EAHP's position on biosimilar medicines

Stephanie Kohl

In June, the European Association of Hospital Pharmacists (EAHP) published its position paper on biosimilar medicines outlining the Association's views on the role of the hospital pharmacist, naming of biosimilar medicines, extrapolation of indications, information about biosimilar medicines as well as interchangeability, switching and substitution of biosimilar medicines.

Biological medicines have become indispensable in the treatment of patients with serious diseases such as cancer and inflammatory diseases. An increasing number of biological medicines are biosimilar medicines. These are developed to be similar to already existing biological medicines. The European Medicines Agency (EMA) is the body responsible for their approval in the European Union.

The position paper of EAHP closely follows the line of EMA on matters concerning naming of biosimilar medicines and extrapolation of indications. The evidence acquired over 10 years of clinical experience has shown that biosimilar medicines approved through EMA can be used as safely and effectively in all their approved indications as other biological medicines. Thus, EAHP has expressed confidence in EMA's regulatory pathway for biological reference products and biosimilar medicines.

Hospital pharmacists are stewards of appropriate selection, procurement, logistics and use of medicines as well as key players in pharmacovigilance. Consequently, they are uniquely positioned and capable to promote the appropriate utilisation of biosimilar medicines. Their knowledge is therefore particularly relevant with regard to switching and providing the evidence on patient safety and treatment quality.

In terms of interchangeability, switching and substitution of biosimilar medicines, EAHP supports the view that a reference product and its biosimilar(s) are interchangeable and therefore can be switched. EAHP holds the same view for biosimilars to the same reference product. These

views are based on evidence presented in the position paper. Nevertheless, due to patient-specific issues, EAHP acknowledges that there are instances where it is not appropriate to make a switch. It should therefore be ensured that the considerations of the prescriber, the pharmacist and the patient whether to choose the reference product or its biosimilar are taken into account. Provided that the above safeguards are in place, EAHP supports substitution at hospital pharmacy level.

The decisions regarding switching and substitution may be taken on either national or local level. The key positions of EAHP on biosimilar medicines are summarised on the first page of the position paper. Each position does however not stand by itself and thus should be read in conjunction with the corresponding supportive information presented in the position paper.

STATEMENT IMPLEMENTATION DEVELOPMENTS AND FUTURE PLANS

Adopted in 2014 with the collaboration of EAHP's 34-member country associations (Montenegro joined in 2016) and more than 30 patient and professional healthcare organisations, the European Statements of Hospital Pharmacy are patient driven and represent what every European healthcare system should aim for in the delivery of hospital pharmacy services to improve patient outcomes.

EAHP is now working to implement the European Statements within its 35-member countries. Since the approval of the project by our members during the 46th General Assembly in Prague (June 2016), the Statement implementation team has progressed the following actions:

- ▶ Developing a Strategic Implementation Plan;
- ▶ Creating strong support of national implementation networks (33 national associations are represented through their national implementation ambassadors);
- ▶ Designing an awareness campaign;
- ▶ Setting up a Statement Implementation website;
- ▶ Approaching European and national relevant stakeholders;

- ▶ Designing national implementation strategies;
- ▶ Building up resources to help hospital pharmacists and other healthcare professionals to move towards implementation.

EAHP is also working on two major initiatives: the development of a self-assessment tool and the setting up of a network of Statement Implementation Learning Collaborative Centres (SILCC).

The self-assessment tool is an online tool that will allow hospital pharmacists to assess the level of implementation within their hospitals and will provide them with an individualised action plan to assist them during the implementation process. The online tool will be available in October. It will be officially launched during the 23rd EAHP Congress in Gothenburg (21–23 March 2018).

The set-up of SILCCs involves the identification of hospitals willing to provide training to hospital pharmacists within EAHP's member countries in procedures related to the Statements. Like the self-assessment tool, the SILCC initiative will be launched during the next EAHP Congress in Gothenburg.

Do you want to learn more about the Statements and the Implementation project? Do you want to collaborate with EAHP and your national association to help your countries and others moving towards the implementation of the Statements? Send us an email at Statements@eahp.eu and visit our new website www.statements.eahp.eu!

