Heads and IT directors meeting during the EU presidency of the Netherlands

During the 83rd HMA Meeting in Rotterdam organised by the Medicines Evaluation Board (MEB) of the Netherlands, a combined HMA - IT Directors meeting was held on 1 June. The objective of this joint HMA and IT Directors meeting was to underpin the business case for developments to exchange information, stimulate interaction between business and IT and to confirm some actions at National Competant Authority (NCA) level particularly around the Substance, Product, Organisation, Referential (SPOR) initiative for the Identification of Medicinal Products (IDMP).

The IT directors of all the NCAs and EMA have been discussing the EU Telematics governance structure for some time. Progresses has been made with the aim of encouraging a strong concept between HMA, EMA and IT directors to promote Telematics developments. In Rotterdam, the IT directors had the opportunity to interact intensively with their heads around the various important Telematics projects.

Information management and technology are seen as important enablers for the NCAs. The welcome and opening of the meeting was conducted by Hugo Hurts, the director of the MEB and chair of the HMA. He highlighted that it's the first time that a joint meeting with heads and the IT directors had been organised.

The meeting started with a presentation of the results of the survey on telematics by Belen Crespo, the head of the Spanish agency (AEMPS). The aim of the survey was to have a holistic overview on the consequences of implementing Telematics issues for NCAs. The telematics and information systems are at the core of the regulatory business, and is a strategic issue for the network and for every NCA.

The overview identified several areas and their impact for NCAs, both financial and in terms of capacity:

1. Clinical Trials Portal and database (for human NCAs)
2. Integration with the PSUR repository (for human NCAs)
3. Use of the electronic Application Forms (eAF) (for human and vet NCAs)
4. Mandatory VNeeS Use (for vet NCAs)
5. Common Repository for CAP Vet dossiers (for vet NCAs)
6. EudraVigilance Stakeholder Change Management Plan (for human NCAs)
7. EUVetMedProd (for vet NCAs)

It was concluded that HMA and EMA should continue to cooperate and keep each other informed on the progress of the different Telematics projects. At the same time, an intensive, global initiative around the IDMP/SPOR has a major impact on the IT infrastructure and databases across the Network.

Another agenda item was the HMA Multi Annual Work Plan (MAWP) which includes priorities such as Implementation of the Telematics Strategy. Another priority is the Optimisation of the regulatory

operations. Optimising regulatory operations should not only lead to reducing administrative burden, but should at the same time build a sustainable Network and promote operational excellence.

The Central Electronic Submissions Portal: CESP 3.0

An update was provided on CESP 3.0 and showed some of the building blocks that the Network have already implemented. The aim of the Network is to improve the quality of the data, and SPOR and CESP are amongst the building systems to achieve this.

Different scenarios were presented and discussed on the automated process for a new authorisation and submission of variations.

The participants mentioned that the following options could be considered to enable CESP :

- Update regulatory procedures to leverage the advantage of technology;
- Eliminate the need for paper / original signatures and national requirements;
- Have a critical review of the data within submissions, identifying and eliminating duplicate and redundant data;
- Ensure that ICT Systems are designed and built for the long term network vision.

The SPOR was also discussed and it's potential to the Network which can be summarised as follows:

- Operational savings and efficiency;
- Increase in data quality, simplification of data management practices;
- Fulfilment of regulatory requirements more efficiently;
- Better decisions, faster regulatory action.

Currently SPOR is being implemented in a step by step approach to ensure that all NCAs have sufficient time to implement changes. Examples of implementation of SPOR were given by Spain, Estonia and Austria.

A discussion took place on how to best develop the European Medicines Web Portal (EMWP). Eventually, EMWP will replace the current EudraPharm human database and will be the common window to information on medicines for patients.

At the end of the meeting all heads and their IT directors agreed to establish an *EU multi agency cross functional working group for optimisation of regulatory processes*.

It was concluded that this first meeting with all heads and IT directors resulted in an interactive and fruitful discussion.