

Participation of clinicians in the Medical Device Regulations

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The Plan for Immediate Actions – PIP

Eucomed-AdvaMed_PIP and way forward_6.3.2012_PBE [Compatibility Mode] - PowerPoint

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6 Measures for immediate action under the current medical devices directives
3. Coordination (1)

7 Measures for immediate action under the current medical devices directives
3. Coordination (2)

8 Measures for immediate action under the current medical devices directives
4. Communication and transparency

9 Scientific assessment

European Commission

Measures for immediate action under the current medical devices directives

4. Communication and transparency

- Enhanced participation of healthcare professionals and patients
 - Member States to require healthcare professionals and encourage patients to report adverse events
 - Dialogue with medical societies and Member States about device registers
- Enhanced traceability of devices
 - COM Recommendation regarding establishment of UDI

Click to add notes

How you can contribute

- **Reporting adverse events or incidents, participating to registries**
- **Participating in drafting guidance documents, Common Specifications, standards – Working Groups, Taskforces, Expert Panels (via ESC or directly)**
- **Scrutinising the clinical evidence for certain high-risk devices – member of an Expert Panel**
- **Scientific and technical opinions on request from COM, MDCG, Member States, Notified Bodies, manufacturers – member of an Expert Panel**

Expert panels renewal 2023

https://health.ec.europa.eu/medical-devices-expert-panels/expertise-eligibility-and-application_en

How you and your patients can benefit

- **Enhanced requirements for clinical evidence, use of equivalence, post-market surveillance, post-market clinical follow-up, vigilance and market surveillance**
- **Transparency and access to information**
 - Public Clinical Investigations Report and Summary
 - Public Field Safety Corrective Actions and Field Safety Notices
 - Summary of Safety and Clinical Performance
 - More detailed IFUs and labelling
 - Implant cards
 - Devices and their certificates
- **EUDAMED**

https://ec.europa.eu/growth/sectors/medical-devices/new-regulations/eudamed_en

Additional information

Main page of the new Regulations

https://health.ec.europa.eu/medical-devices-sector/new-regulations_en

Resources for health care professionals and health institutions

<https://>

health.ec.europa.eu/medical-devices-new-regulations/getting-ready-new-regulations/healthcare-professionals-and-health-institutions_en

Information kit and various resources

https://health.ec.europa.eu/medical-devices-sector/overview_en

Thank you



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