Joint HMA/EMA task force on big data established

Stephanie Kohl

To further evaluate the role of Big Data in the healthcare system, the Heads of Medicines Agencies (HMA) and the European Medicines Agency (EMA) have established a new task force on Big Data. The group, which is headed by the Dutch Medicines Agency and EMA, will be exploring how medicines regulators in the European Economic Area (EEA) can use big data to support research, innovation and robust medicines development to benefit both human and animal health.

Within the next 18 months the task force will be working on establishing a roadmap and recommendations for the use of Big Data in the assessment of medicines. Preparatory work will include the mapping of sources and characteristics of big data and the exploration of the potential applicability and impact of big data on medicines regulation. The task force will also collaborate with other regulatory authorities and partners outside the EEA to consider their insights on big data initiatives.

Once the work is concluded the task force is planning to present a roadmap for the development of big data capabilities for the evaluation of applications for marketing authorisations or clinical trials in the national competent authorities, as well as, recommendations on necessary changes to legislation, regulatory guidelines or data security provisions.

Further information on the activities of the task force will be published soon by EMA on its website.

IN THE INTEREST OF PATIENTS, COMMISSION RECOMMENDS IMPROVEMENTS TO PACKAGE LEAFLETS

Package leaflets are contained in each medicine that is marketed within the EU. These leaflets include among other elements the name of the product, the manufacturer as well as information on therapeutic indications, dosage, shelf life and adverse reactions.

The European Commission noted in its report to the European Parliament and the Council shortcomings in the summary of product characteristics and the package leaflets. Recommendations have thus been put forward within the report to better meet the needs of patients and healthcare professionals.

The recommendations of the European Commission centre on the following:

- ▶ Improving the readability and comprehensibility of package leaflets, especially for the elderly and individuals with low literacy skills;
- ▶ Modifying the layout (font size, line spacing and length) of package leaflets;
- ▶ Increasing the utilisation of user-testing, a feature that ensures patient input is considered during the leaflet development process;
- ▶ Sharing best practices by making available good examples of package leaflets to pharmaceutical companies;
- ▶ Exploring the possibility to make product information available in electronic form.

Amendments to existing legislation such as Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use are not planned. Instead the European Commission seeks to update existing regulatory guidelines in collaboration with the EMA and competent authorities of Member States.

IHE PHARMACY PUBLISHED EDUCATIONAL ARTICLE DESCRIBING HOW INTEROPERABILITY CAN SUPPORT THE EFFORT AGAINST FALSIFIED MEDICINES

The educational article is an initiative of the Pharmacy Domain of IHE (Integrating the Healthcare Enterprise). *Falsified Medicines Directive—Supply chain interoperability in support of safer medication usage* explains how the standard interoperability architecture for the supply of healthcare products of IHE could help to monitor the supply chain and support the enforcement of the Falsified Medicines Directive.

The paper also:

- ▶ Describes briefly the requirements under the Falsified Medicines Directive;
- ▶ Highlights the operational challenges of barcode scanning for users in the hospital setting;
- ▶ Advocates for the use of standardised Automated Identification and Data Capture (AIDC) as well as standardised dispatch advice documents in order to simplify, automate and control the delivery of medicines for both suppliers and customers;
- ▶ Illustrates in an exemplary manner how an interoperable supply chain could improve the situation of hospitals regarding the reporting obligations under the Falsified Medicines Directive.

EUROPEAN PARLIAMENT'S OWN INITIATIVE REPORT ON EU OPTIONS FOR IMPROVING ACCESS TO MEDICINES ADOPTED

Following up on a discussion that started in September 2016, on the 2nd of March, the European Parliament voted on the initiative draft report *EU options for improving access to medicine*.

In a period where the high prices, unaffordability and shortages contribute to the lack of essential medicines and poor access to healthcare, the report recaps the main reasons that lead to them, such as illegitimate business strategies in the pharmaceutical sector, parallel trade or political, manufacturing and distribution problems.

By touching upon issues such as research and development, intellectual property, pricing and reimbursement, as well as, transparency the report adds to the current debate on access to medicines.

Building on the concerns expressed in the 2016 Council Conclusions on strengthening the balance in the pharmaceutical system in the EU and its Member States the European Parliament's own initiative report calls inter alia for

- ▶ National and EU-wide measures to guarantee universal, affordable, effective, safe and timely access of patient to essential and innovative therapies;
- ▶ An evaluation of a number of regulatory frameworks including the Transparency Directive, the Regulation on Orphan Medicinal Products and the Paediatric Medicines Regulation;
- ▶ An innovation friendly environment that fosters research and development.

Besides Member States and the Commission the pharmaceutical sector is also approached in regard to ensuring the accessibility of

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pharmacies, quality advice, counselling service and promoting campaigns and educational programmes aimed at making citizens aware of the rational use of medicines, avoiding overconsumption (in particular of antibiotics) and promoting the issue of prescriptions by active principles by the healthcare professionals.

Finally, the Commission and Council are called to take actions aiming at reducing, better defining and analysing the causes of shortages of medicines, assessing the impact of parallel trade and supply quotas.

