

## POSITION STATEMENT

### The manufacture of medicines

All medicines should be prepared in such a way that they are safe, effective, fit for their intended purpose and that their quality consistently complies with the defined requirements. The manufacture (or compounding) of medicines intended for use by a specific consumer, or 'immediate' use within the facility is part of a pharmacist's professional services and should be undertaken in line with Domain 5 of the *National Competency Standards Framework for Pharmacists in Australia 2010*.

### Position

The Society of Hospital Pharmacists of Australia (SHPA) reiterates the need for **all types of medicines prepared by Australian hospital pharmacy services (aseptic and non-aseptic) to be prepared in line with *SHPA Guidelines for Medicines Prepared in Australian Hospital Pharmacy Departments***.

Where cytotoxic medicines are prepared, the *SHPA Standards of practice for the safe handling of cytotoxic drugs in pharmacy departments*, and the International Society of Oncology Pharmacy Practitioners' (ISSOP) *Standards for safe handling of cytotoxics*, should also be consulted.

Preference must be given to using medicines registered as therapeutic goods through Therapeutic Goods Administration (TGA). Where a registered product is not available pharmacists should attempt to source a product provided by a TGA licensed manufacturer before making the decision to manufacture the medicine within the pharmacy.

Hospital pharmacy services need to assess their ability to comply with the Guidelines and develop and implement a risk management plan. This plan should focus on procedural and quality assurance measures to achieve a similar outcome as facilities that comply with these Guidelines and satisfy actions 4.1.1 and 4.11.2 of the *National Safety and Quality Health Service Standards*.

Where medicines are prepared in anticipation of need, or in bulk (i.e. for more than one consumer) by externally contracted pharmacists (or companies) these providers should be licensed by the TGA and comply with the *TGA Code of Good Manufacturing Practice*.

Hospital pharmacy services who prepare medicines for other healthcare organisations (for example medicines intended for use by a specific consumer) should undertake a thorough risk management assessment and investigate if the TGA license exemption is applicable to the pharmacy service under these circumstances.

Hospital pharmacy services / healthcare organisations should confirm that externally contracted pharmacists (or companies) who prepare medicines for specific consumers conform with the *SHPA Guidelines for Medicines Prepared in Australian Hospital Pharmacy Departments* and where applicable *SHPA Standards of practice for the safe handling of cytotoxic drugs in pharmacy departments*, and the ISSOP *Standards for safe handling of cytotoxics* as a minimum requirement. The contract between the parties should include a statement on the provider meeting the Guidelines or the *TGA Code of Good Manufacturing Practice*.

In addition the contract with external providers should clearly state whether the hospital pharmacy service / healthcare organisation is purchasing services or products; which in part defines accountability and liability between the parties.

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## The Society of Hospital Pharmacists of Australia

## Background

Standard 4 of the National Safety and Quality Health Services Standards require appropriate governance and systems for medication safety. The Standard states that “*health service organisations have mechanisms for the safe prescribing, dispensing, supplying, administering, storing, manufacturing, compounding and monitoring of the effects of medicines.*”

The high number of deaths and hospital admissions in the United States associated with the recent outbreak of fungal meningitis linked to a contaminated steroid injection (triamcinolone) compounded by the New England Compounding Centre in Massachusetts highlights the potential for considerable consumer morbidity and mortality associated with the manufacture and compounding of medicines.

**The use of all medicines has inherent risk; minimising the risk associated with the manufacture of medicines requires a medication safety approach** which includes:

- the development and implementation of appropriate processes, record keeping and standard operating procedures;
- risk assessment of the manufacture of each product and development of appropriate formulation and manufacturing technique;
- appropriately qualified, trained and validated staff; and
- appropriately designed and maintained facilities and where required licensed facilities.

### ***The preparation of medicines by hospital pharmacy services***

Guidelines such as the *SHPA Guidelines for Medicines Prepared in Australian Hospital Pharmacy Departments* or *TGA Code of Good Manufacturing Practice* provide an overview of the approach required to minimise the inherent risk associated with the manufacturing and compounding of medicines. In part the Guidelines state that hospital pharmacy services that prepare non-aseptic, aseptic, batch and single-use products require:

1. appropriately trained personnel;
2. procedures for purchase of materials, safe handling, warehousing and storage;
3. processing instructions (specification, volume calculation, instruction, expiry, storage, record) to collect all ingredients required to prepare the product, prepare labels and confirm quantity of ingredients (for preparation);
4. double-check (where possible) of ingredients, labels and orders; as well as all weighing (tare, final weight) and volumes;
5. a suitable environment, correct technique, appropriate equipment and processing instructions;
6. double-check (where possible) of final product accounting for all ingredients, including remaining ingredients and labelling of product;
7. to retain documentation as record of preparation according to local requirements; and
8. appropriate safety packaging and made ready for transportation.

**Hospital pharmacy services that are unable to comply with the Guidelines because of infrastructure limitations should develop and implement a risk management plan.** This plan should focus on procedural and quality assurance measures to achieve a similar outcome as facilities that comply with these Guidelines and satisfy actions 4.1.1 and 4.11.2 of the *National Safety and Quality Health Service Standards*.

Hospital pharmacy services which prepare medicines for other healthcare organisations should undertake a thorough risk management assessment and investigate if the TGA license exemption is applicable to the pharmacy service under these circumstances.

