EU MDR and its effect on the device supply (perspective of the notified body)

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Disclosure

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I have the following potential conflicts of interest to report:

- Consulting
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

☒ I do not have any potential conflict of interest
Agenda

– Will the curtain fall May 27, 2020?

– It is all around clinical data...
The MDR from May 27, 2020

The number of Notified Bodies reduced significantly while the work load per certification increased.

Both MDR and IVDR are up classifying products. Companies that never worked with Notified Bodies now have to prepare regulatory dossiers AND…find a Notified Body with time to help them.

EU agreed that initial MDR rule, no transition period for Class I reusable and up classified Class I devices, was not sustainable.

It remains questionable if the (late) adaptation of the regulations will help with potential negative impact of availability of those classes of devices.
The transition period of 4 years is helping to spread the work, however staying on MDD also has consequences.

Article 120 “By way of derogation…a device with a certificate that was issued in accordance with Directive 90/385/EEC or Directive 93/42/EEC…may only be placed on the market … provided there are no significant changes in the design and intended purpose.”
Some common examples of changes that may be considered significant:

- Extension of the intended purpose
- Targeting new user or patient populations
- Changing materials or ingredients of animal or human origin
- Changes that:
  - Affect safety and/or performance
  - Affect usability of the device
  - Require more clinical and usability data
  - Introduce new hazards
- Change to key suppliers
- Change to sterilization method or packaging that may impact sterilization

- Change in company ownership
- Extension to manufacturing and/or design control
- New facility or line modification/relocation
- Significant modifications to special processes
- Change in authority of the management representative
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Medical devices with MDD certificate will not receive significant changes.

Devices with unintended significant changes (example mandatory change vendor, move of manufacturing) could be taken off the market.
Going for MDR, impact on clinical evaluation

What kind, how much, data will I need?
Is my data (still) good enough?
Clinical Requirements

The requirements for Clinical Evaluation and Clinical Investigations are given in:

- Chapter VI Clinical Evaluation and Clinical Investigations (Articles 61-82)
- Annex XIV Clinical Evaluation and Post-Market Clinical Follow-Up (PMCFU)
- Annex XV Clinical Investigations
For any device, proportionate to the risk class and appropriate for the type of device, manufacturers shall plan, establish, document, implement, maintain and update a post-market surveillance system which shall be an integral part of the manufacturer’s quality management system according to Article 10(9).
Clinical Requirements

• How can the manufacturer obtain data on the use of the device?

• Non Active Devices ➔ Quality Registries, Customer Feedback like structured Surveys,

• Active Medical Devices ➔ Data from the devices use/framework (ICU)

• Software ➔ generate data by use

• All devices:
  – Discharge records
  – Hospital internal system
  – Payers (Sick Funds, AOK, Medicare)
Clinical Requirements

• Every Company/Device need it’s own solution

• Hospitals and healthcare providers MUST (be willing) collect device/patient data, Ethics Committees MUST accept “less scientific” studies/registries.

• Better access for the Industry in governmental databases.
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Information we receive from the field

- Many (old) devices will not be submitted for CE certification under MDR.
  - Unclear how clinical data can be collected
  - Scientific value studies minimal
  - Difficult to get investigators, unethical?

“we only have limited clinical budgets, we can either spend them on new products or on maintaining the old products on the market’
Summary

We see indications for the following:

• With the reduction of Notified Bodies and the additional MDR work the demand will significantly outgrow the supply.

• Devices on the market (with MDD Certificate) will not be updated on a regular basis as done until now.

• A risk that old devices will disappear from the market at the end of the transition period.

• **Not discussed but major impact could be on high risk devices MDD approvals based on clinical equivalence from third party device.**
Thank you for your attention