



New Zealand HealthCare Pharmacists' Association (Inc)

Aotearoa Hauora Kai Whakaranu Rongoa

Position Statement on the Closure of Hospital Pharmacy Aseptic Compounding Units

Introduction

Aseptic compounding is the manipulation of sterile ingredients to achieve an end-product which remains in the sterile state.¹ Such compounding is necessary when no commercial parenteral product is available. Parenteral products are used frequently in hospital environments when immediate pharmacological effect is necessary such as in emergency situations or when other routes of administration are not appropriate. Types of parenteral products range from patient controlled analgesia (PCA) syringes, to the infusion of therapies via intravenous bags including chemotherapeutic agents, total parenteral nutrition (TPN) and eye drop medications.

The aseptic process is carried out in an environment which minimises the risk of microbiological or particulate contamination² such as within laminar flow cabinets which provide a controlled environment for the sterile end-product. These cabinets are located in clean-rooms in which the environment is regularly and closely monitored for air flow, humidity, pressure differential, temperature, particles and microbial contamination. The cabinets within these rooms are also monitored for air flow, particles and microbial contamination. Chemotherapeutic agents are also compounded in specially designed laminar flow isolators which offer protection for both the products and the aseptic operators. In the hospital environment aseptic compounding is usually carried out in specially designed aseptic units situated within the pharmacy department.

Background

In New Zealand an aseptic compounding unit is not present in every District Health Board (DHB). Sterile products may be sourced from other DHB's with aseptic compounding units, commercial products already available or an alternative medication used. There are currently two DHBs in the process of upgrading their existing facilities which should be acknowledged, however it is a concern that there are a greater number of DHBs considering closing their aseptic compounding units or have done so in the recent past.

NZHPA Position

The New Zealand HealthCare Pharmacists' Association (NZHPA) registers its concern regarding the impending closure of a number of aseptic compounding units in hospital pharmacy services across New Zealand. The NZHPA warns that these closures will be detrimental to patient safety, the timely delivery of aseptically compounded medicines, the pharmacy profession in New Zealand, and in the long term will not achieve the anticipated cost savings.

Our vision statement:

Supporting innovation in the practice of pharmacy and promoting effective medicines management

The reasons behind this are:

- A reduction in the flexibility of production of medicines that require aseptic manipulation. For example, medicines that are needed 'out of hours', medicines with complex regimens or short expiries, and medicines that are promptly needed for newly admitted, unwell patients. This will result in a longer wait for treatment for these patients, an increased wastage of products, and a reduced 'individualising' of products to the patient being treated.
- An increase of unqualified personnel compounding 'sterile' products under non-sterile conditions resulting in low safety standards. Research evidence of this has been used in the UK to promote the safer use of injectable medicines.³
- Limitations in the range of sterile products that can be made - especially in the area of clinical trials or complicated, hazardous medicines. This will directly impact on the treatment options available and ultimately it will be the patients who suffer.
- A reduction in the number of pharmacists in New Zealand with important knowledge of product stability, quality control, and chemical composition. This background knowledge is essential for the quality assurance and final release of aseptically compounded products. Once reduced this knowledge may not be able to be recovered.
- A reduction in the wide range of training on offer for hospital intern pharmacists, rotational pharmacists and technicians in the hospital setting, which will impact on the future recruitment and retention to the hospital sector.
- A reduction in the number of pharmacists and pharmacy technicians in New Zealand with important skills in aseptic manipulation.
- Limitations in the availability of hospital pharmacy departments to support their community pharmacy colleagues, hospices and rest homes in the compounding of sterile medicines.
- As many services are being replaced by outsourcing to one major pharmaceutical compounding company there is a risk of commercial monopoly; hospitals will not have an option but to buy from this one company. It is acknowledged that a second pharmaceutical compounding company has recently increased the range of sterile products compounded but the effect of this on hospital pharmacy aseptic services is unknown at present.
- The future of these companies in New Zealand should be considered as pharmaceutical companies in the past have retrenched and quit the country.
- Short term savings from not having to build new or update existing aseptic compounding units will not be offset in the long term by outsourcing.

The NZHPA believes in terms of patient safety that it is essential that hospital pharmacy services are supported in providing sterile medicines to patients with DHB's investing in the development and maintenance of hospital pharmacy based aseptic compounding units.

References

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2. [No author listed]. Guidance for Industry. Sterile Drug Products Produced by Aseptic Processing - Current Good Manufacturing Practice. [FDA website]. September, 2004. Available at <http://www.fda.gov/cder/guidance/5882fml.htm>. Accessed: March 2006.
3. <http://www.npsa.nhs.uk/nrls/alerts-and-directives/alerts/injectable-medicines/>

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