

press release

Meeting Heads of Agencies, 29-30 November 2001

The second meeting of Heads of Agencies under the Belgian presidency took place in Tournai on 29th 30th November 2001. Representatives of all Competent Authorities, European Commission and EMEA attended the meeting. Participants from the EEA countries: Iceland and Norway were also present, as well as observers from CADREAC.

EC reported on the meeting on bioterrorism, held on 13 November 2001 in Strasbourg with EFPIA. It was decided to create a task force to further examine a number of issues. A first meeting was held on the 23 November 2001.

Follow-up was given on the implementation plan for Eudratrack. Two member states and JRC will make a proposal to temporarily take over this tracking system, until the EMEA will have the legal capacity to take the system on board (2004/2005). Also the Commission will explore ways to keep EudraTrack at JRC for a limited period. JRC made a statement that they are ready to finance a feasibility study to guarantee the continuity of the system, working with a spin-off company. This has to be decided at the latest by February 2002.

Concerning the review of the pharmaceutical legislation, the proposals of the Commission for modification are published on the web.

About the coming into force of Commission Directives 2000/37/EC and 2000/38/EC concerning the veterinary and human pharmacovigilance in December 2001, a report on the progress was given by the EMEA.

The "CPMP Position Paper on compliance with Pharmacovigilance Regulatory Obligations" was endorsed and will come into operation on 1st January 2002.

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 way to handle the electronic transfer of reports during the transition period (01/12/01-31/01/03), was endorsed. At the EMEA, the system is operational.

The Chair of the MRFG gave an overview of the progress in activities of the Mutual Recognition Facilitation Group (MRFG). An overview of new and updated MRFG documents was given. MRFG agreed to install a 'Frequently Asked Question' tool on the HoA website and to keep day 50 instead of day 55 as a deadline for CMS to send their comments. An update on the monitoring programme on withdrawals was presented. No important difference can be seen compared to the latest data. The Heads agreed on the proposals only to make a detailed withdrawal report when a new reason is identified and to ask for amendments of Eudratrack to create statistics on withdrawals.

Tomas Salmonson (SE), chair of the "Joint CPMP / MRFG Working Group on the Harmonization of SPCs", reported on the SPC harmonization project. Taking into account that industry is not willing to support the harmonization exercise, it was decided to continue with an extensive "presubmission" in close collaboration with industry, and evaluate the way further on a case by case basis. **The importance of the role of the Commission was also underlined.**

A report was given of the main items discussed at the last EMACOLEX meeting in Gent on the 22nd and 23rd October 2001: besides the harmonization of SPCs, a/o new strategies to block generic competition and the new definition of medicinal product (Review Community Code) have been discussed.

The Chair of the CPMP, reported on the outcome of the European Conference on the good use of antibiotics, which was held on the 15th-17th of November 2001 in Brussels.

The scope of one of the workshops was to reach an EU consensus on indications for major antibiotic classes, taking 'macrolides' as an example. Scientific discussion in a forum with regulators and experts in the field of microbiology and infectious diseases led to the definition of 'basic indications' for macrolides. This 'best use' of opinion leaders should serve as a starting point for discussion with companies.

In November, an EMEA Workshop on 'Ethical considerations in clinical trials' took place.

A Working Group coordinating initiatives regarding the training of assessors in close collaboration with the EMEA and the different Working Parties of the CPMP/CVMP had their first meeting. They presented a proposal for a mandate as well as the way to proceed on a short- and long-term basis.

The delegates of the CADREAC expressed their desire to be part of the EudraNet, including EudraTrack. Their second request concerned their possible involvement (as observers) in the Biotech Working Party and the Bloodproducts ad hoc Working Group.

The Heads of Agencies were consulted by the EMEA in preparation of the 2002 work plan. Key activities of the EMEA work plan and of the working parties work plan were presented to the group. The significant contribution made by experts to the EMEA drawn from competent authorities of the Member States was recognized and input to the overall planning process was sought.

The EMEA presented a document on simplification of the review process of product information for centrally authorized products.

Concerning the publication of documents prepared by the Herbal Medicinal Products – Working group, it was decided to publish any scientific guideline adopted by the CPMP on the EMEA website under the relevant CPMP WP. The other herbal specific documents, not approved by the CPMP, will be published on the EMEA website under a separate window.

The next meeting will be held under the Spanish Presidency on the 12th and 13th of February 2002 in Barcelona.