The EAHP EU Monitor is a regular round up of news relevant to hospital pharmacy in Europe.

You can subscribe to receive the EAHP EU Monitor by email ***HERE*** *[1].* *[1]*

Watch the new CTF video and register for the consultation today

EAHP has released a new short video [2] encouraging all individuals and associations with an interest in hospital pharmacy education to register to participate in a pan-European online Delphi consultation on a common training framework [3].

With over 100 individuals and associations already registered to participate in the online Delphi consultation that will commence from 28 February, EAHP is keen that no person who wishes to make an input to the process of finalising agreement on the framework's content misses their chance to express their view.

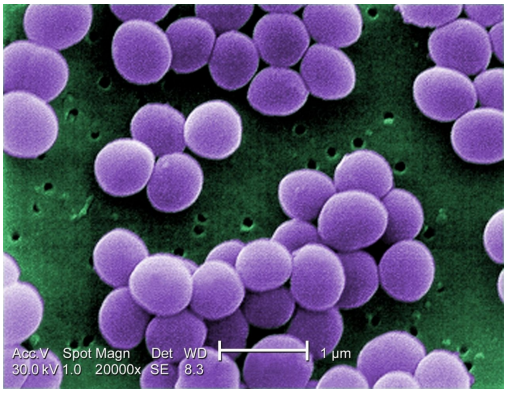
Accordingly, the deadline to register is being extended for a further three weeks, until 1700 CET on Monday 20 February 2017. The registration portal is available **HERE** [3]

To those who have registered already, details about how to participate, as well as the draft version of the framework, will be sent shortly.

More information about the common training framework project is available **HERE** [4].

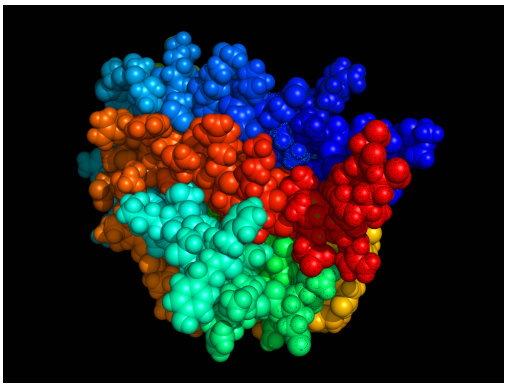
**EAHP thanks Catarina Nobre, President of the European Pharmaceutical Students Association (EPSA) for her assistance in producing this video.*

Readers of the EAHP EU Monitor with an interest in the Common Training Framework may also be interested in Keynote Speech 3 at the upcoming EAHP Congress in Cannes (22-24th March 2017). Entitled "Introducing the Common Training Framework", EAHP President Joan Peppard will explore the purpose, challenges and future of the framework. More information **HERE **[5]**.



European Commission open consultation on an EU Action Plan to tackle AMR

Ahead of launching a new 5-year action plan to tackle Antimicrobial Resistance (AMR) the European Commission has opened a consultation to collect stakeholders' perceptions on a range of available actions. The consultation is open to all citizens and will close on 28th April 2017. More information **HERE** **[6]**.



3 new positions published on hot topic of biosimilar interchangeability

The European Society for Medical Oncology (ESMO) [7], the USA's Food and Drug Administration [8] (FDA) and a collection of scientists from national medicines regulators have each made new and important interventions to current debates about biosimilar interchangeability. The public positioning comes as an increasing number of biosimilar products coming to market in an environment where cost pressures highlight the need to utilise less expensive medicinal products where this can be done without detriment to patient treatment or safety.

In the case of small and large chemical medicines, moving patients to cheaper generic versions of the originator product has been a long-standing and successful means to reduce a health system's medicines bills. In the case of biologic medicines however, the level to which a reference product and a biosimilar product can be considered interchangeable is sometimes made subject of debate. Because of this, healthcare professional organisations and regulators are increasingly making known their positions on the matter.

The USA's medicines regulator, the Food and Drug Administration (FDA), opened the new year by publishing long-awaited draft guidelines on the interchangeability of a biosimilar with its reference product. The draft guidelines call for developers of biosimilars to produce a switching study (or studies) to demonstrate that the risk in terms of safety or diminished efficacy between a biosimilar and its reference product is not greater than the risk of using the reference product without such switch. In short, an interchangeable product is expected to produce the same clinical result as the reference product in any given patient. Achieving the status of 'interchangeable' is especially important in the USA as only such designated biosimilars can then be substituted for the reference product by a pharmacist without the intervention of a health care provider.

The FDA consultation is open for comments by interested parties until the 20th March 2017. The guidelines can be found **HERE** [9].

