Past and Present
From MDD to MDR

Edwin den Braber, PhD
How do you do?
Edwin den Braber

- Clinical Toxicologist
- Doctorate in Medicine - “Biomaterials, Implants, Wound Healing, and Tissue Engineering” (1997, NL/ USA)

Pharma...
- GW/ GSK - Medical Adviser, Product Manager
- AKZO Nobel/ Organon - Regional/ Global Medical Director, Clinical Development/ Life Cycle Management Leader, GMT member

...and Medical Devices
- Tyco Healthcare/ Covidien - VP Medical & Clinical Affairs
- Wright Medical - VP Compliance, Regulatory Affairs, Clinical Affairs, and QA

- GR Consulting, Alira Health - Partner
- Radboud University, NL
Going from MDD to MDR

Why is EWMA interested in MDR?

- Enforcement of MDR comes with new and additional challenges for (advanced) wound care.
- The HCP EWMA represents want to remain able to serve wound care patients optimally.
- Availability of a broad range of wound care therapies is indispensable to achieve this objective.
- Regulation which could limit availability of current, and hamper or stop the development of new wound care therapies could impact patient burden and quality of life significantly.

1. If desired, facilitate discussion platform of HCP and (regulatory) industry representatives on MDR;
2. Identify, discuss, and short list industry-wide common MDR wound care specific challenges;
3. Mediate discussion on MDR with relevant regulatory authorities in order to address short-listed wound care specific MDR challenges.
Medical Device Development
From idea to helping patients...

Class I   Class IIa    Class IIb   Class III

Source: Bundesverband Medizintechnologie, 02/2014
Going from MDD to MDR

Summarising...

IT’S A LOT!
Going from MDD to MDR

Summary changes

“It is a lot!”

- 123 articles, split into 10 chapters and 17 annexes.
- MMD + AIMD = 95 pages --- MDR = 566 pages (+ 590% !)

**Remarkable:** fundamental arrangements for regulation, put in place 25 years ago, are essentially unchanged.

Still have general requirements:
- Safety
- Performance
- Use of harmonised standards
- Risk based calculation
- Third party conformity assessment based on risk

Within familiar framework (much) more prescriptive requirements in almost every area.
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- It is possible speculate on many reasons...
- But...
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French breast implant chief wanted by Interpol

Jean-Claude Mas is the founder of PIP whose breast implants are at the centre of a global health scare

Interpol is seeking the arrest of Jean-Claude Mas, the founder of a French company whose breast implants are at the centre of a global health scare.

The international police agency has issued a red notice for Mas. His firm Poly Implant Protheses (PIP), which went into administration last year, supplied implants to tens of...
Going from MDD to MDR

Summary changes

**Why?**

- It is possible speculate on many reasons...
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*Image of The Guardian article on breast implant scandal*
Going from MDD to MDR

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Going from MDD to MDR

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Medical device industry: international investigation exposes lax regulation

Jeanne Lenzner, ICIJ reporters

The BMJ

The results of an international investigation tracking the harms of medical devices that have been tested inadequately or not at all are being released today. The investigation, called the Implant Files, was led by the Pulitzer prize winning International Consortium of Investigative Journalists (ICIJ) and conducted by 252 journalists from 36 countries representing 59 media partners, including The BMJ and UK partners BBC and the Guardian.

The investigation was inspired by a Dutch investigative journalist and broadcaster, jet Schouten, who led a sting operation by convincing the private companies called notified bodies that are responsible for assessing devices that mesh netting from a bag of mandarin oranges was surgical mesh. Schouten said that the results made her want an investigation into device approval around the world.

Over the course of the Implant Files investigation ICIJ and its partners filed more than 1500 public records requests and collected more than eight million device related health records. These included recall notices, safety warnings, legal documents, and corporate financial filings. More than 5.4 million “adverse event” reports sent to the US Food and Drug Administration over the past decade make up the greatest share of this trove. These reports came from doctors, manufacturers, patients, and even lawyers and described cases where a device was suspected

Nevertheless, ICIJ’s analysis, which included identifying some devices listed under hundreds of different brand names or spellings, gives an unprecedentedly comprehensive view of medical product safety.

The ICIJ has established a publicly searchable international Medical Device Database (https://medicaldevices.icij.org) that tracks faulty versions of medical devices across the globe for which there have been special warnings or alerts. A description of how and why the database was built is available on the ICIJ’s website (https://www.icij.org).

Deep dive investigations from the Implant Files will be released throughout the week on devices ranging from nerve stimulators and cardiac defibrillators to hip implants, transcutaneous aortic valve replacements, breast implants, surgical mesh, and Essure, a permanent implanted contraceptive, among other devices.

