

# eahp euMonitor

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

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## EAHP present common training framework at SIFO

### national Congress

Representatives from EAHP's common training framework (CTF) project [2] recently presented at the annual Congress of the Italian Society of Hospital Pharmacy [3] (Società Italiana di Farmacia Ospedaliera -SIFO) and encouraged all interested individuals and organisations to register to participate in the February 2017 consultation [4] on its content.

Dr Roberto Frontini, Immediate Past President of EAHP, facilitated a dedicated panel session [5] about the CTF at the Congress in Milan on Saturday 3rd December. The event heard the perspectives of providers of hospital pharmacy education in Italy, an Italian hospital pharmacist working in Spain, a representative of the European Pharmaceutical Students Association (EPSA), and Professor Ian Bates, Chairman of the Steering Committee of the Common Training Framework.

EAHP Policy and Advocacy Officer, Richard Price, gave a presentation on the background to the common training framework, and the intended practical value to be achieved by its creation. Presentation available HERE. [6]

Dr Andreia Bruno, leader of the working group developing the draft content of the framework [7], gave a presentation on how her pan-European group of hospital pharmacists embarked upon the project of defining core competencies of the hospital pharmacy profession common across European countries. Presentation available HERE. [8]

Speaking after the event, Dr Andreia Bruno said:

“It was so encouraging to receive the enthusiastic support of so many at the SIFO Congress for what the common training framework project is aspiring to create: a pharmacy development tool that all countries and all hospitals can make use of in driving continuous improvement.

Via the European Statements of Hospital Pharmacy [9] there is a clear sense of what hospital pharmacy strives to be, and via the common training framework [2] a clear sense of the individual competencies required for pharmacists to deliver it.

However the more input we can receive on the content from those in practice, those in education and those pharmacy works for and works with, such as patients and other healthcare professionals, the better.

I encourage all interested in hospital pharmacy to register to participate in the open consultation on the framework's content, and to do so before the 31 January 2017 deadline.”

The registration portal for the common training framework consultation is available HERE [4] [4]

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More information about the common training framework project is available here: <http://www.hospitalpharmacy.eu> <sup>[10]</sup>

The consultation on the framework's initial content will be conducted according to Delphi principles. The online portal will enable contributors to participate anonymously and continuously, as well as be informed by the ongoing contributions of others. Consecutive rounds of consultation, facilitated by an independent moderator team, will aim to achieve a consensus on the content in time to be voted on at the EAHP annual general assembly in Malta in June 2017.

The registration portal for the consultation will close on **31 January 2017**, with the first round of consultation commencing in February 2017.

#### European Union:

- 684 designated orphan drugs
- 63 received marketing approval



Flora Peyvandi

## Authors of PLOS One study suggest current orphan drug legislation may be skewing medicine research priorities too far

A recent study by two UK academics suggests that orphan medicine regulation, in place across the EU <sup>[11]</sup> and more globally, designed to incentivise investment in treatments for rare diseases, could be making orphan products so profitable that investment in broader indications is being stifled. The study comes at a time when the European Commission has been considering stakeholder views <sup>[12]</sup> on potential revisions to the orphan medicine regulatory framework.

According to the authors' analysis of 83 publicly quoted companies, which together market nearly 200 orphan drugs, compared to control companies matched by size, country and R&D investment, orphan drugs companies are five times more profitable and have a 10 percent to 15 percent higher market valuation.

All of the world's 10 most expensive medicines have orphan status, with Alexion Pharmaceuticals Inc.'s Soliris (eculizumab), for treating atypical hemolytic uremic syndrome and paroxysmal nocturnal hemoglobinuria, heading the list, at more than \$400,000 per year.

*"Although these [10 drugs] are prescribed to fewer patients, their high prices can result in revenues equivalent to traditional blockbusters", said [Dyfrig Hughes](#) <sup>[13]</sup>, professor of pharmacoeconomics, and co-director of the Center for Health Economics & Medicines Evaluation at Bangor University, Wales.*

Almost one-third of drugs approved for rare diseases now exceed \$1 billion in annual sales. The global orphan drugs market is expected to reach \$176 billion by 2020, accounting for 19 percent of prescription drug sales. The European Medicines Agency (EMA) has authorised 123 orphan drugs since EU legislation was enacted in 2000.

For Hughes, who has acted as an external expert for the [EMA's Committee of Orphan Medicinal Products](#) <sup>[14]</sup>, incentives have tipped the balance, allowing companies to make excessive profits. *"This may have had the adverse and unintended consequence of directing R&D resources away from other areas of unmet clinical need, such as antibiotics", he said.*

More [HERE](#) <sup>[15]</sup>.

The European Commission conducted a consultation on the current interpretation of orphan medicine regulation earlier this year. More information [HERE](#) <sup>[16]</sup>.

