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What can we expect in changes to the MDR in 2025?

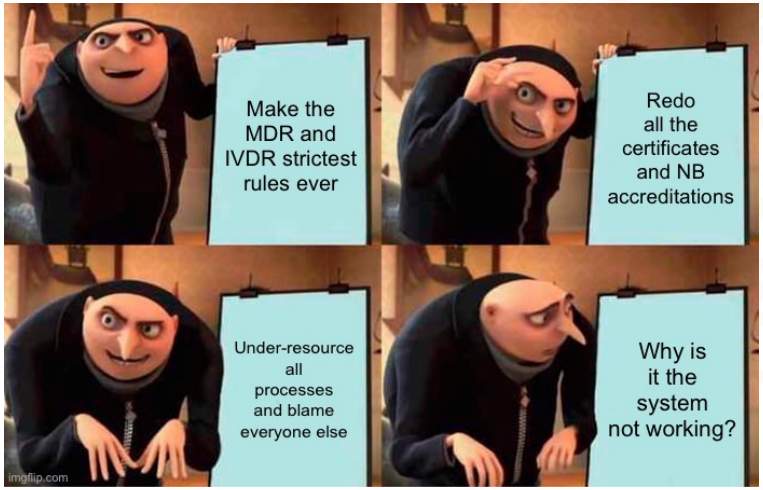
OSMA Winter Meeting
21-23 January 2025

The EU regulatory system is suffering from a bad case of lasagna – in a blender

- MDR and IVDR overshot the mark as a result of political hype
- Layer upon layer of horizontal legislation is added
- While the MDR and IVDR themselves are subject to constant churn regarding substantive requirements and formalities
- Frustrated by some truly disastrous choices for the transitional regime
- Not helped at all by divergent practice and implementation between Member States and notified bodies (instructed by the Member States)
- And finally set up to overpromise but underdeliver as a result of under-resourcing on EU and member state level

In the beginning there was political hype and the choices underlying the transitional regime

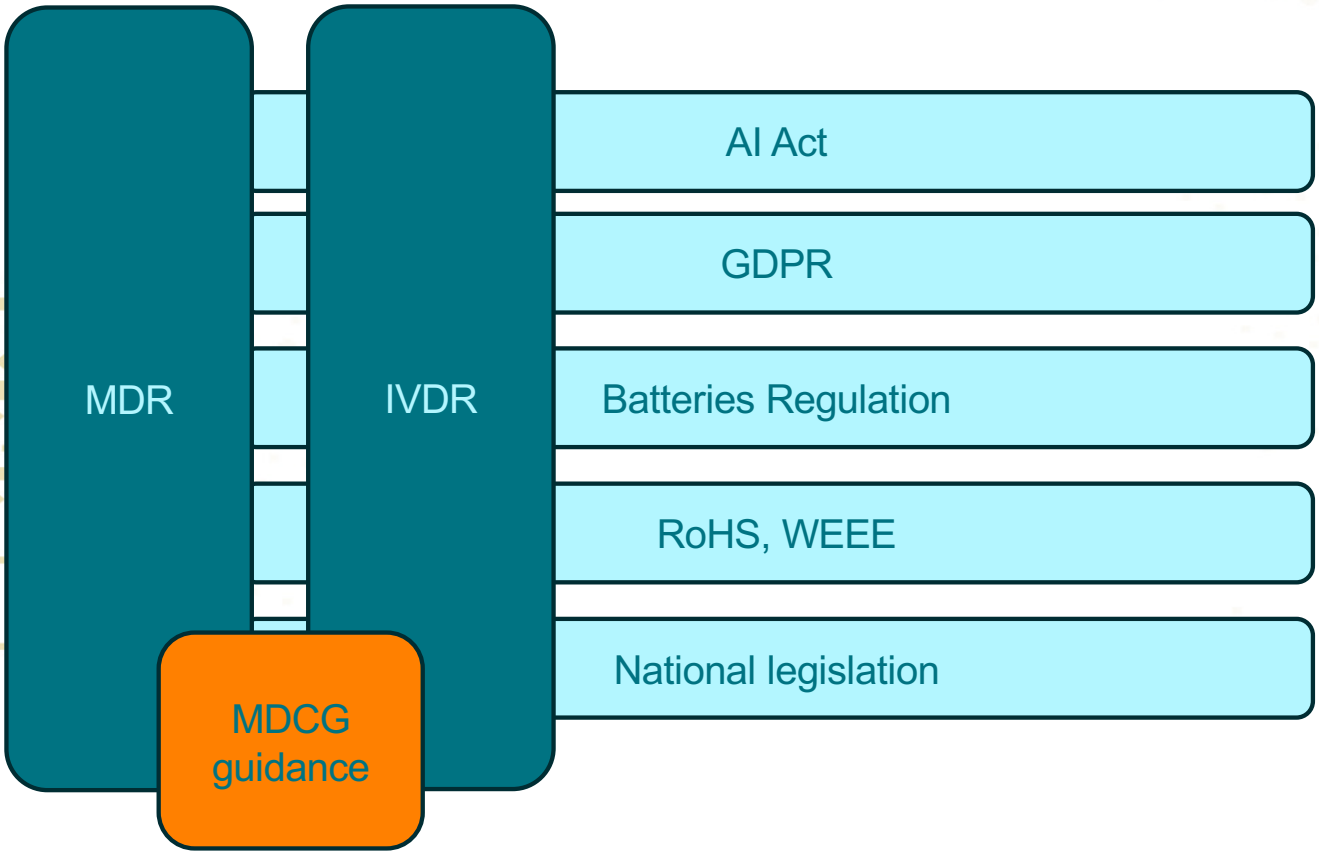
- “No more of this fraud”
- Implants must have much more pre-market clinical data
- “Single use is like printing your own money”
- Manufacturers and notified bodies are bad actors, and must be subject to much stricter oversight
- MDR and IVDR are framework regulations, to be implemented during transitional regime during which all NBs are reaccredited and certificates are renewed under new rules
- Increase ‘proceduralisation’ enormously, but not resource the processes



