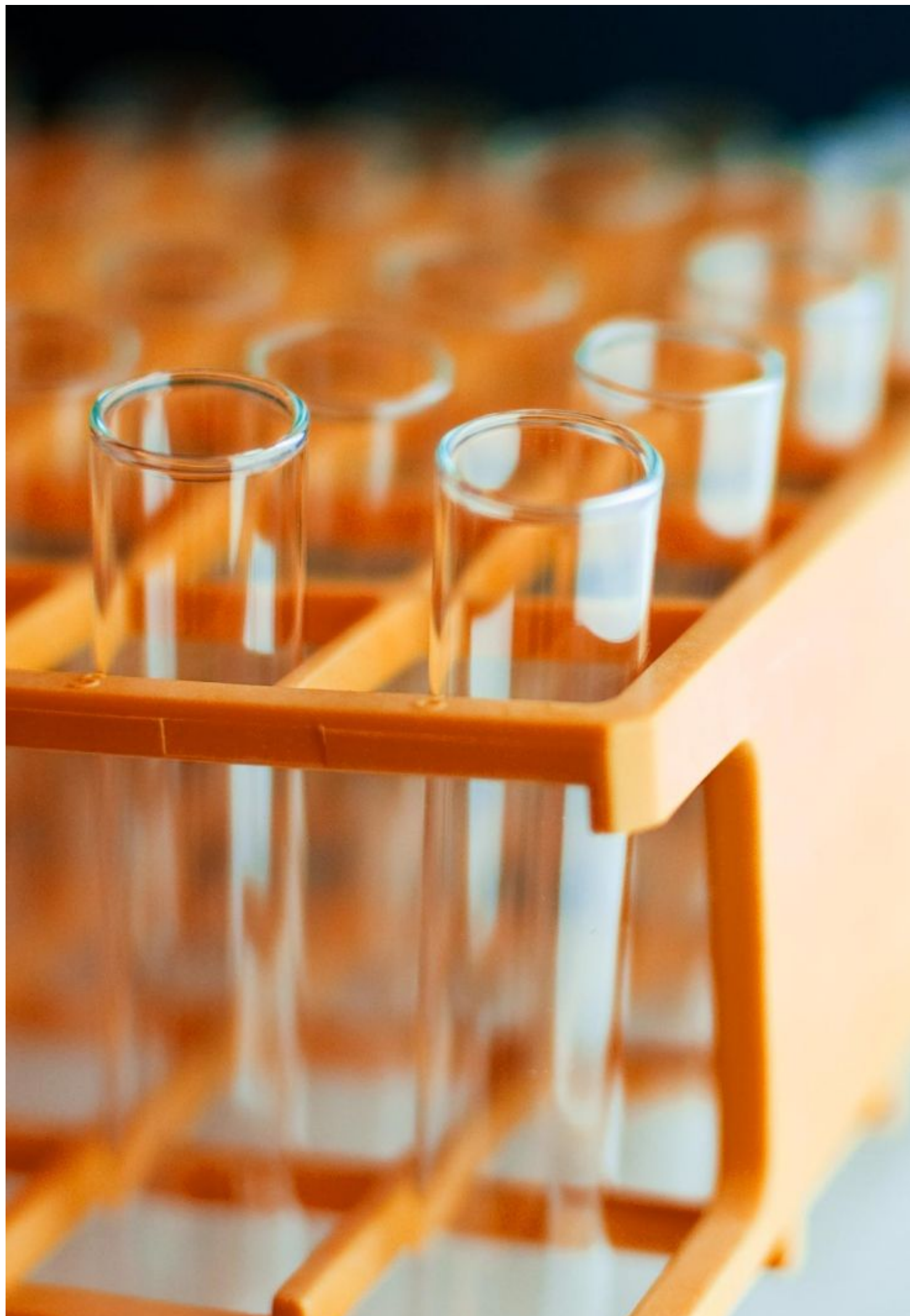


The EAHP EU Monitor is a weekly round up of news relevant to hospital pharmacy in Europe.

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Europe's Hospital Pharmacists join AllTrials call for clinical trial transparency



The European Association of Hospital Pharmacists has joined over 200 health sector associations and organisations from across Europe in calling for improved transparency and disclosure of clinical trial results.

More information [here](#) [2].

European Parliament and Council of Ministers reach provisional agreement on reform to professional qualification recognition change



The Internal Market Committee (IMCO) of the European Parliament has announced it has reached a level of agreement with the EU's Irish Presidency of the Council of Ministers on the issue of reforming the existing Directive on the mutual recognition of professional qualifications.

Following the passage of a report by the European Parliament on the subject file at the end of January 2013, a period of 'trilogue' discussion between the European Parliament, European Commission and Council of Ministers has been conducted with the aim of reaching compromise and consensus on the key changes.

Speaking at the end of a recent trilogue meeting, Bernadette Vergnaud MEP (France, Parti Socialiste) announced that a provisional deal had been struck and that "We have delivered a text with many concrete improvements for citizens and especially the introduction of a European professional card, which I have advocated since 2007 and will soon become a reality. Tools for facilitating mobility, are also instruments of European citizenship, proving that Europe can work to improve everyday life".

