HMA human stakeholder meeting in Rotterdam

The HMA human stakeholder meeting took place on the 31st of May 2016 in Rotterdam. The meeting was organised by the Medicines Evaluation Board (MEB) during the EU Presidency of the Netherlands. Hugo Hurts, director of the MEB, introduced the HMA Multi Annual Work Plan (MAWP) and highlighted that during this meeting, two of the eleven strategic priorities in the MAWP were debated:

- Optimisation of the regulatory operations
- Availability of good quality appropriately authorised medicines for human use

Optimisation of the regulatory operations

A joint industry presentation was provided by Beata Stepniewska, Deputy director general of Medicines for Europe, on behalf of the trade associations; Medicines for Europe, EFPIA, EuropaBio, AESGP and EUCOPE.

A plea was made to avoid duplications regarding assessment of the same data set by NCAs. It was also stated that data should be provided to NCAs only once and all Telematics systems need to communicate with each other to allow access to all authorities within the Regulatory Network.

Work-sharing remains the cornerstone of the EU network and also the reliance on assessments performed by other NCAs.

The question was raised whether Telematics is the 'promised land'. Industry sees a huge potential in using Telematics tools in the simplification of regulatory processes. The best result can be achieved by identifying business needs for the authorities and industry, and by working together in close cooperation from the very beginning of projects. The development of the Common Electronic Submissions Platform (CESP) is a good example which reduced burden for both industry and regulators with the submissionof applications on CD-ROM and DVD.

It is the view of the industry that on-going developments and investments in the ISO IDMP brings enormous opportunity if implemented in a smart way. Providing data on Substance, Product, Organisation and Referential (SPOR), although very time and resource intensive, could offer some new opportunities to reduce the administrative burden for pharmaceutical companies and NCAs, particularly for the purpose of product maintenance and submission of variations and life cycle management.

As the new system would lead to a reduction of the number of variations to be processed by the authorities, the industry made a pledge for a flat maintenance fee in all Member States in order to stimulate a cost effective regulatory mechanism, without undermining the Authorities' financial stability.

Another discussion point was the increase of number of variations due to several weaknesses of the current variations system, particularly visible in off-patent sector where several duplications were identified (e.g. API/ supply chain, supply to multiple customers, company-wide changes, grouping

etc). Industry called for a serious debate and actions at EU level to simplify and optimize the variations system.

Availability (of good quality appropriately authorised medicines) and shortages

The HMA has announced the issue on availability as a priority and included in the 2016 in the Multi Annual Work Plan (MAWP). Heads underlined that the situation is alarming in some cases and may affect the public health in Member States.

The causes of medicine shortages can be diverse, in smaller Member States a reasonable amount of the registered medicines are not marketed whereas in other Member States re-exported or parallel exported to other European countries where the prices are low create availability issues.

The reality of medicine shortages in the European hospital sector was outlined by two members of EAHP, Aida Batista and Richard Price. Two cases were presented namely shortage of Human IV Immunoglobulin and antimicrobials. These examples clarified the need for transparency (what kind of shortages, how long will it take, are alternative pharmaceuticals available) and for suppliers to provide information in a pro-active way. Quicker responses are needed by the Network and preventable measures should be established.

Another joint industry presentation was presented by Pär Tellner and Koen Nauwelaerts on behalf of all the EU trade associations. Clearly the issues raised were unavailability and shortages which are a global and multifactorial issue. This results in a complexity of causes for medicines shortages and calls for an integrated approach involving both analysis of each individual cause and of their combination.

Interrupted supply of medicines can be caused by, but is not limited to quality and manufacturing issues. However, the problem can only be solved if tackled holistically. A call on NCAs was made to harmonise the reporting procedure, content, template and trigger point with a single point of contact. Some regulatory processes (i.e. “0-Day” renewal or pragmatic approach to a linguistic version of the PIL, including e-leaflet) shall be explored. The stakeholders stressed the importance of harmonization of reporting shortages within the different Member States.

The HMA human stakeholders meeting resulted in a fruitful and interactive discussion.