How does a regulatory lasagna develop?

- Classical case of Maslow's Hammer
- Leads to use of more regulation as a solution to every problem, without considering coherence between legislation adopted
- The EU is very good at making the most fancy high quality product rules but does not focus on how these rules work together or whether they serve the overall policy goals best
- Leads to a self-engineered crisis in healthcare due to manufacturers discontinuing devices or not launching them first in Europe

Horizontal – vertical with a dash of (non) existent guidance



Notfied body availability and designation

NCA staffing and proliferation

Different phase-in roadmaps for regulation

EU silos largely correspond to Commission organisation

- Devices are in HEALTH but separate unit that does not really talk to pharma
- AI is in CONNECT which considers health not a top priority
- Battteries and EEE are in ENVIRONMENT, which considers environment the only priority
- Yet, all regulation has lofty goal of stimulating innovation and not imposing undue burden, especially not on SMEs

Member State level

- Member States find it very hard to equip the Commission as a centralised source of policy and execution in the devices system
  - MDCG legislates by guidance
- Member States are very much holding on to national competence and often do not see how things can be improved on Brussels level
  - Lack of expertise and overall understanding at national government health policy level
  - Health policy via devices has not really been discovered and is therefore under resourced
- Thought experiment: “What is this were pharma policy?”

Examples of Maslow's lasagna

- Stacking DoCs with different requirements of what should be in a DoC
- Requirements to declare conformity to one set of rules under another set of rules
  - GDPR conformity declaration under AI Act
- Different definitions in NLF legislation for the same concepts while allowing sharing technical documentation between regulations (AI Act and MDR/IVDR)
- Having separate national NCAs for each regulation while the regulations overlap for products / services, decreasing relevance and effectiveness of NCAs
- Allowing for exemptions under one regulation (in-house under MDR and IVDR) but not under the other (CE marking for in-house AI systems under AI Act)
- Make notified bodies that already assess AI systems under MDR and IVDR re-apply for designation under AI Act

More examples of Maslow's lasagna

- Using different concepts of risk and risk management under regulations that apply cumulatively to the same device (AI Act, GDPR, MDR/IVDR)
- Implementation by guidance developed by under-resourced NCAs with no legal training and no awareness of coherence with other legislation on a consensus basis
    - MDCG
- Overengineering notified body re-notification procedures and then understaffing the process and combining this no grandfathering, creating a shortage crisis
    - for MDR and IVDR notified bodies
    - and potentially replicating this for AI systems that are already CE marked as devices

Another layer of Maslov's lasagna

- Notified bodies guidance documents
  - Harmonisation but often very open ended
- MDCG guidance documents
  - Legislation by guidance

Facts and figures

- ‘De wal keert het schip’ (the shore turns the ship) – industry starts to vote with its feet
    - ~50% manufacturers are not launching Europe first anymore due to costs, duration and general unpredictability of market access process
    - Certain devices are not brought to market in EU at all / portfolio reductions and discontinuations
    - Health institutions are starting to experience shortages of specific devices, such as orphan and niche devices

