Pharmacy Council of New South Wales

Protecting the public
Regulating pharmacists and pharmacies

Public consultation

11 February 2019

Consultation on *Pharmacy Council of New South Wales DRAFT premises and equipment guidance for non-sterile complex compounding*

Public consultation

The Pharmacy Council of New South Wales (the Council) is seeking feedback on the *DRAFT Pharmacy Council of New South Wales premises and equipment guidance for non-sterile complex compounding* (draft guidance).

The guidance has been developed by the Council as a resource for pharmacists involved in non-sterile complex compounding activities. It is intended to provide premises and equipment guidance for New South Wales pharmacies where non-sterile complex compounding activities are conducted.

You are invited to provide feedback on the draft guidance to mail@pharmacycouncil.nsw.gov.au by close of business **Friday, 12 April 2019**.

Submissions

The Council is seeking general feedback on the draft guidance, as well as in response to the following questions:

1. Is the structure, language and tone of the draft guidance easy to follow and appropriate?
2. Is the purpose and scope of the draft guidance clear?
3. Do you have any specific comments on the content of the draft guidance? If so, please outline.
4. Do you have any other comments to make about the draft guidance? If so, please outline.

Role of the Council

The Council's primary objective is to protect the health and safety of the public and to ensure that high professional standards are maintained. In accordance with the *Health Practitioner Regulation National Law (NSW)* and the *Health Practitioner Regulation (New South Wales) Regulation 2016*, the Council manages complaints about the performance, conduct and health of registered pharmacists and pharmacy students in New South Wales. The Council also regulates pharmacy ownership and pharmacy premises, which includes the maintenance of a register of New South Wales pharmacies.

Background

In recent years, the Council has dealt with an increasing number of complaints relating to compounded preparations. As a growing area of concern, the Council is working to provide practical guidance to New South Wales pharmacists to support improved pharmacy practices in compounding. This work is designed to complement existing legislation and publications such as the Pharmacy Board of Australia's *Guidelines on compounding of medicines* and the Pharmaceutical Society of

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Australia's *Australian Pharmaceutical Formulary and Handbook*. The Council also acknowledges existing guidelines published by the Victorian Pharmacy Authority with respect to compounding.

Pharmacists are reminded that compounded preparations should only be prepared in certain circumstances. The Pharmacy Board of Australia's *Guidelines on compounding of medicines* states that "the compounding of a medicine (whether prescribed or not) that would be a close formulation to an available and suitable commercial product, and would not be likely to produce a different therapeutic outcome to the commercial product, should not take place."

Next steps

Submissions received during this public consultation process will be used to inform the Council's refinement of the draft guidance prior to publication.

Contact

Submissions should be forwarded to mail@pharmacycouncil.nsw.gov.au by close of business **Friday, 12 April 2019.**

For questions, please contact Katharina Nicholson via (02) 9219 0220 or mail@pharmacycouncil.nsw.gov.au.

DRAFT
Pharmacy Council of New South Wales premises and equipment guidance for non-sterile complex compounding

Introduction

Role of the Pharmacy Council of New South Wales

The role of the Pharmacy Council of New South Wales (the Council) is to protect the health and safety of the public and to ensure that high professional standards are maintained. In accordance with the *Health Practitioner Regulation National Law (NSW)* and the *Health Practitioner Regulation (New South Wales) Regulation 2016,* the Council:

- manages complaints about the performance, conduct and health of registered pharmacists and pharmacy students in New South Wales together with the Health Care Complaints Commission (HCCC), and
- regulates pharmacy ownership and pharmacy premises in New South Wales.

