



Press release

HoA & HEVRA meetings, 27 – 28 November 2002

The second HoA & HEVRA meeting during the Danish Presidency took place 27 – 28 November 2002 in Hillerød, Denmark. Representatives of all Member States' regulatory agencies on medicinal products, except Luxembourg and Greece, attended the meetings. Representatives of the European Commission, the EMEA, EEA (Iceland, Liechtenstein and Norway), CADREAC and CAVDRI were also present.

The main topics of the meetings were Pharmacovigilance and EudraTrack. The results achieved emphasised the good cooperation between the regulatory agencies.

The Heads of Human and Veterinary Regulatory Agencies took a historic decision in the on going cooperation between agencies by signing an Agreement on a common "*Communication and Tracking System for the Mutual Recognition Procedure (CTS)*".

By signing the Agreement the Heads took onboard the responsibility of the CTS and gave the BfArM mandate to run the system on behalf of the agencies of the Member States and of the other EEA countries. By 16 December 2002 the CTS will be in operation, and thus replacing the EudraTrack system run by the Community Joint Research Centre (JRC).

A report from a working group on "*Establishing a European Risk Management Strategy*" was presented and discussed at the meeting of the Heads of Human Regulatory Agencies. The general approach of the report was endorsed. Furthermore, the Heads decided that further work on the establishing of a European Risk Management Strategy was required. It was therefore agreed, that a new mandate for a working group shall encompass the conduct of a survey of the resources available for pharmacovigilance in the agencies, a proposal for a revision of the mandate of the Pharmacovigilance Working Party and procedures for the exchange of information between agencies.

At the meeting of Heads of Veterinary Regulatory Agencies also issues on vigilance were discussed concerning the improvement of pharmacovigilance in the veterinary area and prioritising the effort and resources in veterinary pharmacovigilance.

The Heads of Human and Veterinary Regulatory Agencies also discussed the important issue of the *Enlargement of EU* and its implications for the networks of HoA and HEVRA and their future cooperation. The Heads underlined the need to be well prepared in order to meet the challenges of the Enlargement and to have the challenges identified. The Heads agreed to work on issues of relevance to HoA and HEVRA that are not covered by the European Commission or PERF.

Furthermore, the issue of governance was revisited at this meeting with presentations of the work programmes of the Working Parties of the EMEA. Again, the necessity of keeping focus on the appropriate prioritising of resources - whether at national or Community level - was underscored.