26
de maio

Implementação MDR/IVDR

MDR and IVDR implementation RAAR 2021

Apontamentos RAAR 2021

Reunião Anual do Colégio de
Assuntos Regulamentares

ORGANIZAÇÃO

OLÉGIO de ESPECIALIDADE ASSUNTOS REGULAMENTARES

ORDEM DOS FARMACÊUTICOS 1835

Implementação MDR/IVDR

Agenda

1. Introduction: The changing landscape of medical devices

2. The MDR and the IVDR: Background and main objectives
    1. Why new regulations?
    2. What do they do?

3. Experiences with Covid-19

4. Limitations to the new regulations

5. Two systems coming together

Thomas Wejs Møller

Resumé:

- Head of Medical Devices Unit in the Danish Medicines Agency
- Chair of the competent authorities (CAMD)

Agenda

1. Introduction: The changing landscape of medical devices

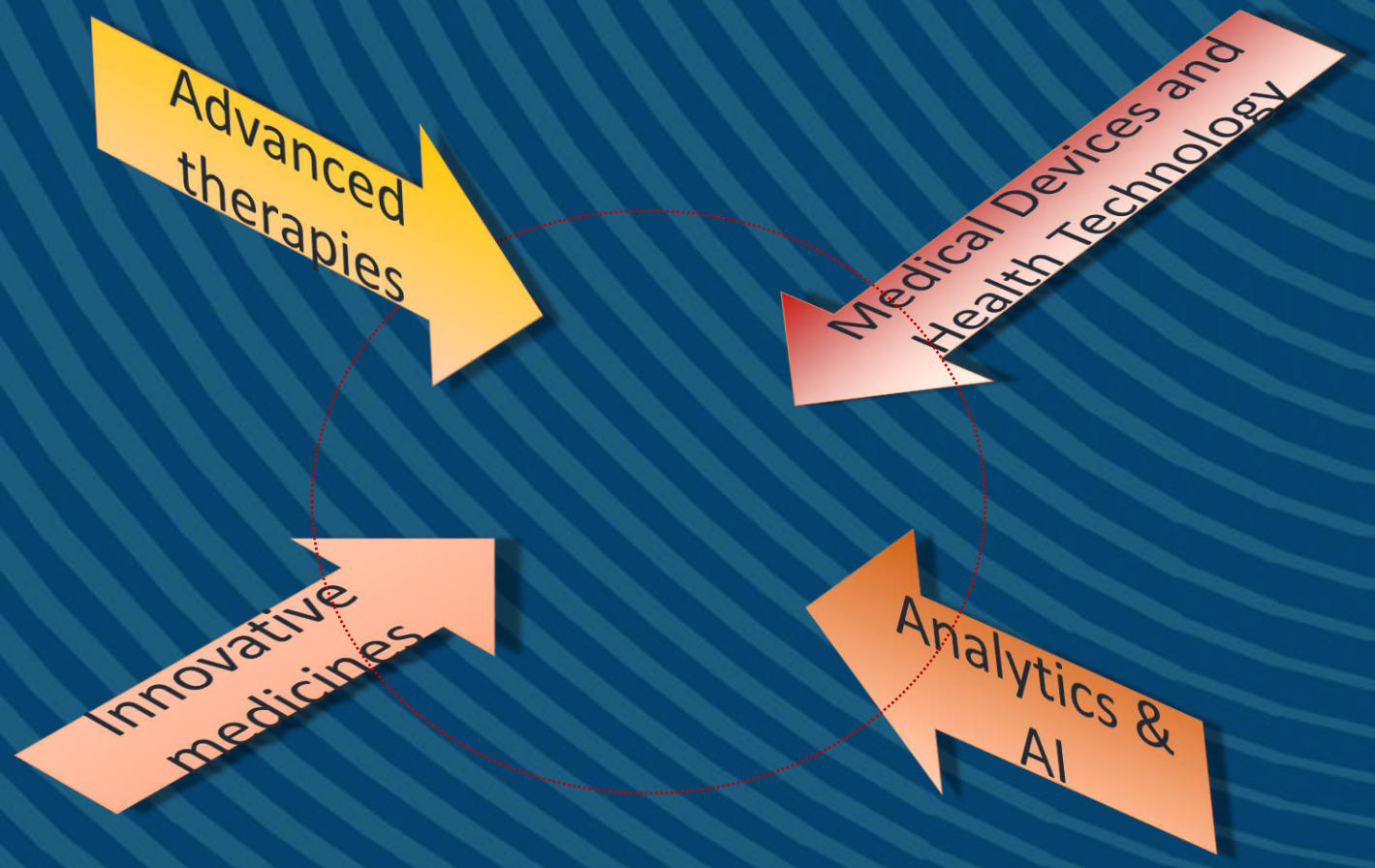
2. The MDR and the IVDR: Background and main objectives
   1. Why new regulations?
   2. What do they do?

