Certification of JRIs under the MDR

UK Superbrands 2017

INVESTORS IN PEOPLE

By Royal Charter

This Presentation …

- Overview of key actors
- Some changes at EC level
- Steps to conformity assessment for JRIs under the MDR
- Discussion

Overview of key actors

MDR Actors – Who are they and what do they do?

European Commission

- Administration
- Develop legislation
- Support Member States (eg assign joint assessment teams for assessment of NBs, management of SR, UDI and electronic data systems, etc)
- Supported by MDCG, expert panels and expert laboratories

Competent Authorities

- National Law Enforcement
- Ensure only safe, compliant products on market
- Designate Notified Bodies

Notified Bodies

- Conformity Assessment of Manufacturers, Suppliers, Subcontractors

Manufacturers

- '... ultimate responsibility for conformity ...'

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Some changes at European Commission level

European Commission – a few additional responsibilities

- Oversight of Class III implants and Class IIb active drug delivery devices
- Modify legislation through Delegated (“what”) and Implementing (“how”) Acts
- Establish Medical Device Coordinating Group
- Set up and manage electronic data system (device and manufacturer registrations, certification status, vigilance, clinical investigations, etc)
- Establish Expert panels and Expert laboratories (w/ MDCG)

MDCG (Articles 103 - 105 MDR)

- “An expert committee… composed of persons designated by the Member States based on their role and expertise in the field of medical devices… to fulfil the tasks conferred on it by this Regulation … to provide advice to the Commission and to assist the Commission and the Member States in ensuring a harmonised implementation of this Regulation.” (Recital 82)

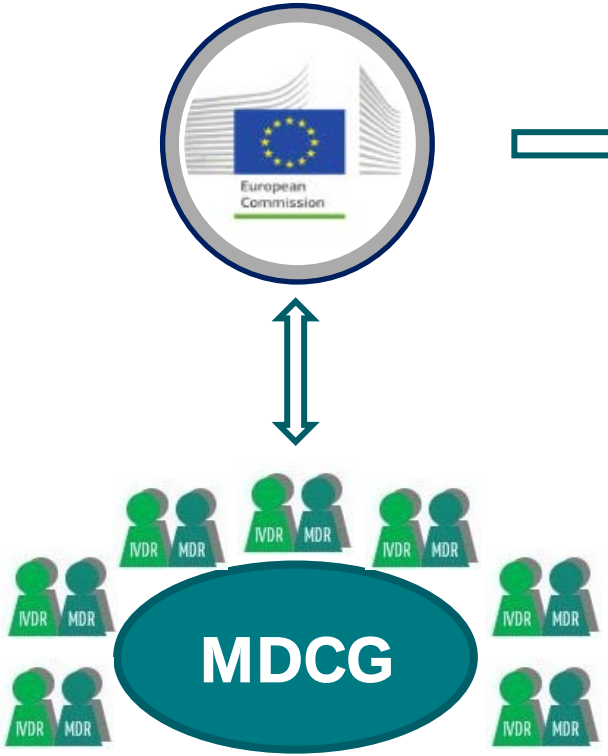
MDCG (Articles 103 - 105 MDR; Article 98-99 IVDR)

- contribute to assessment of CABs and NBs
- development of regulatory guidance (eg designation and monitoring of NBs, SPRs, vigilance, etc)
- development of device standards, common specifications, scientific guidance
- assist MS in coordination activities (eg clinical investigations, vigilance, market surveillance, etc)
- provide advice on any issue related to implementation of the Regulations

MDCG (Articles 103 - 105 MDR; Article 98-99 IVDR)

"The MDCG should be able to establish subgroups in order to have access to necessary in-depth technical expertise in the field of medical devices ...When establishing subgroups, appropriate consideration should be given to the possibility of involving existing groups at Union level in the field of medical devices." (Recital 82)

MDCG (Articles 106 MDR)



Expert panels

- Provide scientific, technical and clinical assistance to Commission and MDCG
- Contribute to development and maintenance of guidance, standards and CS (clinical, technical)
- Assist with MS, NB and manufacturer consultations
- Assist with identification of emerging safety and performance concerns

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Steps to conformity assessment for JRIs under the MDR