Meanwhile, the European Society for Medical Oncology (ESMO) has made an intervention into the current discussions on biosimilar interchangeability and substitution by publishing a formal position paper. The paper embraces the opportunity biosimilars provide in keeping medicines costs sustainable for health systems, but also strongly emphasises the need for physicians to retain authority in respect to any switch of a patient between reference and biosimilar product, or between different biosimilars.

The ESMO position paper states: "*Automatic substitution, which might be practice for generics, should... be avoided in the field of biosimilars. Interchangeability and switching should only be permitted if: (1) the physician is well-informed about the products; (2) the patient is fully briefed by the physician and (3) a nurse is closely monitoring the changes and tracking any adverse events*".

The ESMO position paper is available **HERE** [10].

Also entering the debate, a collection of authors drawn from the European medicines regulatory community have recently published a paper in the Journal BioDrugs with the statement: "*Our conclusion is that a switch between comparable versions of the same active substance approved in accordance with EU legislation is not expected to trigger or enhance immunogenicity. On the basis of current knowledge, it is unlikely and very difficult to substantiate that two products, comparable on a population level, would have different safety or efficacy in individual patients upon a switch. Our conclusion is that biosimilars licensed in the EU are interchangeable*".

The authors are drawn from regulatory agencies in Finland, the Netherlands, Germany and Norway. Their article is available **HERE** [11].

Finally, the European Commission continue to follow matters closely, and to assist national discussions has published a "Q&A" document about biosimilars in seven different languages. Entitled "*What I need to know about Biosimilar Medicines - Information for patients*", the document seeks to explain in simple language such issues as extrapolation and provide links to reputable sources of further information. The published languages are English, German, French, Spanish, Portuguese, Italian and Polish. The document is available **HERE** [12].

EJHP: are nanosimilars evaluated and substituted correctly?

The online first edition of the European Journal of Hospital Pharmacy (EJHP) has published an open access article describing a study into the drug selection and dispensing behaviour of hospital pharmacists of intravenous iron products including iron sucrose and iron sucrose similar, with special emphasis on substitution and interchangeability in France and Spain.

The article is available **HERE** [13].

EAHP and GS1 collaborate on special bedside scanning session in Berlin

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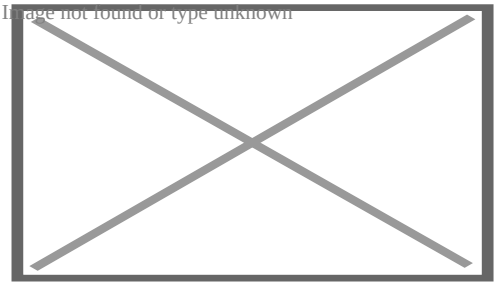

The European Association of Hospital Pharmacists (EAHP) is delighted to be collaborating with barcode standards organisation GS1 [14] in facilitating a special session of the annual GS1 healthcare conference on the topic of bedside scanning. Taking place in Berlin on Tuesday 4th April, the event [15] will learn from the experiences of Gelre Hospital in the Netherlands [16] in taking up the patient safety and life-saving practice of bedside scanning, how challenges to implementation were overcome, and the results achieved. Ms Peggy Staver, Director of Product Integrity at Pfizer, will give a manufacturer's perspective about how postulated barriers to barcoding medicines to the primary package can be surmounted.

GS1's healthcare conference is free for hospital pharmacists in practice and contains many more sessions of interest to practitioners over its 3 day programme including sessions focusing on traceability, patient safety, supply chain management, the Falsified Medicines Directive, and medical devices. The conference also includes poster sessions, case study expositions and side visits to various exemplar hospitals in the Berlin area.

More information about the conference programme and how to register is available **HERE** [17].

2 February 2017

Links
[1] http://www.eahp.eu/newsletter/subscribe [2] https://www.youtube.com/watch?v=2HQvjqStsQ8 [3] http://www.hospitalpharmacy.eu/ctf-consultation/ [4] http://www.hospitalpharmacy.eu/ [5] http://www.eahp.eu/congresses/goals/keynote-3-introducing-common-training-framework-ctf [6] http://ec.europa.eu/dgs/health_food-safety/amr/consultations/consultation_20170123_amr-new-action-plan_en.htm [7] http://www.esmo.org/ [8] http://www.fda.gov/ [9] http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM537135.pdf [10] http://esmoopen.bmj.com/content/1/6/e000142 [11] http://link.springer.com/article/10.1007/s40259-017-0210-0 [12] http://ec.europa.eu/DocsRoom/documents/20961%20.%20 [13] http://ejhp.bmj.com/content/early/2017/01/23/ejhpharm-2016-001059 [14] http://www.gs1.org/ [15] http://healthcare-event.gs1.org/ [16] https://www.gelreziekenhuizen.nl/Gelreziekenhuizen [17] http://www.healthcare-event.gs1.org/