

HEVRA/06/08

Meeting of the Heads of European Veterinary Regulatory Authorities, 8 June 2001

The 11th meeting of the Heads of European Veterinary Regulatory Authorities (HEVRA) took place in Stockholm, on the 8th June 2001. It was the second HEVRA meeting under the Swedish Presidency and representatives of eleven Member States of the European Union, the EMEA, the European Commission and observers from Iceland and Norway were present.

HEVRA endorsed the conclusions from the workshop on future telematics in pharmaceuticals, held under the Swedish Presidency at EMEA in London on 20 April 2000, including goals, objectives, transparency, efficiency and financing. Minutes from the workshop are published on the HEVRA and EMEA web sites.

Thomas Lönngren announced that EMEA is prepared to take on the responsibility of number of IT-projects of EU dimension if the Commission verifies the funding. Such transfer of responsibility can however not take place prior to January 2003.

An update of activities of the Veterinary Mutual Recognition Facilitation Group (VMRFG) was made. The results of the monitoring programme on withdrawals within the mutual recognition system were presented. The figures included the first three months of the year and showed a reduced number of withdrawals (8%). However the limited number of procedures can result in misleading statistics. HEVRA decided that the monitoring of withdrawals should continue during the next presidency.

A proposal for changing the timetable in VMRP, from Day 55 to Day 50, was discussed. The current trial period for the MRFG (human side) has been extended until 31 December 2001. HEVRA was in favour of awaiting the results on the human side.

Some of the interesting findings from the yet incomplete VMRFG/FEDESA survey on veterinary mutual recognition procedures were discussed. The numbers of procedures and CMS's has increased. There has been an improvement in approval time (though time for translation is still a problem). Even if a high level of success is maintained there is still a need of reducing withdrawals. Next week the survey will be finalised and later on also published on the HEVRA web site.

A TSE-database, where also national assessment reports can be included, is now in force. It was stated that such a database can be very useful for sharing assessment reports and member state staff should be encouraged to put in information in the system. The discussion on TSE was followed by a tour de tables on the national situation. It was concluded that the situation has improved tremendously and that all present countries have come quite far in their regulatory handling. The position taken at the last HEVRA meeting on the regulatory handling and assessment priorities were also confirmed by the group.

A ban to use catgut in veterinary medicine is not possible under the pharmaceutical legislation, as this product is not a veterinary medicinal product according to Council Directive 81/851/EEC. However, HEVRA stated that non-animal material should be used instead as far as possible. This has already been considered at a national level in some Member States.

Regarding a stricter approach on premature applications HEVRA endorsed that VMRFG is to be given the task to establish uniform checklists during the Belgian presidency.

The next meeting will be held in Belgium, on the 27 September 2001.