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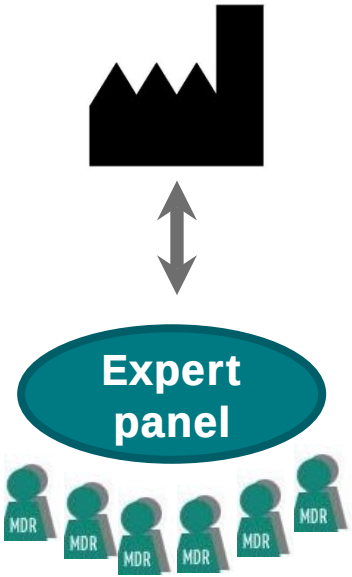

1. Manufacturer compiles technical documentation (including clinical evaluation and PMS / PMCF Plan)

1a. As part of above process, manufacturer may consult expert panel for comment on its clinical development strategy and proposals for clinical investigation (Article 61(2))

1b. Article (Article 61(4)) “In the case of implantable and Class III devices, clinical investigations shall be performed, except if…”

1c. Common Specifications (Article 9) may eventually apply, particularly with respect to requirements for safety and performance, technical documentation, clinical evaluation, PMCF, and clinical investigation

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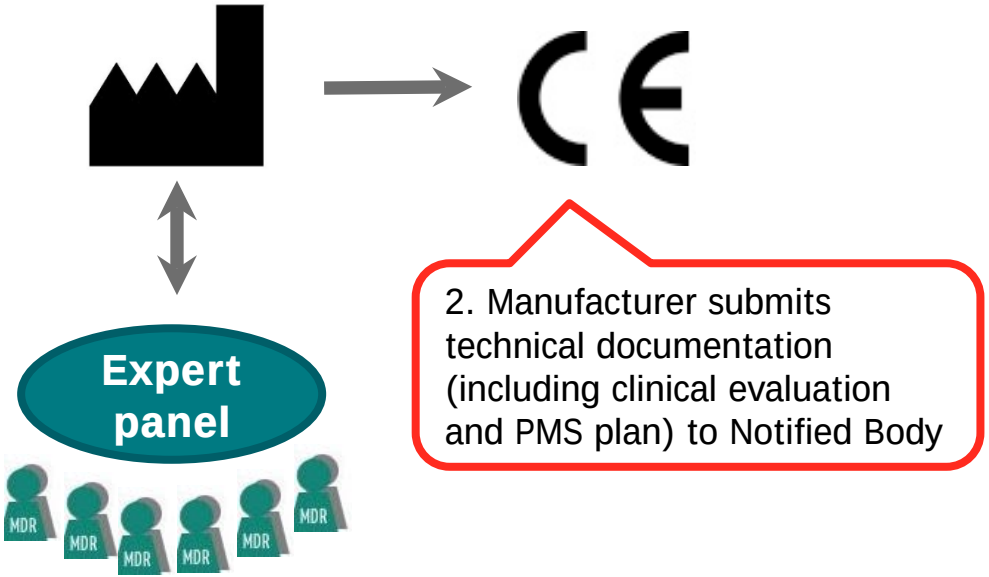

