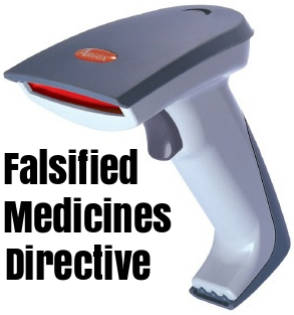
Published on *European Association of Hospital Pharmacists* (https://www.eahp.eu)

eahp euMonitor

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

receive the EAHP EU Monitor by email ***here*** *[1].* *[1]*



FALSIFIED MEDICINES DIRECTIVE DELEGATED ACT ACCEPTED

BY EUROPEAN PARLIAMENT

The 'Delegated Act' of the European Commission that sets out hospital pharmacies are expected to fulfill requirements on 'check out' verification of all medicines they receive has been accepted by the European Parliament. The Act is now formal European Union law and must be implemented by a deadline of 9 February 2019.

The EAHP EU Monitor of 25 August 2015 [2] previously provided briefing on the main elements of the Delegated Act for hospital pharmacists to be aware of, including:

1. The unique identifier that will be contained on the outer packaging of all medicines, and its components
2. The end-to-end verification principle, requiring all hospital pharmacies to conduct 'check out' scans of the medicines packages they receive
3. The governance model of the system
4. The flexibility provided to hospitals in respect of 'when' they choose to conduct the scan
5. The 10 day limit on returns

Following this, EAHP is now advising all its member associations to engage as fully as they are able in national discussions on implementation issues, taking place via the current construction of 'national medicines verification organisations' (NMVOs). These national organisations will, for example, be in charge of defining the national user requirements under which verification systems will operate in the country in question. More here. [3]

In addition to this, EAHP is currently preparing a further briefing for its member associations ahead of its Members' Meeting in Vienna on 15th March 2016.

The Delegated Act is now available to read in all principal EU languages here. [4]

Hospital pharmacists should give particular attention to Articles 25 and 26.

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EAHP RESPONDS TO EUROPEAN COMMISSION ORPHAN DRUG CONSULTATION

The European Association of Hospital Pharmacists (EAHP) has responded to a European Commission consultation on the EU's orphan drug regulatory framework.

The response:

- supports the suggestion that hospital produced medicines be included in the comparisons made to establish whether a candidate for orphan designation offers the potential of "significant benefit" over existing

treatments;

- further suggests that the significant benefit comparison also includes off label use;
- suggests "clinically relevant advantage" be also widely understood as meaning improvements in the ease of administration, safety of the patient, and/or quality of life/options of the patient. This would, as an example, be represented in a switch from intravenous administration to oral administration;
- supports the suggested reforms to the regulatory framework designed to encourage orphan drug designation for treatments targeted at low to zero prevalence but infectious diseases in the EU such as Ebola or the Zika virus;
- calls for the Commission to undertake further review of the orphan medicine regulatory framework especially in respect to pricing and surveillance and monitoring of the outcomes of treatment by medicines given orphan drug authorization with unsettled benefit-risk profiles at the time of approval.

More information on the consultation here. [5]

EAHP's response is available here. [6]

INTERNATIONAL COMMITTEE OF MED (ICMJE) PROPOSES INDIVIDUAL PATIENT DATA SHARING

The International Committee of Medical Journal Editors (ICMJE) is proposing that authors must share the anonymised individual patient data (IPD) underlying clinical trial results published in its member journals.

On January 20th 2016 the ICMJE published an editorial in 14 major medical journals sharing their proposal, and are inviting feedback until April 18th 2016.

The ICMJE also propose that authors include a plan for data sharing as part of clinical trial registration. To be considered for publication, ICMJE already requires the prospective registration of all clinical trials before enrolment of the first participant.

The deadline for responses is 18 April 2016.

More information here. [7]

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EUROPEAN PROFESSIONAL CARD AVAILABLE FOR

PHARMACISTS FROM 18 JANUARY 2016

The European Commission has announced the opening of a 'European Professional Card' (EPC) system for pharmacists and four other professions (general care nurses, physiotherapists, real estate agents and mountain guides) as from 18 January 2016.

The EPC is not a plastic card, but an electronic certificate issued via the first EU-wide fully online procedure for the recognition of qualifications. This digital procedure is based on the well-established Internal Market Information System (IMI) and allows professionals to communicate with the relevant authorities inside a secure network. The IMI also provides for an official, multilingual communication channel between the regulating authorities for professionals in EU countries to facilitate their cooperation and enhance mutual trust.

The EPC does not replace the 'traditional' recognition procedures under the Professional Qualifications Directive, but it does offer an advantageous option for professionals who wish to work either temporarily or permanently in another EU country.

More information here [8].

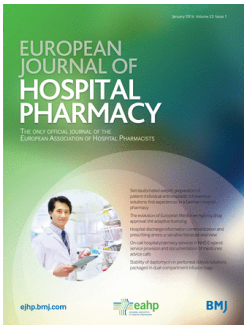
PATIENT ACCESS PARTNERSHIP SEEK HOSPITAL PHARMACIST VIEWS ON ISSUES OF ACCESS TO HEALTHCARE

The Patient Access Partnership, a patient-led multi-stakeholder network, are seeking hospital pharmacist views on the matter of access to healthcare by way of a short survey. Results will be shared at European and national level to develop the policy debate on actions to be taken to reduce disparity in access across Europe.

Hospital pharmacists are encouraged to respond if able, potentially promoting the need for shortages of medicines to be considered an access issue, especially in respect to availability of healthcare. EAHP is also encouraging access to healthcare professional advice and information about medicines to be considered within issues of access. Potential support for such views can be given via the comment box provided under question 14.

Survey here [9].

NEW EJHP ARTICLE: Impact of pharmacy care upon adherence to cardiovascular medicines



The online first edition of the European Journal of Hospital Pharmacy (EJHP) this week published a new article examining the feasibility and potential impact of a pharmacy care intervention, involving motivational interviews among patients with acute coronary syndrome, on adherence to medication and on health outcomes.

Full article here [10].

15 February 2016

Links
[1] http://www.eahp.eu/newsletter/subscribe [2] http://www.eahp.eu/news/EU-monitor/eahp-eu-monitor-25-august-2015 [3] http://www.eahp.eu/news/EU-monitor/eahp-eu-monitor-08-december-2015 [4] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2016.032.01.0001.01.ENG&toc=OJ:L:2016:032:TOC [5] http://ec.europa.eu/health/human-use/orphan-medicines/developments/index_en.htm [6] https://www.eahp.eu/sites/default/files/eahp_response_to_commission_on_orphan_drugs15feb2016.pdf [7] http://www.icmje.org/recommendations/ [8] http://ec.europa.eu/growth/single-market/services/free-movement-professionals/policy/european-professional-card/index_en.htm [9] https://docs.google.com/forms/d/1l1_aUL4klDUPlgVtcOKaXRiFmgfv-qO62mKHumQh8N8/viewform [10] http://ejhp.bmj.com/content/early/2016/02/02/ejhpharm-2015-000790.long