Limited initiatives to solve the lasagna in AI Act (and always after the fact)

- AI Office is supposed to lead to better coordination and coherence between Commission services
    - Would be nice if the MDR/IVDR had something like that (it's included in Peter Liese initiative)
    - AI Office and MDCG seem to be in discussion about overlaps and incoherence
- A designation code based solution seems to be in the works for MDR/IVDR notified body designation for AI Act

But also at least one familiar solution

- We ‘nail’ the shortage problem with more regulation before fixing any of the root causes
  - We use broadly worded language that is at odds with *lex certa* principle and leave ‘implementation’ to MDCG and then refuse to listen to stakeholders in stakeholder feedback exercise
  - Article 10a MDR / IVDR is a case in point – shortages are caused by the transitional regime and its consequences

(1) the following article is inserted:

‘Article 10a

Obligations in case of interruption or discontinuation of supply of certain devices

1. Where a manufacturer anticipates an interruption or a discontinuation of the supply of a device, other than a custom-made device, and where it is reasonably foreseeable that such interruption or discontinuation could result in serious harm or a risk of serious harm to patients or public health in one or more Member States, the manufacturer shall inform the competent authority of the Member State where it or its authorised representative is established, as well as the economic operators, health institutions and healthcare professionals to whom it directly supplies the device, of the anticipated interruption or discontinuation.

The information referred to in the first subparagraph shall, other than in exceptional circumstances, be provided at least 6 months before the anticipated interruption or discontinuation. The manufacturer shall specify the reasons for the interruption or discontinuation in the information provided to the competent authority.

2. The competent authority that has received the information referred to in paragraph 1 shall, without undue delay, inform the competent authorities of the other Member States and the Commission of the anticipated interruption or discontinuation.

3. The economic operators who have received the information from the manufacturer in accordance with paragraph 1 or from another economic operator in the supply chain shall, without undue delay, inform any other economic operators, health institutions and healthcare professionals to whom they directly supply the device, of the anticipated interruption or discontinuation.’

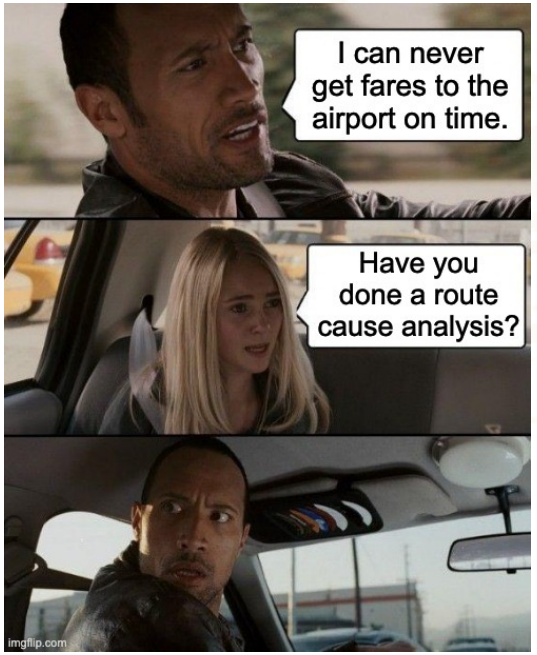
;

Although there is no lack of initiative and good solutions

- BVMed / VDGH White Paper
- MTE white paper
- Liese initiative
- Commission ponderously working itself through targeted evaluation
- Mission letter to new Health Commissioner: fix this and talk to the European Parliament
- EPSCO Counsel non-paper
- Various other initiatives by COCIR and Biomedical Alliance
- Notified bodies continue to develop code of conduct and Team-NB documents
- And where are the member states?
    - German bureaucracy initiative

But wouldn’t we need something more root cause oriented?

- The Commission is working on the ‘targeted evaluation’
  - ‘Targeted’ does not seem to assume intention to address root causes but maybe it will
- Peter Liese has proposed an initiative that will address at least some root causes
  - But the Commission and Council will need to like these too
- Member states still seem very invested in policy choices from the past that turned out disastrous for Union devices availability
  - No grandfathering
  - All NBs and certificates must be redone



What would really work (in my opinion)?

