in the EEA EFTA States will, without any further re-assessment, accept the certification as evidence of compliance with the premarket requirements of the relevant European Directives.

For evaluating against Canadian requirements, the CABs of the EEA EFTA States or other Conformity Assessment Bodies recognized as competent by Canada shall establish the conclusions of the examination and submit to Health Canada an abbreviated supporting report and certificate of compliance which includes such conclusions. Based on these documents, and without any further re-assessment, Health Canada will accept the certification as evidence of compliance with the premarket requirements of the Canadian Medical Devices Regulations.

Canada, on the one hand, and each of the EEA EFTA States, on the other, shall make available to the other Party concerned, upon reasoned request, any information which has been reviewed as part of the assessment of a medical device for the purpose of issuing certificates of compliance.

Canada, on the one hand, and each of the EEA EFTA States, on the other, reserves the right, at any time, to question information with respect to the designation process or the performance of conformity assessments against the requirements of its regulatory regime. Furthermore, Canada, on the one hand, and each of the EEA EFTA States, on the other, reserve the right to conduct its own conformity assessments for reasons identified to the other Party concerned. Justification for such audits shall be based on documented evidence and notification is to be provided in advance to the other Party concerned. Recourse to such audits should be an exception.

7.2 Procedures for Designation of CABs

The procedures to be followed by the Designating Authorities of each Party in designating CABs shall respect the criteria laid down in the regulations or guidelines of the other Party concerned (non-binding guidance is provided in Attachment 5).

7.3 Information Sharing

In accordance with the general provisions of the Annex, Canada, on the one hand, and each of the EEA EFTA States, on the other, will exchange all information necessary to determine and maintain equivalence of conformity assessment procedures. In addition, each Party shall share with the other Parties information generated within the framework of its regulatory system which is relevant for the operation of conformity assessment procedures (i.e. guidance documents, publications of references to standards, forms, documents relating to the application of legal requirements). Each Party shall associate Regulatory/Designating Authorities and Conformity Assessment Bodies of the other Party concerned in activities of exchange of information and experience.