CORE-MD

Coordinating Research and Evidence for Medical Devices

Public Responsibilities of Notified Bodies

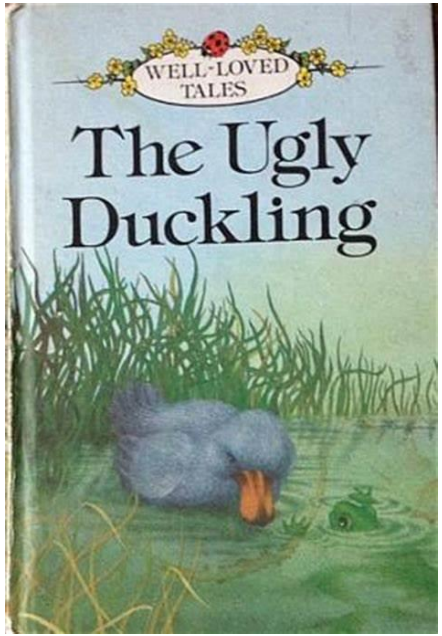
Sabina L. Hoekstra-van den Bosch

Introduction: fairy tale by H.C. Andersen

"The Ugly Duckling"

- Different (from the other ducklings)
- Not well understood (by mother duck and by the other ducklings)

Are notified bodies "The Ugly Duckling" of the medical device regulatory system?



Agenda

- What are notified bodies?
- Performance of global regulatory systems
- MDR as gamechanger
- CORE-MD & Team-NB
- Conclusion

What are notified bodies?

- Semi-public or private organisations
- Executing legal tasks for medical devices in mid- and high-risk classes *on behalf of the authorities*
  - decisions on market access (‘certification’)
  - certain post-market monitoring tasks
- Mandated (‘designated’) by and under strict control of authorities
- Employing a vast array of experts in very diverse areas
- Fulfilling extensive legal requirements on
  - Training and authorization
  - Independence and impartiality

Vast amount of technical/scientific expertise

MDR Annex VII 3.2.5

The personnel responsible for carrying out product-related reviews (product reviewers), such as technical documentation reviews or type examination, including aspects such as **clinical evaluation, biological safety, sterilisation and software validation**, shall have **all of the following proven qualifications**

- successful completion of a **university or a technical college degree** or equivalent qualification in relevant studies, e.g. **medicine, pharmacy, engineering or other relevant sciences**;
- **four years' professional experience** in the field of healthcare products or related activities, such as in **manufacturing, auditing or research**, of which **two years** shall be in the **design, manufacture, testing or use of the device or technology** to be assessed or **related to the scientific aspects** to be assessed;

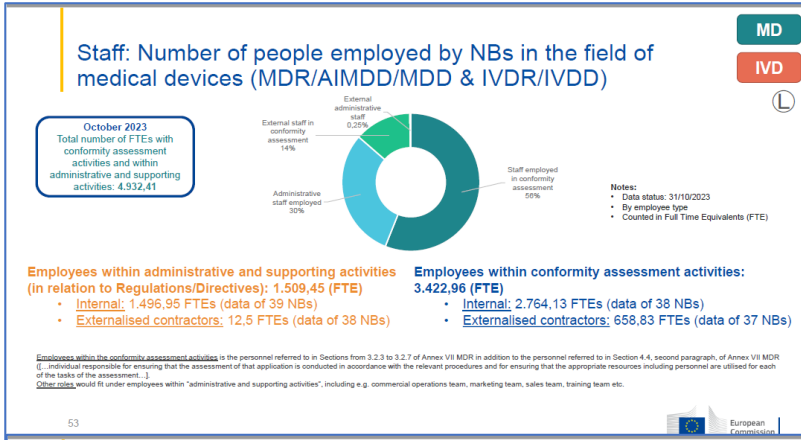
- Notified body staff authorization procedures are based on a very granular medical device coding system
- Resulting in a work force with a big variety of very specific expertise

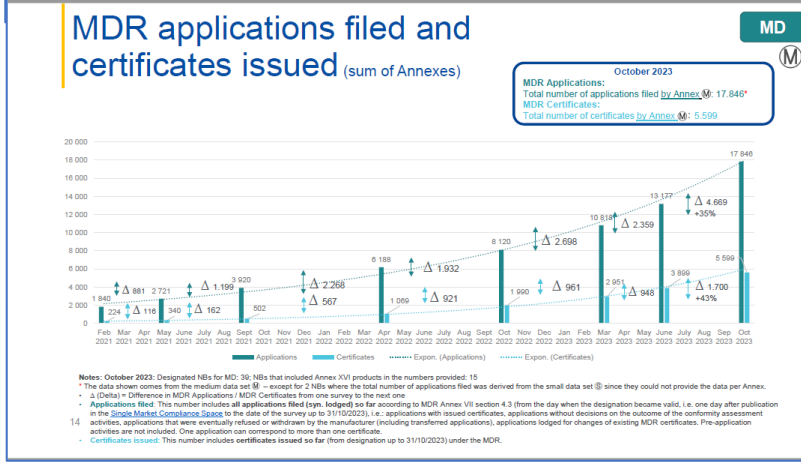
Performance regulatory systems

	EU	US#	
Staff (FTE)	NBs: **5000** Authorities: ?	FDA-CHDR: **2300**	
Devices 'cleared' for market access Oct 22-Oct 23	**2600** MDR certificates	PMA	2148
		HDE	82
		De novo	44
		Total*	**2274**