The deal, on a draft directive, would require member states and the Commission to take into account the wish of the professional bodies to opt for EU professional qualifications card for their members. If so, member states would grant the cards, which professionals could use then as a "passport" for mutual recognition purposes.

The deal also should accelerate the recognition process, which in some cases could take no more than four weeks, and would be based on the existing electronic information exchange system between member states' administrations.

The European Parliament had also signalled its support for the recommendation of EAHP, and other organisations representing specialist professions, that new mechanisms for qualification recognition for post-graduate training in the pharmacy, veterinary and nursing professions be created, similar to those already in existing for specialties of dentistry and medicine. EAHP understands this proposal is still under active consideration.

More information [here](#) [3].

ENVI Committee votes on its clinical trials report



On 29 May the European Parliament's Committee on Environment and Public Health (ENVI) voted on its scrutiny report on a proposed new clinical trials regulation, which intends to improve data transparency by requiring that detailed summaries be published in a publicly accessible EU database and by fining those sponsors who do not comply.

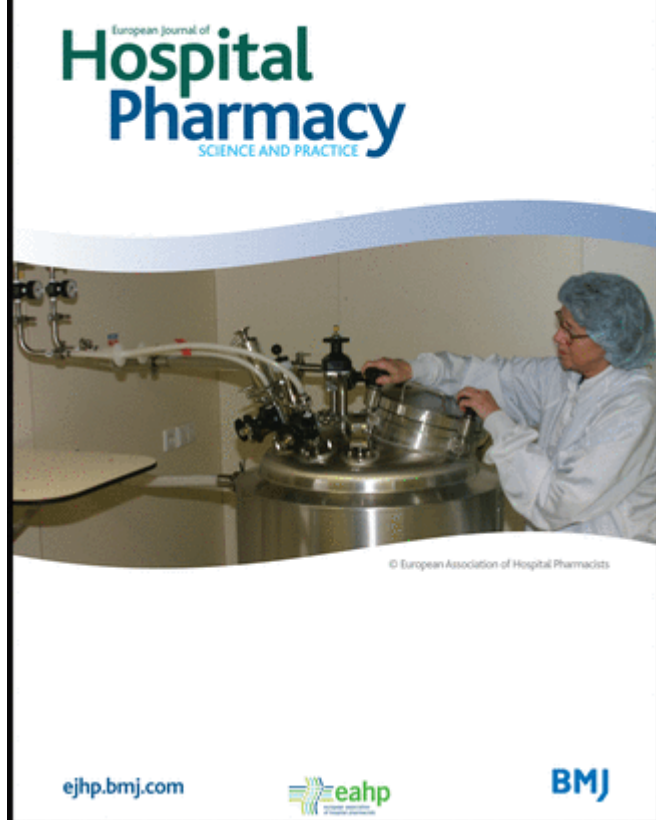
The Committee's report, led by Glenis Willmott (UK, Labour Party) includes amendments to the Commission's proposed regulation on clinical trials that would require trial sponsors to publish full clinical study reports once a marketing authorization decision has been taken. These amendments also make clear that such publication should take place irrespective of the outcome of the clinical trial, or if the trial was terminated early. Such trial results should be "accompanied by a summary presented in terms that are easily understandable to a layperson."

However a proposed amendment by the Socialists and Democrats Group (S&D), the Greens/EFA, and European United Left - Nordic Green Left, which would have included in the legal text of the regulation the statement that "Data and information contained in the clinical study report shall not be considered commercially confidential once a marketing authorisation for the medicinal product for which trial was conducted has been granted" was rejected. An aspiration amendment along these lines, to be included in the non-legal part of the Directive, was accepted (amendment 41).

A further amendment was also passed stating that what is considered as commercially confidential has to be in accordance with EMA guidelines and cannot override public health research interests

In response to the vote, the European Federation of Pharmaceutical Industries and Associations released a statement in which they welcomed the Commission's proposal for an effective, safe simplified, and robust clinical trials authorization process, also a part of the new legislation, but expressed concerns over confidentiality of clinical data saying that "several of the amendments supported by the ENVI committee with jeopardize patient privacy, the integrity of regulatory systems, and incentives for investment in biomedical research in Europe."

The ENVI committee final report on the clinical trials regulation will now go on to be voted by the Parliament as a whole (in plenary session). After that negotiations with national governments will begin.



EJHP: June 2013, Volume 20,

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This issue includes: editorial articles on assessing the shelf life of injectable biologicals in ready-to-administer containers, and the management of fatigue in patients; and original articles on effective clinical decision support, the application of lean methods to compounding services in hospital pharmacy, and a comparison of antimicrobial prescribing between two specialist paediatric centres in the UK and Latvia.

More information [here](#) [4].

13 June 2013

Links

[1] <http://www.eahp.eu/newsletter/subscribe> [2] <http://www.eahp.eu/press-room/hospital-pharmacists-join-campaign-clinical-trial-transparency> [3] <http://www.europarl.europa.eu/news/en/pressroom/content/20130612IPR11615/html/Mutual-recognition-of-professional-qualifications-MEPs-strike-deal-with-Council> [4] <http://www.eahp.eu/publications/journals/june-2013-volume-20-issue-3>