

## Meeting of Heads of European Medicinal Products Agencies

### Heads of Agencies

12<sup>th</sup>-13<sup>th</sup> February 2002, Barcelona, Spain

---

#### Press Release

The first Heads of Agency meeting under the Spanish Presidency was held in Barcelona last 12<sup>th</sup> and 13<sup>th</sup> February 2002. All European Agencies were represented. The Commission and the EMEA were also represented as well as Iceland, Liechtenstein, Norway and representatives from CADREAC (Bulgaria and Slovakia).

Hotensia Segrelles (Spanish Medicines Agency, hereafter AEM) reported on the Review of the pharmaceutical legislation. The discussion in the Council Group "Pharmaceuticals and Medical Devices" of the three legislative proposals concerning the Review of the Community Pharmaceutical Legislation started during the Spanish Presidency and two meetings have taken place so far. It is the intention to advance as far as possible in the discussion on the Regulation, and to achieve as much consensus as possible in the 3 legislative acts, taking into account that this item will be on the Agenda of the Council Meeting (Health) on the 26<sup>th</sup> of June.

That Council Group could also discuss the Proposal of the Directive on the Traditional Herbal Medicinal Products, that the Commission will soon issue.

As per Telematic issues a follow up was given on Eudra Track. The subject is heavily discussed and the following decisions were taken by the Heads of Agencies:

1. Set up an *ad hoc* working group to carry out all necessary activities under the mandate of Heads of Agencies. The members of the WG are the Trojka plus NL plus volunteer MS (FR and DE). The chair shall correspond to the Presidency of the EU. Under the Spanish Presidency the group is to be chaired by Carlos Lens.
2. Submit letters to both JRC and the Commission requesting the formal transfer of the application to the Member States
3. Evaluate the application and identify proper hosting sites whether for EudraTrack or for a new system. It is preferred to get today's version of EudraTrack since it is working properly.
4. Perform any activity that may be of help to sorting out the problem, since a breakdown of EudraTrack by the year end would be extremely deleterious to MRP.

Carlos Lens (ES) reported on the status of the bioterrorism subject. It is accepted that health in itself may become a target for terrorist attacks. The Council, as of 15Nov2001, has stated that public health institutions would play a key role in the event of bioterrorist attacks and therefore the EU must increase its reaction capacity by co-ordinating activities of MS. Several initiatives are already in motion and the

European Commission is undertaking the role of co-ordinator through a Network Working Group (Pharmaceutical Committee, chaired by Philippe Brunet). The objectives of the working group have been defined.

Christer Backman (SE) explained all the delegates the situation of the harmonisation of SPCs. The HoA have decided it is important to choose the type of referral and the first products to be harmonised. The products should be chosen taking into account certain criterias as: differences in the SPC, if they are widely used, if they are authorised in a great number of MS, the possibility of generics, possibility of success. Christer Backman added that in the review of Pharmaceutical legislation all the difficulties encountered in the referrals should be taken into account and that HoA should clarify that EMACOLEX is supposed to come up with a proposal.

The chairperson of MRFG informed about the progress in the group's activities: documents on the web page, Leponex (clozapine) referral, TSE and milk derivatives, Day 50 vs 55 (MRFG/VMRFG), withdrawals and the Review 2001.

The group urged the national authorities to give solutions with the aim of sending one of their experts to the EMEA with sufficient time to take care of the MRFG's Secretariat. This problem was already raised in December 2002 when the person who was in charge of the group's secretariat left. Since then, the personnel of the EMEA is handling this job although it is not being within their tasks.

Jose Félix Olalla, Head of the Subdirección for Human Medicinal Products, explained the situation in Spain related to the Instruction 15/00 related to the note of guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via medicinal products. He explained the way Pharmaceutical companies submit documents to the AEM in compliance with the above mentioned Instruction.

Rui Santos Ivo as representative of the EMEA informed about the programme foreseen for year 2003.

A report was given on the HoA decisions: Joint Audit Program for GMP (FR), Homeopathic Medicinal Products (PO), Pediatrics (FR) and Cell Therapy (BE) product

Concerning training of assessors, it was requested to all MS to inform about their programs on training of assessors. IR presented the program of the seminar on "Quality Aspects of Biopharmaceutical Products"

Ludevic Martinec (CADREAC) explained the objectives foreseen to facilitate the EU enlargement process.