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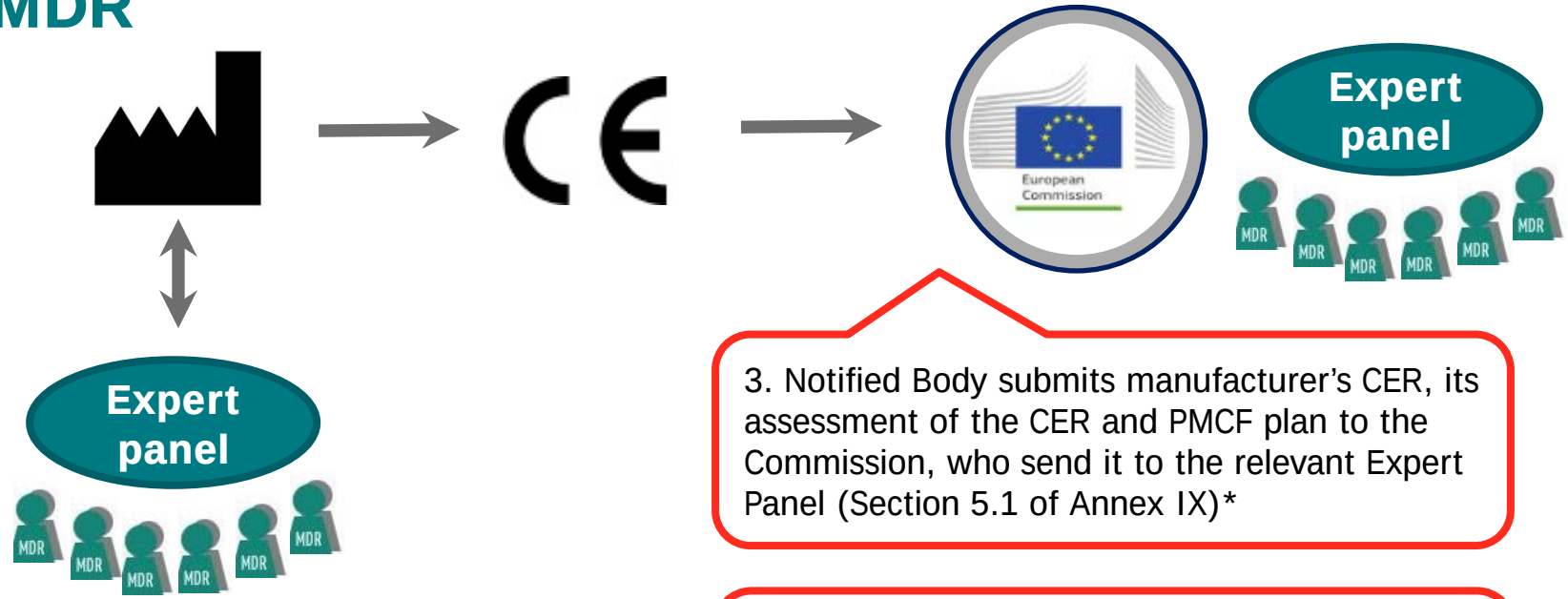

3. Notified Body submits manufacturer's CER, its assessment of the CER and PMCF plan to the Commission, who send it to the relevant Expert Panel (Section 5.1 of Annex IX)*

*note: this consultation will not apply to renewals, design modifications not considered to adversely affect the benefit-risk ratio, or for which a clinical CS exists and has been applied

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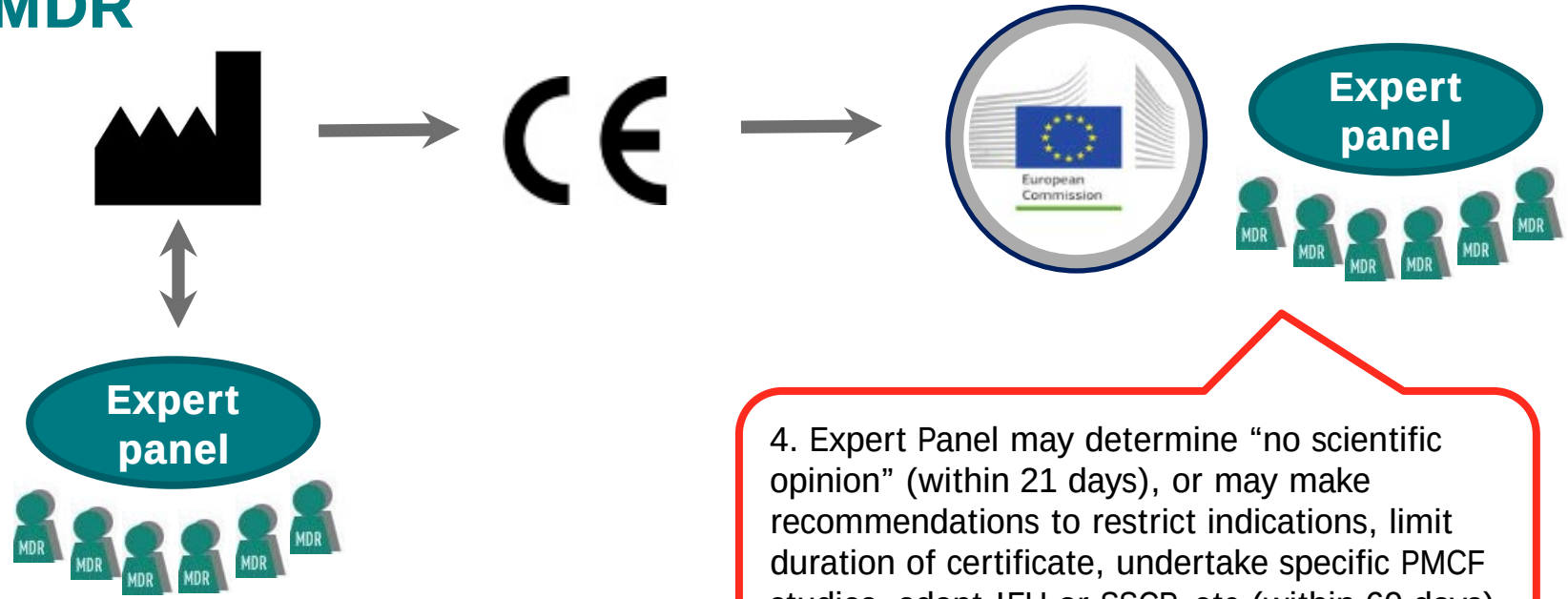