3. Experiences with Covid-19

4. Limitations to the new regulations

5. Two systems coming together

1. The changing landscape of medical devices



Agenda

1. Introduction: The changing landscape of medical devices

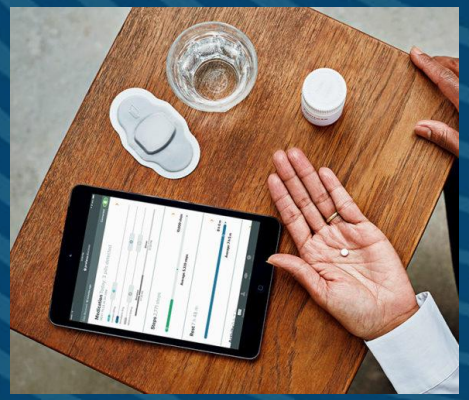
2. The MDR and the IVDR: Background and main objectives
   1. Why new regulations?
   2. What do they do?

3. Experiences with Covid-19

4. Limitations to the new regulations

5. Two systems coming together

1. The changing landscape of medical devices



Agenda

1. Introduction: The changing landscape of medical devices

2. The MDR and the IVDR: Background and main objectives
   1. Why new regulations?
   2. What do they do?

3. Experiences with Covid-19

4. Limitations to the new regulations

5. Two systems coming together

2.1 MDR and IVDR: Why the new regulations?

Boneloc case – The Ministry of Health admit they made mistakes

