EAHP Opinion on the Medical Device Regulations

- **To improve patient safety, EAHP urges all involved actors to ensure an effective implementation of the new Medical Device Regulations.**
- **EAHP calls on the European Commission to ensure protection against the potential misuse of the Medical Device Regulations.**
- **Collaboration of healthcare professionals in the selection, procurement and evaluation of medical devices should be encouraged.**

Medical devices are essential for the delivery of high quality healthcare to patients. Their procurement and management in the European hospital setting is often carried out under the authority of hospital pharmacists. To ensure that medical devices are secure for patients, the European regulatory regime for their assessment, use and vigilance was revised. This revision lead to the adoption of the two Medical Device Regulations[1] in spring 2017.

The European Association of Hospital Pharmacists (EAHP) generally welcomed the new Medical Device Regulations since they aim at improving post-assessment vigilance and traceability of devices. In addition, they tackle the issue of inconsistent application of approval procedures by notified bodies.

Despite the efforts of the European Commission to modernise the current regulatory framework concerns in relation to the safety of European medical devices have been raised. In light of these concerns, the EAHP would like to reiterate some of the points made in the Association's Statement on the Medical Device Regulation.[2]

The EAHP urges Member States to harmonise the processes for vigilance reporting by healthcare professionals in respect of medical devices and existing systems of pharmacovigilance reporting in respect of medicines. Targeted information campaigns should be launched to encourage and enable healthcare professionals to report to the competent authorities suspected serious incidents. Such campaigns should also encompass information on the use of the European database on medical devices (Eudamed) by healthcare professionals.

Moreover, the EAHP calls on the European Commission to ensure protection against the potential misuse of the Medical Device Regulations. During the transition period, particular focus should be put on medicines-containing devices to ensure that the robust assessment procedures required in relation to medicines cannot be bypassed.

Close collaboration between healthcare professionals is key for the successful application of the new Medical Device Regulations. Hospital pharmacists should be involved in the selection, procurement and evaluation of medical devices in the hospital sector with other healthcare professionals. In particular medicine containing devices should not be procured without the expertise of the hospital pharmacist. Due to their knowledge and skills hospital pharmacists are specialists in the field of all medicines procurement.[3] They should lead in all phases of the procurement processes to ensure the continuity of supply of cost-effective and quality medicines and medical devices to patients in close collaboration with other healthcare professionals.

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[1] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.
[2] EAHP Statement on the Medical Device Regulation of August 2013, available at:
http://www.eahp.eu/sites/default/files/files/EAHP%20Devices%20statement%20August%202013.pdf
[3] EAHP Position Paper on Procurement of June 2018, available at:
http://www.eahp.eu/sites/default/files/eahp_position_paper_on_procurement_1.pdf