



The 67th meeting of The Heads of Medicines Agencies

Draft of Stakeholders Information

VETERINARY SESSION

Strategic Plan on Antimicrobial Issues

In the scope of antimicrobial resistance (AMR) work an update of the action plan on AMR was presented. The objective of this plan is to identify areas where HMA has responsibility to catalyse, facilitate and directly implement activities within the EU and identify areas where involvement of HMA with other parties would be beneficial. The documents have been published on the HMA website for information.

EU Database for veterinary medicines

In the light of the revision of the veterinary legislation which will bring new challenges to the veterinary medicinal products system, HMA reflected on a global strategic direction with regard to its IT infrastructure in particular medicinal products databases.

JOINT/HUMAN SESSION

Safeguarding public and animal health

Implementation the new Pharmacovigilance Legislation: HMA and EMA continued the discussion of future implications and finance of the new legislation which applies to human medicines.

Sustainable Development and Pharmaceutical Production

Sweden introduced the aspects of sustainable development for the production and use of pharmaceuticals e.g. Baltic Sea Strategy and Swedish proposal of introducing environmental aspects for production into EU legislation. This was the first time HMA addressed topic and the discussions will continue.

Update on Quality and Inspections Work Area

An update was given by the Work Area lead for Quality and Inspections on the progress achieved throughout 2011 towards implementing the objectives of the HMA Strategy 2011-15 in enforcement, product testing and inspections.

Future actions were indicated in some priority areas for Quality and Inspections in 2012, including implementation of the Falsified Medicines Directive, further collaboration against counterfeit medicines, risk based selection of products by the decentralized procedure for testing and resourcing issues in inspections programmes.

Product Supply

The EMA and HMA analysed the situation concerning acute and chronic supply shortages of medicinal products, mainly due to manufacturing and GMP compliance problems. A "lessons learned" report was presented and the issues discussed. This item will be discussed further by the EMA and HMA.

Benchmarking (Benchmarking of European Medicines Agencies – BEMA)

The HMA continued the discussion on various aspects of the third benchmark cycle among European Medicines Agencies, namely on results of the questionnaire, the database for the reports, assessors for BEMA III, scheduling of visits for next cycle, revision of supporting documents, BEMA cycle length, and the pharmacovigilance audit facilitation group.

BEMA is an internal benchmarking process among human and veterinary agencies, the aim of which is to improve the efficiency of the European Medicines Regulatory System.

Telematics Support Group work plan with emphasis on the Common EU Submissions Platform

The TSG presented the current status of its work plan. The status of implementation of the proof of concept of the Common European Submission Platform was presented. HMA supported the continuation of the project.

HUMAN SESSION

Inspections and co-operation with enforcement authorities with regard to preventing entry of falsified medicinal products into the supply chain.

The Polish Presidency presented an overview of the situation of counterfeiting of medicinal products in Poland and possible areas of co-operation between competent authorities.

Communicaton and Tracking System (CTS) – Memorandum of Understanding (MoU)

HMA agreed to the continuation of the MoU for European Directorate for the Quality of Medicines', (EDQM), access to data from the CTS for the EDQM's Mutual recognition/Decentralized Procedure Product Market Surveillance Programme database and in the framework of the EDQM's certification of suitability to the monographs of the European Pharmacopoeia activities.