Context

At all times, proprietor pharmacists in New South Wales must adhere to the premises, equipment and publication requirements for pharmacies as prescribed under the *Health Practitioner Regulation (New South Wales) Regulation 2016.*

Pharmacists have an obligation to ensure that compounded preparations are safe, efficacious and of consistently high quality. Pharmacists involved in pharmaceutical compounding should be familiar with the Pharmacy Board of Australia's *Guidelines on compounding of medicines,* the current *Australian Pharmaceutical Handbook and Formulary,* relevant Commonwealth and state legislation, the Australian Health Practitioner Regulation Agency's *Guidelines for advertising regulated health services,* relevant Work, Health and Safety requirements and relevant codes, practice standards and guidelines published by professional organisations. At a minimum, a pharmacist's professional obligations with respect to pharmaceutical compounding should be determined with reference to all publications listed above. Proprietor pharmacists should also have regard for the Pharmacy Board of Australia's *Guidelines for proprietor pharmacists.*

As a matter of practice, the Council considers published guidelines and policies when assessing what constitutes appropriate professional conduct or practice for pharmacists.

Purpose of this document

This document has been developed by the Council as a resource for pharmacists involved in non-sterile complex compounding activities. It provides premises and equipment guidance for New South Wales pharmacies where non-sterile complex compounding activities are conducted.

Intended audience

The intended audience of this document includes all pharmacist proprietors of New South Wales pharmacies, pharmacists, pharmacist interns and pharmacy students where non-sterile complex compounding services are offered. The Council acknowledges that compounding within New South Wales public hospitals is subject to NSW Health policy directives.

Scope

Pharmaceutical compounding is generally categorised into 'simple compounding' and 'complex compounding'. This document provides premises and equipment guidance for New South Wales pharmacies where non-sterile complex compounding activities take place. Some aspects may also be relevant to pharmacists involved in simple compounding activities. It is not intended to provide premises and equipment guidance where sterile complex compounding activities take place.

Definitions

Simple compounding refers to the extemporaneous preparation and supply of a single 'unit of issue' of a therapeutic product intended for a specific patient.[1] Pharmacists entering the profession are deemed competent to undertake 'simple compounding', which routinely involves compounding preparations from formulations published in reputable references such as the *Australian Pharmaceutical Handbook and Formulary* (excluding sterile preparations, which is considered complex compounding), or using other formulations where quality, stability, safety, efficacy and rationality is available and can be confirmed.[1] Premises and equipment requirements for simple compounding are outlined in the current version of the *Australian Pharmaceutical Handbook and Formulary.*[2] Examples include Salicylic acid in aqueous cream and Coal tar and zinc paste.

Complex compounding refers to the extemporaneous preparation and supply of a single 'unit of issue' of a therapeutic product intended for a specific patient that requires or involves special competencies, equipment, processes or facilities.[2] Examples are sterile preparations, preparations containing ingredients that pose an occupational health and safety hazard (such as ***hazardous materials***), micro-dose single-unit dosage forms containing less than 25mg (or up to 25% by weight or volume) of active ingredient, and sustained release or other modified release preparations.[1]

> References to ***hazardous materials*** in this document refer to materials, relevant to a pharmacy and supply of medicines, with the potential to cause harm to individuals from exposure.[3] In the pharmacy context, hazardous materials include medicines requiring special handling and disposal and must be labelled accordingly. Examples include hormones, antibiotics, cytotoxic medicines, contact irritants, immunosuppressants, teratogenic medicines.[3]

Complex compounding involving ***sterile preparations*** such as eye drops, eye lotions, irrigations, injectable preparations and infusions requires additional staff training and compliance with additional premises and equipment requirements. As per the Pharmacy Board of Australia's *Guidelines on compounding of medicines,* pharmacists are expected to adhere to the principles and procedures outlined in one of the following references (whichever is most appropriate and relevant to their compounding practice):

a. The Pharmaceutical Inspection Convention Scheme (PIC/S) Guide to Good Practices for the Preparation of Medicinal Products in Healthcare Establishments [PE010],

b. The PIC/S Guide to Good Manufacturing Practice for Medicinal Products [PE009], or

c. The *USP-NF <797> Pharmaceutical Compounding – Sterile Preparations.*[1]

