

EAHP STATEMENT ON MEDICAL DEVICE REGULATION

AUGUST 2013

INTRODUCTION AND SUMMARY OF EAHP POSITION

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 pharmacistsⁱ.

As an impacted stakeholder EAHP therefore takes a particular interest in the current discussions on the future regulatory regime for the assessment, use and vigilance of medical devices in Europe. Our statement on medical device regulation sets out the position of the Association on a range of topical discussions about the Commission's [September 2012 proposals](#)ⁱⁱ and subsequent considerations [in the European Parliament](#).

EAHP generally welcomes the Commission's proposals to improve post-assessment vigilance and traceability of devices, and to tackle the issue of inconsistent application of approval procedures by notified bodies. Whilst we note that devices cannot necessarily be considered in the same manner as pharmaceutical products, in view of the documented disparity in standards of assessment for high risk devices between the USA and Europeⁱⁱⁱ, concerns expressed by national device regulators within Europe^{iv}, and the need to ensure patient safety, we consider that the case for central authorisation of class III devices, as proposed in the draft report of the European Parliament ENVI Committee (April 2013)^v, is merited. EAHP supports the more robust level of assessment scrutiny offered by a centralised procedure for those devices were insufficiently considered assessment decisions present high risk to patient safety i.e. class III devices.

Further to this EAHP underlines the need for:

- **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** (e.g. [ESM](#), [E-tact](#))

The European Commission and national governments should be aware of the risk that hospitals across Europe could be made to implement two separate verification/traceability systems, one for medicines, and one for devices, with separate equipment, software, training requirements and costs involved¹. Therefore there is need to ensure units of DG SANCO speak with other and work towards sensible convergence of system requirements e.g. the use of compatible UDI systems (2D barcode etc). We note the Commission's proposals already contains a commendable aspiration to coordinate requirements for device-related clinical investigations with the Commission's current proposals on clinical trial regulation (3.6). EAHP request the Commission take the same care to coordinate device traceability requirements with those under development for the purposes of medicines verification.

- **harmonisation where possible between the processes for vigilance reporting by health professionals in respect of medical devices and existing systems of pharmacovigilance reporting in respect of medicines**

¹ The 2011 Falsified Medicines Directives requires every EU Member State to implement verification systems for medicines by 2017.

EAHP supports the new requirements contained within the Commission proposal mandating manufacturers to report serious incidents and corrective actions they have taken to reduce the risk of recurrence and to further empower healthcare professional and patient reporting.

Systems for pharmacovigilance reporting by health professionals in respect of medicines are well established across Europe. Any further developments in respect of vigilance reporting for devices should aim to take both cognisance of systems already in operation for medicines, and strive to ensure device reporting processes are not needlessly different. In EAHP's consideration, ensuring reporting processes for devices and medicines are of a similar nature will help to reduce the burden of reporting, and, by increasing the familiarity of the process to the health professional, increase the likelihood of reporting.

- **protection against the potential misuse of medical device regulation to enable medicines-containing devices to bypass the robust assessment procedures required in relation to medicines.**

As regulation currently stands, medical devices may contain medicinal substances which act on the body in a manner ancillary to the device. However, where such substances act in a manner that is more than ancillary, the product is regulated as a medicinal product rather than a medical device. This appears to EAHP as a reasonable definition, but requires necessary oversight to ensure definitions are not being stretched or applied in a relaxed manner. In this sense, we hope the Commission's proposals for new collective oversight procedures of the decisions of notified bodies can be effective in policing this area of regulation.

IMPROVING THE CURRENT SYSTEM OF APPROVAL FOR MEDICAL DEVICES IN EUROPE

EAHP supports the European Commission's rationale for reforming existing pan-European regulation of device approval mechanisms. We concur with the Commission's assessment that with 80 notified bodies for device approval operating in 32 countries: "*substantial divergences in the interpretation and application of the rules have emerged*". Measures to address this, and close any perceived 'loopholes' in regulation are therefore warranted and sensible. In this sense, we welcome the Commission's proposals to:

- enable notified bodies to review, scrutinise and comment on assessments performed by others;
- give new powers for notified bodies to conduct unannounced factory inspections and to conduct physical and laboratory tests on devices;
- provide for stricter and more detailed criteria for the designation and monitoring of Notified Bodies by Member States' competent authorities (including their financial and human resources capacities); and,
- place notified bodies more generally under the scrutiny of the proposed expert committee, the Medical Devices Coordination Group.