Taking into consideration the political momentum the report is, undoubtedly, useful to support the European Council's conclusions and to encourage the European Commission to move forward.

EAHP Statement 6: Education and Research

Competing interests None declared.

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EAHP News

European Statements of Hospital Pharmacy—moving from statement to implementation

Stephanie Kohl

The Statement implementation project began with the adoption of the European Statements of Hospital Pharmacy in May 2014 and has reached another milestone.

During the 22nd congress of EAHP, Joan Peppard, the EAHP President officially launched the Statements website. It is an addition to the EAHP website that offers an overview of why the European Statements of Hospital Pharmacy are so important.

The Statements website provides stakeholders—such as hospital pharmacists, patients, policy makers, healthcare practitioners, academics or our many partners in industry—with access to a variety of different resources which should help individual hospitals throughout Europe with the implementation of the Statements. These resources include an evidence base for each of the Statements and are complemented by general material aimed at assisting EAHP's member associations with implementation.

And there is still more to come. At the moment, EAHP is working on an online self-assessment tool that will allow hospital pharmacists to assess the level of Statement implementation within their countries. Such a tool was first developed for

the American Society of Health-System Pharmacists (ASHP). EAHP's self-assessment tool will complement the information collected through our regular statement surveys. Its primary purpose is to help individual hospitals show progress with implementation. Users will be provided with a tailored action plan to assist them in further advancing the implementation of individual Statements in the hospital setting.

A beta version of the self-assessment tool was tested by interested stakeholders during EAHP's Congress in Cannes. The finalised version is expected to be made available on the Statement website by June 2017.

EAHP AND OTHER MEDICINES SUPPLY CHAIN STAKEHOLDERS ISSUE CONSENSUS STATEMENT ON SHORTAGES INFORMATION

The European associations representing manufacturers of medicinal products, parallel distributors, pharmaceutical wholesalers and pharmacists have announced a series of recommendations on the provision of information, designed to help tackle medicines shortages.

Focusing on the transparency and the availability of medicine shortage data, the Associations' statement is part of

their wider commitment to tackling the issue. Evidence suggests it is an increasing problem across the European Union, having a significant impact on patients, on health professionals, on healthcare systems and suppliers.

The recommendations call for greater transparency and availability of medicines shortage data, early detection and assessment of potential shortages, consistency of reporting, increased access to the information available across all parts of the supply chain, improved data infrastructure, and collaborative governance processes.

The recommendations aim to mitigate the impact of shortages on patients, provide patients and health professionals with up-to-date, meaningful information and improve the ability of health systems to diagnose and solve supply issues as they arise.

This statement builds on existing good practices and recommends some specific features of ideal medicines shortages information systems. The European associations representing manufacturers of medicinal products, parallel distributors, pharmaceutical wholesalers and pharmacists hope that, taking into consideration the national specificities of each country, these recommendations can help enhance information systems at a national level, and potentially form the basis of future European level action.

DRAFT VERSION OF HOSPITAL PHARMACY COMMON TRAINING FRAMEWORK PUBLISHED AHEAD OF CONSULTATION

The European Association of Hospital Pharmacists (EAHP) has published a draft version of a potential common training framework (CTF) for hospital pharmacy in Europe. The publication comes ahead

of an online Delphi method consultation on its content.

The draft framework was developed over 18 months by a pan-European group of 16 hospital pharmacists, led by Dr Andreia Bruno of the Portuguese Pharmaceutical Society.

The working group developed the draft framework in 3 phases:

- Consolidating information and understanding on the current status of hospital pharmacy education across Europe;
- Review and analysis of the hospital pharmacist competencies provided by national programmes; and,
- Proposing the core knowledge, skills and competencies that should form a draft common training framework for hospital pharmacy in Europe.

Background references for the proposed framework included the 44 European Statements of Hospital Pharmacy, the 2011 European Commission sponsored project Pharmine, as well as the curricula for a broad range of existing hospital pharmacy post graduate education programmes across Europe.

Speaking of the publication, Dr Andreia Bruno, chair of the Working Group that developed the draft framework, said:

'What our working group discovered was that, although structures for hospital pharmacy (formal and informal) across Europe may differ, the skills and competencies delivered at the end of the process are really quite similar. They all meet the same needs of leveraging the pharmacist's expertise and potential within the hospital setting, where acute conditions, rare diseases, complex and specialised medicinal therapies, clinical trials and many other particularities have a strong presence. The draft framework therefore offers a synthesis of practice realities across Europe based on firm foundations such as the 2011 Pharmine project and existing hospital pharmacy curricula.'

Now we are providing scrutiny opportunity to the wide variety of impacted stakeholders via a Delphi method consultation. I encourage every interested individual and stakeholder to sign up for the consultation before the 20 February deadline!'

A CTF for hospital pharmacy will represent an agreement on the competencies, knowledge, skills and attitudes required by the profession to deliver the 44 European Statements of Hospital Pharmacy.

EAFP Statement 6: Education and Research

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