[1] Pharmacy Board of Australia, *Guidelines on compounding of medicines,* 2015

[2] Pharmaceutical Society of Australia, *Australian Pharmaceutical Formulary and Handbook 24,* 2018

[3] Pharmacy Guild of Australia, *AS85000:2017 Quality Care Community Pharmacy Standard,* 2017

Guidance

1. **Compounding environment**

Non-sterile complex compounding activities should take place in a secure, sanitary and dedicated area (a compounding laboratory), separated from other parts of the pharmacy premises by floor to ceiling walls or partitions and at least one lockable door to prevent unauthorised or public access. A compounding laboratory:

a. Should be separate to the dispensing area. The dispensing area is specified in Clause 12 (1)(c) of Division 1 to the *Health Practitioner Regulation (New South Wales) Regulation 2016,*

b. If within an approved professional services room, should be separated from non-compounding activities by floor to ceiling walls or partitions and at least one lockable door to prevent unauthorised access. An approved professional services room is specified in Clause 13 of Division 1 to the *Health Practitioner Regulation (New South Wales) Regulation 2016,*

c. Should have an impervious floor (floor covering with covered edges continuing up the wall for at least 15 centimetres to minimise the harbouring of dirt etc. and permit effective cleaning is recommended),

d. Should be of an area of at least 9 square metres to permit the orderly layout and segregation of materials and equipment as well as sufficient space to undertake compounding activities,

e. Should have a clearly identifiable and labelled dedicated area which can be utilised to isolate raw materials and compounded preparations not to be used or released (e.g. unchecked orders, product recalls, expired stock),

f. Should have easy to clean surfaces (walls, bench tops and shelves) made from an impervious material,

g. Should be adequately lit and ventilated,

h. Should have facilities to maintain and monitor an ambient temperature of 25 degrees Celsius or less,

i. Should have a dedicated stainless steel or similarly impervious sink positioned to avoid contamination and be supplied with hot and cold running water,

j. Should have at least one bench (excluding the powder containment cabinet) of at least 2 metres in length and 90 centimetres in width to provide sufficient working space for compounding, and

k. Must be free from food and drinks at all times.

2. **Equipment**

Equipment used in non-sterile complex compounding activities must be in good working order and be dedicated to pharmaceutical compounding. This equipment should include:

a. An appropriate powder containment cabinet with high efficiency particulate air (HEPA) filtration and a continuous pressure monitoring device to be used to confine all activities likely to release powders (e.g. recirculating fume cabinet or double HEPA filter where appropriate). A risk assessment should be conducted and expert advice sought prior to

purchase and installation. Powder containment cabinets should be purchased from a reputable manufacturer and be accompanied by a Certificate of Compliance stating the Australian Standard to which it complies,

b. Appropriate scales that enable quantities to be measured with a sensitivity of ±2% (in practice, electronic balances with 2 decimal places should not be used to weigh amounts lower than 500mg). To achieve this, electronic balances linked to barcode readers and integrated compounding software are recommended,

c. An appropriate heating source (i.e. hot plate/stirrer) for use in heating formulations where required. A microwave oven is not recommended as an appropriate heating source due to the potential to affect drug stability as the temperature cannot be adequately monitored,

d. Consideration should be given to equipment to enable the appropriate storage of compounded preparations and the storage of raw materials in accordance with the manufacturer's recommended conditions (and which can be operated in the event of a mains power failure), such as:

    i. A dedicated refrigerator (with continuous temperature monitoring equipment able to alert staff if the temperature range has been compromised) to enable the storage of raw materials and compounded preparations between 2 and 8 degrees Celsius,

    ii. A dedicated freezer (with continuous temperature monitoring equipment able to alert staff if the temperature range has been compromised) to enable the storage of raw materials and compounded preparations below -5 degrees Celsius (freeze) or below -18 degrees Celsius (deep freeze),

e. Drugs of addiction must be stored in accordance with Clause 76 of the *Poisons and Therapeutic Goods Regulation (New South Wales) 2008.* Consideration should be given to whether a dedicated safe is required to store raw materials or compounded preparations that are drugs of addiction,

