Participation of clinicians in the Medical Device Regulations

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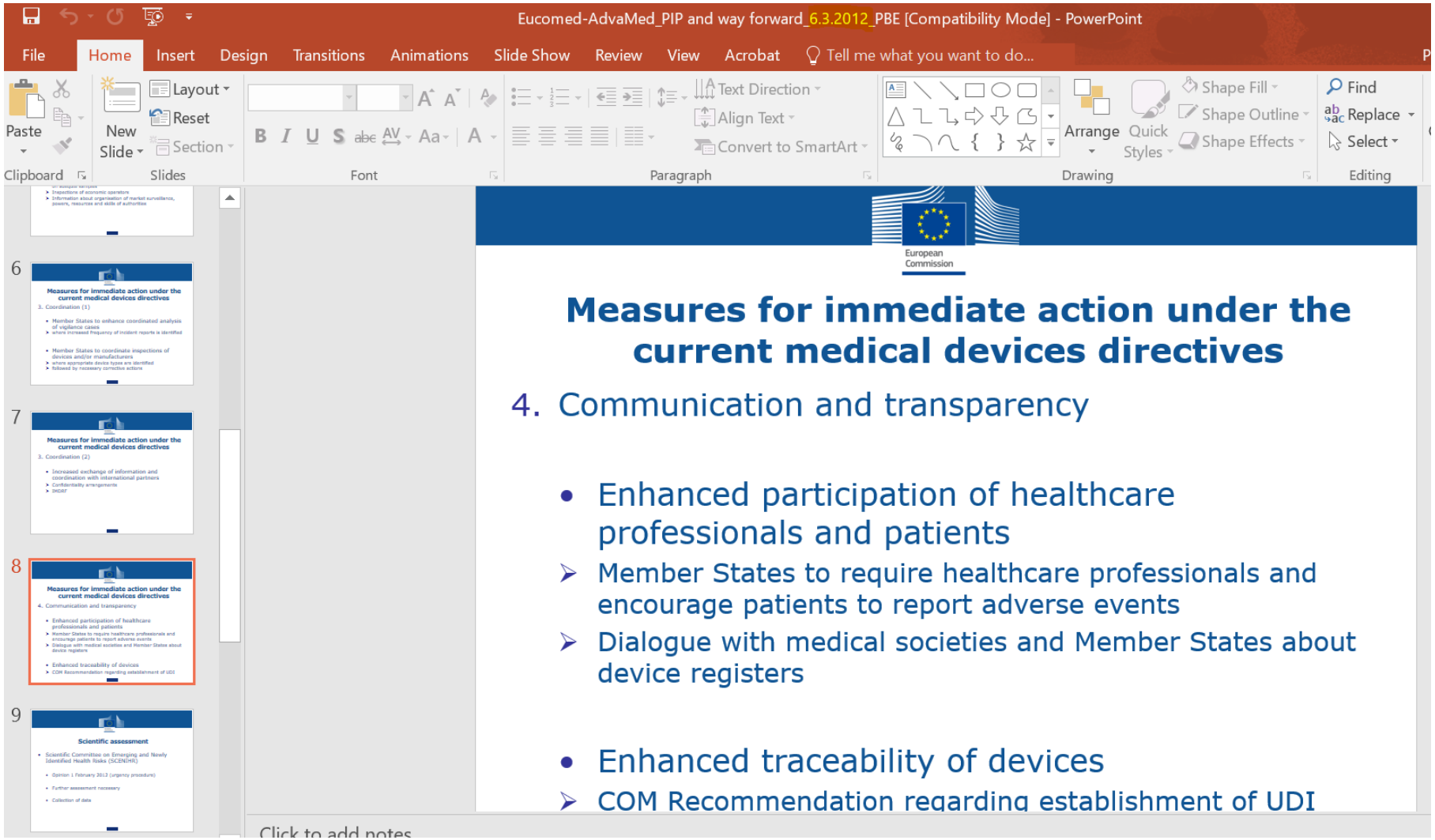
CORE-MD webinar 6 March 2023

European Commission

The Plan for Immediate Actions – PIP



https://health.ec.europa.eu/medical-devices-sector/directives/pip-action-plan_en

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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

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Thank you

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