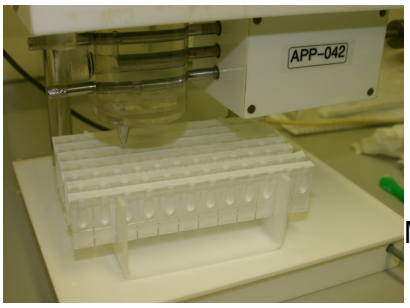

Medical devices are an essential part of the delivery of high quality healthcare and their procurement and management in the European hospital setting is often under the authority of hospital pharmacists.

EAHP Statement on the Medical Device Regulation

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 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 Europe , concerns expressed by national device regulators withing Europe , 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) , is merited.

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);
- 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; and,
- 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.

Further information and the EAHP statement is available here [1].

EAHP Opinion on the Medical Device Regulations

In light of the Implant Files reports the EAHP released an Opinion on the Medical Device Regulations in February 2019 which reiterates some of the points made in the Association's

Statement on the Medical Device Regulation. In particular, the EAHP calls

- on all involved actors to ensure an effective implementation of the new Medical Device Regulations to improve patient safety.
- on the European Commission to ensure protection against the potential misuse of the Medical Device Regulations.
- for the encouragement of collaboration of healthcare professionals in the selection, procurement and evaluation of medical devices.

The Opinion on the Medical Device Regulations is available here [2].

EAHP Opinion focusing on the application of the Medical Device Regulations

To further improve the safety of medical devices for European patients, a new regulatory regime was adopted in spring 2017 encompassing both the Medical Device Regulation (MDR) and the Invitro Medical Device Regulation. With the MDR becoming fully applicable from May 2021 onwards, EAHP used the occasion of its Synergy Certification Course on Medical Devices to reiterate some of the considerations raised by hospital pharmacist in EAHP's Statement on the Medical Device Regulation adopted in 2014 and EAHP's Opinion on this topic released in 2019.

The Opinion focusing on the application of the Medical Device Regulations is available here [3].

Medical device resources for hospital pharmacists

In many European countries, hospital pharmacists are responsible for the handling of medical devices. To support their work, EAHP has joined forces with EURO-PHARMAT, one of the Association's members based in France whose work focuses on medical devices. Together with EURO-PHARMAT, a list of medical device resources was created to assist hospital pharmacists dealing with medical devices across Europe.

Name of the resource	Scope of the resource
Hospital prescription and proper dispensing by community pharmacies - Dressings [4]	The purpose of this recommendation is to facilitate improved coordination between hospitals and community pharmacies for the benefit of patients and to improve the fulfillment of hospital prescriptions dispensed by community pharmacies.
Practical Sheet Reprocessing of Single-Use Medical Devices [5]	This sheet aims to offer a synthesised presentation of the requirements set by the new European Regulation on Medical Devices for those who consider reprocessing single use medical devices.
Model File for a Medical Device ? EURO-PHARMAT [6]	This file can be used to summarise all information relevant for a medical device.

Last update: 26 November 2021

Links
[1] https://www.eahp.eu/sites/default/files/files/EAHP%20Devices%20statement%20August%202013.pdf
[2] https://www.eahp.eu/sites/default/files/eahp_opinion_on_the_medical_device_regulations.pdf
[3] https://www.eahp.eu/sites/default/files/2021_eahp_opinion_focusing_on_the_application_of_the_medical_device_re
[4] https://www.eahp.eu/sites/default/files/29-acl-euro-pharmat-29-hospital-prescription-and-proper-dispensing-by-community-pharmacies-dressings.pdf
[5] https://www.eahp.eu/sites/default/files/practical_sheet_reprocessing_of_single-use_medical_devices.pdf
[6] https://www.eahp.eu/sites/default/files/model_file_for_a_md.pdf