Data from FDA website

* Excluding 510k procedures





Source: Notified bodies survey on certifications and applications - European Commission (europa.eu)

CORE-MD

Coordinating Research and Evidence for Medical Devices

MDR/IVDR as gamechanger

Whereas (4) MDR

Key elements of the existing regulatory approach, such as the **supervision of notified bodies, conformity assessment procedures, clinical investigations and clinical evaluation, vigilance and market surveillance should be significantly reinforced**, whilst provisions ensuring transparency and traceability regarding medical devices should be introduced, **to improve health and safety**.

Resulting in significantly reinforced

- Notified body designation and monitoring
- Clinical data requirements pre- and post market
- Vigilance and other postmarket requirements
- Market surveillance by authorities
- Reporting and recording (many new documents and forms)

And

- ‘no grandfathering’ for device market access and notified body designation
- complex, detailed regulation (legal text + > 80 guidance documents)

CORE-MD & Team-NB: mutual discovery journey

- At the start of Core-MD, Team-NB/notified bodies only involved in
  - **WP 4 Networking and community building: Engaging with stakeholders**
    - **T4.3** Training, education, and capacity building /Educational objectives for stakeholders
- From there a 'mutual discovery journey' started
  - Notified bodies learnt that interaction with the medical/scientific community and clinical professional associations is a real asset
    - Example: Core-MD work on conditional certification
  - CORE-MD learnt that notified bodies staff is highly educated and trained rigorously and continuously according to legal requirements
- Resulting in productive cooperation
- "The future is bright"
  - Further exploration of potential for collaboration between the medical/scientific community and clinical professional associations and notified bodies
  - Mutual high expectations for continued cooperation in EU-funded projects

Conclusion:

Are notified bodies “The Ugly Duckling” of the medical device regulatory system?

- The other ducklings have discovered that notified bodies are not so different and better understand their role in the EU regulatory system
- Mother duck has discoved that the principles behind the EU regulatory system are really fostering health and safety and that notified bodies’ expertise is a key factor

- So the future is bright!

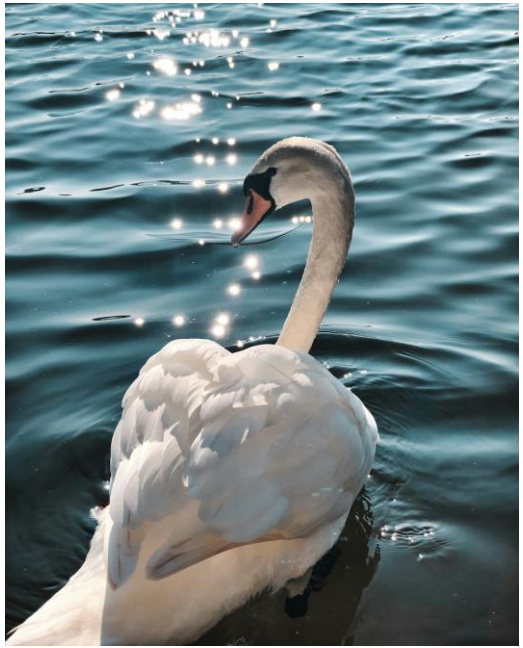
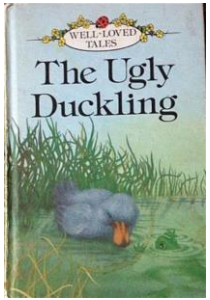


Photo by Emily Sevenoaks on Unsplash



Thanks for your attention!

CORE-MD, Coordinating Research and Evidence for Medical Devices, aims to translate expert scientific and clinical evidence on study designs for evaluating high-risk medical devices into advice for EU regulators.

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 945260

For more information, visit: www.core-md.eu

ESC

EFORT – JOINT EFFORTS

Biomedical Alliance in Europe

European Academy of Paediatrics
Paediatric Section of U.E.M.S

EPF European Patients Forum

LUMC Leiden University Medical Center

University of Oxford

Region Uppsala

RCSI University of Medicine and Health Sciences

INSELSPITAL
Universitätsspital Bern
Hôpital universitaire de Berne

KU LEUVEN

UMIT TIROL
The Tyrolean Private University

University of Gothenburg

Politecnico Milano 1863

HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

LÆGEMIDDELSTYRELSEN
DANISH MEDICINES AGENCY

National Institute for Public Health and the Environment
Ministry of Health, Welfare and Sport

Istituto Superiore di Sanità

aihta HTA Austria
Austrian Institute for Health Technology Assessment GmbH

AETSA

TEAM NB

CORE-MD
Coordinating Research and Evidence for Medical Devices