



Stakeholders information

59th meeting of the Heads of Medicines Agencies 28-29 October 2009 Uppsala, Sweden

Heads of Medicines Agencies – Human session on 28 October 2009

- EMEA presented the revised Note for Guidance on EudraVigilance Human – Processing of Safety Messages and Individual Case Safety Reports (ICSRs), which has been updated based on experience gained. The HMA adopted the revised Note for Guidance and the implementation plan for publication.
- The HMA recognised that not all NCAs will be ready by 1 January 2010 to accept applications for marketing authorisations in electronic format without paper copies. HMA agreed to publish information on e-readiness for all NCAs on the HMA website as soon as the SE presidency has received confirmation on the current status. For complete information, please see separate press release.

Heads of Medicines Agencies – Joint session on 28 October 2009

- The Resource Planning Group (RPG) gave a final report summarising their activities. Since the last report by the RPG to the HMA in April 2008, considerable progress has been made on strategy planning, with resources being a key feature. Further resource planning work will now be taken forward as part of the output from Strategy Day II.
- A report was given by the Task Force on Availability of Resources at NCAs for MRP and DCP. Concrete results have been made in a number of areas including reduction of national requirements, RMS request form, AR feedback form, reduction of parallel assessment and actions to smoothen the procedures.
- EMEA presented the work on the EMEA Road Map 2015. It is a continuation of the Road Map to 2010, building on current achievements, but also taking due account of the Agency's business drivers. The Road Map should be consistent with and complementary to strategic directions provided by the European Commission and

HMA. A public consultation is expected to be launched in January 2010 if agreed by the EMEA MB at its meeting on 10 December 2009.

- A session on Strategic paper II was held, lead by the Task Force on Strategic paper II. During the discussion, among the topics raised were:
 - the role of HMA in the contribution to the development of new medicines
 - the globalisation leading to manufacturing and clinical trials outside our territory
 - health technology assessment
 - need for harmonisation of IT developments
 - interface with politics and media
 - development of scientific assessment
 - impact of revised legislation for veterinary medicinal products

A status report will be provided by the Task Force at the January 2010 HMA meeting. The group aim to publish the strategy paper for public consultation in July 2010, followed by adoption by the HMA in November 2010.

- HMA endorsed that the project on PSUR work sharing for veterinary medicinal products move into consolidation phase starting in January 2010 until the end of 2012, with the active participation of all EEA MSs. The exchange of experience between human and veterinary side is considered very important. Regular updates on the project will be given to the HMA.
- The EMEA informed the group that a workshop on transparency had been held on 19 October 2009 bringing all stakeholders together. Feedback on the transparency policy has also been received from the European ombudsman. EMEA will take the transparency policy and access to documents paper forward after the discussion at the HMA regarding commercially confidential information.
- HMA endorsed the recommendations from the HMA/EMEA transparency group on access to PSURs. The paper will be published on both websites and is to be used as a tool.
- A European strategy for influenza A/H1N1 vaccine benefit/risk monitoring has been developed jointly by the EMEA and the ECDC. The objectives of the strategy are to define and describe the activities needed for the prompt detection and assessment of new information on the benefits and risks of these vaccines, and to propose roles and responsibilities for different partners in these activities. The strategy paper was adopted for publication.
- The HMA agreed that the pilot phase of Voluntary Harmonisation Procedure (VHP) for clinical trials will be extended until September 2010. Following experience gained, the Clinical Trial Facilitation Group has proposed some modifications to the procedure. The modified guidance document will be published on the HMA website.
- The Communication paper on product testing was adopted by the HMA and will be published on the HMA website. The HMA supported the risk-based approach for

selection of MRP/DCP products for testing and the need for high level requirements for tools for sharing of risk data. The Mutual Recognition of Control Results document was endorsed.

- The joint HMA/EMA draft strategy for regulatory and scientific training within the European Regulatory Network is published for consultation on the HMA website.

Heads of Medicines Agencies – Veterinary session on 29 October 2009

- EMA gave a status report on the “Short Report” to the European Commission. The report has been finished and provides the EC with a state of play of the issue of antimicrobial resistance (AMR) and attempts to bring in balance antimicrobials risk arising from the use of antimicrobials in human medicine with risks arising from the use in veterinary medicines. It also provides a risk ranking and identify future research needs. The aim is to complete the report in time for EC to receive it by the 18th November which is “Antibiotics Awareness Day” when the European Commission will be releasing a staff working paper on AMR which is a document reflecting on the current AMR situation.
- EMA also informed that there will be a meeting at the end of November where a pilot project on collation of sales data of antimicrobials will be initiated. Representatives from Stakeholders will also be involved in line with the conclusion from the meeting in Marienbad. Reports from the meeting will be published on the EMA website.
- An updated version of the HMA action plan on AMR was presented. HMA endorsed the document and agreed that HMA will work in accordance with it.
- HMA agreed that a questionnaire on the legal status of antimicrobial veterinary medicinal products will be circulated to the agencies. The preliminary results will be presented at the HMA meeting in January 2010.
- The European Commission reported on the adoption procedure for compilation of all existing MRLs into the new regulation which will be finalised in November/December, until which time the old regulation will be applicable.
- EMA gave an update on the use of the Eudravigilance Veterinary Data Warehouse (DWH) for pharmacovigilance monitoring of centrally authorised products, and on recent progress with the signal detection tools. The revised SOP has been agreed and implemented. From September 2009 the CVMP has access to EVVet data directly via DWH. Signal detection tools are also in place and are available to all regulatory authorities. The CAPS monitoring in EVVet is also improving.
- EMA gave a status report on CVMP workload and challenges in respect to referrals and arbitrations from CMD(v). Some actions have already been taken by the CVMP and the EMA. However the CVMP wishes to highlight the potential impact of the article 34/35 referrals on old products which could result in loss of MUMS indications, as these claims are rarely supported by data which meets the current requirements.

- EMEA informed HMA about a survey which is to collect information from the veterinary NCAs regarding the availability of vaccines against priority diseases of animals. EMEA also clarified that the survey is a part of the network's contribution to the DISCONTTOOLS project within the European Technology Platform for Global Animal Health (ETPGAH). The information will be gathered and screened with regard to commercially confidential information and will be provided to the DISCONTTOOLS project as an input to the gap analysis on disease prioritisation. The aim is to complete the project in the second quarter of the next year (Q2 2010). HMA supported the survey.