Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Re: Adoption of new Code of GMP in Australia

I am writing to Sponsors of medicinal products manufactured overseas to raise awareness of the introduction of new manufacturing requirements in Australia that will have mandatory effect from 1 July 2010. As Australian Sponsors are responsible for ensuring the GMP compliance of their manufacturing sites, it is important that you be aware of the changes that are taking place.

In July of 2009, the TGA published new Manufacturing Principles for medicinal products - *Therapeutic Goods (Manufacturing Principles) Determination 1 of 2009*. The new Manufacturing Principles adopt the PIC/S Guide for Good Manufacturing Practice for Medicinal Products (PE 009-8) dated 15 January 2009 issued by the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S). The PIC/S Guide also incorporates the ICH Harmonised Tripartite Guideline Good Manufacturing Practice for Active Pharmaceutical Ingredients.

The TGA's adoption of harmonised international standards helps to minimise the regulatory burden on Australian companies seeking to compete in the global economy and preserves Australia's equivalence with its regulatory partners under the provisions of several Mutual Recognition Agreements for GMP inspections and certifications. As Europe has already adopted the PIC/S Guide, some overseas manufacturers will be aware of, and be compliant with, the requirements now expected in Australia as well.

A one-year transition period was provided, with mandatory effect of the new requirements taking effect from 1 July 2010.

The main changes you should be aware of are:

- The introduction of the requirement to prepare annual Product Quality Reviews (PQR's), in clause 1.4 of the 2009 Code,
- The formal introduction of a requirement to adopt Quality Risk Management (QRM), in clauses 1.5 and 1.6 of the 2009 Code, in combination with the voluntary Annex 20 on QRM, which provides tools to comply with the mandatory clauses 1.5 and 1.6. This Annex 20 is based on the International Conference on Harmonisation (ICH) guideline Q9,
- The introduction of more detailed requirements on performing an on-going stability programme in clauses 6.23-6.33 of the 2009 Code,
- The introduction of a requirement in clause 8.7 of the 2009 Code to establish a process to inquire whether complaints could be caused by counterfeiting,
- The revision of Annex 1 on the manufacture of sterile medicinal products, which provides more detail on several specific aspects,
- The introduction of a new Annex 19 that provides more detail on the already existing requirement to keep reference and retention samples.

Apart from these changes, several detailed editorial changes apply.

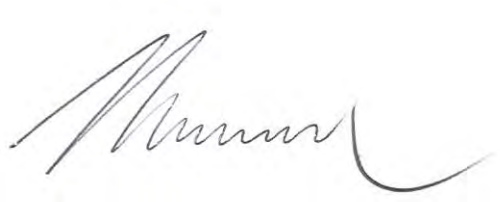
For medicines manufactured overseas, the TGA's interpretation is that both the overseas manufacturer/s and the Australian sponsor share the responsibility for a number of these changes, more specifically for the preparation of PQR's, for performing an on-going stability program and for keeping reference and retention samples.

Although the requirements in the 2009 Code regarding release for supply of medicinal products (clauses 1.1vii and 1.3vii) are not different from current requirements, the changes outlined above do affect the release for supply arrangements made between overseas manufacturers and Australian sponsors. Accordingly, we advise you to review your current contract manufacturing agreements to ensure that the new requirements are included as per 1 July 2010 when the 2009 Code becomes mandatory. This is specifically relevant to manufacturers and sponsors involved in the manufacture of over-the-counter (OTC) and complementary medicines.

A copy of the 2009 Code, as well as a variety of information about this change, including a questions and answers (Q&A) section on this topic, can be found on the TGA web site www.tga.gov.au. You can also submit any additional questions you might have by email to the TGA's Office of Manufacturing Quality on gmp@tga.gov.au.

As mentioned previously, the introduction of the 2009 Code specifically affects manufacturers and sponsors of OTC and complementary medicines. An information letter sent out by the relevant associations to their members about these issues is attached for your information. The TGA is also developing implementation guidance documents in conjunction with industry associations, which will become available on the TGA web site. At this stage, two draft guidance documents are available about Product Quality Reviews for listed complementary medicines manufacture and about on-going stability testing for listed complementary medicines.

Yours sincerely



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