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de maio

Implementação MDR/IVDR

MDR and IVDR implementation RAAR 2021

Apontamentos RAAR 2021

Reunião Anual do Colégio de
Assuntos Regulamentares

ORGANIZAÇÃO



COLÉGIO
de ESPECIALIDADE
ASSUNTOS
REGULAMENTARES





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)

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1. The changing landscape of medical devices



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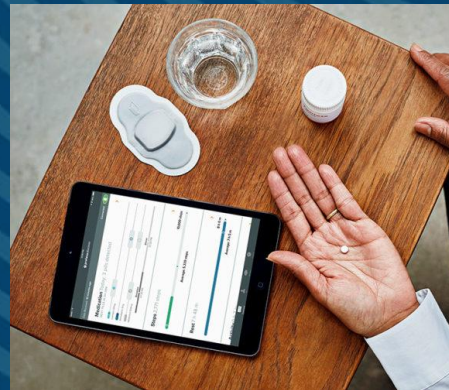
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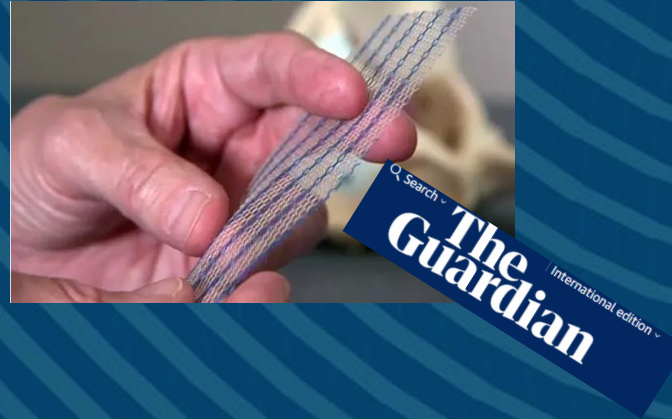
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2.1 MDR and IVDR: Why the new regulations?

Boneloc case – The Ministry of Health admit they made mistakes



PIP BREAST IMPLANT SCANDAL: A STORY THAT TRIGGERED CHANGE

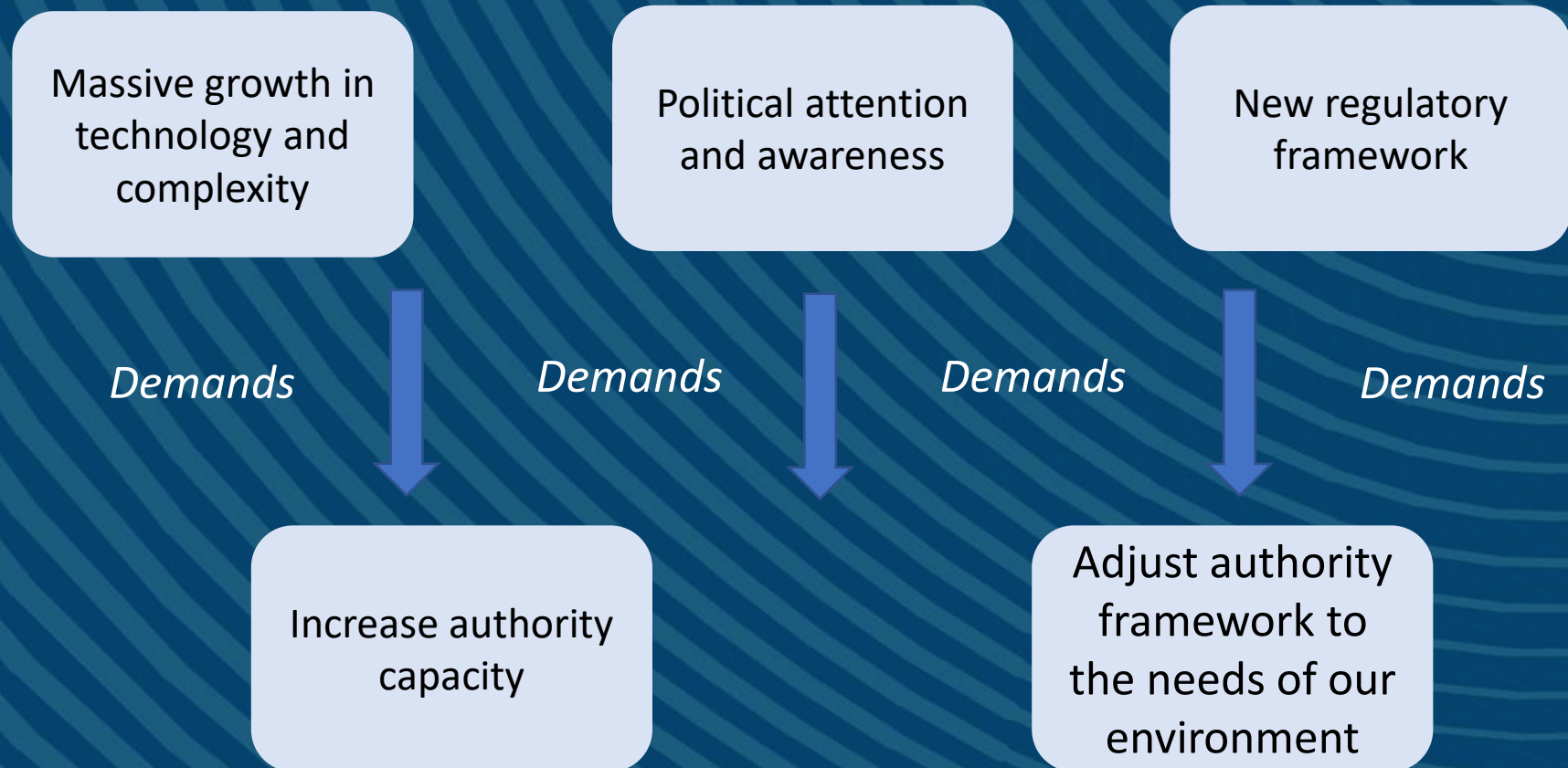
Telegraph UK



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2.1 MDR and IVDR: Why the new regulations?



