



Consumers  
Health Forum  
of Australia

Mr Bill Kelly  
Chair  
Policies, Codes and Guidelines Committee  
Pharmacy Board of Australia  
GPO Box 9958  
Melbourne VIC 3001

Dear Mr Kelly

### **Public consultation on the draft Guidelines on compounding of medicines**

The Consumers Health Forum of Australia (CHF) welcomes the opportunity to the Pharmacy Board of Australia's Public consultation on the draft Guidelines on compounding of medicines (*the Guidelines*)

CHF is the national peak body representing the interests of Australian healthcare consumers. CHF works to achieve safe, quality, timely healthcare for all Australians, supported by accessible health information and systems.

CHF recognises that the community places considerable trust in the pharmacy profession and that pharmacists play an essential role as frontline health professionals in providing expert advice on medicines and healthcare. Pharmacy compounding can provide unique pharmacotherapy health solutions to consumers when commercially available products may be unsuitable or unavailable.

CHF welcomes the improved Guidelines, which aim to minimise the risk associated with pharmacy compounding services for patients, pharmacists and other pharmacy staff, and improve patient outcomes and patient safety. CHF particularly notes and supports the inclusion of a new section which supports the patients' right to choose where to access compounded medicines. We are pleased to note the Guidelines emphasis on "recognising and respecting the rights of patients or clients to make their own decisions."

While CHF broadly supports the provision of traditional pharmacy compounding services there are some significant risks that should be addressed to ensure consumer safety. These inherent risks associated with the production and dispensing have been noted in our submission to the Therapeutic Goods Administration (TGA) consultation on *Options for reform of the regulatory framework for pharmacy compounding: Consultation regulation impact statement*<sup>1</sup>. As detailed in our submission to the TGA, CHF believes that

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<sup>1</sup> CHF 2013, Submission to the Therapeutic Goods Administration Options for reform of the regulatory framework for pharmacy compounding: Consultation regulation impact statement, <https://www.chf.org.au/pdfs/sub/sub-1083-RISPharmacyCompounding-Jul13.pdf>

compounding medications is open to the same range of risks and issues as present in the manufacturing Registered or Listed medicines.

CHF believes there is a need to strengthen the regulatory environment for the production and dispensing of compounded medicines and the key risks are associated with:

1. Pharmacovigilance and adverse event reporting
2. Consumer Medicines Information (CMI) and Product Information (PI) provision.

### **1. Pharmacovigilance and adverse event reporting**

Pharmacovigilance refers to the collection, detection, assessment, monitoring, and prevention of adverse effects with pharmaceutical products and this is very important for compounded medicines for which clinical trial data does not exist to support effective and efficacious use. Pharmacovigilance is critical in supporting consumer safety and CHF has recommended to the TGA that these requirements should be extended to prescribers and pharmacists of extemporaneously compounded medicines, making it mandatory to provide all reports of adverse events to the TGA for investigation.

CHF is pleased to note that the revised Guidelines include a new section which encourages pharmacists to report adverse reactions to compounded medicines to the TGA, and to maintain adequate documentation to assist with this.

*CHF recommends that the reporting of adverse event be emphasised as a mandatory and reportable criteria in the Guidelines.*

### **2. Consumer Medicine Information (CMI) and Product Information (PI) Document Equivalent**

Manufacturers of compounded medicines should be required to produce Consumer Medicine Information (CMI) and Product Information (PI) document-equivalents for consumers.

Compounded medicines can include high risk or scheduled substances which would normally require a CMI and PI. However, as noted in our submission to the TGA<sup>2</sup>, currently no legal imperative exists for prescribers and pharmacists of extemporaneously compounded medicines provided a CMI or PI for compounded medicines. CHF notes that the unique 'one-off' production of compounded medicines would make developing a PI document for each compounded medicine unfeasible particularly as a substantial amount of the content in a PI document is from clinical trial data. However developing and providing a CMI document equivalent at the point of dispensing is feasible. Most, if not all, the information required under each heading of CMI documents could be prepared by the person compounding the medicine.

*CHF recommends a CMI document equivalent be developed and provided to consumers with each dispensed compounded medicine. This document should include instructions on how to report adverse events.*

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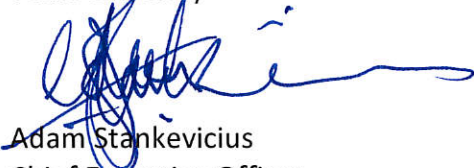
<sup>2</sup> Ibid.

## Conclusion

Overall, CHF is supportive of the Guidelines and welcomes the focus on ensuring consumer choice and decision-making. But given that compounded medicines are exempt from the regulatory requirements applicable to Registered or Listed medicines, CHF advocates for strengthening of the regulatory environment in which pharmacists compound medication. We recommend a risk based approach that focuses on providing CMI and PI to better inform consumers and ensures the reporting of adverse events.

We appreciate the opportunity to provide and input to this significant document, and look forward to the final release of the new Guidelines. If you would like to discuss the issues raised in this submission in more detail, please contact Priyanka Rai, CHF Policy Officer, [REDACTED]

Yours sincerely



Adam Stankevicius  
Chief Executive Officer  
25 June 2014