Complementary Healthcare Council of Australia

Technical Alert

Call for Comment: Proposal for Automatic Adoption of New Versions of the PIC/S GMP

Dear member,

The CHC invites you to comment on the TGA consultation for a proposal for automatic adoption of new versions of the PIC/S Guide to Good Manufacturing Practice for Medicinal Products.
Submissions are welcome to the CHC **by COB Friday, 2 August 2013** for submission to the TGA by the 12 August 2013. Full consultation documents can be found here.

Submissions may comment on any, or all, aspects of the proposal to introduce an automatic adoption of new versions of PIC/S GMP in the Manufacturing Principles, while simultaneously introducing a consultation for Australian industry prior to PIC/S adoption of any revisions to PIC/S GMP.
Good Manufacturing Practice (GMP) describes a set of principles and procedures that when followed helps ensure that therapeutic goods are of high quality.

Please note a comparison between the 2009 and 2013 editions of the PIC/S Guide to GMP provides a short summary of main changes, and subsequently a table that provides a full overview of all differences between PE 009-10 (the current version adopted by PIC/S as per 1 January 2013) and PE 009-8 (15 January 2009—currently adopted in the Manufacturing Principles). Annex 7 highlights considerations for Herbal Medicinal Products.

This consultation
The proposal for a 'rolling' adoption of the current version of PIC/S GMP aims to assure the Australian industry that consultation input can be considered before PIC/S decides about adopting a revision rather than later on when Australia decides on adopting a published new version.

- Adoption of harmonised standards is crucial to maintaining the mutual equivalence of Australia and the TGA with its Mutual Recognition Agreement (MRA) partners (EU, Switzerland, Canada, Singapore) and its partners with which a Memorandum of Understanding (MoU) is effective (USA).
- PIC/S GMP is the internationally harmonised GMP standard that is also used by the European Union and New Zealand. Other partners (Canada, USA, Singapore) have their own national GMPs that are strongly aligned with PIC/S GMP.
- Mutual equivalence arrangements like MRAs and MoUs are essential to Australian medicines manufacturers as these arrangements allow partner regulatory agencies for Australian based

exporting manufacturers to accept TGA licensing and inspection results in lieu of conducting their own GMP inspections.

- Australian sponsors also benefit from mutual equivalence arrangements as these arrangements allow the TGA to issue GMP clearance for the majority of overseas manufacturers involved in production for the Australian market, based on TGA acceptance of GMP inspection results from those partners in lieu of a TGA GMP inspection.
- In order to maintain equivalence, the TGA adopted the PIC/S Guide in 2009 with a view to periodically updating to future revisions of PIC/S GMP in the years following their publication.

Consultation with the Australian industry

When adopting a new version of PIC/S GMP, the TGA is required to consult with industry. Currently however, at the time of consultation PIC/S has already adopted that version and consequently any outcomes from an Australian consultation can no longer be considered by PIC/S, unless another revision project is started.

Rolling adoption

The TGA suggest the best way to address this issue is to introduce a 'rolling' adoption to whichever is the current version of PIC/S GMP. This would mean adopting version PE 009-10 now with a provision that following publications by PIC/S of any future versions of PIC/S GMP, these new revisions will automatically be adopted with a fixed transition period.

PIC/S has indicated that following the introduction of such a 'rolling' adoption, it is willing to amend its revision processes to allow full consideration of any outcomes of Australian industry consultations before a revision is adopted.

Based on these considerations, the TGA proposes to introduce such a 'rolling' or automatic adoption of new versions of PIC/S GMP with a fixed transition period after its publication date while simultaneously introducing a consultation for Australian industry prior to PIC/S adoption of any revisions to PIC/S GMP.

As differences between subsequent versions of PIC/S GMP are usually small and industry will be made aware of any upcoming revisions during the consultation rather than after publication, a fixed transition period of 6 months after PIC/S publication is proposed.

For further information contact:

CHC Head of Regulatory Affairs Emma Burchell 0451 681 663
Emma.Burchell@chc.org.au