Pharmaceuticals - Preparation in NSW Public Health Facility Pharmacy Services

Summary  Consolidates best practice principles for the preparation of pharmaceuticals by, or on behalf of, NSW public health facility Pharmacy Services.

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Distributed to  Public Health System, Health Associations Unions, Ministry of Health, Tertiary Education Institutes

Audience  All clinical and allied health staff; Pharmaceuticals Procurement - HealthShare NSW; HETI

Secretary, NSW Health
This Policy Directive may be varied, withdrawn or replaced at any time. Compliance with this directive is mandatory for NSW Health and is a condition of subsidy for public health organisations.
POLICY STATEMENT

PHARMACEUTICALS – PREPARATION IN NSW PUBLIC HEALTH FACILITY PHARMACY SERVICES

PURPOSE

This policy consolidates best practice principles for the preparation of pharmaceuticals by, or on behalf of, NSW public health facility Pharmacy Services.

The policy applies to Pharmacy Services at all NSW Public Health Organisations, including where:

a) The provision of the Pharmacy Service to the Public Health Organisation is contracted to a non-government provider, and

b) A contracted provider supplies compounded or reconstituted pharmaceutical preparations to the Public Health Organisation.

MANDATORY REQUIREMENTS

By 1 April 2015 all NSW Public Health Organisations must implement this policy.

IMPLEMENTATION

ROLES AND RESPONSIBILITIES

NSW Ministry of Health:

• Provide the mandatory requirements and standards to support implementation of the policy.

Clinical Excellence Commission:

• Support implementation of the policy where applicable to medication safety.

Chief Executives, Health Service Executives, Managers:

• Assign responsibility, personnel and resources to implement the policy

• Provide line managers with support to implement the policy in their areas

• Ensure that local policies, protocols and procedures are in place at each facility to support implementation of the policy.

Drug and Therapeutics Committees:

• Develop, approve and oversee the implementation of local policies, protocols and procedures where required

• Provide local oversight of the safe implementation of this policy.

Directors of Clinical Governance:

• With other Executive members, ensure successful implementation of the policy within each Public Health Organisation.
REVISION HISTORY

<table>
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<tr>
<th>Version</th>
<th>Approved by</th>
<th>Amendment notes</th>
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<tr>
<td>February 2015</td>
<td>Secretary, NSW Health</td>
<td>Updates and replaces PD2005_590 and PD2005_200</td>
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<td>(PD2015_007)</td>
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<tr>
<td>June 2005</td>
<td>Director-General</td>
<td>Re-issue of Circular No. 95/86 as a Policy Directive</td>
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<td>(PD2005_590)</td>
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<td>(PD2005_200)</td>
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1 BACKGROUND

Public health facility Pharmacy Services must not dispense compounded or reconstituted pharmaceutical preparations unless the Director of Pharmacy has confirmed there are appropriate standards of training, skill, facilities, and preparative and quality assurance procedures in place to provide a high level of confidence that the preparations are of a consistently high quality standard.

In accordance with NSW Health Policy Directive Medication Handling in NSW Public Health Facilities pharmaceutical preparations at NSW public hospitals must be formulated in accordance with the Society of Hospital Pharmacists of Australia SHPA Guidelines for Medicines Prepared in Australian Hospital Pharmacy Departments (2010) which references the Guide to good practices for the preparation of medicinal products in healthcare establishments published by the Pharmaceutical Inspection Co-Operation Scheme under the Pharmaceutical Inspection Convention (PIC/S, 2008) as the standard for medicines prepared in Australian Hospital Pharmacy Departments (Services).

The Society of Hospital Pharmacists of Australia also publishes practice standards relevant to the preparation of pharmaceuticals in various clinical settings which should be implemented where possible (see webpage at http://www.shpa.org.au/Practice-Standards), including for:

- Investigational drugs services
- Palliative care pharmacy services, and
- Safe handling of cytotoxic drugs.

Additionally, the Pharmacy Board of Australia ‘Guidelines for the dispensing of medicines’ (available at http://www.pharmacyboard.gov.au/Codes-Guidelines.aspx) includes guidance on appropriate professional pharmacist practice for extemporaneous dispensing (compounding).

