eahp euMonitor

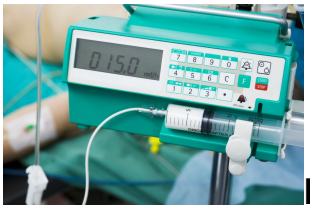
The EAHP EU Monitor is a regular round up of news relevant to hospital pharmacy in Europe.

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

Calling all hospital pharmacies – join the EAHP-EPSA Internship Platform!

The European Association of Hospital Pharmacists (EAHP) has launched a recruitment call to hospital pharmacies across Europe encouraging them to sign up to the EAHP-EPSA Internship Platform [2]. The platform enables hospital pharmacies to offer students and young pharmacists from other European countries the opportunity of gaining cross-border practice experience.

More information here [3].



Political agreement achieved on future EU medical devices regulation

It has been announced that after nearly 4 years of deliberation, political agreement between the European Parliament and European Union (EU) Governments has been reached on the legal texts of a new medical device regulatory regime for the EU.

The full texts of the agreed regulations had not been released at the time of writing, and will still require confirming votes in both the European Parliament and the structures used by representatives of national Governments. Nonetheless, the announcement of the agreement remains significant given the protracted debate thus far between EU institutions about the detail of the proposals.

One of the major sticking points had been difference of view on the reprocessing of medical devices for single use. Quoted on the website of the Regulatory Affairs Professionals Society, Jérôme Unterhuber, spokesman for the Council of the European Union (the coordinating body for EU national governments) said: *"The NL Presidency of the Council and the representatives of the EP [European Parliament] agreed that reprocessing and further use of such devices will only be possible where it is explicitly authorised by national law and will be subject to strict rules ensuring safety. For reprocessed single-use devices all the responsibilities of the original manufacturer go over to the reprocessor. The EP had originally asked to allow reprocessing of single-use medical devices unless it is banned by member states."*

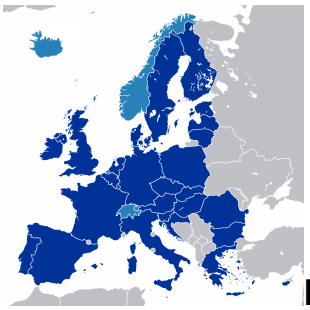
Beyond new rules around reprocessing of single use devices, the Regulation also aims to achieve:

- Additional scrutiny during the conformity assessment procedure for high risk medical devices and in vitro diagnostic medical devices;
- Strengthening of the clinical data requirements related to medical devices;

- Strengthening of the designation and monitoring processes governing notified bodies;
- New classification rules for in vitro diagnostic medical devices;
- The obligation for manufacturers and authorised representative to have a person responsible for regulatory compliance continuously at their disposal;
- Authorised representatives to be held legally responsible and liable for defective products placed on the EU market;
- Increased traceability of medical devices following the introduction of a Unique Device Identification (UDI) system;
- Increased transparency via the establishment of EUDAMED III with information from several databases concerning economic operators, CE Certificates of Conformity, conformity assessment, clinical investigations, the UDI system, adverse event reporting and market surveillance made available to the public.

This article was made with reference to reporting on the Lexocology blog [4] and RAPS Regulatory Focus [5].

European Council of the EU Press Release here [6].



European Commission launch public consultation on professional regulation

The Directorate General of the European Commission with responsibility for free movement of professionals (DG GROW) has launched a public consultation to seek stakeholder opinions on the proportionality of professional regulation across Europe.

Over the past two years, all EU Member States have been encouraged by the European Commission to conduct what is termed "mutual evaluation" as a means of *"screening their regulatory arrangements for professions and ensuring that they are 'proportionate' to legitimate public interest objectives, without creating unnecessary regulatory burden and labour market restriction."*

18 of the 28 EU countries, plus Norway, have now submitted "National Action Plans" on professional regulation on the basis of this mutual evaluation exercise.

The Commission now seeks to know what stakeholder opinion is on:

- the specific changes to professional regulation proposed by the Member States;
- other changes that should be made but which have not been proposed; and,
- whether the Member States' review of their professional regulation landscape was "sufficiently robust".

The consultation will remain open until 19th August 2016.

EAHP is currently reviewing the consultation documentation in respect to areas of hospital pharmacist interest.

More information here [7].

EJHP: A tribute to Professor Per Hartvig Honoré: one of a kind

The Online First edition of the European Journal of Hospital Pharmacy this week published a special editorial in memoriam to Per Hartvig Honoré, long-standing member of the EJHP editorial board, and former editor of EJHP Science.

Editorial article here [8].

2 June 2016

Links
[1] http://www.eahp.eu/newsletter/subscribe [2] http://www.eahp.eu/students/eahp-epsa-internship-platform [3] http://www.eahp.eu/press-room/calling-all-hospital-pharmacies-%E2%80%93-join-eahp-epsa-internship-platform [4] http://www.lexology.com/library/detail.aspx?g=064d68a6-08f0-4bff-bf30-7b4741b4880a [5] http://www.raps.org/Regulatory-Focus/News/2016/05/25/25017/Updated-EU-Reaches-Agreement-on-New-Medical-Device-IVD-Regulations/ [6] http://www.consilium.europa.eu/en/press/press-releases/2016/05/25-medical-devices/ [7] http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_id=8827 [8] http://ejhp.bmj.com/content/early/2016/05/31/ejhpharm-2016-000979.full