### ***The purchase of medicines by hospital pharmacy services***

A third party may be contracted to manufacture or compound medicines where hospital pharmacy services are unable to provide this service. **Hospital pharmacy services / healthcare organisations should ensure that externally contracted pharmacists (or companies) who prepare medicines on their behalf meet or exceed (e.g. licensed by TGA) the same standards expected of the internal service provider.** Particularly for medicines accessed through the Authorised Prescriber or Special Access Scheme that are directly imported and may not be produced by a licensed manufacturer.

As noted in the Pharmaceutical Inspection Cooperation Scheme (PIC/S) *Guide to good practices for preparation of medicinal products in healthcare establishments*: “A technical service level agreement (contract) should specify the details of the work to be done, the specification which it should meet and the responsibilities of each party.”

The PIC/S Guide details the principles that should be followed when services are contracted to a third party and notes that: “*In an emergency, an individual, extemporaneously prepared medicinal product may be obtained without a written contract. This should be an exceptional occurrence.*”

The need for due diligence and contractual arrangements when purchasing from a third party is underscored by the fact that the compounder of the contaminated steroid injection in Massachusetts was providing products to over 3,000 healthcare organisations across the United States and internationally. As an injectable triamcinolone product is used in Australia through the Authorised Prescriber or Special Access Scheme, TGA has contacted all Australian centres with authorised prescribers of this medicine to identify the supplier used to ensure no product from the New England Compounding Centre has been used in Australia.

Pharmacists and healthcare providers in Australia should ensure that medicines compounded on their behalf are being manufactured by providers licensed by the TGA or if sourced from the United States, that the provider is a Food and Drug Administration (FDA) accredited compounder.

The hospital pharmacy service / healthcare organisation should clearly understand through the contract if it is purchasing services or products; i.e. purchasing a compounding service or purchasing a completed product. This understanding will drive the risk assessment of the agreement and in part, define accountability and liability between the parties.

The outbreak of fungal meningitis linked to the contaminated steroid injection has prompted a medical ethicist to highlight, via the 1 November 2012 Medication Safety Alert from the American Institute for Safe Medication Practices (ISMP), that it may be prudent to advise prescribers and patients regarding the source of externally compounded preparations; specifically to disclose that these products are not FDA-approved, and to discuss the benefits and risks, including possible adverse effects. **Pharmacists and healthcare providers in Australia should consider the need for disclosure when providing externally compounded preparations.**

### ***Pharmacist competency***

The manufacture (or compounding) of medicines intended for use by a specific consumer, or ‘immediate’ use within the facility is part of a pharmacist’s professional services and should be undertaken in line with Domain 5 of the *National Competency Standards Framework for Pharmacists in Australia 2010*.

The 1 November 2012 Medication Safety Alert ISMP notes that like Australia “many pharmacy schools and educational programs for pharmacists and technicians lack appropriate “hands-on” training in aseptic technique and sterile compounding”.

The alert quoted Lawrence Trissel regarding the competency of pharmacists and pharmacy technicians: “New pharmacy graduates have been short-changed regarding needed traditional skills in pharmaceutical mathematics, pharmaceutical compounding and preparation, and the basics of pharmaceutical chemistry and clinical pharmaceuticals. From repeated episodes of contamination of supposedly sterile preparations...patients have repeatedly been injured and killed because of the inadequacy of this traditional drug knowledge in practice.”

Mr Trissel went on to say that it was hoped that the meningitis outbreak will serve as an impetus for the profession and regulatory bodies in the United States to re-examine how we train pharmacists and pharmacy technicians to carry out sterile compounding, particularly given the current trend to expand the role of pharmacy technicians in both sterile compounding and compliance monitoring.

SHPA has highlighted similar concerns regarding the undergraduate training of pharmacy students in recent submissions to the Pharmacy Board of Australia and the Australian Pharmacy Council.

### **Approved by SHPA Federal Council – November 2012**

#### **References:**

1. National Competency Standards Framework for Pharmacists in Australia 2010  
<http://www.psa.org.au/download/standards/competency-standards-complete.pdf>
2. SHPA Guidelines for Medicines Prepared in Australian Hospital Pharmacy Departments standards [http://jppr.shpa.org.au/lib/pdf/2010\\_06/Manufacturing\\_Standards\\_0610.pdf](http://jppr.shpa.org.au/lib/pdf/2010_06/Manufacturing_Standards_0610.pdf)
3. SHPA Standards of practice for the safe handling of cytotoxic drugs in pharmacy departments [http://www.shpa.org.au/lib/pdf/practice\\_standards/cyto\\_drugs\\_ro.pdf](http://www.shpa.org.au/lib/pdf/practice_standards/cyto_drugs_ro.pdf)
4. ISSOP Standards for safe handling of cytotoxics standards
5. National Safety and Quality Health Service Standards <http://www.safetyandquality.gov.au/wp-content/uploads/2011/09/NSQHS-Standards-Sept-2012.pdf>
6. TGA Code of Good Manufacturing Practice <http://www.tga.gov.au/industry/manuf-pics-gmp-medicines.htm>
7. PIC/S Guide to good practices for preparation of medicinal products in healthcare establishments see <http://www.tga.gov.au/industry/manuf-pics-gmp-medicines.htm>
8. November 2012 Medication Safety Alert from the American Institute for Safe Medication Practices <http://www.ismp.org/Newsletters/acutecare/showarticle.asp?id=35>