservations about the definition of compounding used in the draft guidelines for when a compounded medicine should be prepared. We strongly suggest the inclusion of the legislative definition; "for a particular person, for therapeutic application to that person", to the current definition on page 10.

Complex compounding

Medicines Australia supports the differentiation between simple and complex compounding proposed in the draft guidelines and the corresponding need for additional requirements for pharmacists performing complex compounding. The significant increased safety risk associated with their preparation makes compelling argument for regulatory reform and increased requirements for those preparing the products.

However, Medicines Australia is concerned that facilities where the compounding of complex formulations including sterile injectables takes place must be required to acquire and maintain adequate standards of manufacture, such as a TGA licence to manufacture under *Good Manufacturing Practice*, particularly given the inclusion of sterile preparations in the current definition of complex compounding.

Industry is also concerned by the increased risks associated with preparing formulations for which precedents do not exist or safety evidence is insufficient or has been rejected by the TGA, specifically sterile eye formulations, due to the reduced oversight of non-TGA-licensed manufacturing sites.

Sterile injectables and eye formulations

Medicines Australia is particularly concerned with the increased risk profile for sterile injectables comprising syringes, bags, infusers and other delivery mechanisms. The increased public safety risks associated with preparation in non-TGA licensed facilities include:

- Risk of microbial infection and contamination from non-aseptic preparation in unregulated compounding premises;
- Absence of validated environmental monitoring or controls throughout the supply chain;
- Dosage errors from insufficient checks, operator handling and inadequate training according to standard operating procedures; and
- Sub-potent or degraded compounded products resulting from inadequate stability data or excursions outside registered storage conditions.

Further to this, consideration of the adequacy of labelling standards should be taken into account. Such that the label clearly documents the compounding pharmacist, preparation and expiry times, mandatory storage conditions, and the contact details for the reporting of adverse events and product complaints .

Medicines Australia also notes the broad consensus on this approach among industry stakeholders due to:

- the recognition that sterile injectables pose the highest intrinsic risk to consumers; and
- the obvious patient safety benefits that would result from licensing and regulating their preparation to ensure conformity with quality and safety standards.

Medicines Australia strongly endorses regulatory change to ensure all pharmacy premises on which compounding of sterile injectables takes place are required to acquire and maintain appropriate standards of manufacture, such as a TGA GMP licence.

Recommendations

Medicines Australia has strong reservations about the suitability of the facility, working environment and equipment specifications being at the discretion of the pharmacist subject to relevant practice standards as outlined in item 5 and strongly endorse that all complex compounding take place in TGA-licensed or facilities of equivalent manufacturing standards to reduce adverse events and lower the risk profile of extemporaneously compounded medicines.

Medicines Australia strongly believes that a TGA manufacturing licence must be obtained before undertaking the manufacture of complex formulations. Medicines Australia also supports the manufacture of sterile dosage forms in pharmacies becoming licensable activities and we recommend that the Pharmacy Board consider the licensing of facilities and pharmacists and amend the current draft guidelines to more clearly identify the increased risks associated with complex compounding activities.

As there are now at least 13 TGA-licensed facilities operated by six separate organisations across Australia that can provide high quality sterile injectables, Medicines Australia believes the

requirements for pharmacies preparing these sterile formulations should be increased to match those of the TGA-licenced facilities, particularly those compounding in high volumes currently exempt from TGA licencing.

Medicines Australia also supports the development of professional practice guidelines for pharmacists undertaking complex compounding that reflect the added difficulty and the riskier outcomes for patients from these activities.

If you have any questions or comments please contact Regulatory Manager

[REDACTED]

Kind regards,



Elizabeth de Somer
Director Policy and Advocacy
Medicines Australia