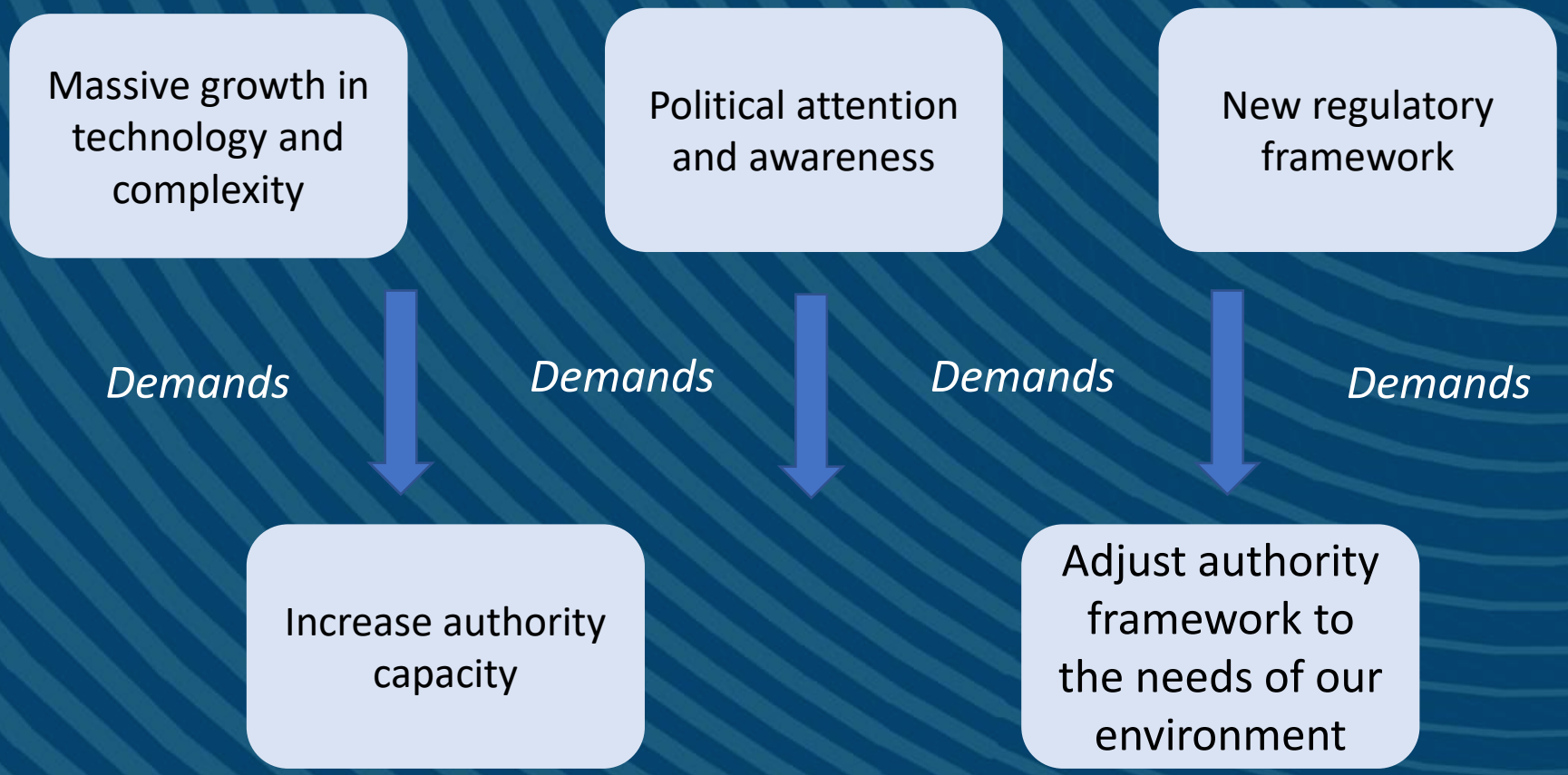
DR

PIP BREAST IMPLANT SCANDAL: A STORY THAT TRIGGERED CHANGE

Telegraph UK

Agenda

2.1 MDR and IVDR: Why the new regulations?



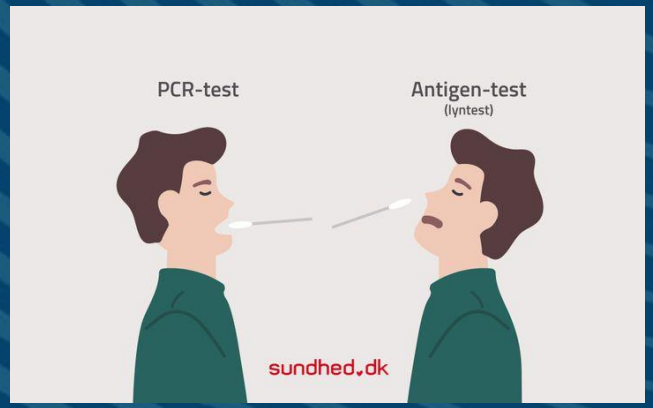
Agenda

2.2 MDR and IVDR: What do they do?

Patient safety and market access

Agenda

3. Experience with Covid-19



Agenda

1. Introduction: The changing landscape of medical devices

2. The MDR and the IVDR: Background and main objectives
   1. Why new regulations?
   2. What do they do?

3. Experiences with Covid-19

4. Limitations to the new regulations

5. Two systems coming together

4. Limitations to the new regulations

Medical Devices system is:

- Patient Safety
- A surveillance system
- The regulatory size: 10 % of pharma*
- Fully distributed system
- Only focused on access to market
- Free pricing**
- Asf.