However, EAHP shares the concerns about current assessment procedures for high risk devices in Europe that have been expressed by the Food and Drug Administration (FDA) in the USA, the European Consumers Organisation (BEUC)^{vi}, the Association Internationale de la Mutualité (AIM), the European Social Insurance Platform (ESIP), and the International Society of Drug Bulletins (ISDB) and the Medicines in Europe Forum (MiEF)^{vii}. We further agree with their conclusions, that there is a good case for a centralised authorisation procedure for such devices, potentially under the remit of the European Medicines Agency. EAHP also support the need for the demonstration of

clinical efficacy – not simply “performance” – and of clinical safety for high-risk medical devices, prior to the granting of a centralised marketing authorisation.

TRANSPARENCY OF INFORMATION ON DEVICES, THE OPERATION AND DEVELOPMENT OF EUDAMED, AND COORDINATION OF VIGILANCE SYSTEMS

EAHP supports the Commission’s proposals to develop and add transparency in relation to information contained within the EUDAMED database. In addition to this, we recommend that the synergies between the EUDAMED and Eudravigilance databases be explored and reporting tools used for both be streamlined to encourage and facilitate reporting.

EAHP wholly supports the empowerment of healthcare professionals and patients to report suspected serious incidents at national level using harmonised formats and endorse the ENVI Committee amendment to place a strong onus on Member States to „take all necessary measures to raise awareness among healthcare professionals, users and patients about the importance of reporting suspected serious incidents.“ In the hospital context this could be supported by giving specific healthcare professionals vigilance responsibilities. In many, but not all, countries in Europe, this area of responsibility might normally fit within the hospital pharmacy.

EAHP otherwise supports the proposed development of the EUDAMED database and urges best practice lessons be learned from similar databases. For example, EAHP note the fully transparent nature of the FDA MAUDE (Manufacturer and User Facility Device Experience)² database which extends access to members of the public without need for any prior registration.

CLASSIFICATION SYSTEM AND BORDERLINE PRODUCTS

EAHP shares the concerns of our colleagues in community pharmacy that there is „an increasing tendency for some products which are ostensibly medicines to be in fact be categorised as medical devices³. Examples we are aware of in the hospital context include dialysis preparations, classified as devices, which contain electrolytes - yet the exchange of electrolytes can be observed to have metabolic effects with the patient. Such examples highlight the need to have robust scrutiny of how notified bodies are applying definitions in this area. EAHP hope that, alongside centralised assessment procedures for high risk devices, the Commission’s proposals for new oversight procedures for notified bodies can be used to address this concern. It must certainly be a focus for the Commission, Parliament and Council of Ministers in their ongoing review of medical device regulation needs.

² Available at: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM>
Accessed 27 April 2013

³ PGEU response to the public consultation on the recast of the medical devices directives, 2008. Available at: <http://www.pgeu.eu/en/policy/10-medical-devices.html> Accessed 27 April 2013.

ⁱ 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. *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 at: <http://www.eahp.eu/sites/default/files/files/Eur%20J%20Hosp%20Pharm-2012-Frontini-460-3%20Part%202.pdf> Accessed 27 April 2013.

ⁱⁱ European Commission document, *Proposal for a Regulation of the European Parliament and of the Council on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009*, September 2012. Available at: [http://www.europarl.europa.eu/registre/docs_autres_institutions/commission_europeenne/com/2012/0542/COM_COM\(2012\)0542_EN.pdf](http://www.europarl.europa.eu/registre/docs_autres_institutions/commission_europeenne/com/2012/0542/COM_COM(2012)0542_EN.pdf) Accessed 27 April 2013.

ⁱⁱⁱ FDA Report, *Unsafe and ineffective devices approved in the EU that were not approved in the US*, May 2012. Available here: http://www.elsevierbi.com/~media/Supporting%20Documents/The%20Gray%20Sheet/38/20/FDA_EU_Devices_Report.pdf Accessed 27 April 2013

^{iv} BMJ article, *Medical Devices: Europeans are left to their own devices*, D Cohen, M Billingsley, *BMJ* 2011;342:d2748 Available at: <http://www.bmj.com/content/342/bmj.d2748> Accessed 27 April 2013.

^v European Parliament document, *Draft Report by the ENVI Committee on the proposal for a regulation of the European Parliament and of the Council on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 (COM(2012)0542 – C7-0318/2012 – 2012/0266(COD))*, April 2013. Available at: <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-%2f%2fEP%2f%2fNONSGML%2bCOMPARL%2bPE-507.972%2b02%2bDOC%2bPDF%2bV0%2f%2fEN> Accessed 27 April 2013.

^{vi} *BEUC position on the forthcoming revision of the EU legislation on medical devices*, July 2012. Available at: http://taenk.dk/sites/taenk.dk/files/beuc_position_paper_on_medical_devices_legislation.pdf Accessed 27 April 2013.

^{vii} AIM - ESIP - ISDB - MiEF Joint Position Paper, October 2012, available at: http://english.prescrire.org/Docu/DOCSEUROPE/20121022_ESIP-AIM-ISDB-MiEF-MedicalDevices.pdf Accessed 27 April 2013.