

#### 6.4. End of Transition Period

No later than eighteen months after the entry into force of this agreement, the Joint Sectoral Group shall proceed to a joint evaluation of the experience gained. This evaluation will cover the adequacy of the Confidence Building Programme, the capabilities of Regulatory/Designating Authorities and the capabilities of the designated Conformity Assessment Bodies.

Recommendations to list CABs in Attachment II of this Annex shall be made by participating Designating/Regulatory Authorities, listed in Attachment I, to the Joint Sectoral Group on the basis of the results of the Confidence Building Programme. Conformity Assessment Bodies that have been accepted by the Joint Sectoral Group will be listed in Attachment II with an indication of their specific conformity assessment expertise and the fields of medical device technologies for which they are recognized. The corresponding Regulatory/Designating Authority responsible for a CAB will also be listed in Attachment II. Proposals to limit the recognition of capabilities of CABs should be based on objective evidence and documented. The Joint Sectoral Group may recommend that a CAB not be listed in Attachment II, provided there is documented evidence demonstrating its lack of capabilities. Excluded CABs may apply for re-consideration of their status once the necessary corrective measures have been taken and confirmed.

Where no agreement on any of the above matters has been reached in the Joint Sectoral Group, the matter will be referred to the Joint Committee under the Framework Agreement.