



30 June 2014

Comments by the Pharmacy Guild of Australia to the Pharmacy Board of Australia Public Consultation:

- Guidelines on compounding of medicines
 - Professional practice profile for pharmacists undertaking complex compounding
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The Pharmacy Guild of Australia

The Pharmacy Guild of Australia is the national peak pharmacy organisation representing community pharmacies. The Guild 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.

Introduction

The Pharmacy Guild of Australia (Guild) welcomes the opportunity to respond to the public consultation of the Guidelines on compounding of medicines and related Professional practice profile for pharmacists undertaking complex compounding.

The Guild broadly supports the guideline and practice profile released as part of this consultation. Pharmacies providing quality compounding will be able to implement these guidelines. It recognises the specialised scope of complex compounding and provides a clear differentiation of simple versus complex compounding.

The Guild makes the following specific comments regarding the guidelines:

1. Competence to undertake ‘complex compounding’:

The guideline clarifies the requirements for training and maintaining competency in this scope of practice and the practice profile provides a competency framework with evidence examples for training providers to address in the development of their programs, and for pharmacists to identify their learning needs.

We interpret that this professional practice profile is expanded practice, in a defined area of practice and not ‘advanced practice’.

There is an expectation of identifying continuing professional development (CPD) needs relevant to identified competencies in the form of a CPD learning plan. The Guild has concerns that there is currently insufficient training available in the area of complex compounding to allow complex compounding pharmacists the ability to achieve the requirements of the CPD registration standard to undergo education/CPD activities in this area of their practice.

There has been a limited market for the development of these courses to date, and current courses could be considered as commercially biased, developed ‘in-house’, or not of the level required for a complex compounder. The Board would need to provide guidance to complex compounders as to which courses are of an appropriate level of technical quality and complexity to meet their needs.

2. Formulation considerations:

Formulations for which precedents do not exist:

The guidelines state that in preparing a formulation for which there is no precedent etc. ‘the pharmacist must ensure that the patient has been made aware that the compounding is taking place under these circumstances’.

The Guild supports formalisation of this conversation by way of a signed consent form to demonstrate that the patient is aware of the formulation and its potential risks or limitations. Signed consent is required in other circumstances such as the ‘Special Access Scheme’ for medicines unregistered in Australia.

Manipulation of products in accordance with manufacturer’s instructions:

The guidelines state that manipulation of a commercially available product in accordance with the manufacturer’s instructions in order to produce a product in a ‘ready-to-administer’ form is considered compounding and thus the requirements of this guideline applies.

The Guild recognises that these products fall within the definition of simple compounding. This implies that dispensing worksheets/batch records would be required for each extemporaneous dispensing of these products, for example, paediatric antibiotic mixtures. This requirement would need to be strongly communicated by the Board as it would be a substantial change in practice for the majority of community pharmacies.

Completing quality assurance documentation for each extemporaneous dispensing of these products would create an additional burden for pharmacists. The Australian Pharmaceutical Formulary and Handbook (APF), Pharmaceutical Society of Australia (PSA) Professional Practice Standards, and the Quality Care Pharmacy Program (QCPP) all outline the requirements for use of quality raw ingredients, including water. An exemption of the requirement for keeping batch records for common, ‘ready-to-administer’ products for oral consumption for low risk patients should be considered.

3. Facilities, working environments and equipment:

Currently, when compounding, pharmacists have obligations under state, territory and Commonwealth legislation. State/territory based pharmacy premises regulatory authorities currently audit pharmacies to ensure compliance with state/territory or national guidelines.

The Board may wish to consider whether a quality management framework should be recommended in the guidelines. This would help to dispel concerns over premises and practices, and may help bridge the ‘gap’ between pharmacies offering simple compounding and those offering complex compounding without the need for Therapeutic Goods Administration (TGA) licensing or further regulation.

The Guild recommends that compounding pharmacies undergo an accredited independent assessment against the professional practice standards through a compliance audit or similar. There is an existing framework in the Quality Care Pharmacy Program which could enhance scope to take on this function.

An industry auditor with extensive knowledge of 'Good Manufacturing Practice' (GMP) would allow complex compounding to continue to operate in the best interest of public safety without the increased financial burden of further red tape and licenses. . This would ensure the ongoing ability of compounding pharmacies to provide ongoing patient access to this specialised service. Compounding pharmacies could operate under the basic principles of compounding and good manufacturing practice but with a much higher level of public safety.

Contact Officer:

Name: Claire Bekema
Position: Pharmacist Consultant
Quality Pharmacy Practice
Pharmacy Transformation Group
[REDACTED]