Sectoral Annex Medical Devices

questions and issues. Conformity Assessment Bodies and Regulatory/ Designating Authorities must continue participation in maintenance activities, as established by the Joint Sectoral Group, within the framework of this Annex in order to maintain their status under this Annex as indicated in Attachment 2.

Parties may request the addition of Regulatory/Designating Authorities or Conformity Assessment Bodies to Attachment 2. The procedure for the acceptance of new Regulatory/Designating Authorities will be as described in the confidence building programme. Conformity Assessment Bodies will be added to Attachment 2 upon recommendation from a Regulatory/Designating Authority and joint decision by the Joint Sectoral Group.

7.7 Contact Points

Contact points are identified in order to permit Regulatory Authorities and manufacturers to inform the Regulatory Authorities of the other Party concerned with the appropriate speed in case of quality defects, recalls, and adverse incidents, which could necessitate additional controls or, suspension of the distribution of the product or, suspension or cancellation of a certificate of compliance.

For the purpose of this agreement, the contact points will be:

for Canada:

The Thereputic Products Directorate, Health Canada; and

for the EEA EFTA States:

Iceland:

Ministry of Health and Social Security

Liechtenstein:

Amt für Lebensmittelkontrolle und Veterinärwesen Kontrollstelle für Arzneimittel

Norway:

Norwegian Board of Health (Medical Devices Section)