2 KEY DEFINITIONS

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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<tr>
<td>must</td>
<td>Indicates a mandatory action requiring compliance by staff at public health facilities, in accordance with a legislative requirement and/or a NSW Health policy or directive.</td>
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<tr>
<td>should</td>
<td>Indicates a recommended action that should be followed unless there is a sound reason for taking a different course of action.</td>
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<tr>
<td>ingredients of animal or human origin</td>
<td>Any component derived from animals or humans that is contained in, or involved in the manufacture of, the pharmaceutical preparation, including but not limited to: - cell lines, embryonated chicken eggs, materials used in cell culture media, deer velvet antler, amino acids, and some excipients such as gelatin.</td>
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<tr>
<td>pharmaceutical preparation</td>
<td>For the purpose of this policy, a medication presented as a completed formulation following a process of compounding or reconstituting, for a purpose that may or may not be an approved indication; a) Compounded pharmaceutical preparation – extemporaneously manufactured using ingredients which may or may not be on the Australian Register of</td>
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**PROCESSES**

**Therapeutic Goods (ARTG).**

b) Reconstituted pharmaceutical preparation – prepared for administration via a process of mixing pharmaceutical products with other ingredients. This would include pre-filled syringes with one or more ingredients, intravenous fluids with added electrolytes, Total Parenteral Nutrition solutions and parenteral oncology medications.

<table>
<thead>
<tr>
<th>Pharmacy Service</th>
<th>For the purpose of this policy, a service administered by a Director of Pharmacy responsible for the procurement, distribution, preparation and dispensing of medications as well as the delivery of clinical and other pharmacist practice services.</th>
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<td>public health organisation</td>
<td>As defined under the Health Services Act 1997, a local health district, statutory health corporation or affiliated health organisation (in respect of its recognised establishments and services).</td>
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3 PRINCIPLES

3.1 Approval for the Use of Pharmaceutical Preparations

Public health facility Pharmacy Services should not supply a pharmaceutical preparation not listed or registered on the Australian Register of Therapeutic Goods (ARTG) when a similar or a substantially similar product on the ARTG is available.

NSW Health Policy Directive PD2008_037 Medicine - Evaluation of Medicines for Use in Public Hospitals describes the role of the Drug and Therapeutics Committee in the evaluation and approval of all pharmaceuticals added to a facility’s formulary.

3.2 Quality Management

To produce a consistently safe and effective product, irrespective of its scale or complexity, for every patient, the Director of Pharmacy of a Pharmacy Service supplying compounding and/or reconstituting pharmaceutical preparations should implement a quality management system which incorporates the elements in the SHPA Guidelines for Medicines Prepared in Australian Hospital Pharmacy Departments pertaining to:

- Personnel
- Premises and equipment
- Production of preparations
- Documentation
- Quality control
- Contracted services, such as the reconstitution of chemotherapeutic agents
- Complaints and product recalls, and
- Self audits.

4 PREPARATION, STORAGE, SUPPLY AND HANDLING OF PRODUCTS

4.1 Sourcing Completed Pharmaceutical Preparations

Where a preparation is not available as an ARTG registered/listed commercial product and the Director of Pharmacy determines that the Pharmacy Service does not meet the
principles in the *SHPA Guidelines for Medicines Prepared in Australian Hospital Pharmacy Departments* to formulate the preparation (compound or reconstitute), the preparation must be obtained from either:

a) Another NSW public health facility Pharmacy Service, provided the Director of Pharmacy of the Pharmacy Service obtaining the preparation has confirmed the product was prepared in accordance with the *SHPA Guidelines for Medicines Prepared in Australian Hospital Pharmacy Departments*, or

b) A community pharmacy, provided the Director of Pharmacy of the Pharmacy Service obtaining the preparation has confirmed the product was prepared in accordance with the *SHPA Guidelines for Medicines Prepared in Australian Hospital Pharmacy Departments*, or

c) An Australian manufacturer appropriately licenced under the Commonwealth *Therapeutic Goods Act 1989* to manufacture pharmaceuticals in accordance with the *Good Manufacturing Practice for Medicines*.

