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The European Association of Hospital Pharmacists (EAHP) has today published a policy statement on the issue of medical device regulation in Europe. It is intended as a contribution to the current


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discussion between the European Parliament and European Commission on the subject of device assessment authorisation, vigilance and traceability. Medical devices are an essential part of the delivery of high quality healthcare and their procurement and management in the European hospital setting is often under the authority of hospital pharmacists.

EAHP has reviewed the September 2012 proposals of the European Commission to update pan-European device regulation, and followed the scrutiny of the European Parliament on the subject. Subsequently EAHP's members have passed policy to:

- support central authorisation of high risk (class III) devices as a proportionate measure to ensure high level scrutiny of device safety;
- call for explicit coordination between future verification and traceability systems for devices, and the systems for medicines verification already in development as a result of the Falsified Medicines Directive; and,
- request harmonisation between the processes for vigilance reporting by health professionals in respect of medical devices and existing systems of pharmacovigilance

EAHP is concerned about evidence that device approval standards have been inconsistently applied by Europe's national level approval authorities (or 'notified bodies'), as well as disparity in standards of assessment for high risk devices between the USA and Europe. Whilst EAHP recognise that devices cannot necessarily be considered in the same manner as pharmaceutical products, the Association views that a distinctive case for centralised authorisation procedures for Class III devices exists (i.e. those devices that support or sustain human life).

Furthermore, EAHP promotes joined-up thinking on device and pharmaceutical regulation. With new traceability, verification and vigilance systems now being put in place across Europe for pharmaceuticals (Pharmacovigilance and Falsified Medicines Directives) there is a need to ensure unnecessary duplication is avoided and interoperability of systems ensured wherever possible in respect of similar developments planned for device regulation.

EAHP President Dr Roberto Frontini said: *"Good regulation can often be a difficult balancing act between protecting patient safety whilst also promoting innovation. In this sense I cannot see a case for centralised authorisation for all medical devices. Yet where a device fits within the category of Class III – high risk – another level of assured scrutiny is needed. From assessing the options, centralised authorisation offers the best opportunity for a transparent, rigorous and well understood process. With discussions on the subject continuing EAHP will seek to ensure that the practice experience hospital pharmacists have with devices positively contributes to the final regulation."*

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NOTES TO EDITORS:

1. EAHP is an association of national organisations representing hospital pharmacists in 34 countries at European and international levels. More information about the EAHP and its history **here** **[2].**

2. The EAHP statement on medical device regulation is available here [3].

3. According to the 2010 EAHP Survey of Hospital Pharmacy Practice, medical devices are selected by 55.8% and purchased by 56.2% of hospital pharmacies. There is variance from country to country however. For example, few hospital pharmacies in Denmark and the Netherlands are involved in this activity, while more than 90% of pharmacies in Slovakia, Belgium and Luxembourg are responsible for selecting and purchasing these products. See EAHP 2010 survey on hospital pharmacy in Europe: Part 2 Procurement and distribution, R Frontini, T Miharija-Gala, J Sykora, Eur J Hosp Pharm 2012;19:5 460-463. Available here [4].

4. The European Commission's September 2012 proposals for updating the regulatory regime for medical devices within the EU is available here [5].

5. The Draft report of the European Parliament's Health (ENVI) Committee after scrutinising the Commission proposals is available here [6].

6. In May 2012 the Food and Drug Administration, the regulatory body for medical devices in the USA published a report entitled 'Unsafe and ineffective devices approved in the EU that were not approved in the US'. The report is available here [7].

7. The 2011 Falsified Medicines Directives requires every EU Member State to implement verification systems for medicines by 2017. More information here [8]. Meanwhile the European Commission's proposals for reform of the medical devices regulation will require a new system of unique device identification (UDI) to be put in place. EAHP identify an overlap between these developments and call for system designs to be coordinated to avoid duplication or interoperability difficulties.

8. The 2010 Pharmacovigilance Directive introduced new requirements upon EU member states in respect of the systems expected to be in place for health professional and patient reporting safety concerns about medicines. More information here [9]. Meanwhile the European Commission's proposals for reform of the medical devices regulation will also introduced new systems for reporting of concerns about device safety. EAHP calls for efforts to be made to reduce unnecessary differences in the respective vigilance procedures for medicines and devices in order to encourage active levels of reporting.

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Links
[1] https://www.eahp.eu/contact/info/eahp/eu [2] http://eahp.cxn.be/about-us [3] http://www.eahp.eu/practice-and-policy/medical-device-regulation [4] http://www.eahp.eu/sites/default/files/files/Eur%20J%20Hosp%20Pharm-2012-Frontini-460-3%20Part%202.pdf [5] http://www.europarl.europa.eu/registre/docs_autres_institutions/commission_europeenne/com/ [6] http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-%2f%2fEP%2f%2fNONSGML%2bCOMPARL%2bPE-507.972%2b02%2bDOC%2bPDF%2bV0%2f%2fEN [7] http://www.elsevierbi.com/~/media/Supporting Documents/The Gray Sheet/38/20/FDA_EU_Devices_Report.pdf [8] http://ec.europa.eu/health/human-use/falsified_medicines/index_en.htm [9] http://ec.europa.eu/health/human-use/pharmacovigilance/