f. Appropriate personal protective equipment (PPE) for all staff engaged in complex compounding activities:

    i. Laboratory coat, surgical face mask, disposable gloves and hair and beard covers (it is recommended that these are disposable),

    ii. Additional PPE for staff handling **hazardous materials** including eye protection (protective eye wear with side shields), non-shedding, impermeable, disposable gown or coveralls with elasticised cuffs and closures up to the neck, a particulate respirator mask (N95 rated) or HEPA filtered (P100) respirator masks, nitrile gloves, hair and beard coverings and shoe covers,

    iii. Any other PPE required to comply with statutory occupational health and safety laws,

    NB: It is recommended that all gowns and coveralls used are disposable and discarded after each compounding session, particularly when handling hazardous substances. Reusable gowns and coveralls can be used provided they are **appropriately** laundered regularly.

g. A spill kit, and

h. Any other equipment and packaging appropriate to the dosage forms of preparations and quantities to be compounded.

3. Non-sterile complex compounding involving hazardous materials

In addition to the guidance outlined in paragraphs 1 and 2, complex non-sterile compounding activities involving hazardous materials (e.g. hormones) must be separated from all other compounding activities. This means that no other compounding activities should take place in the compounding laboratory while compounding activities involving hazardous materials takes place and only one preparation may be compounded at a time. The compounding laboratory and equipment (including the powder containment cabinet) must be thoroughly cleaned before and after the compounding session involving hazardous materials using appropriate cleaning methods in order to minimise the risks of cross-contamination. PPE used should be discarded at the conclusion of each compounding session.

4. Storage of raw materials and compounded preparations

Raw materials and compounded preparations:

a. Should be stored in the compounding laboratory,

b. Must be stored in accordance with the *Poisons and Therapeutic Goods Regulation (New South Wales) 2008* according to their classification under the current *Poisons Standard (Standard for the Uniform Scheduling of Medicines and Poisons) (Cth)* in force as proclaimed in New South Wales under the *Poisons and Therapeutic Goods (Poisons List) Proclamation 2016* where applicable,

c. Raw materials must be stored in accordance with the manufacturer's recommended conditions,

d. Compounded preparations must be stored in accordance with conditions as dictated by stability information, and

e. Hazardous materials and compounded preparations involving hazardous materials:

    i. must be labelled clearly as hazardous, and

    ii. should be stored in a separate dedicated area in the compounding laboratory, separate from other material and equipment to minimise risk of mix-ups, contamination and compounding staff exposure e.g. on a dedicated shelf in the compounding laboratory.

5. Additional requirements

The following should be accessible from the compounding laboratory and available to all compounding staff:

a. A customised operations manual for complex non-sterile compounding that is implemented, regularly reviewed at least annually and demonstrates that the pharmacy has systems in place to ensure efficacy, safety and stability of all products prepared.[3] At a minimum, the customised operations manual should include Standard Operating Procedures (policies and procedures) for:

    i. Engaging appropriately trained (or provide training for) and monitoring of, compounding staff,

ii. Minimising the risk of exposure to hazardous materials for compounding staff, including circumstances for exclusion (e.g. pregnancy, wounds)

iii. Circumstances where baseline and regular pathology monitoring is required (e.g. compounding hormone preparations),

iv. Receiving a compounding request, conducting a risk assessment, undertaking a compounding request (including dispensing of a prescription where applicable) and patient counselling,

v. Equipment operation (e.g. powder containment cabinet),

vi. Procuring quality raw materials for use in compounded preparations,

vii. Labelling, storing and handling raw materials in accordance with safety requirements,

viii. Circumstances where samples are to be submitted to a an appropriately accredited analytical laboratory for assay (e.g. for novel formulations or high potency substances) and frequency of analytical tests (at least annually),

ix. Maintaining and monitoring (where required) a clean and appropriate compounding laboratory. This includes cleaning of compounding laboratory and equipment regularly as well as before and after use, continuous monitoring of ambient temperature and pest control measures,

