



Draft Stakeholders' Information

Heads of Medicines Agencies Meeting

Brdo, Slovenia

6 – 8 April 2008

The Heads of Medicines Agencies (HMA) held their second meeting under the Slovenian EU Presidency in Ljubljana/Brdo on 7-8 April 2008.

HMA-h (Human Medicines)

The Heads of Agencies for human medicines met on 7 April 2008.

The main discussion points were as follows:

- The Draft EudraVigilance Access Policy document prepared by the Eudravigilance Expert Working Group (EV-EWG) was recognised by HMA as an initial step in implementing the requirements of the current legal framework concerning the provision of appropriate levels of access to EudraVigilance data while guaranteeing personal data protection. The document will be released for consultation once the EudraVigilance Access Policy has been discussed by the EMEA Management Board and the final version prepared based on the consultation feedback.
- HMA discussed options for sharing the workload of and facilitation of the implementation of the EudraVigilance system.
- HMA discussed the future representation of the European Network at FDA International Summits of Heads of Medicines Regulatory Bodies aimed at discussing the impact of Drug Regulatory Agencies (DRA) missions and globalisation processes, new technologies and multiple expectations regarding DRA roles in product development, authorisation and regulation.

HMA-j (Joint Meeting)

The Heads of Agencies for human and veterinary medicines held their joint meeting on 7 April

The main discussion points were as follows:

- HMA discussed resources available to the Network both in terms of the resources made available for the work relating to in particular the centralised procedure and the EMEA and in terms of the resources available at National Competent Authorities (NCAs) for the MRP/DCP.
- TIGes updated HMA on the survey on eCTD implementation carried out through a questionnaire showing that NCAs were progressively adapting their infrastructure, processes and even legislation in order to be able to receive and handle paperless submissions by 2009. Further follow up was endorsed.



Best Practice Session

Bulgaria presented its experience with counterfeit medicinal products and France presented on the transparency of pharmacovigilance reporting in the veterinary sector.

HMA-v (Veterinary Medicines)

The Heads of Agencies for veterinary medicines met on 8 April 2008.

The main discussion points of the Heads of Agencies for veterinary medicines were as follow:

- EMEA presented to the HMA the EudraVigilance Veterinary draft access policy with three defined levels of access: for NCAs, MAHs and the public (including health care professionals). In particular the ability for Industry to access appropriate data on all products, not only their own, and the associated possible risks and benefits were discussed. HMA supported the EMEA policy.
- EMEA presented the Procedure for Designation by CVMP of products indicated for use in limited markets (follow up to the Art. 79 paper at the January meeting). HMA endorsed the measures proposed for implementation of Art. 79. The next step is to put an implementation plan by the EMEA in place so that applicants can take advantage of the measures proposed.
- HMA was informed that the Guideline for the Specifications of e-Submissions of Veterinary Medicinal Product Documents has been made available on the EMEA website and that industry is encouraged to submit any electronic applications in accordance with the guideline. EMEA was encouraged to work on the e-application form.
- HMA reviewed progress with the inclusion of warning statements for (Fluro)quinolone products and concluded that urgent action is necessary to conclude this important harmonisation of safety information on the product labelling.
- The HMA agreed that suspected adverse reactions should be reported electronically by marketing authorisation holders except when mechanical programme, electronic or communication failures prevent electronic reporting" and that the interpretation of "exceptional circumstance" should be the same in both the human and veterinary sectors.