



Agency for Medicinal Products
and Medical Devices
of the Republic of Slovenia



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Draft Stakeholders' Information

Heads of Medicines Agencies meeting in Ljubljana/Brdo 13-15 January 2008

The Heads of Medicines Agencies (HMA) held their first meeting under the Slovenian EU Presidency in Ljubljana/Brdo on 13-15 January 2008.

HMA-v (Veterinary Medicines)

The Heads of Agencies for veterinary medicines met on 14 January 2008.
The main discussion points were:

- Following an Update on Eudravigilance Veterinary. HMA endorsed the need for a harmonised interpretation with regard to electronic reporting of ADRs into, and out of, the system. All necessary details will be further developed within Vet JIG and the PhV WP-V/CVMP.

EMA presented a document on Measures/incentives to MAH that the regulatory network might offer in relation to applications through the centralised procedure for products for limited market; a decision on this proposal was deferred pending the development of more detailed proposals on procedures. HMA supported a document on incentives in terms of fee reductions for centralised applications for Blue Tongue vaccines.

- HMA discussed points of interest highlighted during the Meeting of HMA(v) and Stakeholders (Madeira, 7 November 2007) and recognised a need for strengthening cooperation between NCAs and industry and welcomed common points of understanding. The issue will be further discussed at HMA April Meeting.
- Report from the chairperson of CMD(v) was recognised by the HMA. The Veterinary Generic Medicines issue was discussed and HMA supported a set of general principles that member states would follow. CMSs should usually accept additional indications and species included in the SmPC of the RMS. Additional data may be requested in case of potential serious public health risk. The acceptance of the general principles does not override Member States right and responsibility to ensure quality, safety and efficacy of medicines at the national level.
- Veterinary experiences with DCP were presented showing that DCP is enjoying a growing popularity and becoming a first choice for new products which are not obliged to go through the centralised procedure.

HMA-j (Joint Meeting)

The Heads of Medicines Agencies for human and veterinary medicines held their joint meeting on 14 January 2008.

The meeting started with the Best Practice Session. NL presented Spontaneous reporting in the NL and LV presented pre-approval of advertising materials.

The main discussion points were:

- Update Reports from the chairperson of CMD(h/v) (Esther Werner and Truus Janse de-Hoog) were recognised by the HMA.
CMD(h)-EMEA Workshop on Readability testing was the opportunity to compare the progress and conclude that there is a more harmonised approach on how to address various issues.
CMD(v) presented list of finalised guidelines and reported on the subgroup/ad hoc group activities on document management, labelling and packaging, and the joint IFAH-CMD(v) survey.
- HMA endorsed the proposed extension of the CTS. System development needs to be undertaken in order to include further regulatory processes/procedures and to extend functionalities on tracking of the Assessment of Paediatric Data.
- EMEA Proposal for an ad hoc Pharmacovigilance Inspectors WG was endorsed. It was agreed that separate Human and Veterinary meetings would be held, although once a year a joint meeting will be scheduled. These groups will deal with issues such as: conduct of inspections, programming of inspections, risk based frequency of inspections, communication, and exchange of information.
- HMA endorsed the replacement of Steve Dean (UK) by Patrick Dehaumont (FR) in the HMA Management Group.
- HMA were informed on the recent adoption through written procedure of the mandate for the Clinical Trials Facilitation Group. HMA adopted the draft mandate for the Working Group of Quality Managers and also the Draft Rules of Procedure for the Working Group of Communication Professionals.
- HMA considered the lack of resources in NCAs in the European Medicines Regulatory Network and will continue to discuss the issue in relevant Working Groups in order to consider possible solutions. A questionnaire will be circulated to all NCAs in order to establish what resources are available within the network.
- The revised Vision/Mission for HMA was adopted and was posted on the website.

HMA-h (Human Medicines)

The Heads of Agencies for human medicines met on 15 January 2008.

The main discussion points were:

- HMA received report from the European Risk Management Strategy Facilitation Group (ERMS FG) stressing the lessons learned from the Viracept incident as an opportunity for improvements of the system, particularly dialogue with industry and work on the development of an EU Regulatory System Incident Management Plan.

- Action plan on Availability of Medicines was adopted. It was recognised that unavailability of medicines is a serious problem particularly for Member States with small markets and that the problem should be addressed in part by improving the implementation of the current legislative framework as well as by improving the legislation and introducing some changes to it in order to address the availability problem. Other stakeholders should also contribute to the solutions.
- HMA discussed the problem of availability of resources in connection with mutual recognition and decentralised procedures and supported establishing a joint HMA-CMD(h) ad hoc WG on the issue that will be further discussed at HMA April Meeting.