NSW Health Policy Directive PD2014_005 ‘*Goods and Services Procurement Policy*’ and NSW Health ‘*Goods and Services Procurement Policy Manual*’ provides information on purchasing procedures and contracts with providers.

### 4.2 Sourcing Ingredients of Animal or Human Origin

The Director of Pharmacy must implement procedures to ensure that ingredients of animal or human origin are not included in preparations unless the product is on the ARTG. Exception is provided for the use of non-ARTG products where appropriate steps have been taken by the pharmacist, under a protocol approved by the Director of Pharmacy, that the evaluation of the material confirms there is a minimal risk of any disease transmission.

The information from the Therapeutic Goods Administration (TGA) to sponsors of ARTG medications on the use of material of animal or human origin in ‘*Guidance 10: Adventitious agent safety of medicines*’ (TGA August 2013) may assist pharmacists in confirming the safe inclusion of such materials in pharmaceutical preparations – see for example reference to the European Pharmacopoeia (Ph. Eur.) *Chapter 5.2.8, ‘Minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products’*.

### 4.3 Packing, Labelling, Recording of Pharmaceutical Preparations

Pharmaceutical preparations prepared by or on behalf of the Pharmacy Service must be supplied (when for imprest stock) and dispensed (for a particular patient) in accordance with the packing, labelling and recording requirements in section 5 of NSW Health Policy Directive PD2013_043 *Medication Handling in NSW Public Health Facilities*, including where the product requires child resistant packaging (in section 5.5.6).

The labelling should also include the name and contact details of the source of a compounded or reconstituted pharmaceutical preparation.
4.4 Assignment of Expiry Dates

The Pharmacy Service must assign an appropriate expiry date to compounded or reconstituted preparations and recommend corresponding storage conditions.

Once it has been confirmed that the Pharmacy Service can supply the preparation with a consistently high level of quality assurance, including sterility where appropriate, the limiting factor for assigning the expiry date for use will be the stability of the preparation. The expiry date allocated to a preparation may be varied according to the circumstances, within the limits of the estimated stability.

Accordingly, the Director of Pharmacy of the Pharmacy Service must implement procedures to ensure that:

a) The preparation is chemically and physically stable for the recommended period included on the label, and

b) Appropriate storage facilities are used to maintain the quality of the preparation over that period.

**Pre-filled syringes for immediate use**

Pharmacists must confirm there is no incompatibility arising from the contact of a compounded or reconstituted pharmaceutical preparation with the materials of the syringe plunger and barrel used to administer the product.

When a preparation in a pre-filled, single-use syringe intended for immediate use is supplied to a patient care area the appropriate staff member must be alerted accordingly.

4.5 Storage of Pharmaceutical Preparations

Compounded or reconstituted products should be stored for the shortest possible period prior to administration.

Where not required for immediate use, preparations must be stored in accordance with the requirements in PD2013_043 *Medication Handling in NSW Public Health Facilities* both at the Pharmacy Service (in section 5) and the patient care area (in section 6).

Temperature storage conditions must be monitored both at the Pharmacy Service and at the patient care area where the preparation is to be used.

For a preparation used to treat a patient in their home, the pharmacist should, where possible, confirm that appropriate storage is available and that the patient is educated accordingly. The use of a temperature monitoring device should also be recommended to the patient.

4.6 Discarding and Destruction of Expired, Unusable or Unwanted Pharmaceutical Preparations

Expired, unusable or unwanted preparations must be destroyed in accordance with the requirements PD2013_043 *Medication Handling in NSW Public Health Facilities* at the Pharmacy Service (section 5.8) and the patient care area (section 6.15).
Where only a part of the prepared unit dose of the product (for example, capsule, ampoule, infusion) is required for administration, the unwanted portion must be discarded in a manner that is safe to the public and renders the preparation unusable. Further information on discarding part units of Schedule 8 preparations is in section 7.9 of PD2013_043 Medication Handling in NSW Public Health Facilities.