Question 1

Is it possible to apply for the renewal of a marketing authorisation granted via the Mutual Recognition Procedure or the Decentralised Procedure in the situation where not all of the Member States involved in the procedure have issued the national marketing authorisation?

**Answer:** The CMDh has agreed that it should be possible to apply for the renewal of a marketing authorisation granted via the MRP or DCP, in the situation where not all of the Member States involved in the procedure have issued a national marketing authorisation, in view of the legal requirement to apply for the renewal of a marketing authorisation at least nine months before the expiry of the marketing authorisation. However, if the national marketing authorisations have not been issued due to the lack of submission of high quality translations of the agreed SmPC, PL and labelling after the end of the MRP or DCP, the renewal procedure will not be concluded until the respective national translations are provided.

Question 2

The new documentation requirements for renewals include provision of a history of pharmacovigilance inspections. What information should be included in this section?

**Answer:** You should provide a table of all the pharmacovigilance inspections that have been performed by any regulatory authority globally during the period covered by the renewal. You do not need to list every finding but should provide a summary/analysis of the impact of the findings on the risk: benefit of the product. Where no pharmacovigilance inspection has been performed, this should also be confirmed by the MAH in the renewal file.