Impact on Industry of the New Medical Device Regulation (MDR)

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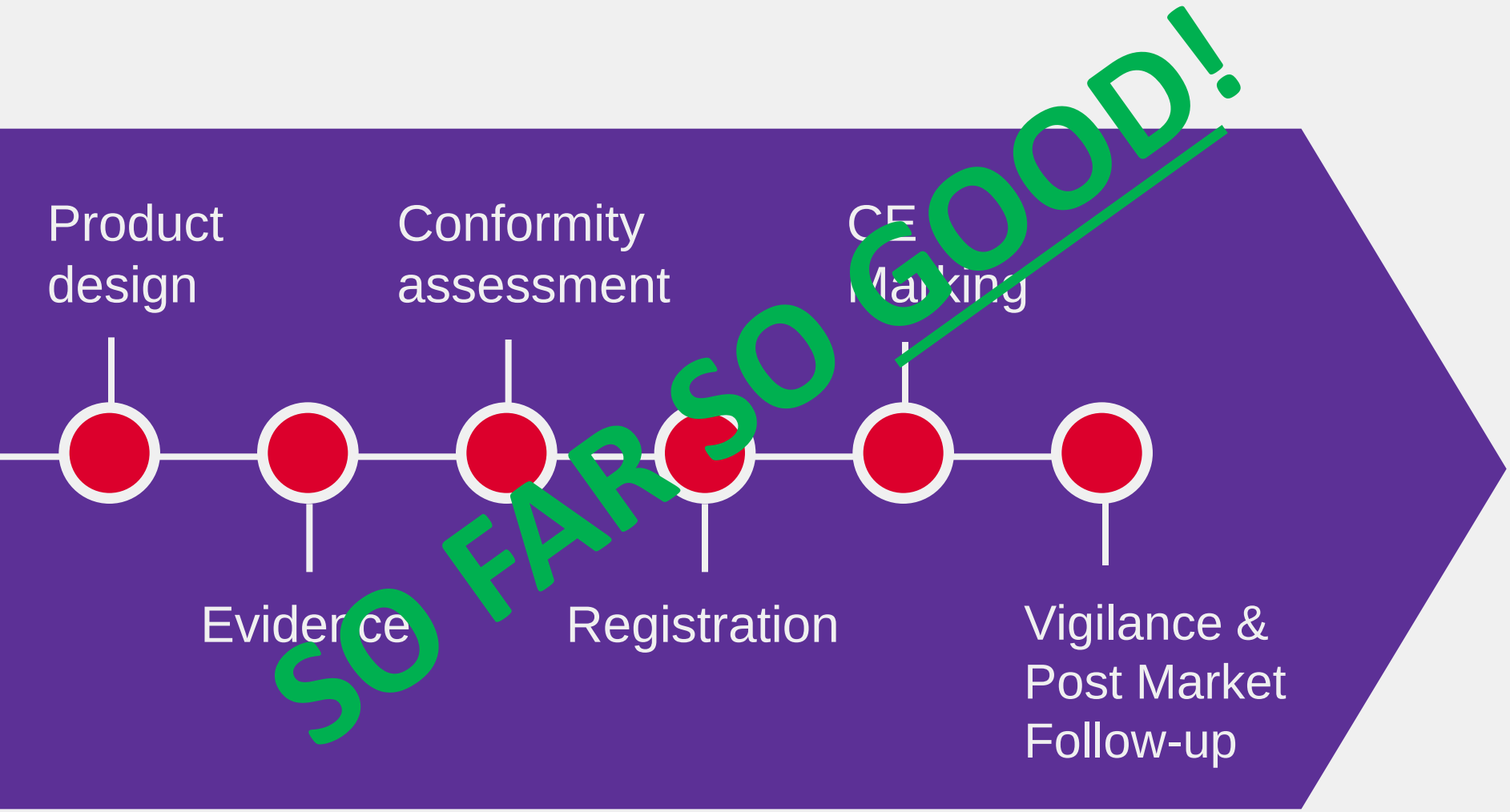
from diagnosis to cure

MDR: Same Basic Regulatory Process



A Modernised, Strengthened System

High Risk Devices

- **Up-classification** of joint or spinal disc replacements, or devices in contact with the spinal column or central circulatory system
- **'Scrutiny' process:** Extra time to market?

Notified Bodies

- **Stricter:** Especially on clinical evidence
- **Availability**: Concerns over timing
- **Capacity**: (serious) concerns in general

Clinical Evidence

- **Clinical data**: Greater need for clinical investigations and clinical data transparency
- **Clinical investigations**: Dedicated EU rules

...and many more

- **Eudamed database**: Central data submission
- **Documentation**: Stricter requirements
- **Labelling & IFUs**: Modifications needed
- **Reprocessing** of single use devices regulated

NO GRANDFATHERING...

Key Industry Impacts: Examples

1) Labelling

- New labels and user manuals
- Implant cards, plus online info
- Unique identifier barcodes (UDI)
- Certain hazardous chemicals named on device or its packaging

2) Post-market Surveillance

- Periodic safety update reports
- Periodic summary & trend reports
- Shorter reporting times for serious incidents: 15 days max. (versus 30)
- Granular reporting nomenclature

3) Eudamed Database

- Registration of companies, devices, UDI, certificates, etc.
- Strengthened data transparency
- Regular checks and updates of submitted information