The responses of stakeholders, including the European Association of Hospital Pharmacists (EAHP) are available [HERE](#) <sup>[12]</sup> <sup>[12]</sup>.



## **MEPs seek improvements to EU Paediatric Medicines Regulation**

A group of Members of the European Parliament (MEPs) are seeking to influence the European Commission's current considerations on whether to revise the EU's regulation on [Paediatric medicine development](#) <sup>[17]</sup> with a set of their own suggestions for improvement.

The group of 7 MEPs includes the Chair of the European Parliament's [Health Committee](#) <sup>[18]</sup>, [Giovanni La Via](#) <sup>[19]</sup> ([European Peoples Party](#) <sup>[20]</sup>, Italy), and representatives of other political groupings in the Parliament. They consider that while the EU's 2007 Paediatric Regulation has boosted research into childhood medicine, there is still scope for further improvements. The benefits they note the Regulation as achieving include:

- Obliging companies to conduct a [Paediatric Investigation Plan](#) <sup>[21]</sup> (PIP) for each new molecule they want to market;

- Improving the level of information available on the paediatric use of approved medicines; and,
- Increasing the relative number of paediatric clinical trials.

However, the MEPs express hope that more may yet be achieved via amendments to regulation to improve the research landscape for paediatric oncology and neonatology. Supporting their view, they cite the fact that childhood cancer remains the first cause of death by disease in children aged one year and over and 6,000 young people die of cancer each year in Europe.

Amongst the barriers in this respect, include the suggestion that for those cancers that only occur in children, little financial incentive exists for the pharmaceutical industry to bring new treatments to market. The MEPs also consider that the Regulation's obligations on companies to conduct paediatric medicine development should be based on a drug's mechanism of action matched to a tumour's biology rather than on indication limiting the drug's use to a specific type of cancer.

The MEPs tabled a resolution to this effect, to be voted upon by a full plenary meeting of the European Parliament. The resolution attracted over 80 proposed amendments, including one calling for the Paediatric Regulation to be amended to ensure "*that promising trials in the paediatric population cannot be terminated early due to disappointing results in the target adult population*" tabled by MEPs [Dame Glenis Willmott](#) <sup>[22]</sup> (UK, Socialist & Democrat Group) and [Elena Gentile](#) <sup>[23]</sup> (Italy, Socialist & Democrat Group).

The original motion for a resolution is [HERE](#). <sup>[24]</sup>

The 87 suggested amendments to the motion are available [HERE](#) <sup>[25]</sup>.

Commentary by [Francoise Grossetete](#) <sup>[26]</sup> MEP (European Peoples Party, France), one of the 7 MEPs behind the resolution, is available [HERE](#) <sup>[27]</sup>.

***\*EAHP EU Monitor subscribers interested in the current debate about improving the EU's paediatric medicine regulation are reminded of a currently open consultation by the European Commission on the topic. The consultation closes on 20th February 2017. See [EAHP EU Monitor of 22nd November 2016](#) <sup>[28]</sup> for more information.***



## 1st EAHP Meeting of Implementation Ambassadors

The 1st EAHP Meeting of Implementation Ambassadors was held in Brussels on October 15 2016, and 26 countries were represented at the meeting through their national ambassadors. EAHP President Joan Peppard attended the meeting.

EAHP and ambassadors discussed strategies and the next steps to move towards Statement Implementation within all member countries.

The main role of the ambassador can be summed up on the following:

- - Act as primary link in between EAHP, their national associations and the work that is done within their countries;
- - Convey to EAHP the needs and priorities of their countries when it comes to Statement implementation;
- - Build resources that will help hospital pharmacists, healthcare professionals and other relevant stakeholders to implement the Statements.

Since the meeting, more ambassadors have been appointed and 31 associations are now represented through their national associations. EAHP wants to thank again the great work done by the national associations and the national ambassadors! By working together, we will move from Statement to implementation.

For more information, you can read the Statement Implementation Newsletters [HERE](#) [29].



## EJHP: Compatibility of proton pump inhibitors in a preservative-free suspending vehicle

The online first <sup>[30]</sup> edition of the European Journal of Hospital Pharmacy <sup>[31]</sup> (EJHP) has recently published a study from Brazil evaluating the microbiological and physicochemical compatibility of commonly used proton pump inhibitors (PPIs) esomeprazole, lansoprazole, omeprazole and pantoprazole compounded at a single concentration using SyrSpend SF Alka and stored at refrigerated temperatures

More information [HERE](#) <sup>[32]</sup>.



## Congratulations to Prof Lee Vermeulen!

The European Association of Hospital Pharmacists sends its warmest congratulations to Professor Lee Vermeulen on being awarded the prestigious Donald E. Franke Medal <sup>[33]</sup> for his contributions to international pharmacy practice.