COMMON TRAINING FRAMEWORK—HOW THE PROJECT IS PROGRESSING?

In 2014, the EAHP embarked on a journey towards the development of a Common Training Framework (CTF) for the hospital pharmacy specialisation. Its initiation was influenced on the one hand by the Pharmine project and on the other hand by the 2013 amendment of the Professional Qualification Directive, which created the possibility to set up common training frameworks.

A common training framework should, pursuant to Article 49a of Directive 2005/36/EC (the Professional Qualification Directive), be based on a common set of knowledge, skills and competences necessary to pursue a profession. Qualifications obtained under such a framework could automatically be recognised by Member States that choose to voluntarily apply the framework. Professional associations, like EAHP, are entrusted by Article 49a of

Correspondence to Stephanie Kohl, European Association of Hospital Pharmacists, Boulevard Brand Whitlock 87 Box 11, 1200 Brussels, Belgium; Stephanie.Kohl@eahp.eu

the Professional Qualifications Directive with the right to take the lead in developing such frameworks and to apply to the Commission for legal recognition. Enabled by this regulation, EAHP set up three Working Groups which are led by a Steering Committee. The Association tasked them with the construction of a common training framework to advance labour mobility for hospital pharmacists and to set a European benchmark for the hospital pharmacist specialisation.

In the first stage of the CTF project, EAHP worked on securing voluntary agreement across countries about the knowledge, skills and attitudes/behaviours that underpin advanced practice in the hospital sector. Working Group 1, led by Dr Andreia Bruno, developed a draft competency framework after examining the competencies required to deliver the vision of practice set out in the European Statements of Hospital Pharmacy. This draft framework was reviewed through a Delphi Consultation in which a diverse group of stakeholders consisting out of hospital pharmacists, other healthcare professionals, patients/representatives of patient organisation and regulatory bodies participated. The results of this consultation are currently being analysed by Working Group 1. The input provided by the different stakeholders will be used to finalise the draft competency framework within 2017.

The second Working Group—chaired by EAHP Immediate Past-President Dr Roberto Frontini—conducted a research exercise in support of the project CTF. It analysed on the one hand literature on hospital pharmacy education and explored on the other hand the experience and attitudes of hospital pharmacists on labour mobility. The results of both the literature review and the labour mobility survey undertaken by Working Group 2 will be published in the next few months.

A series of communication tasks was carried out by Working Group 3, which is led by EAHP President Joan Peppard. The group ensured a clear understanding of the project among the EAHP membership, wider hospital pharmacy profession and liaised with the European Commission and other professions developing common training framework approaches. Working Group 3 will continue its activities in accordance with a new communication plan to ensure a clear understanding in the wider pharmacy profession including academia and regulators. Once the draft competency framework is finalised, the CTF Working Groups will start preparing

the next phase on the journey towards CTF realisation.

EAHP JOINS EUROPEAN MEDICINES VERIFICATION ORGANISATION AS AFFILIATE MEMBER

EAHP has become an affiliate member of the European Medicines Verification Organisation (EMVO), the body that oversees the implementation of the European Medicines Verification System (EMVS) for medicines verification across Europe.

In 2011, Falsified Medicines Directive introduced rules to improve the protection of public health with new harmonised, pan-European measures to ensure that medicines are safe and that the trade in medicines is rigorously controlled. To achieve this the Directive sets out obligatory safety features on the outer packaging of medicines. Detailed rules on these features are regulated by a delegated act which lays down the characteristics of the safety features, how medicine authenticity should be verified and by whom. Medicines verification in accordance with this delegated act will enter into force on 9 February 2018.

EMVO, which is founded by five pan-European medicines supply chain organisations—The European Association of Euro-Pharmaceutical Companies, The European Federation of Pharmaceutical Industries and Associations, The European Healthcare Distribution Association, Medicines for Europe (The European Generic and Biosimilar Medicines Association) and The Pharmaceutical Group of the European Union—will be responsible for the implementation of the EMVS.