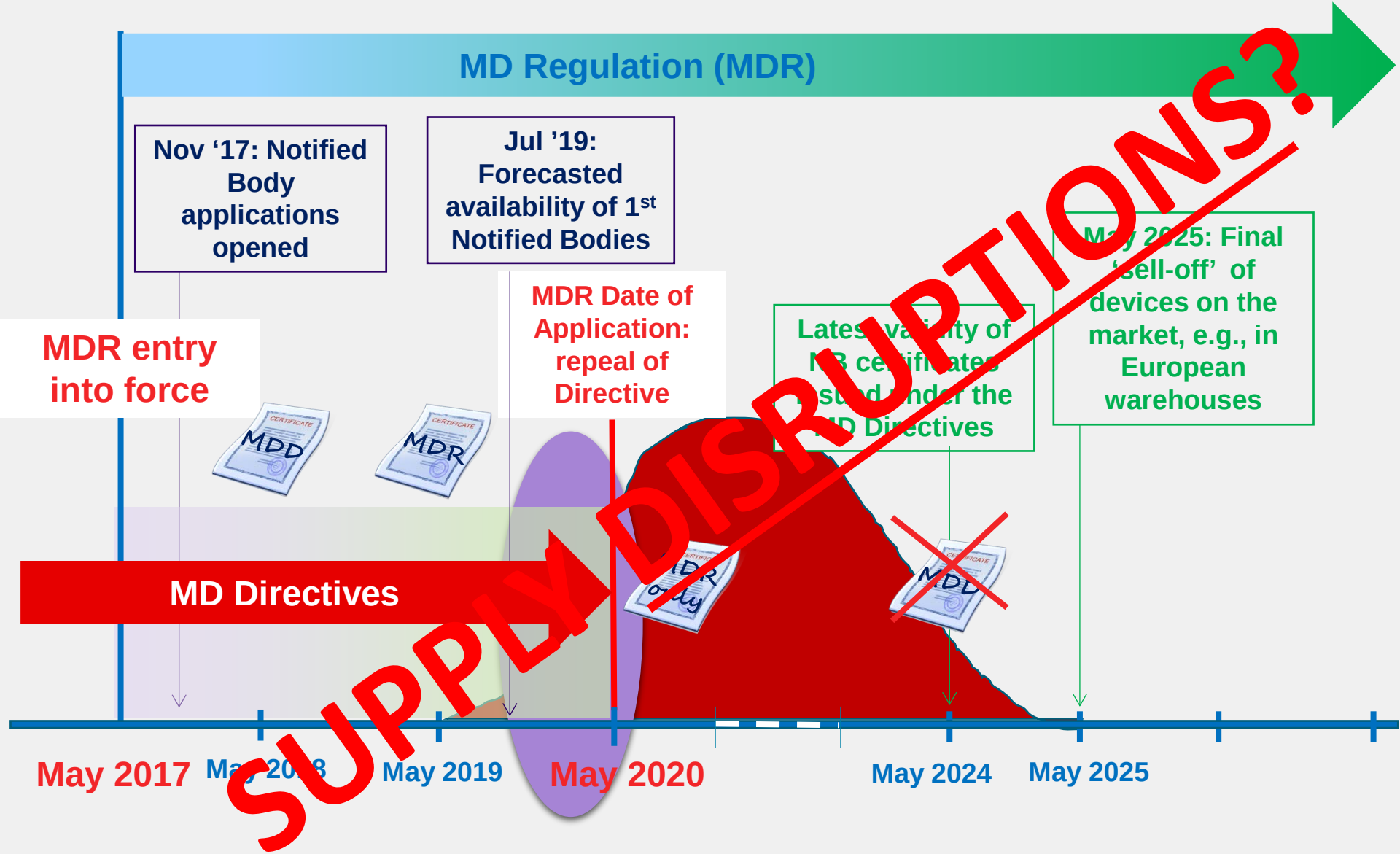
3) Clinical Evidence

- Public, annually-updated summary of the clinical evaluation (SSCP)
- Product-specific clinical rules (common specifications)
- Mandatory pre-market studies for high risk devices and implants

MORE INFORMATION

BUT AT A COST…

2019: A Crucial Year for MDR Transition



Clinical Evaluation across the Lifecycle

(44) 'clinical evaluation' means a systematic and planned process to continuously generate, collect, analyse and assess the clinical data pertaining to a device in order to verify the safety and performance, including clinical benefits, of the device when used as intended by the manufacturer;

(48) 'clinical data' means information concerning safety or performance that is generated from the use of a device and is sourced from the following:

— clinical investigation(s) of the device concerned,

— clinical investigation(s) or other studies reported in scientific literature, of a device for which equivalence to the device in question can be demonstrated,

— reports published in peer reviewed scientific literature on other clinical experience of either the device in question or a device for which equivalence to the device in question can be demonstrated,

— clinically relevant information coming from post-market surveillance, in particular the post-market clinical follow-up;

POST-MARKET CLINICAL FOLLOW-UP

PMCF shall be understood to be a continuous process that updates the clinical evaluation referred to in Article 61 and Part A of this Annex and shall be addressed in the manufacturer's post-market surveillance plan. When conducting PMCF, the manufacturer shall proactively collect and evaluate clinical data from the use in or on humans of a device which bears the CE marking and is placed on the market or put into service within its intended purpose as referred to in the relevant conformity assessment procedure, with the aim of confirming the safety and performance throughout the expected lifetime of the device, of ensuring the continued acceptability of identified risks and of detecting emerging risks on the basis of factual evidence.

ROLE OF POST-MARKET DATA + REGISTRIES?

Final Thoughts

1. **MDR promises certain benefits**
   - **Stricter rules** and greater emphasis on clinical data
   - **Transparent information** both online and on paper

2. **But compliance costs more than before**
   - **Existing products**: Several may be retired
   - **New innovations**: Longer time to market?

3. **So let's be practical**
   - **Bureaucracy**: Doesn't necessarily improve safety
   - **Real-world data**: Numerous kinds can have merit (and thus deserve recognition as clinical evidence)

Thank you for your time