



The 66th Heads of Medicines Agencies Meeting 4-5 July, Warsaw, Poland

Stakeholders' information

HMA meetings' agendas currently reflect the main work streams which form the basis of the HMA Strategy 2011-2015. Therefore, the format of the HMA stakeholders' information will also reflect the format of those agendas.

Safeguarding Public and Animal Health

PHARMACOVIGILANCE – HMA and EMA continued the discussion on future implications of the new legislation which applies to human medicines, including the implementing measures and the Network's technical support provided to the European Commission in this regard.

REVISION OF THE EU VETERINARY LEGISLATION - HMA concluded the discussion on a common document elaborating on various aspects to be considered by the European Commission in the forthcoming process of revision of the EU veterinary legislation. This HMA paper is now published at www.hma.eu .

VETERINARY INCIDENT MANAGEMENT PLAN – HMA adopted an Incident Management Plan for Veterinary Medicines (IMP) to be applied in a two year pilot phase. The main scope of the document covers products for which EMA has the responsibility for coordination of safety incidents and crisis situations, such as centrally authorised products and products subject to referral. However, the IMP may also be invoked for nationally authorized products on the request of the Member States.

Supporting Innovation / emerging issues, operational efficiency of the Decentralised Procedure (DCP)/Mutual Recognition Procedure (MRP)

HEALTH TECHNOLOGY ASSESSMENT (HTA) - The Polish Presidency presented for discussion the interaction between regulatory assessment and HTA, identifying areas where improvement is needed and recognizing national differences requiring some further reflections. Recent activities of the Polish HTA agency were also presented and discussed.

CLINICAL TRIALS - HMA discussed and endorsed changes to the Voluntary Harmonisation Procedure (VHP) for clinical trials on human medicines. The main issues addressed were the introduction of a Reference and Co-reference National Competent Authority for the assessment of clinical trial applications based on a risk-based approach. An assessment report template in English will be introduced, a repository for VHP applications is going to be organised and the concept of the second round of VHP was introduced.

QUALITY CONTROL - HMA reviewed the pilot project supporting the risk based approach for the selection of MRP/DCP products for sampling from the EU marketplace and for quality control testing.

Operational efficiency of MRP/DCP Procedures

HMA WEBSITE - HMA agreed on a revision of the HMA website. In line with the HMA's strategy 2011-15, it is envisaged to improve its legibility and maintenance, thus strengthening the transparency of the whole Network.

MRP/DCP PROCEDURES - The HMA Task Force on the Availability of Resources in National Competent Authorities for MRP/DCP procedures for human medicines dedicated special attention to the HMA Strategy to 2011-2015 targets, highlighting the need to improve transparency on availability and use of slots for DCP applications in a efficient way and to reduce the number of cancellations of agreed submissions and to reduce the time for (harmonised) validation of applications including the technical validation of e-submissions.

BENCHMARKING (Benchmarking of European Medicines agencies - BEMA) - HMA continued the discussion on various aspects of the third benchmark cycle among European medicines agencies, namely on Key Performance Indicators, the visits schedule and database. 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.

Contacts:

Grzegorz Cessak

Head of the Office for Registration of Medicinal Products,
Medical Devices and Biocidal Products - Poland

grzegorz.cessak@urpl.gov.pl

T. +48-22-492-12-80

Aginus Kalis

Chair of the HMA Management Group

hma-ps@imb.ie

T. + 353 16343453