15 November 2010
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Patient Health Protection

Work Program 2011 of the EMA/CAT and Medical Devices' Notified Body (EMA/CAT-NG) Collaboration Group

Item No.	Items
1	Coordinate and finalise the development of document on procedural advice on the consultation of notified bodies in accordance with Article 9 of Regulation 1394/2008
2	Coordinate the development of specific template document on NB report and discussion on the need for development of dossier requirements guidance
3	Coordinate the development of procedural guidance on post-authorisation procedures and post-market surveillance/Pharmacovigilance
4	Development of a document to clarify the terminology used in the pharmaceutical and Medical Device frameworks
5	Identify the need of inspections guidance for combined ATMPs in the context of Article 9 of Regulation 1394/2008 and if required coordinate the development of such guidance(s).
6	Be the initial general discussion forum on scientific/technical aspects of combined ATMPs to be brought to the attention of the CAT.

Publication of EMA/CAT – NB Collaboration Group meeting dates for 2011 will be included in an upcoming CAT Monthly report.

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