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Slots/Windows of Opportunities HTA – Medical Devices

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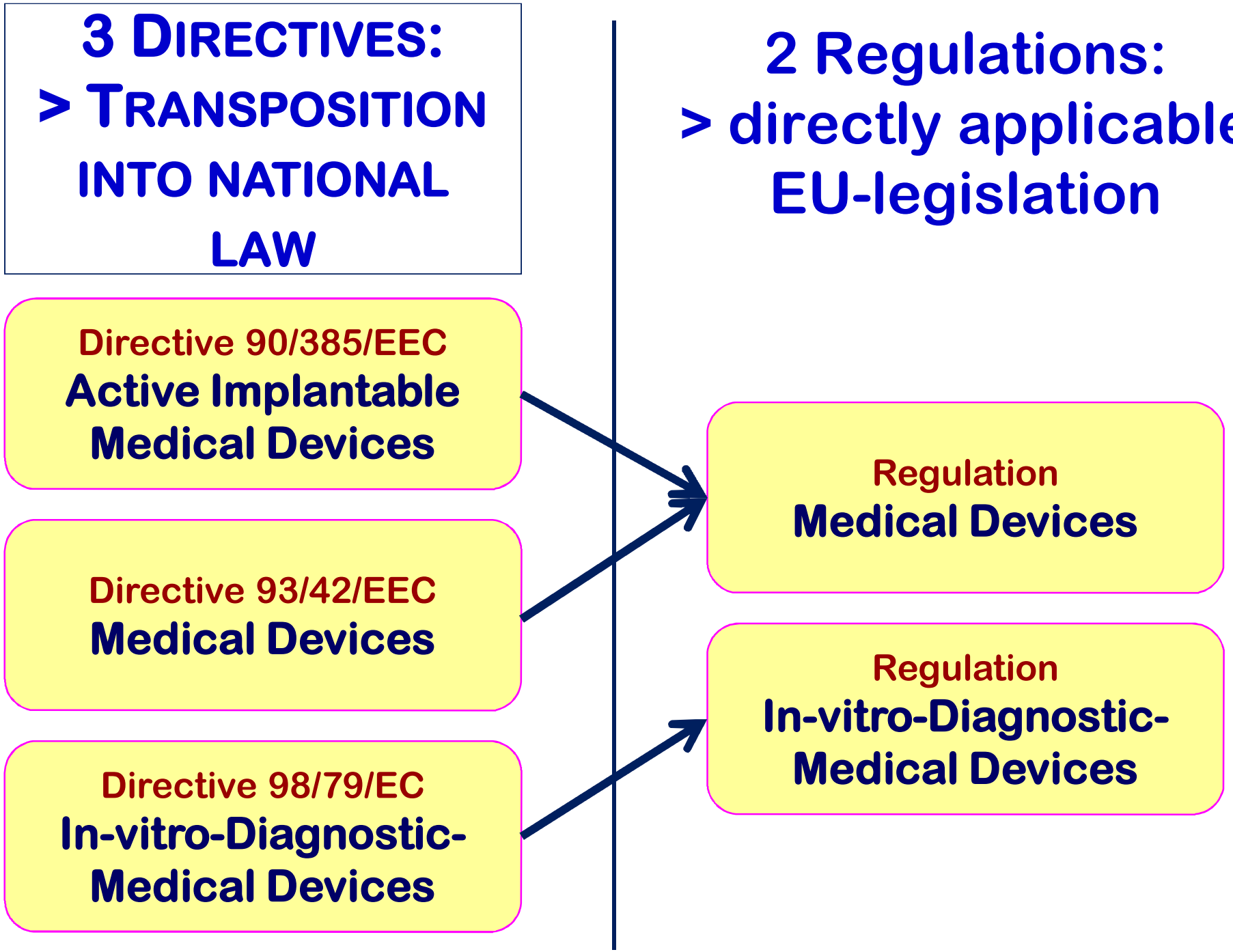
3 DIRECTIVES:
> TRANSPOSITION INTO NATIONAL LAW
2 Regulations:
> directly applicable EU-legislation
Directive 90/385/EEC
Active Implantable Medical Devices
Directive 93/42/EEC
Medical Devices
Directive 98/79/EC
In-vitro-Diagnostic-Medical Devices
Regulation
Medical Devices
Regulation
In-vitro-Diagnostic-Medical Devices

MD - Progress on Clinicals

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Considerable improvement in Clinicals expected:

- Notified Bodies – better clinical qualification
- **Notified Bodies** under better EU-scrutiny
- **Scrutiny procedure** (pre-/post-market?)
- **Clinical Evaluation (MD)** – Life cycle process
- **Performance Evaluation (IVD)** – better defined process
- **Scientific infrastructure**: Device/expert Panels; RefLabs
- Long term: Registries, PMCF, PMPF
- Better clinical transparency

But: Still weakness in terminology! (Efficacy? Effectiveness?)