More information [HERE](#) <sup>[34]</sup>.

9 December 2016

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### Links

[1] <http://www.eahp.eu/newsletter/subscribe> [2] <http://www.hospitalpharmacy.eu/> [3] <http://www.sifoweb.it/>  
[4] <http://www.hospitalpharmacy.eu/ctf-consultation/> [5] <http://www.ega.it/congressosifo/wp-content/uploads/Sabato.pdf> [6] [https://www.eahp.eu/sites/default/files/sifo\\_ctf\\_slides\\_dec\\_2016.pdf](https://www.eahp.eu/sites/default/files/sifo_ctf_slides_dec_2016.pdf) [7] <http://www.hospitalpharmacy.eu/who-is-involved/> [8] [https://www.eahp.eu/sites/default/files/sifo\\_ctf\\_framework\\_afb.pdf](https://www.eahp.eu/sites/default/files/sifo_ctf_framework_afb.pdf) [9] <http://ejhp.bmj.com/content/21/5/256.full.pdf+html> [10] <http://www.hospitalpharmacy.eu> [11] [http://ec.europa.eu/health/human-use/orphan-medicines\\_en](http://ec.europa.eu/health/human-use/orphan-medicines_en) [12] [http://ec.europa.eu/health/human-use/orphan-medicines/developments/2015\\_11\\_pc\\_orphans\\_en](http://ec.europa.eu/health/human-use/orphan-medicines/developments/2015_11_pc_orphans_en) [13] <http://cheme.bangor.ac.uk/DyfrigHughesBiography.php> [14] [http://www.ema.europa.eu/ema/index.jsp?curl=pages/about\\_us/general/general\\_content\\_000263.jsp](http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000263.jsp) [15] [http://rmi.com.ru/en/print/media/theme\\_news/p/5780](http://rmi.com.ru/en/print/media/theme_news/p/5780) [16] [http://ec.europa.eu/health/human-use/orphan-medicines/developments\\_en](http://ec.europa.eu/health/human-use/orphan-medicines/developments_en) [17] [http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document\\_listing/document\\_listing\\_000068.jsp](http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000068.jsp) [18] <http://www.europarl.europa.eu/committees/en/envi/home.html> [19] [http://www.europarl.europa.eu/meps/en/96816/GIOVANNI\\_LA+VIA\\_home.html](http://www.europarl.europa.eu/meps/en/96816/GIOVANNI_LA+VIA_home.html) [20] <http://www.epp.eu/>

[21]

[http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general\\_content\\_000608.jsp&mid=WC](http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000608.jsp&mid=WC)

[22] [http://www.europarl.europa.eu/meps/en/35743/Dame\\_GLENIS\\_WILLMOTT\\_home.html](http://www.europarl.europa.eu/meps/en/35743/Dame_GLENIS_WILLMOTT_home.html) [23]

[http://www.europarl.europa.eu/meps/en/124847/ELENA\\_GENTILE\\_home.html](http://www.europarl.europa.eu/meps/en/124847/ELENA_GENTILE_home.html) [24]

[https://www.eahp.eu/sites/default/files/draft\\_mfr\\_paediatric\\_medicines\\_en1.docx](https://www.eahp.eu/sites/default/files/draft_mfr_paediatric_medicines_en1.docx) [25]

[http://www.europarl.europa.eu/sides/getDoc.do?type=COMPARL&reference=PE-](http://www.europarl.europa.eu/sides/getDoc.do?type=COMPARL&reference=PE-593.984&format=PDF&language=EN&secondRef=02)

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[http://www.europarl.europa.eu/meps/fr/2025/Francoise\\_GROSSETETE\\_home.html](http://www.europarl.europa.eu/meps/fr/2025/Francoise_GROSSETETE_home.html) [27]

<http://governmentgazette.eu/?p=7317> [28] [http://www.eahp.eu/news/EU-monitor/eahp-eu-monitor-22-](http://www.eahp.eu/news/EU-monitor/eahp-eu-monitor-22-november-2016)

[november-2016](http://www.eahp.eu/news/EU-monitor/eahp-eu-monitor-22-november-2016) [29] <http://www.eahp.eu/content/statement-implementation-newsletter> [30]

<http://ejhp.bmj.com/content/early/recent> [31] <http://ejhp.bmj.com/> [32]

<http://ejhp.bmj.com/content/early/2016/11/25/ejhpharm-2016-001034.full> [33]

<http://www.ashp.org/menu/AboutUs/Awards/FranckeMedal> [34] <http://www.eahp.eu/news/facilitator-european-summit-hospital-pharmacy-receives-award-international-pharmacy-practice>