

press release

### **Meeting Heads of Agencies, 28 September 2001**

The first meeting of Heads of Agencies under the Belgian presidency took place in Ghent on 28<sup>th</sup> September 2001. Representatives of 14 Competent Authorities, European Commission and EMEA attended the meeting. Observers from the EEA countries : Iceland, Norway, and for the first time Liechtenstein, were also present, as well as CADREAC.

The group took note that the EMEA and national agencies released the CPMP recommendations concerning the 'third generation' combined oral contraceptives and the risk of venous thromboembolism (VTE).

All member states reported on their national situation concerning TSE. Most of the member states are still assessing data provided by the MAHolders. In some countries, authorisations have been withdrawn or suspended. The attention of the Heads was drawn to the conclusion of the previous meeting to keep each other informed of withdrawals and suspensions.

An update of the activities of the Mutual Recognition Facilitation Group (MRFG) was made. An overview of the documents published on the Heads of Agencies website since June 2001 was presented. The new version of this website is launched since the 27<sup>th</sup> of September 2001. The Joint CPMP/MRFG Working Group on Harmonisation of SPC's including representatives from CPMP, MRFG, EMEA and EC met for the first time on the 17<sup>th</sup> of September 2001 and will present a report discussing the issues outlined by the Heads of Agencies at their next November meeting. Mr. Tomas Salmonson was elected as chairperson.

A presentation describing the development and implementation of the eCTD was presented. The problems are to build a system that allows the assessors to use the electronic version of the submission and to store this electronic version.

A European Conference on the good use of antibiotics including workshops will be held on the 15<sup>th</sup>-17<sup>th</sup> of November 2001 in Belgium. Also experts in infectious diseases and microbiology will be involved in the scientific discussions. The scope is to reach a consensus on the indications and to consider the level of resistance across Europe.

The Ad Hoc Group of the CPMP on Paediatrics will discuss possible working methods to promote more paediatric applications.

CADREAC presented a summary of issues of relevance for cooperation with the EU authorities. A practical problem identified in the Mutual Recognition Procedure is that the applicant does not always send them the assessment report. They also stated that they would like to have observers in the different working parties. CADREAC will make a concrete proposal for the next meeting.

The Heads of Agencies supported the proposal to create a Working Group to coordinate the already existing initiatives regarding the training of assessors in close collaboration with the EMEA and the different Working Parties of the CPMP. This proposal will also be presented to the HEVRA in November.

The EMEA Executive Director reported on the planning for 2002-2003 including upcoming activities and resource implications for national competent authorities and invited heads of national agencies to become more closely with the process.

The next meeting of the Heads of Agencies will be held in Tournai on 29-30 November 2001.