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]*

EAHP President Joan Peppard advises members to heighten their

awareness of the Falsified Medicines Directive in 2016

Writing to national member associations, EAHP President Joan Peppard has encouraged hospital pharmacists in all EU and European Economic Area (EEA) countries to take time to familiarise themselves with the forthcoming impacts to practice arising from the 2011 Falsified Medicines Directive and ensure hospital pharmacy representation at the national level on the issue.

The Directive will bring about a new system in which all packages of medicine will be given a "unique identifier" via a 2D barcode on the outer packaging. This will be placed on the packaging at the manufacturing level, and the serialisation code then "checked in" to a repository marking the package as legitimate. Importantly for hospital pharmacy, this code must then be "checked out" at the end of the supply chain, before the medicine is dispensed or administered to patients. This scan both assures the pharmacist that the product is not counterfeit, while the "check out" ensures the 2D barcode can not be reused by counterfeiters. In practice, this means the hospital pharmacy will need to oversee scan checkouts of every package of medicine entering the hospital. The deadline for implementation will be a date in 2019.

As reported in the August 2015 edition [2] of the EAHP EU Monitor, the European Commission has now published a 'Delegated Act' on how these scan verification processes should operate. The Delegated Act is a binding regulation that all EU Member State and EEA countries must comply with, or face potential penalties and proceedings from the Commission.

The Delegated Act makes clear that the hospital sector is expected to conduct verification checks of medicines, alongside colleagues in community pharmacy. However, flexibility is provided as to 'when' the hospital chooses to conduct the required scanning. For example, the hospital may determine to conduct the scanning at first entry, shortly prior to departure of the medicine from the dispensary to the ward, elsewhere, or at a combination of points depending on the product.

2016 will be an important year at a national level, with the overall systems of verification being constructed via "national medicines verification organisations". In her letter to members, EAHP President Joan Peppard encouraged hospital pharmacists to ensure their voice is heard within these developments.

More information about the European Commission's Delegated Act on implementing the Falsified Medicines Directive's verification requirements is available here [2].

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European Medicines Agency outlines plans for faster authorisation procedures for priority medicines

The European Medicines Agency (EMA) has set out plans to offer early and enhanced scientific and regulatory support to medicine developers where a potential medicine has been deemed "of major public health interest". This would include medicines that "*have the potential to benefit patients who presently have no treatment options, or that may offer a major therapeutic advantage over existing treatments*".

The additional support from the agency would include:

- The early appointment of a rapporteur from EMA's Committee for Medicinal Products for Human Use (CHMP) to facilitate continuity in support and building of knowledge in view of the submission of a marketing authorisation application;
- A kick-off meeting with a multidisciplinary group of experts from relevant EMA scientific committees and working parties to give preliminary guidance on the overall development plan and recommended regulatory pathway; and,
- Scientific advice at key development milestones with potential involvement of multiple stakeholders (e.g. health technology assessment bodies and patients), when relevant.

Following a public consultation on matters such as the eligibility criteria, the Agency intends to the launch the new scheme in the first quarter of 2016.

More information here [3].

Comments to the consultation may provided up to a deadline of 23 December 2015.

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European Commission launches consultation on work life balance for working parents and caregivers

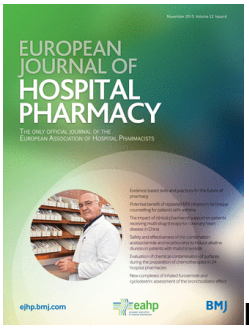
The European Commission is inviting views on how best to address the challenges of work-life balance faced by working parents and caregivers. The consultation takes the form of an online survey to which any member of the public and organisation may respond. The deadline for response is the 17th February 2016.

The initiative for the consultation comes from a publicly expressed desire by the Commission to "*increase the participation of women in the labour market by improving the current EU legal and policy framework and adapting it to today's labour market to allow for working parents and people with dependent relatives to better balance family and work life, allow for a greater sharing of care responsibilities between women and men, and to strengthen gender equality.*"

The percentage of women in employment in 2014 was 63.5%, which is 11.5 percentage points off the Europe 2020 target agreed by EU Member States. Eurofound figures estimate the gender employment gap costs 325 billion euros to the EU, or 2.5 % of the EU GDP. The Commission view the primary factors in lower female labour market participation as a lack of possibilities to balance work and family responsibilities, including lack of affordable childcare, rigid working arrangements or absence of incentives for men to take more care responsibilities in their families.

The Commission's survey seeks views on the potentially available measures to improve the labour market environment for working parents and caregivers, including issues such as family-related leave arrangements and flexible working arrangements.

More information here [4].



EJHP - Impact of clinical pharmacist intervention on length of stay in an acute admission unit

The online first edition of the European Journal of Hospital Pharmacy has recently published an original research article examining the impact of clinical pharmacist interventions on length of stay in an acute admission unit in Denmark.

The full article is available here: http://ejhp.bmj.com/content/early/2015/12/01/ejhpharm-2015-000767.full [5]

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