Health Canada Santé Canada

Canadian Health Products and Food Branch (HPFB) and Australian Therapeutic Goods Administration (TGA) sign Memorandum of Understanding on Medical Devices

Officials of the governments of Australia and Canada have signed a Memorandum of Understanding (MoU) on the reciprocal recognition of quality management system (QMS) certificates for medical device manufacturers.

The High Commissioner for Canada, His Excellency Mr Michael Leir, and Australia's Parliamentary Secretary for Health, Senator Brett Mason, signed the MoU June 1, 2007 at TGA headquarters in Canberra on behalf of the HPFB and TGA. This follows the signing of an MoU on information exchange in April 2004 and a Mutual Recognition Agreement (MRA) in March 2005 that enables both countries to accept each other's good manufacturing practice (GMP) audits and inspection of the makers of prescription and over the counter medicines.

The signing of this MoU will enable Health Canada to recognize the QMS certifications issued by the TGA to Australian and New Zealand manufacturers exporting to Canada, and for TGA to recognize the QMS certifications issued by Health Canada recognized Registrars to Canadian medical device manufacturers exporting to Australia and New Zealand.

The rigorous confidence building exercise that underpins the memorandum has served to confirm the compatability of the two regulatory systems in assessing a manufacturer's quality systems – systems integral to the consistent production of high quality medical devices.

Once fully operational the MoU will eliminate the duplication of manufacturing audits that is currently required when manufacturers export their medical devices to one another's respective markets. The MoU is also expected to facilitate timely access to new technologies.

The signing of the MoU is a significant milestone and serves as further evidence of the high regard the HPFB and TGA hold for each other's regulatory practices. It also marks the commencement of the final and enabling phase of the confidence building process, after which the MoU would become fully operational.

This final phase, which will include observed audits of medical device manufacturers, is envisaged to be completed before the end of the year. At that time, the QMS certificates issued by the Manufacturers Assessment Branch of the TGA would be recognized by Health Canada and taken into consideration as part of an application for a device licence that would authorize the sale of the product in Canada.

Similarly, QMS certifications issued by a participating Canadian Registrars will be recognized by the TGA and taken into consideration as part of an application for a Conformity Assessment Certificate issued by the TGA. Subsequently, an Australian sponsor may apply for an inclusion in the Australian Register of Therapeutic Goods to allow supply in Australia.

A questions and answers document is currently under development that will provide further detail about the scope and operation of the MoU.

Questions or comments related to this project or notice should be directed to:

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