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83rd HMA Meeting
Amsterdam

Press Release

Heads of Medicines Agencies: Highlights of the 83rd Meeting

HMA

The Heads of Medicines Agencies (HMA) is a network of all heads of the National Competent Authorities (NCAs) whose agencies are responsible for the regulation of medicinal products for human and veterinary use in the European Economic Area (EU and EFTA Member States). The HMA human meeting is for the heads of the National Competent Authorities responsible for the regulation of medicinal products for human use. The HMA veterinary meeting is for the heads of National Competent Authorities responsible for the regulation of medicinal products for veterinary use. The HMA Joint meeting is for both human and veterinary heads.

The HMA is chaired by the head of the NCA that holds the EU presidency. In this case the HMA was organised by the Medicines Evaluation Board, the National Competent Authority (NCA) of the Netherlands at the EU presidency meeting venue in Amsterdam.

The HMA joint meeting was opened by the Dutch Minister of Health, Welfare and Sports, Edith Schippers, via a video message. She mentioned the priority themes of the Dutch presidency: antimicrobial resistance and timely access to innovative medicines for patients at affordable prices. She emphasized the importance of the One Health approach considering antimicrobial resistance. The main goal concerning innovative medicines must be a sustainable healthcare systems in order to ensure the development of these innovative medicines in the future and ensure the availability of innovative pharmaceuticals in all Member States.

Adoption of the HMA Multi Annual Work Program

Previously, the heads adopted the EU Medicines Network Strategy to 2020 and all actions for the coming years for HMA. During this HMA meeting, the Multi Annual Work Program was adopted included agreement on the eleven key business priority areas. These are

the priorities on which the heads and HMA working groups and Task Forces will commit to address in the coming years.

The HMA agreed that a NCA volunteer would be appointed to lead within each key priority area identified. The lead and their support have been appointed and they will work closely together in collaboration with the responsible HMA Working Groups and Task Forces responsible. Those leading will report back to the HMA on the progress.

The Dutch and incoming Presidency, Slovakia, will address four key priorities during their Presidencies in 2016 namely:

- Antimicrobial resistance
- Availability of good quality appropriately authorised medicines
- Innovation and access to new medicines
- Optimisation of the regulatory operations.

The final *Multi Annual Work Program* has been published on the HMA website**.**

Telematics and implications of veterinary legislation

During the HMA meeting the veterinary heads discussed the future implications for IT systems and data requirements as a result of the current revision of the veterinary legislation. Specific data requirements will be put in place for the Network in support of veterinary medicinal products (VMP). The most important proposal is to integrate the EU product database of VMP with the Substances, Products, Organisations and Referential (SPOR) master data management system. This integrated IT service is mandatory in the new legislation and the overall approach is that IT systems for veterinary marketing authorisations will be in line with the "human" IT systems, except where no equivalent human system exists. The heads stressed that engagement at the HMA and NCA level is crucial for the governance of veterinary Telematics**.**

Colistine resistance: Update by chair of AMR-Task Force

It was underlined that Colistine has become a last resort antibiotic for human use. However the situation for veterinary use is different in some Member States where there is still an uneven distribution. The CVMP Antimicrobial Advice Expert group has been asked to investigate the veterinary use of Colistine and report back to the HMA.

Clinical Trial Facilitation Group: Identification of the priorities and work plan

The national implementation of the clinical trial regulation is a huge task for the NCAs the coming years. The HMA Clinical Trials Facilitation Group (CTFG) is dedicated to the implementation of the new regulation and to ensure that all NCAs will continue to

cooperate with actions in the safety report assessment and the Voluntary Harmonisation Procedure (VHP). The HMA expressed their support for the hard work of the CTFG and will ensure the involvement of all NCAs.

A discussion took place with regards the 'must requirements' audits for the clinical trial information system and if it will be possible to go ahead with all functionalities even if not all requirements will need to be audited beforehand. The chair of the HMA concluded that the discussion should not be reopened and all requirements need to be finalised by October 2018.

EMACOLEX

The HMA endorsed the revised Rules of Procedure of EMACOLEX, the legal working group of the HMA. The general remit of the group is to gain mutual knowledge on legislation within the different Member States and to create a European pharmaceutical legal "knowledge base" for all NCAs of the HMA.

European Risk Management Strategy Facilitation Group (ERMS FG); new group on pharmacovigilance

The chair of the ERMS Facilitation Group gave a presentation on the future governance structure which is a requirement for the implementation of the pharmacovigilance legislation. The future pharmacovigilance group will continue to be the link between the HMA, the Pharmacovigilance Risk Assessment Committee (PRAC) and the recently established pharmacovigilance business operational team.

In principle the HMA agreed that the ERMS Facilitation Group needs to be revised, and that firstly, a clear mandate should be presented for consideration.

Public hearing at the Pharmacovigilance Risk Assessment Committee (PRAC)

HMA was informed that the PRAC will adopt the revised draft mandate for the public hearings. This was done on the basis of an analysis of previous safety referrals. Later this year the EMA will organise a test mock up hearing.

The next HMA meeting will take place in Rotterdam on the 1st and 2nd of June 2016.