Reports released today include an investigation into the world’s largest medical device manufacturer, Medtronic, The BMJ and ICIJ investigations include an expose into how for reaching reforms to overhaul safety regulations for millions of patients with medical implants in Europe have been successfully dismantled by industry lobbyists.

A joint investigation between The BMJ, BBC Panorama, and the Guardian newspaper, released tomorrow, will highlight the lax

Other Collaborators:
Medical device industry: international investigation exposes lax regulation

Jeanne Lenzier, ICJ reporters

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The ICIJ has established a publicly searchable international Medical Device Database (http://medicaldevice.icij.org) that tracks faulty versions of medical devices across the globe and high-risk clusters. Many of these devices have been linked to patient deaths or serious harm.

The FDA is still letting doctors implant untested devices into our bodies

A proposed reform would exempt many of the most dangerous products from clinical trials.

Outlook Perspective

Many artificial hips would be grandfathered in. (Edward Olivo)

By Jeanne Lenzier and Shannon Brownlee

January 4, 2019
Going from MDD to MDR

Key Changes

**Notified Bodies**

- All NBs need to re-apply under stronger designation criteria (From 70 to 20!)
- Joint audits (3 member states and Commission), unannounced audits
- Strengthen oversight, multiple parties to ensure consistency and transparency
Going from MDD to MDR

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**Clinical Evidence**
- Less equivalence, more data for high risk devices
- Publish Safety and Performance data
- Post Market Clinical Follow-up (PMCF)

**Pre Market**
- Increased scrutiny for high risk devices
- Common Specifications
- Responsible person for manufacturers and Authorised Representatives (Qualified and Certified Personnel)
Going from MDD to MDR

Key Changes

**Post Market Surveillance and Vigilance**
- Central database and coordination
- Trend reporting
- Enforcement activities

**Transparency and Traceability**
- Devices and Economic Operators registered centrally
- Unique Device Identification (UDI), Implant Cards
- Summary of Safety and Clinical Performance (SSCP)

**Governance and Oversight**
- Medical Device Coordination Group (MDCG); advises EU Commission
- Expert Panel
- Expert Laboratories
“So is it all bad..?”

- Realistically: Medical Devices regulation adjustment was needed
- Pharma and Medical Devices draw closer together
- MRP now for also Medical Devices (EU, EFTA, MTA)
- Example: “Common Specifications (CS)”
Going from MDD to MDR
Moving Forward in Advanced Wound Care

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(71) ‘common specifications' (CS) means a set of technical and/or clinical requirements, other than a standard, that provides a means of complying with the legal obligations applicable to a device, process or system.
“So is it all bad..?”

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Without prejudice to Article 1(2) and 17(5) and the deadline laid down in those provisions, where no harmonised standards exist or where relevant harmonised standards are not sufficient, or where there is a need to address public health concerns, the Commission, after having consulted the MDCG, may, by means of implementing acts, adopt common specifications (CS) in respect of the general safety and performance requirements set out in Annex I, the technical documentation set out in Annexes II and III, the clinical evaluation and post-market clinical follow-up set out in Annex XIV or the requirements regarding clinical investigation set out in Annex XV. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).
Going from MDD to MDR
Moving Forward in Advanced Wound Care

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Translation: Mysterious documents to be drafted by the Commission to fill the gaps where there are no standards.

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**Article 9**

**Common specifications**

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“Approved devices will be grandfathered automatically into the new MDR without the need for renewed application, approval, clinical investigation, or documentation. Our market access and sales are secured by the CE our devices already have”.

- TRUE
- FALSE
**Transition Timelines MDR**

**Article 120**

- **25 May 2017**
  - MDR into force

- **26 May 2020**
  - MDR applies

- **27 May 2022**
  - Annex IV - 6 certs void

- **27 May 2024**
  - ALL MDD-AIMD certs void

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**NB designation under MDR**

- **26 May 2025**
  - No more devices on market with MDD/AIMD certs

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**MDR certificates**

- **Transition period (3 yrs)**
- **MDD/ AIMD certificates**

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**MDD/ AIMD grace period (4 yrs)**

- **ONLY IF** no significant changes in design and intended purpose. PMS, market surveillance, vigilance registration economic operators and devices according to MDR.

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**MDR certificates**

- **You are HERE...**
  - JAN 2019 - 1st MDR NB (BSI)

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**YOU ARE HERE...**

- JAN 2019 - 1st MDR NB (BSI)
Questions?

Advanced Wound Care and MDR

sk@ewma.org | edwin.denbraber@grconsultingglobal.com | www.grconsultingglobal.com