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Summary Report of HMA meeting

The Hague, 1 December 2004 - The Heads of Medicines Agencies (HMA) of Europe met in Amsterdam, The Netherlands on 29 and 30 November 2004. The meeting took place under the chair of the Netherlands Presidency of the European Union. Discussions covered several important items and these included:

1. The meeting agreed on a common strategy paper regarding the future of the European Regulatory Network. The HMA will closely co-operate with EMEA on this issue and monitor discussions on the EMEA Road Map 2010.

2. HMA were informed on progress regarding preparations for the Europharm Database and noted the final report on the proposed system as presented to the Telematics Steering Committee on 29.12.2004.

3. Regarding implementation of Article 126b of Directive 2001/83EC on transparency, the meeting agreed to discuss a common approach with EMEA. The EMACOLEX was asked to elaborate further on the subject.

4. Training to prepare for the benchmarking exercise for the agencies has been very successful; the Steering Group will continue with preparations for the internal assessment phase within national agencies.

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

1. The mandate of the Clinical Trial Facilitation Group was agreed upon; the mandate will be published on the website (http//www.Heads.med.agencies.com).

2. The meeting agreed on the new mandate as proposed by the Working Group for the HMA Working Group for Homeopathic Medicinal Products which was officially changed to 'Homeopathic Medicinal Products Working Group' as proposed by the Group.

3. During the meeting the worldwide withdrawal of Vioxx was discussed as well as the need to have clear communication rules with the industry, especially on safety issues. EMEA and HMA agreed to invite EFPIA to discuss lessons learned.

4. The HMA endorsed the proposal to ask companies to submit paediatric data and agreed to develop a common procedure to share the workload.

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

1. The meeting was preceded by a meeting between the Heads of Medicines Agencies (Veterinary Medicines) and representatives of the pharmaceutical industry. The items discussed included: the mutual recognition procedure, harmonisation of SPCs and the need for further renewals after October 2005.

2. A discussion took place about the criteria that might be used to construct a list of veterinary medicinal products where the SPC should be harmonised and the risks this may pose for medicine availability. A draft paper would be developed taking these comments into account.

3. The meeting received an update and had a discussion on the issues surrounding Minor Use/Minor Species products. It agreed to consider the issues in more detail at the next meeting.

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. The Agencies usually meet four times a year under the chairmanship of the Member State that holds the Presidency of the EU. The next meeting of HMA will take place in Reykjavik, Iceland on 24th February 2004.

For any additional information related to the issues covered by the summary report please contact the HMA Permanent Secretariat,
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