4. Expert Panel may determine “no scientific opinion” (within 21 days), or may make recommendations to restrict indications, limit duration of certificate, undertake specific PMCF studies, adapt IFU or SSCP, etc (within 60 days)

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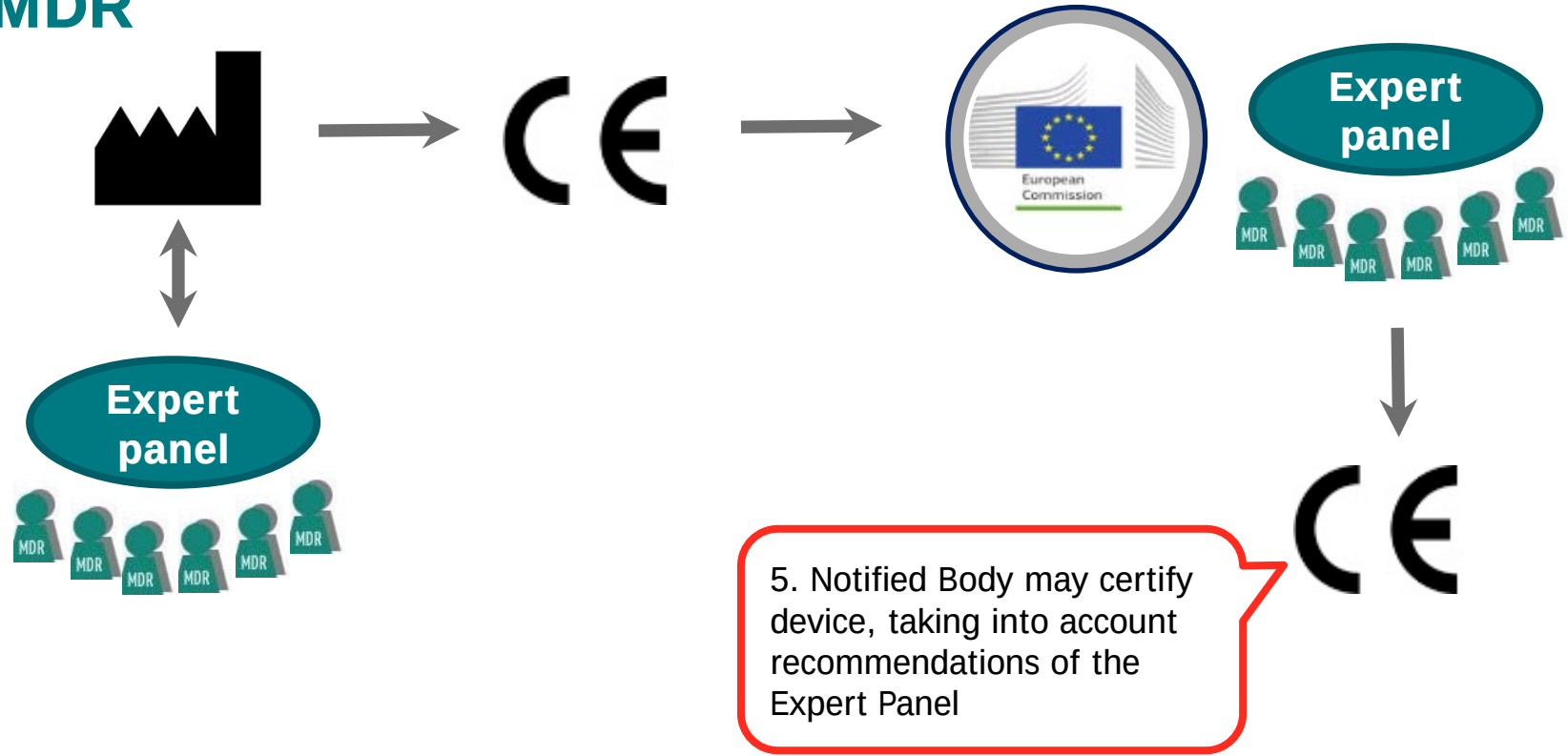