x. Maintaining, continuously monitoring and servicing and calibration of equipment at least annually in accordance with the manufacturer's recommendations (e.g. refrigerator, powder containment cabinet, scales),

xi. Appropriate waste disposal and management of spills,

xii. Product recalls, complaints and incident management,

xiii. Adverse reaction reporting and monitoring,

b. Records and/or logs of:

i. Recalls, complaints and incident reports,

ii. Training for compounding staff,

iii. Signatures of all compounding staff, their position title and job description (signed by staff member and manager),

iv. Cleaning of the compounding laboratory and equipment,

v. Baseline and regular pathology monitoring of compounding staff,

vi. raw materials used in compounded preparations, including details of manufacturers and suppliers (if appropriate) as well as evidence of authenticity,

vii. Analytical reports of assays,

viii. Maintenance relating to equipment (e.g. servicing of air conditioning filters, powder containment cabinets, pest inspections),

ix. Workplace risk assessments (including hazards register),

x. Temperature monitoring for ambient temperature, refrigerators and freezers,

to be retained for a minimum of 3 years,

c. Documentation relating to each episode of compounding and/or compounding request, including:

i. Completed risk assessments,

ii. Completed compounding worksheets,

iii. Prescription records where applicable and

iv. Evidence to support the suitability and stability of formulations where non-pharmacopoeial formulations are used or where there is no precedent for formulations from reputable references

to be retained for a minimum of 3 years,

NB. Details of prescriptions for compounded preparations must be recorded in accordance with the *Poisons and Therapeutic Goods Regulation 2008 (NSW).* Prescriptions must be retained on the pharmacy premises for a minimum of 2 years.

d. An up to date register of safety data sheets (SDS) (sometimes known as material safety data sheets (MSDS)) for hazardous materials (this may be an electronic register),

e. A database of extemporaneous formulations (including references) used (sometimes known as a master formula database),

f. All current New South Wales and Commonwealth legislation relating to pharmaceutical compounding, such as:

i. The *Therapeutic Goods Act 1989 (Cth)*, *Therapeutic Goods Regulations 1990 (Cth)* and relevant Therapeutic Goods Orders,

ii. The *Agricultural and Veterinary Chemicals Code Act 1994 (Cth)* (AgVet Code),

iii. The *Health Practitioner Regulation National Law (NSW)* and *Health Practitioner Regulation (New South Wales) Regulation 2016*,

iv. The *Poisons and Therapeutic Goods Act 1966 (NSW)* and *Poisons and Therapeutic Goods Regulation 2008 (NSW)*, and

v. The current *Poisons Standard (Standard for the Uniform Scheduling of Medicines and Poisons) (Cth)* in force as proclaimed in New South Wales under the *Poisons and Therapeutic Goods (Poisons List) Proclamation 2016*,

g. Current references, guidelines, standards and resources relating to pharmaceutical compounding, including:

   i. The Pharmacy Board of Australia's *Guidelines on compounding of medicines*,

   ii. The Pharmacy Board of Australia's *Guidelines for dispensing of medicines*

   iii. The Pharmaceutical Society of Australia's *Australian Pharmaceutical Formulary and Handbook*,

   iv. Relevant resources published by the Council e.g. *Pharmacy Council of New South Wales premises and equipment guidance for non-sterile complex compounding* (this document),

   v. *The national competency standards framework for pharmacists in Australia*,

   vi. The Pharmacy Board of Australia's *Guidelines for proprietor pharmacists,*

   vii. Relevant professional practice standards and guidelines published by the Pharmaceutical Society of Australia and the Society of Hospital Pharmacists of Australia,

   viii. The PIC/S Guide to Good Manufacturing Practice for Medicinal Products [PE009],

   ix. Any other relevant standards, codes and guidelines relevant to compounding published by the Pharmacy Board of Australia, and

   x. Reference texts relevant to the area of compounding activity undertaken.