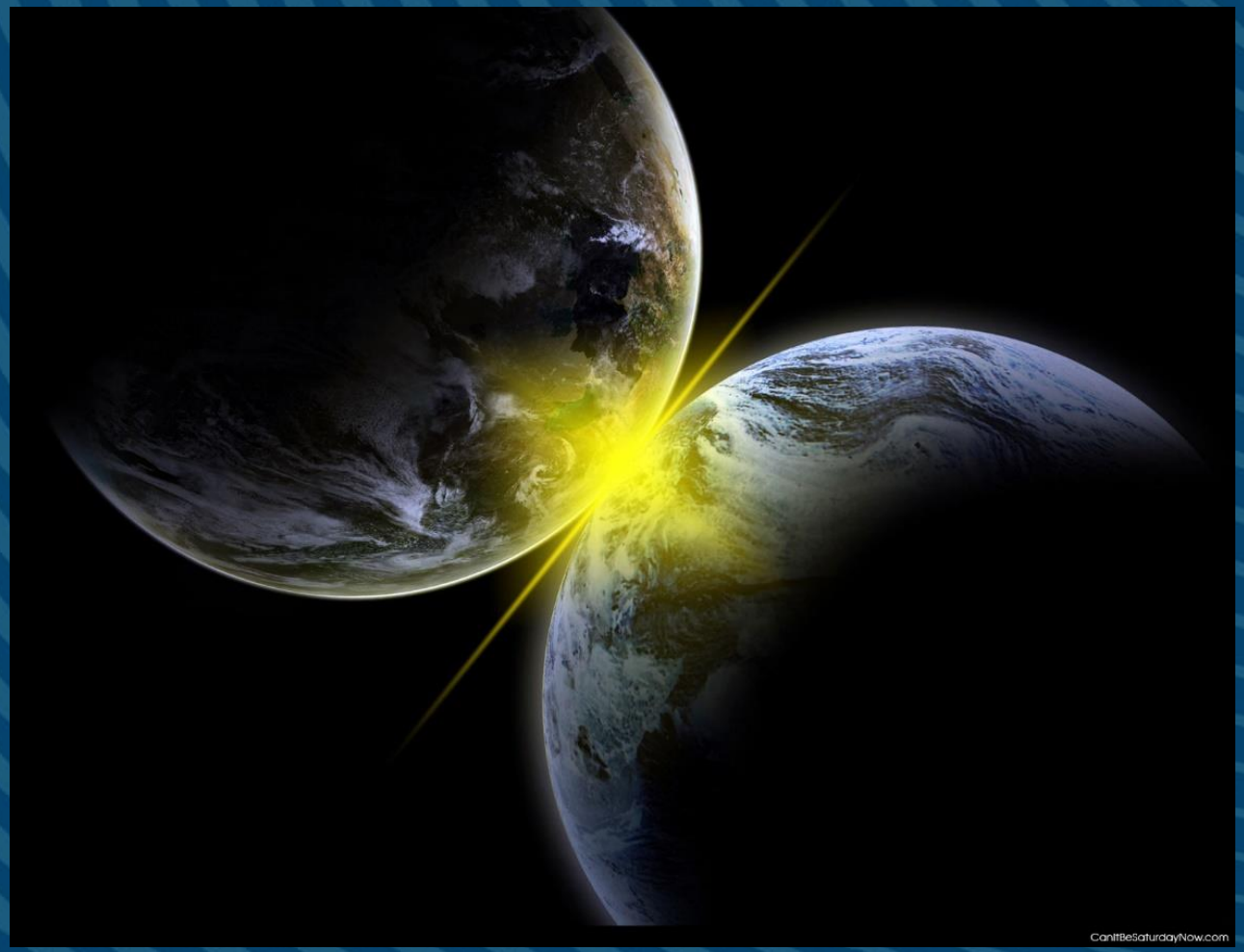
Pharma system is:

- Patient Safety
- An approval system
- 10 times the regulatory size of medical devices
- A large centralised agency
- Is responsible for supply
- Controlled pricing**
- Asf.

*NB as approval system
**Varies from country and product

Agenda

5. Two systems coming together



Agenda

Sum up and challenges ahead

a. Today it is a market driven accessibility of Medical Devices

b. Coordination, complexity and stringency vs. the need for regulatory flexibility. There is room in the regulations for flexibility nationally – but we need a harmonized Europe

c. If politicians need more accessibility – there is a need for more coordination and there is a lack of capacity in the system
   a. IVDR in 2022! Need for cooperation and more notified bodies

d. This is two systems coming together – an approval system and a marked surveillance system
   a. Need for cooperation between all stakeholders