

HEVRA 27/09/2001: Press release

Meeting of the Heads of European Veterinary Regulatory Authorities

The 12th meeting of the Heads of European Veterinary Regulatory Authorities (HEVRA) took place in Ghent on the 27th September 2001 under the Belgian presidency. Representatives of 13 Competent Authorities, European Commission and EMEA attended the meeting. Observers from Norway, Iceland were also present. Two CAVDRI (Collaboration Agreement between Veterinary Drug Registration Institutions of the accessing countries) representatives attended the meeting for the first time.

An update of activities of the Veterinary Mutual Recognition Facilitation Group (VMRFG) was made. An updated report on the monitoring programme of withdrawals was presented. HEVRA took note of the final version of the Best Practice Guide for handling renewals. A short overview of the Informal Joint meetings CVMP/VMRFG/Commission which took place in Liège at the end of August, was given.

A "tour de table" on the TSE regulatory actions taken so far in the different Member States was made. Priority was being given according to the HEVRA decision tree to the assessment of products containing material from ruminant origin and to be administered to ruminants. Member States reported on progress made since the June Meeting.

Participants discussed the recent entry in force of the new VICH-CVMP guideline on Good Clinical Practices. HEVRA discussed the necessary legal requirements, the need for appropriate resources at national level and the possible consequences on availability of medicines.

After a first discussion on harmonisation of SPCs for existing Veterinary Medicinal Products, HEVRA concluded that it would be premature to move forward at this time. It also expressed concern about the limited resources to undertake the work.

The CAVDRI representatives made some comments on issues of relevance for cooperation with EU Authorities and a report of the ongoing activities on veterinary topics within the Perf II programme was given.

The status of the HEVRA website was presented and Member States were encouraged to forward national SPCs.

Some points of mutual interest (IT, pharmacovigilance) discussed during the joint meeting Heads of Agencies/HEVRA are summarized in a separate press release.

The next meeting will be held in Brussels on the 22 November 2001.