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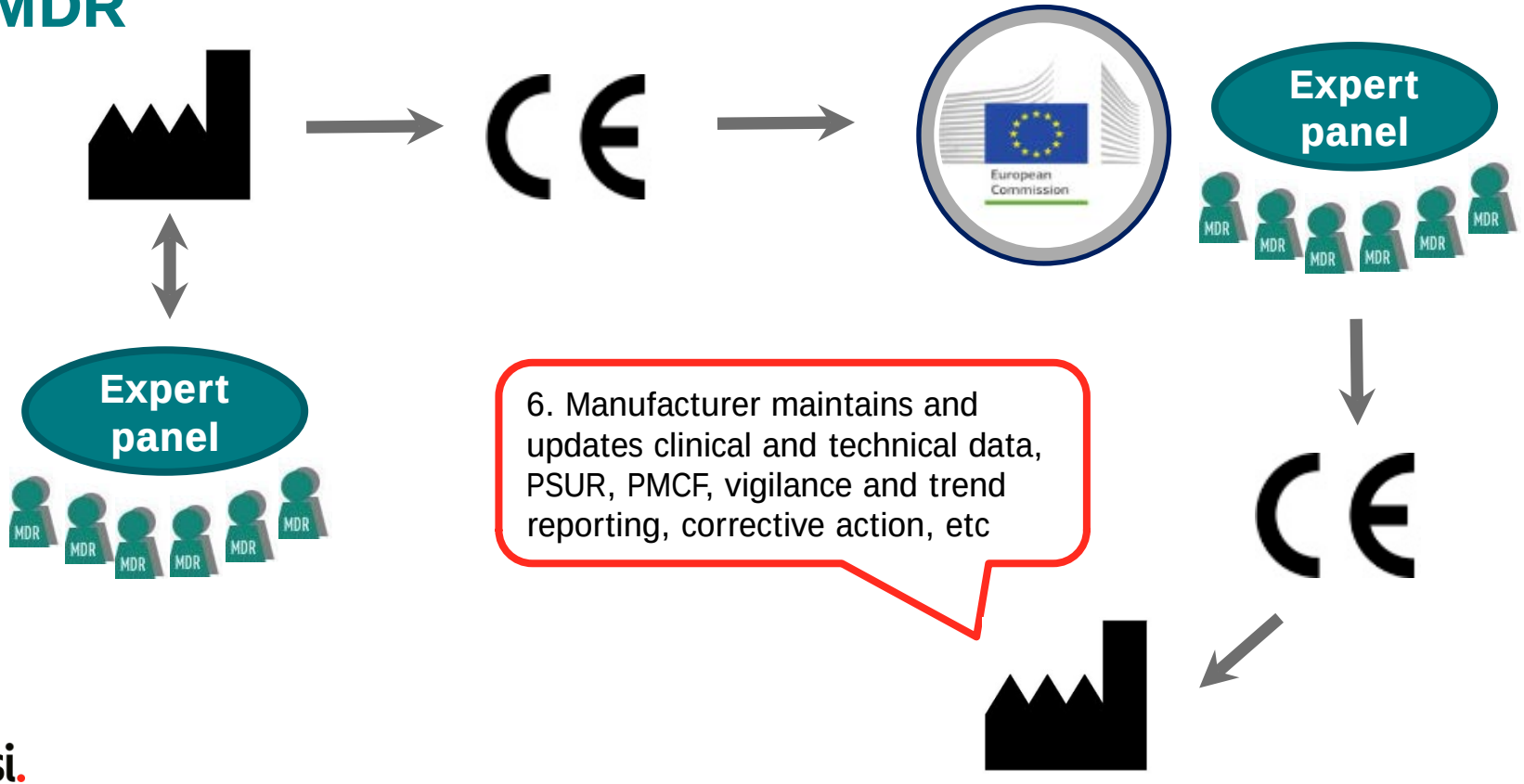