The medicines verification system prevents falsified medicines from entering the legal supply chain and thus tries to improve patient safety. In accordance with the Falsified Medicines Directive and the delegated act, manufacturers will be required to print a Data Matrix code, which incorporates a unique identifier and apply an antitampering device on the outer packaging of all medicines for each individual sales package. Information on the unique identifiers will be uploaded by manufacturers via the European Hub—which is operated by EMVO—while verification of medicines will take place in the National Medicines Verification Systems of the country in which the package is supplied.

Each package falling within the scope of the Falsified Medicines Directive will be scanned, checked and verified for authenticity against a national (or

supranational) repository on its dispense. If the unique identifier on the package matches the information in the repository, the package can be decommissioned and supplied to the patient. Packages whose unique identifier does not match the information in the repository will trigger an alarm in the system resulting in them not being supplied to the patient. An investigation will be carried out which needs to determine whether the package has been falsified or not. EAHP is represented within EMVO, as affiliate member. Together with the European Hospital and Healthcare Federation, EAHP forms the hospital constituency of EMVO.

GENERAL ASSEMBLY ADOPTS POSITION PAPER ON BIOSIMILAR MEDICINES

In mid-June, the EAHP gathered hospital pharmacists from across its member countries for its annual General Assembly in St. Paul's Bay in Malta. Delegates from 34 of EAHP's 35-member countries discussed the Association's current and future projects—including the implementation of the 44 European Statements of Hospital Pharmacy and the development of a CTF for hospital pharmacy specialisation in Europe—as well as policy developments in areas of interest to hospital pharmacists.

Due to increasing interest in the opinion of hospital pharmacists on biosimilar medicines, EAHP's members adopted a position paper on this topic. The position paper provides an appropriate mandate to better respond to requests relating to biosimilar medicines. It addresses the role of the hospital pharmacist as well as other matters relevant to EAHP, such as naming of biosimilar medicines; extrapolation of indications; interchangeability, switching and substitution of biosimilar medicines and information about biosimilar medicines. Like for all other medicines, EAHP also recommends informed patient involvement and shared decision making for biosimilar medicines.

EAHP's member countries also saw a need to revise the existing position paper on eHealth and mHealth due to rapid changes in this policy field. The revision addressed the developments that took place in relation to mobile technology over the past few years. In addition, it acknowledged that both eHealth and mHealth are continuing to play an important role on the EU's policy agenda. It is EAHP's belief that eHealth/mHealth technologies should be developed in close collaboration with healthcare professionals including hospitals

pharmacists and patients. Therefore, the Association calls on national governments and health systems across Europe to work towards

- ▶ Systematic and EU-wide achievement of electronic prescribing, administration and use of electronic medical records (EMR);
- ▶ Ensuring barcoding of medicines to the single units in primary packages to enable more widespread take-up of bedside scanning in European hospitals, thus improving patient safety;
- ▶ Appropriate regulatory oversight mechanisms for mHealth applications to ensure that they have a positive impact and adequately protect patient data;

▶ Provision of appropriate eHealth/mHealth training opportunities to healthcare professionals and promotion of digital health literacy;

- ▶ Involvement of hospital pharmacists in the design, specification of parameters and evaluation of ICT within the medicines processes.

Besides on important policy decisions, the delegates of EAHP's General Assembly also voted on three new board members and a new President-Elect. Over the next 12 months, Petr Horák, will be acting as President-Elect, before commencing his 3-year term as President of the Association. The new members who were welcomed to the Board of EAHP are Despina Makridaki

(Greece), Nenad Miljković (Serbia) and Steffen Amann (Germany). They are all elected to serve 3-year terms as Directors of Professional Development.

Competing interests None declared.

Provenance and peer review Commissioned; internally peer reviewed.

© European Association of Hospital Pharmacists (unless otherwise stated in the text of the article) 2017. All rights reserved. No commercial use is permitted unless otherwise expressly granted.

CrossMark

To cite Kohl S. *Eur J Hosp Pharm* 2017;**24**:308–310.

Eur J Hosp Pharm 2017;**24**:308–310.
doi:10.1136/lejpharm-2017-001372