

press release

Joint meeting Heads of Agencies / HEVRA 27 September 2001

A joint meeting Heads of Agencies / HEVRA took place in Ghent on 27th September 2001 under the Belgian presidency. 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 and CAVDRI.

The main discussion points concerned IT in the European Pharmaceutical sector. From January 2003, the EMEA would take on the responsibility for a number of EU IT- projects, except for Eudratrack. All Heads stressed the central role of the EMEA for all common IT systems and the crucial role of Eudratrack in the Mutual Recognition Procedure. An intermediate implementation plan for Eudratrack was presented and several proposals were discussed. All MS agreed JRC should be asked whether there is a possibility to continue the maintenance of Eudratrack until the EMEA takes responsibility, perhaps in 2004/2005. The Heads also explored other possibilities of taking care of the tracking system.

The European Commission announced a new legislation for herbal medicinal products of traditional use ; the idea was to modify the codification Directive. It was announced that this last one was adopted by the Council of Ministers of Internal Affairs and Consumer Interests on the day of the Joint Meeting.

EMEA stated that the Commission Directives 2000/37/EC and 2000/38/EC concerning the veterinary and human pharmacovigilance will come into force in December 2001. A status report on Eudravigilance was presented as well as the policy paper for the Implementation of the Electronic Transmission of Individual Case Safety Reports for Medicinal Products for Human Use Authorised in the European Union, namely concerning the possibilities of electronic transfer of reports during the transition period (01/12/01-31/01/03). Member States will provide the EMEA with the necessary information to proceed and the policy paper will be adopted at the November Heads of Agencies meeting. Because of delays in implementation of Eudravigilance in the veterinary sector, due in part to electronic reporting standards not having been finalised in VICH, the electronic reporting of adverse drug reactions to veterinary medicinal products will not be in place until later next year.