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2.2 MDR and IVDR: What do they do?

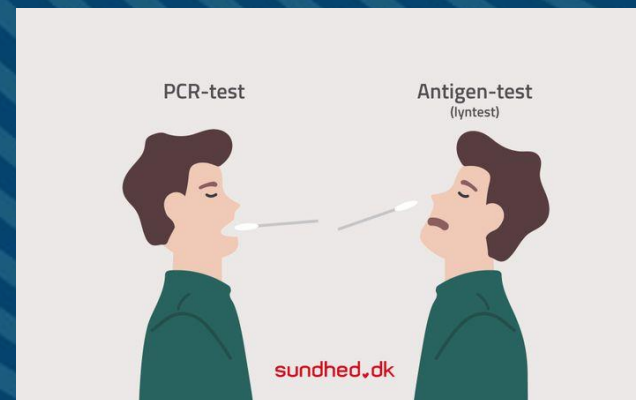
Patient safety and market access



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3. Experience with Covid-19



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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.



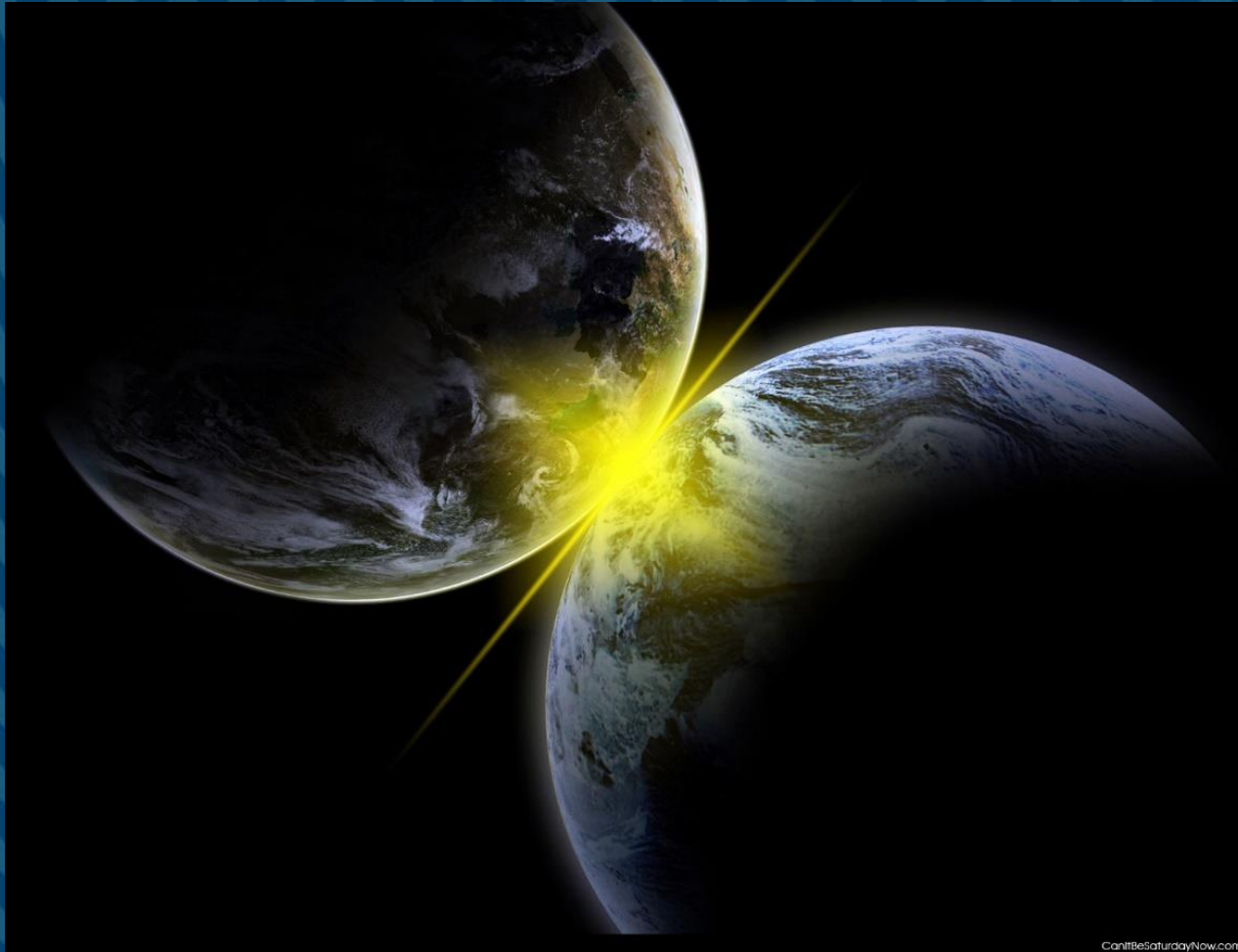
*NB as approval system

**Varies from country and product

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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

