

## Important changes to Australian Medicines Handbook (AMH) content in 2016

Until now the Australian pregnancy category has been included in the Pregnancy section in *AMH* drug class or individual drug monograph information. However, we have been increasingly unhappy about its inclusion. The categorisation has become less useful since the expert Medicines in Pregnancy Working Party (which oversaw the previous TGA publication *Prescribing medicines in pregnancy*) was disbanded a number of years ago. Recently, articles discussing the limitations of the categories have been published in *Medical Journal of Australia (MJA)* and *Australian Prescriber*. The *MJA* article also outlines relevant history both in Australia and other countries, in particular the US.

We think the key points are that:

- most people incorrectly assume that the alphabetical code is one of safety (although the TGA explains that this is not the case)
- categories do not indicate which stages of fetal development might be affected
- categories may not change despite the availability of new information
- categories are not able to convey information about the balance between risks and benefits in a particular situation.

The Food and Drug Administration (FDA) has recently announced that the pregnancy categories used in US product information are to be removed and replaced by more helpful information; this will be phased in from 30 June 2015. Their reasons for the change are similar to those we outline above.

During 2015 we reviewed and updated much of the information about medicines use in pregnancy in *AMH*, and we deleted the pregnancy categories for all medicines we list. For many drugs we have included additional helpful information. We have revised *Prescribing for pregnant women* in the Guides section of *AMH* accordingly.

These changes appear in the *AMH* 2016 book and electronic versions published in January 2016.

**Nick Buckley, Chair, and Simone Rossi, Managing Editor, Editorial Advisory Committee.**  
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1. Kennedy 2014 <http://www.australianprescriber.com/magazine/37/2/38/40>

2. Kennedy 2011 <https://www.mja.com.au/journal/2011/195/10/x-problem-categorisation-drugs-pregnancy-australian-perspective>

