

## Meeting of Heads of European Human and Veterinary Medicinal Products Agencies

### HoA/HEVRA

28<sup>th</sup> May 2002, Segovia, Spain

---

#### Press Release

The first joint HoA/HEVRA meeting under the Spanish Presidency was held in Segovia last 28<sup>th</sup> May 2002. All European Agencies were represented (except Italy and Luxembourg). The Commission and the EMEA were also represented as well as Iceland, Norway and observers from CADREAC (Czech Republic and Hungary).

Eudra Track: the chairman of the *ad hoc* working group, Carlos Lens, reported on the status of the subject. As of March 18, 2002, the Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) submitted a proposal to the group by virtue of which it would volunteer to host the application and have it operated for the rest of the Agencies. The working group welcomed the proposal and thanked BfArM for it on behalf of the Agencies.

The Heads of Agencies express their acknowledgement to the working group and agree on the following:

- ✂ Issue a mandate to BfArM to evaluate the frozen application and come up to the following meeting (Denmark, July 3, 2002) with an operating plan therefor.
- ✂ Request the working group to start discussing with the legal services of the European Commission / JRC how to document the transfer of the application to the Member States in the best suitable way.

The Director of the AEM, Fernando García Alonso, informed about the current situation of the review of the pharmaceutical legislation.

Andrè Pauwels (BE) explained the training programmes for assessors co-ordinated by the “training group” created, after following a mandate of the HoA, in November 2001 and, Frank Hallinan (IR) reported on the Biopharmaceutical Quality Course that took place in Kinsale (Ireland) last 7-9 May 2002.

Rannveig Gunnarsdottir, head of the Icelandic Medicines Control Agency, made a presentation on the problems small countries have on keeping Medicinal Products on the market.