EU revision of Medical Device and In Vitro Diagnostic Medical Device Directives

MedTech Europe, EDMA and Eucomed's views

www.medtecheurope.org

MedTech Europe
from diagnosis to cure

MedTech Europe
from diagnosis to cure

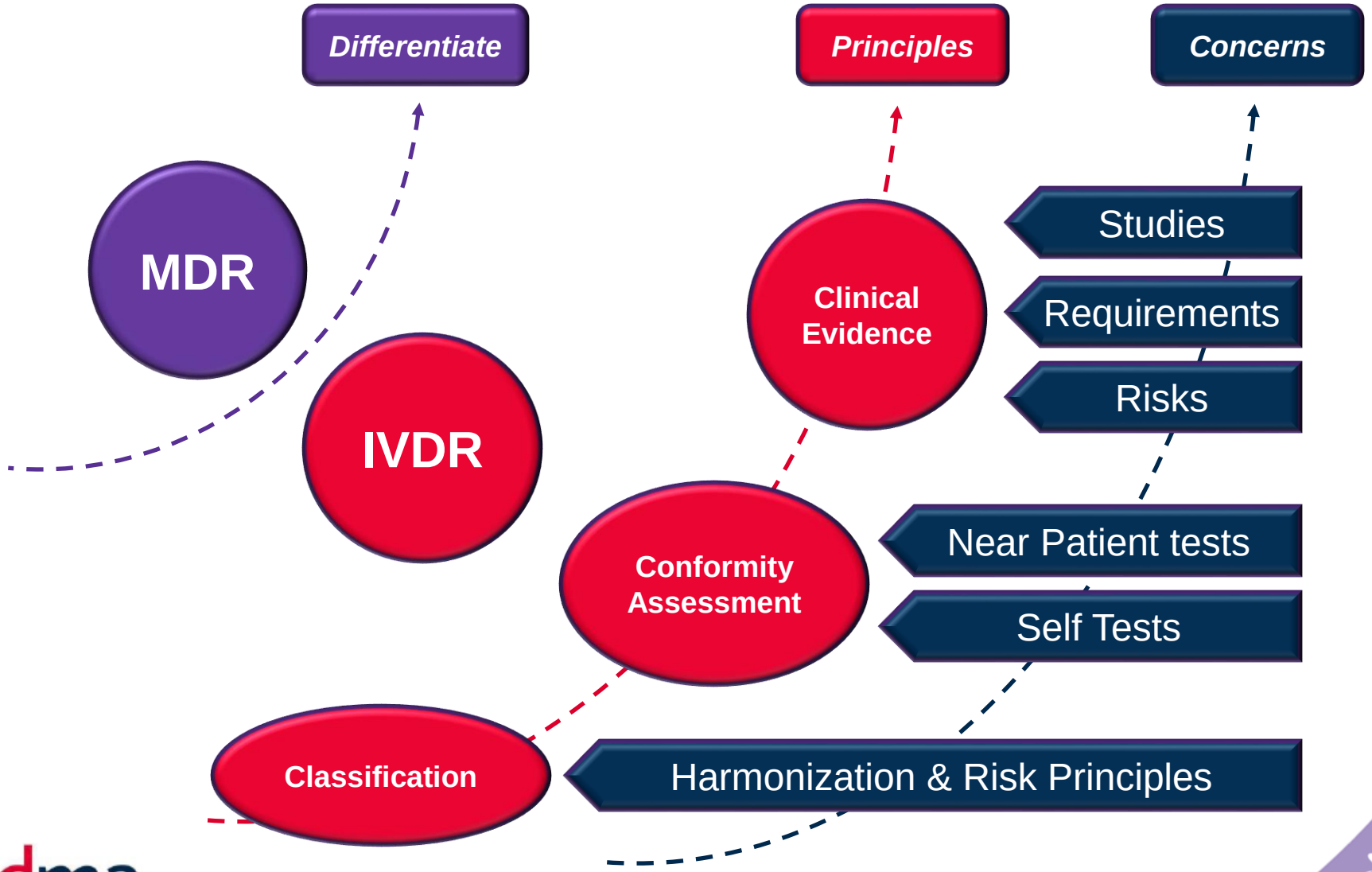
MedTech Europe, an alliance of EDMA and Eucomed

MedTech Europe

- Represent the Medical Technology industry and its various segments' interest at the European level.
- Promote the value and contribution of Medical Technologies.
- Contribute to balanced EU general and specific policies to make value based, innovative medical technology available to more people from diagnosis to cure.
- Support the transformation of healthcare systems onto a sustainable path.

Medtech Europe is an alliance of European medical technology industry associations. the alliance was founded by EDMA, representing the European in vitro diagnostic industry, and Eucomed, representing the European medical devices industry.

IVD Regulation



Scrutiny

Elements of the proposals:

- **Scope and exceptions**
- **Mechanism**
- **Entity responsible for scrutiny**
- **Nature of scrutiny (what elements to be scrutinised?)**
- **Timelines**

Scrutiny – Industry position

- **Maximum predictability & legal certainty**
- **Complete logical exclusions**
- **Provision to review scrutiny usefulness**
- **‘Scrutinisers’ should work together and in parallel with Notified Body and not after**
- **Incentivise early scientific advice process**
- **Add implementing act for efficient governance of the system**

Single-use devices

What is on the table:

- **Commission: Reprocessor = Manufacturer; Hospital partial exemption**
- **European Parliament: All products reprocessable; Manufacturers to justify if not possible; Reprocessor exempted from some rules**
- **Council: Banned unless allowed; Reprocessing = manufacturing via harmonised rules; Hospital partial exemption**

Industry position:

- ***Reprocessor = Manufacturer***
- ***Hospitals and subcontractors appropriately covered***

Hazardous substances

What is on the table:

- **Commission: Information to users on presence of phthalates**
- **European Parliament: Restrict the use of substances and introduction of a 4-year derogation process**
- **Council: Information to users on presence of CMRs 1A, 1B and EDCs**

Industry position:

- ***A ban is disproportionate and unnecessary***
- ***No heavy derogation process***
- ***We support labelling which follows a risk-based approach***
- ***We support an independent scientific process for the identification and eventual restriction of substances***

Any Questions