

22 July 2014

Dear CMRB,

Regarding the draft Guidelines for Safe Chinese Herbal Medicine Practice, it seems that the document does not correctly inform practitioners of the legal requirement to hold a GMP licence to manufacture therapeutic goods, in certain dispensing situations. For the protection of patients and practitioners, and the reputation of the industry, it should.

The glossary entry “Extemporaneously prepared medicine (compounding):” is not entirely correct. It suggests that all extemporaneous compounding is exempt from Part 3-3 of the Therapeutic Goods Act, but this is incorrect. Extemporaneous compounding is only exempt from operation of Part 3-3 of the Act (the need to hold a manufacturing licence) when the conditions of Schedule 8 of the Therapeutic Goods Regulations are met.

Item 4 of Schedule 8 of the Regulations says that practitioners of traditional Chinese medicine are exempt provided they:

- supply the preparation for administration to a particular person after consulting with that person; and
- use his or her own judgment as to the treatment required.

Based on this, it is only the prescriptions prepared following a consultation that are exempt, NOT the filling of a prescription for a particular patient when no consultation has occurred. Any formula that is made up in the absence of a consultation, including those made up by a third party dispensary and those made up for self-medicating patients, are not exempt, and therefore the dispenser must hold a TGA-issued licence to manufacture therapeutic goods (GMP licence).

The Board should be clear in notifying practitioners, when issuing Chinese Herbal Dispenser registrations, and in the Guidelines for Safe Chinese Herbal Medicine, that the filling of prescriptions without a consultation must be done under a GMP licence.

Board-issued dispensing guidelines should not apply to dispensing which is not exempt from Part 3-3 of the Act since the legal obligation is already the far more inclusive Australian Code of GMP.

Kind regards

Christopher Booth