

**Meeting of the Heads of European Veterinary Regulatory Authorities (HEVRA)
Brussels 22 November 2001 : Press release**

The 13th meeting of the Heads of European Veterinary Regulatory Authorities (HEVRA) took place in Brussels on the 22nd of November 2001 under the Belgian Presidency.

Representatives of 13 Competent Authorities, European Commission and the EMEA attended the meeting. A representative from Norway, EEA country, was also present, as well as two CAVDRI (Collaboration Agreement between Veterinary Drug Registration Institutions of the accessing countries) observers.

A thorough discussion was held on the future maintenance of the Eudratrack system. Hevra recognised that the take over of the maintenance of the system is a responsibility of the Member States. Hevra was of the opinion that if MS had to take over the maintenance of the system, a formal demand from the Commission to the Member States with a clear mandate for support of the Eudratrack system was needed. Future options under study include transfer of the responsibilities to one of the Member States or the involvement of a private organisation. The decision on the matter will be taken at the latest by February 2002.

An update of activities of the Veterinary Mutual Recognition Facilitation Group (VMRFG) during the October and November meetings was made. An updated report on the monitoring programme of withdrawals 2001 was presented. Hevra took note of the concern expressed by the VMRF-G with regard to the continuation of the functioning of the Eudratrack system. Other issues discussed included the management of MRL modifications, Standard Operating Procedure (SOP) for line extensions and parallel applications. Hevra was informed of the nomination of one observer from CAVDRI who will attend the December plenary VMRFG meeting.

Concerning the review of the EU pharmaceutical legislation, a meeting of the working group in Council meeting is scheduled during the Belgian Presidency in December, which will serve to introduce the legislative proposals and to formulate general remarks. These proposals will then be further discussed under the Spanish Presidency.

The chairman of Emacolex presented a report on the discussions in this group concerning the item of harmonisation of the SPC. Emacolex was of the opinion that the harmonisation of Summary Product Characteristics (SPC) of the same medicinal products i.e medicinal products containing the same active substances should be considered very carefully, taking into account the possible attitude of industry.

The training of assessors was an important topic discussed, as it is a common goal for both Hevra and HoA. Liaisons with the EMEA and its working parties are necessary as well as the involvement of industry and Academia. Hevra recognised the need to coordinate all available relevant training programs in Member states, public sectors, associated countries and Cadreac countries and to elaborate on an harmonised and efficient way to proceed .

The functioning of the Hevra web site was commented upon, indicating that about 6500 hits were registered on a monthly basis which reflects the success of this web site.

The next Hevra meeting will be part of a joint Hevra/ HoA meeting to be held in Spain, on the 28-29 of May 2002 under the Spanish Presidency. An earlier meeting would be held in February in order to finalise a decision in co-operation with the human Heads of Agency meetings on the future of Eudratrack.