HTA – MD Interaction: Governance

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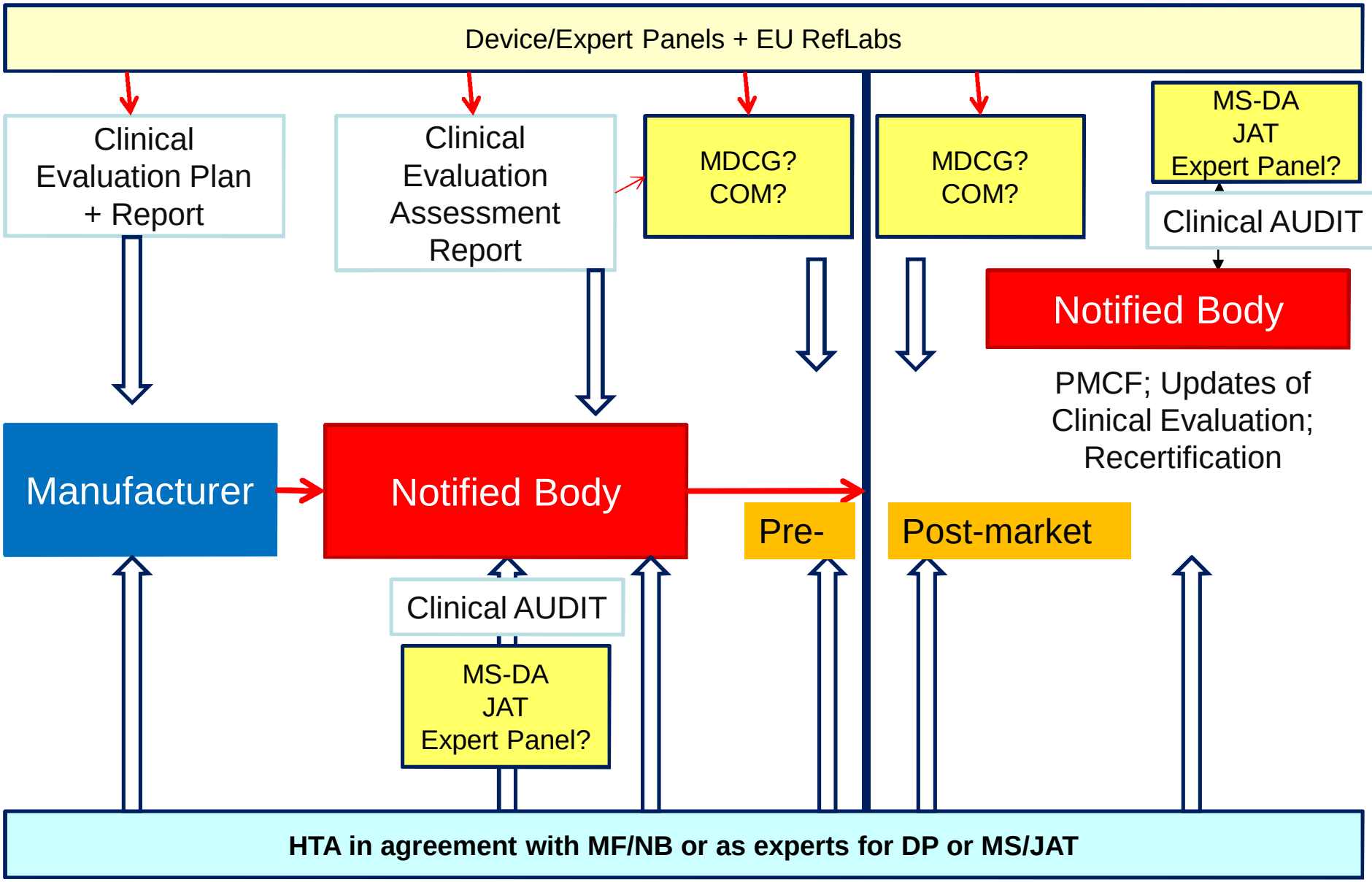
HTA to serve as experts for Expert/Device Panels and/or for MS, MDCG, JAT:

- **Device/Expert Panels**
- **MS Competent and Designating Authorities**
- **MD Coordinating Comittee (MDCG)**
- **Joint Assessment Team (JAT)**
- **(EU Reference Labs for IVDs?)**
- **Device Registry evaluations**

Scrutiny Discussion: pre-/post market?



HTA – MD Interaction: Guidance

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HTA as part of Expert/Device Panels could contribute to Guidance for specific device types:

- **Common Specifications (CS)**:
  - Clinical Investigations
  - Clinical Evaluation
  - Post Market Follow-up (PMCF)
- **Summary of Safety and Clinical Performance Data (SSPD) Templates**
- Harmonised Standards?

HTA – MD Interaction: Training

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HTA to cooperate on web-based training for MD-stakeholders

- **Literature reviews**
- **Grading quality of clinical investigations**
- **Current state of the art in medicine (HTA, EBM)**

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Thank You!