

Draft press release

Meeting of the Heads of Agencies

The second Heads of Agencies meeting under the Swedish presidency took place at Krusenberg manor house, on 12th and 13th June 2001. All European agencies but Luxembourg and Liechtenstein were represented. In addition the European Commission and the EMEA took part. Observers from Iceland, Norway and Slovakia, the latter as a representative from CADREAC were also present.

The European Commission made a report from the Telematic Steering Committee, where the group had agreed on a strategy paper and an implementation plan for telematics in the pharmaceutical sector. The aim is to build up a European network in order to ensure a high level of protection to public health. EMEA will from January 2003 take on the responsibility of a number of IT-projects of EU dimension (Eudranet, Eudra PHARM Database, EudraVigilance and E-submissions). The question of EudraTrack remains to be solved and this will be discussed during meetings in autumn 2001.

The European Commission gave an update on the progress on Review 2001 and encouraged Member States to respond to a number of proposed changes to the pharmaceutical legislation. Issues as the scope of centralised and decentralised procedure, data protection, automatic arbitration and advertising were discussed with a paper from MRFG as a background. The proposals from the Commission will be the main topic at the joint Human and Veterinary Pharmaceutical Committee 5th July 2001.

TSE compliance of parallel imported product was discussed. The Heads agreed on an exchange of information regarding regulatory action taken nationally e.g. for products for which companies have failed to present the necessary TSE-data. Such regulatory action can have an impact on parallel imported products in other Member States.

Belgium made a report from the first informal meeting on advertising, information and e-commerce for medicinal products. Member States reaffirmed their opposition to any form of direct advertising for prescription medicines to the public. Nevertheless, considering the patient right to get information and the possibility of allowing pharmaceutical companies to apply some such information, the need to better define "advertising" and "information" was identified.

Following the decision of the Heads of Agencies meeting in France (December 2000) the chair of the MRFG reported on the project of harmonisation of SPC's. The report includes a proposal for products to be subject for harmonisation but also outlines issues that need further consideration. Heads of Agencies supported a continuation of the project but stressed that before triggering the harmonisation process the identified issues including resource implications, special legal uncertainties and timetable has to be examined. The scope of this project should be with a 4-5 year perspective and with a realistic number of products with an ongoing evaluation of the process during this time. The call for continued input and support from the European Commission was recognised. To co-ordinate the future work, the Heads of Agencies proposed to form a group including representatives of the EMEA, European Commission, CPMP and MRFG. The working party should be initiated by MRFG and report to Heads of Agencies.

There was an update of activities of the Mutual Recognition Facilitation Group (MRFG). The results of the monitoring programme on withdrawals were also presented. The figures showed a similar percentage of withdrawals as the recent two years. Due to a small sample size for 2001 it's difficult to draw conclusions. Heads decided to increase the ambition to understand the reasons for withdrawals and that the monitoring program should continue. The group endorsed the proposal for a new improved web site for Heads of Agencies and that the design of the web site could be launched after a parallel endorsement from the MRFG. Heads also endorsed that open positions in agencies and public documents prepared by EMACOLEX could be presented at Heads of Agencies web site.

A report was made from the CADREAC Annual Assembly 1-2 April, 2001. The meeting had focused on obstacles in harmonisation of regulatory practises between CADREAC countries and EU. A discussion paper summarising issues of relevance for co-operation with EU authorities will be on the agenda at the next Heads of Agencies meeting.

Attention was drawn to the conference on "Antibiotic Use in Europe" on 15th to 17th November organised by the Belgian presidency.