Retired guideline

28 April 2015

Guideline 5 *Extemporaneous dispensing (compounding)*

Background

The guideline below from the Pharmacy Board of Australia's *Guidelines for dispensing of medicines* has been retired and from today is replaced by the *Guidelines on compounding of medicines.*

Board guidelines are available in the Codes and guidelines section on the Board's website.

Guideline 5 Extemporaneous dispensing (compounding)

The Board recognises that pharmacists are required to compound and dispense medicines extemporaneously.

An extemporaneous preparation should be used only in circumstances where a commercial product is unavailable or unsuitable.

Guidelines

Pharmacists must ensure that, in the absence of any formulation published in a standard reference, there is good clinical and pharmaceutical evidence to support the quality, safety, efficacy and rationality of any extemporaneous formulation. Evidence is best obtained from peer-reviewed journals, rather than being solely based on testimonials and impressions.

Particular care should be exercised in the case of medicines for which there are no precedents in standard references. Examples are oral and topical hormone preparations, those containing substances whose use has not been approved in Australia for therapeutic use, and preparations that contain well-established drugs for oral use, but for which there are inadequate safety and efficacy data when the same drug is used topically.

Modified-release formulations should only be made up if there is credible in vivo and in vitro data that support the quality, safety, efficacy, rationality and relevance of the precise formulation.

Adding substances to commercially manufactured medicines is discouraged because the full formulation details of the latter are not generally available.

The Board has regard to the *Australian Pharmaceutical Formulary and Handbook's* statement on extemporaneous dispensing, to established practice and quality standards, and to current State or Territory, and Commonwealth legislation.

Note: The Board is aware that there is a review of current compounding practices in pharmacy being undertaken by the Therapeutic Goods Administration and this guideline will be further considered when the results of that review are known.