

The draft guidelines are helpful, easy to read and offer pharmacists a guide to the requirements necessary. The following issues need addressing –

Specific questions

Do the draft guidelines clearly differentiate between simple compounding and complex compounding?

The delineation between the two groups is appropriate. However, the inclusion of monoclonal antibodies under “complex compounding” should be reconsidered. There has been much work on the preparation of monoclonal antibodies recently in regards both the occupational health and safety aspects as well as the complexity aspects.^{1,2} It may be prudent to not class all monoclonal antibodies together, but consider each as an individual entity.

1. Siderov J. Safe handling of monoclonal antibodies in the health care setting. Position Statement. COSA November 2013 available at <https://www.cosa.org.au/publications/position-statements.aspx>
2. Western & Central Melbourne Integrated Cancer Service. Australian consensus guidelines for the safe handling of monoclonal antibodies for cancer treatment by healthcare personnel. WCMICS April 2014 available at <http://www.wcmics.org/guidelines/>

Other comments

Page 7: “*If employed in a public hospital...*”

Is the intent of this sentence to allow pharmacists in one public hospital to prepare simple and/or complex compounding for administration to patients in another hospital in the same state or territory? It seems to contradict the earlier sentence “*Pharmacists may only supply medicines...*”

Page 9: *These guidelines must be read in conjunction with*

The suggested list of guidelines should be reviewed. The 4th dot point is redundant (from memory also receded by SHPA). One other standard which should be included is:

- a) Carrington C, Stone L, Koczwara B, et al. The Clinical Oncological Society of Australia (COSA) guidelines for the safe prescribing, dispensing and administration of cancer chemotherapy. *Asia Pacific J Clin Oncol* 2010; 6:220-37

The final sentence in this section is ambiguous. Many medicines are compounded by hospital pharmacy departments which may be administered as a continuous infusion over 7 days, or which have a shelf life of greater than 24 hours. This final sentence suggests that items with a shelf life of more than 24 hours must be compounded elsewhere? Is this the intent of this sentence?

One major issue lacking in these guidelines is guidance on appropriate workload. One major source of error in compounding is fatigue. Therefore, it is imperative that these guidelines offer a reasonable and appropriate benchmark for staff numbers for complex compounding. For example, how many complex compounding items is considered acceptable for one staff member to prepare in a set period of time?

There has been substantial evidence on workplace contamination with cytotoxic agents, both in Australia^{3,4} and overseas.^{5,6} These are despite compliance with accepted standards of practice. It would seem appropriate for these guidelines to include a statement on the importance of closed system drug transfer devices in the compounding of complex medicines where an occupational health and safety concern exists. These devices minimise the risk of occupational exposure to hazardous agents, as well as eliminate needle stick injury (page 14, section 6).

3. Siderov J, Kirsa S, McLauchlan R. Surface contamination of chemotherapy preparation areas with cyclophosphamide in Australian hospital pharmacy departments. *J Pharm Pract Res* 2009; 39:95-9
4. Siderov J, Kirsa S, McLauchlan R. Reducing workplace cytotoxic surface contamination using a closed-system drug transfer device. *J Oncol Pharm Pract* 2010; 16:19-25
5. Sessink P, Connor T, Jorgenson J, Tyler T. Reduction in surface contamination with antineoplastic drugs in 22 hospital pharmacies in the US following implementation of a closed-system drug transfer device. *J Oncol Pharm Pract* 2011; 17:39-48
6. Connor T, Anderson R, Sessink P, Broadfield L, Power L. Surface contamination with antineoplastic agents in six cancer treatment centres in Canada and the United States. *Am J Health Syst Pharm* 1999; 56: 1427-32

The “Australian injectable drugs handbook” is an SHPA publication and should be acknowledged.

Jim Siderov BPharm MCLinPharm BCOP

Cancer Pharmacist