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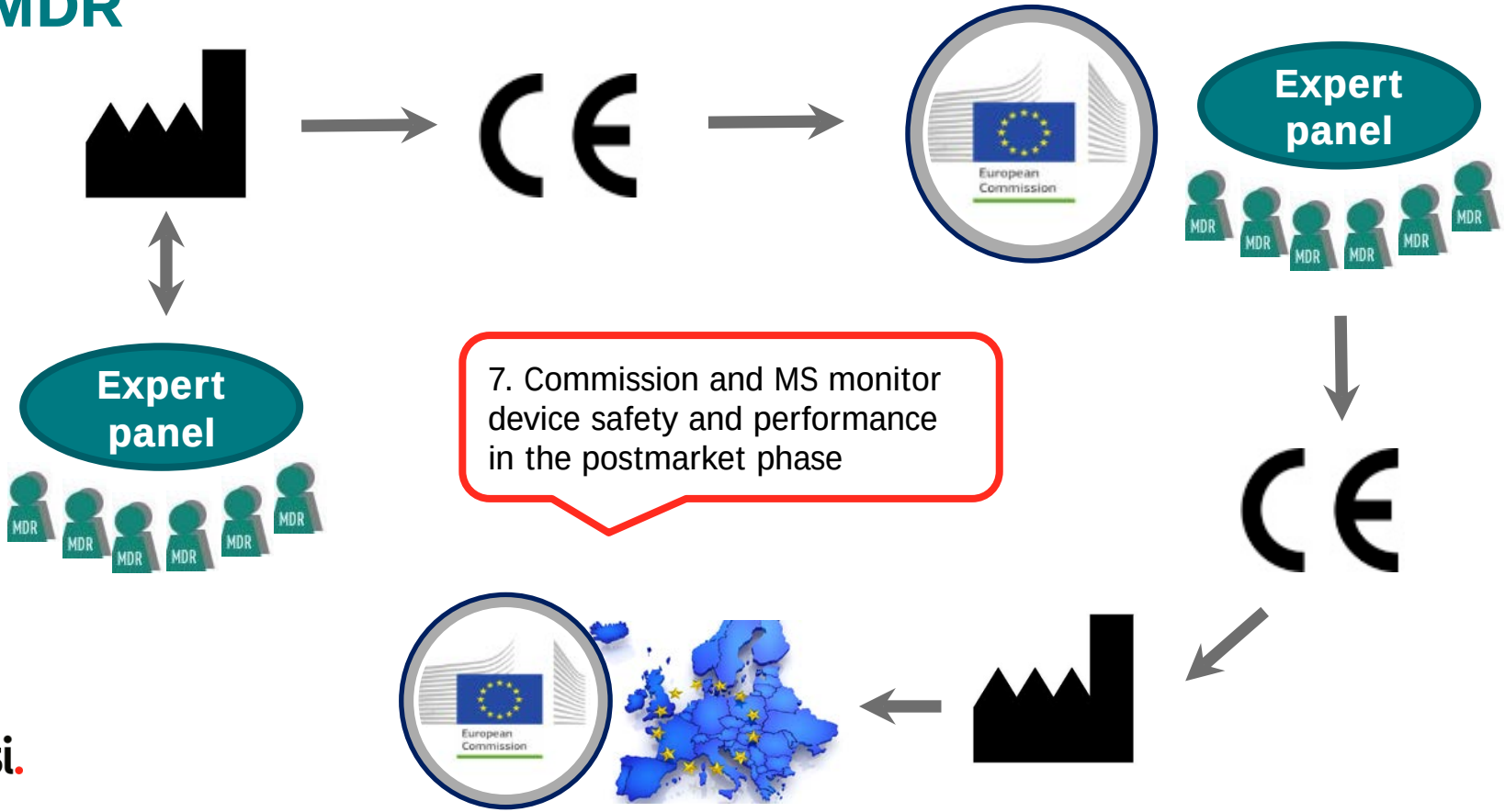

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Input of NORE & related groups to MDR

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- MDCG subgroups
- Experts panels
- Development of Common Specifications (particularly safety, performance, PMCF)
- PMCF mechanism and monitoring

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