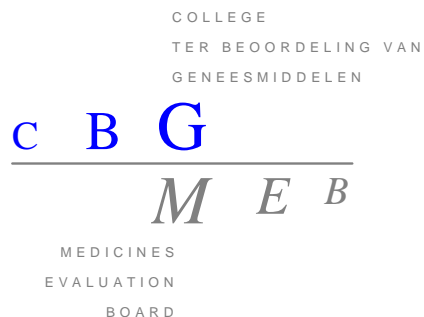




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Press Release

The Hague, 13 September 2004 - The Heads of the Medicines Agencies (HMA) in Europe met in Scheveningen, The Netherlands on 8 and 9 September 2004. The meeting took place under the chair of the Netherlands Presidency of the European Union. Discussions covered several important items and these included:

- a) An update from the European Commission on the direction and management of projects in the EU Telematic Strategy inclusive the Europharm project took place.
- b) Agreement was also reached that from now on meetings would be focused upon the joint meeting of human and veterinary agency heads and these would operate under the title of Heads of Medicines Agencies (HMA).
The meeting noted the successful start-up of the HMA Management Group and the HMA Permanent Secretariat which is intended to facilitate and support the work of the HMA working groups and support the HMA meetings.
- c) A proposal on plans to introduce a benchmarking exercise for the agencies dealing with human medicines was agreed but the proposed time schedule was extended. The inclusion of the veterinary Medicines Agencies in a similar exercise was also debated.
- d) The Framework Document for the two Co-ordination Groups being formed under the revised medicines legislation, was approved for publication on the websites of HOA and HEVRA (Heads of Veterinary Regulatory Agencies) websites (<http://Heads.medagencies.com> and <http://www.hevra.org>).
- e) The EMEA Road Map 2010 was extensively debated and the progress made with the development of this initiative and the timetable given by EMEA for final acceptance by the end of 2004 was noted.

Specific Items from the meeting of the Heads of Medicines Agency Meeting (Human Medicines)

- The meeting agreed to continue with the proposed work-sharing in the assessment of Periodic Safety Update Reports (PSURs) under the umbrella of the European Risk Management Strategy (ERMS).
- The membership and details of the first meetings of the clinical trials facilitation group was announced.
- A proposal for a HMA working group for Homeopathic Medicines was endorsed. This working group will be linked to the future Mutual Recognition and Decentralised Procedures Coordination Group.



Specific Items from the meeting of the Heads of Medicines Agency Meeting (Veterinary Medicines) included:

- Adoption of a procedure for the VMRF group to refer issues to the HEVRA for guidance.
- Discussion on the re-testing of veterinary medicines imported from third countries where a mutual recognition agreement for GMP inspection does not exist with the EU.
- Discussion of the potential criteria to be used to create a list of veterinary medicinal products for harmonisation of the SPC.
- A report of a meeting held in France and the latest update from CVMP on the availability of veterinary medicines for minor uses and minor species.

The Heads of Medicines Agencies (HMA) is a network of both human and veterinary medicines agencies of the EEA. This network provides a forum for the co-ordination and the exchange of views and proposals on issues concerning the European System of Medicines Regulations and the role of the HMA within that system. They meet four times a year usually under the chairmanship of the Member State that holds the Presidency of the EU.

The next meetings of Heads of Medicines Agencies will take place in Amsterdam on 29 and 30 November 2004.

For any additional information related to the issues covered by the press release please contact the HMA Permanent Secretariat, mrs Nuala Harman, tel +353 1 634 3453.