Public consultation on draft revised Board guidelines

6 March 2015

Responses to consultation questions

Please provide your feedback as a Word document (not PDF) by email to pharmacyconsultation@ahpra.gov.au by close of business on Friday 1 May 2015.

Stakeholder Details

If you wish to include background information about your organisation please provide this as a separate word document (not PDF).

Organisation name
Elizabeth Thompson Pharmacist
Contact information *(please include contact person's name, position title and email address)*
Elizabeth Thompson Pharmacist [redacted]
Submissions will generally be published unless you request otherwise. Do you want all or part of it treated as confidential?
Please redact contact information provided above

Your responses to consultation questions on the draft revised guidelines

Guidelines on dose administration aids and staged supply of dispensed medicines (Currently titled *Guidelines on specialised supply arrangements*) *Please provide your responses to any or all questions in the blank boxes below*
1. From your perspective, how are the current *Guidelines on specialised supply arrangements* working?
yes
2. Is the content and structure of the draft revised guidelines helpful, clear, relevant and more

workable than the current guidelines?

yes

3. Is there any content that needs to be changed or deleted in the draft revised guidelines?

no

4. Is there anything missing that needs to be added to the draft revised guidelines?

Yes. A guidance on how and how long to store the dosage aid, once tablets/capsules placed in it as well as additional advice regarding the shelf life to assign to the aid.

Whilst there is reference to the physical compatibility of co-packaging products, there is no consideration to the stability of the product in the dose administration aid. The stability of products can vary and many are presented in packaging materials to limit exposure to moisture and/or light. The quality and efficacy of the product can only be guaranteed if it is stored in accordance with the recommended storage conditions and in the packaging materials that the product is originally supplied in.

It would not be possible to generate meaningful stability data for tablets/capsules packaged in dosage administration aids, so the guideline should contain some direction to pack the dosage aid as close to the time that it is required as practical, thus limiting the time that the products are stored in the dosage administration aid.

The guidelines should also contain advice that the packaged dose administration aid should be stored in a manner that is appropriate to the contents i.e. protect from light, moisture and at the recommended temperature.

Whilst the guidance document currently recommends that the dosage aid should be labelled with an expiry date, there is no advice as to what this should be. The assumption would be it should be the shelf life of the shortest dated component included in the pack. However, the shelf life of a product is only applicable when the product is stored in in the original packaging material, in accordance with the manufacturer's details.

It is suggested that the guidelines should recommend a shorter expiry date in the absence of data to establish the stability of the products in the dose/administration aid. The proposed expiry date should be sufficient for practical purposes, but shorter than the original shelf life assigned to reduce the risk of potential impact on quality and efficacy.

A standard calculation for expiry date should be included in the guideline such as "date of packaging + "X' weeks" where "x" is defined based on the time defined by the Board as sufficient to enable the process to work. The assigned shelf life should not exceed the manufacturer's recommended expiry date.

5. Do you have any other comments on the draft revised guidelines?

no

6. Do you think that that the proposed review period of five years, with the option to review earlier if the need arises, is appropriate?

yes

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