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The European Association of Hospital Pharmacists (EAHP) is calling on the European Commission to ensure that the future pan-European system of medicines verification facilitates, and does not hinder, barcoding of single dose medicines administered in hospitals. The request came in EAHP's response to a consultation on a regulatory instrument which will set out the requirements for the unique identification of medicines throughout the European supply chain. The system is required to be introduced under the 2011 Falsified Medicines Directive and is intended to safeguard the public against counterfeit products.

EAHP emphasised the positive role barcoding of the single dose of medicine can have in terms of patient safety. It enables bedside scanning and checking of the medicine immediately prior to its administration to the patient. Studies have suggested barcoding and checking medicines in this way can reduce medication errors by as much as 40%.

However EAHP warned the Commission that choices made on the specification of anticounterfeiting systems could have unintended consequences for the possibility of pan-European barcoding of the single dose. This might include, for example, stipulating manufacturers apply a form of barcode for medicines packaging, suchas linear code, that, due to size, may not easily also be applied to single doses of medicine within blister packages. EAHP favours 2D GS1-compliant datamatrix codes for this reason.

Dr Roberto Frontini, President of the EAHP said:

"Hospital Pharmacists in Europe feel very strongly about the patient safety benefits of single dose barcoding. It is therefore important that EAHP brings to the attention of all relevant policy makers in the medicines sector the advantages of introducing this approach. We also must ensure the achievement of single dose barcoding is not threatened by developments elsewhere, such as the forthcoming introduction of an anti-counterfeit medicines verification system.

"Single dose barcoding for medicines in hospitals is already a requirement in the United States, and was recommended in the 2006 report of a Group of Experts to the Council of Europe. EAHP is stepping up its efforts to highlight the patient safety benefits and looks forward to further conversations with the Commission, and manufacturers on the topic in the months ahead."

ENDS

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- [1] Poon EG et al. Effect of Bar-Code Technology on the Safety of Medication Administration.N Eng J Med 2010;362:1698-707 http://www.nejm.org/doi/full/10.1056/NEJMsa0907115 [2]
- [2] http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManua... [3]
- [3] http://www.coe.int/t/e/social_cohesion/soc-sp/medication%20safety%20cult... [4]

NOTES TO EDITORS:

- 1. The European Association of Hospital Pharmacists (EAHP) is a working community of national associations of hospital pharmacists. Its membership includes representatives of national hospital pharmacy associations in almost all the European Union (EU) member states, in addition to Switzerland, Norway, Serbia, Turkey, Croatia, the Former Yugoslav Republic Of Macedonia (FYROM) and Bosnia Herzegovina. Membership is increasing each year and, at present, EAHP represents the interest of over 21,000 hospital pharmacists in 31 countries all over Europe. www.eahp.eu [5]
- 2. The response of the EAHP to the DG SANCO consultation on a Delegated Act on the detailed rules for a unique identifier for medicinal products for human use, and its verification can be found here [6]. The response also called on the Commission to ensure the requirements of the system were proportionate to practice in hospital pharmacy, which means understanding some of the important differences that exist between hospital pharmacy and community pharmacy. For example, the end point of the medicine in hospitals is not the handover of a packet of medicines to a patient, as in community, but more usually the direct administration of the medicine to the patient at the bedside. Medicines typically arrive at hospital pharmacies in larger bulk quantities than in community pharmacy which has important consequences for decisions about at what stage hospital pharmacists should be required to verify the authenticity of medicines under the new system. EAHP intends to meet with the Commission shortly to seek clarity on these matters.
- 3. Barcoding of the single dose of medicines administered in hospitals has long been an aspiration of the EAHP and has been passed by the Association's General Assembly as a priority policy on two occasions (2007 and 2011). See more information **here** [7]
- 4. The Council of Europe established a Group of Experts on Safe Medication Practices to advise Ministers on the management of patient safety and prevention of adverse drug events in healthcare. Its report in 2006 made a clear recommendation that the national and European legislative framework should "require complete and unambiguous labelling of every single unit of use of all licensed medicines products (e.g. tablet, vial and nebules), including the international nonproprietary name (INN), trade name, strength, expiry date, batch number and a data matrix bar code. The data matrix barcode should contain a GS1 Global Trade Item Number (GTIN) identifier in addition to the expiry date and batch number."
- 5. The 18th Annual Congress of the European Association of Hospital Pharmacists will be held in Paris13-15 March 2013. More information **here** [8]

Glossary of Terms [9]

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http://www.coe.int/t/e/social_cohesion/soc-sp/medication%20safety%20culture%20report%20e.pdf[5] http://www.eahp.eu [6]

https://www.eahp.eu/sites/default/files/files/EAHPconsultationresponseUniqueIdentifiers_27%20April(1).pdf [7] https://www.eahp.eu/practice-and-policy/barcoding-of-single-dose-medicines [8]

https://www.eahp.eu/congresses [9] http://www.eahp.eu/News/Our-News/EAHP-call-for-medicines-verification-that-helps-single-dose-barcoding/Glossary-of-Terms