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20 JUL 2005
BY: Gillian Gould

Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

Ms Gillian Gould
Secretary
Joint Standing Committee on Treaties
Parliament House
CANBERRA ACT 2600

Dear Ms Gould

I refer to your letter of 23 June 2005 concerning a question raised in relation to Article 16 of the proposed treaty titled *Mutual Recognition Agreement on Conformity Assessment in relation to Medicines Good Manufacturing Practice Inspection and Certification between the Government of Australia and the Government of Canada.*

During the finalisation of the text of the *Mutual Recognition Agreement (MRA)*, the Attorney-General's Department suggested that a provision on settling differences be included in the Agreement. It was envisaged that Article 16 *Settlement of Differences between the Parties* would work together with Article 7 (3)(a)(ii) *Joint Sectoral Group.*

The Joint Sectoral Group (JSG) has a role in settling questions of application of the treaty. However, there were concerns with the perceived conflict of the JSG being responsible for determining and monitoring equivalence and also for resolving questions relating to the application of the treaty. The JSG may be able to resolve such questions in many cases, but if the questions arise due to disagreements within the JSG when discharging its other functions, the JSG may have difficulty resolving such questions.

Other similar agreements include a provision for the establishment of a Joint Committee comprising senior representatives from both Parties that oversees the administration of the Agreement and resolves any questions or disputes relating to the application. However, as this MRA is a single-sector bilateral agreement, the provision in Article 16 provides the mechanism for the settlement of differences if required.

The Therapeutic Goods Administration (TGA) and Health Products Food Branch (HPFB), Health Canada are yet to finalise the details of the arrangements for the bilateral discussions. However, it is envisaged that the direct bilateral discussions would be between senior representatives not included on the JSG from the Australian and Canadian Government, for example senior officials from the TGA, HPFB, the Department of Foreign Affairs and Trade, the Attorney-General's Department and the Canadian equivalent. Any decisions made at the bilateral discussions would be at the agreement of all participants.

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Please contact Ms Rita Maclachlan, Assistant Secretary, Office of Devices, Blood & Tissues on (02)6232 8700 or Email – rita.maclachlan@health.gov.au should you have any further queries regarding the operation of the MRA.

Yours sincerely

Terry Slater
National Manager

15 July 2005