- Harmonisation through centralisation
  - The highly decentralised model of devices is not appropriate anymore and does not support EU and national health policy
- Integrate market access and HTA, and preferably reimbursement too (although that requires TFEU amendments)
  - Or at least expand scope of devices under HTA regulation
- Empower Commission and quit legislation by guidance via MDCG (which is unconstitutional by the way)
- Re-conduct impact assessment on outcome of legislative procedure rather than spend a lot of time at the start
- Reduce bureaucracy wherever possible

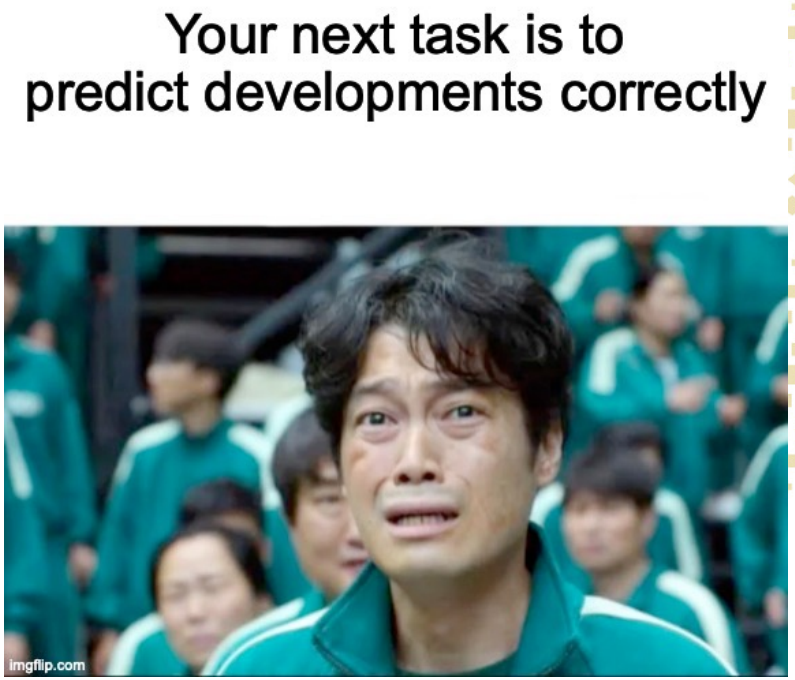
What challenges to fix the system?

Biggest challenges:

- Member states need to realise that
  - EU devices policy is bigger than each of them individually
  - surrender more competence to Brussels for centralised market access controls on NBs and roll-out of the systm
  - resource Commission for proper centralisation
- Avoid pharmacologicalisation of devices via EMA
  - Analogy of AI Office under AI Act
  - There are developments towards more centralisation under the EU Health Union with e.g. HERA but centralisation for devices system governance is problematic

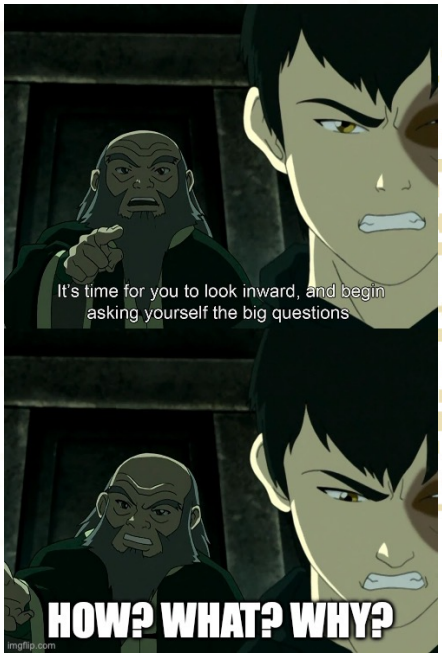
What should manufacturers do?

- Invest in active participation in development of regulation and guidance and have a good channel into to management for developments
    - Manufacturers of devices very critical of additional bureaucracy under overlapping regime but slow to be part of the solution
    - Manufacturers often do not have a good strategy for staying informed of substantive requirements that will be developed
    - E.g. via local and European industry organisations
- Invest in education and compliance of upstream supply chain and service providers



What should manufacturers do further?

- Unsilo design and development within the company
    - For example: do an early data/cyber impact assessment so design is compliant under all applicable regulation
    - Adopt compliance-by-design philosophy
- Start with phase-in of regulatory requirements well before they apply (AI, batteries, etc.)
    - If not possible, develop remediation plan that can be presented externally (e.g. notified body) showing that remediation is underway
    - Careful with internal risk assessments justifying delayed compliance – these can be used against the company
- Create strong links between legal and regulatory functions to implement consequences and manage risks

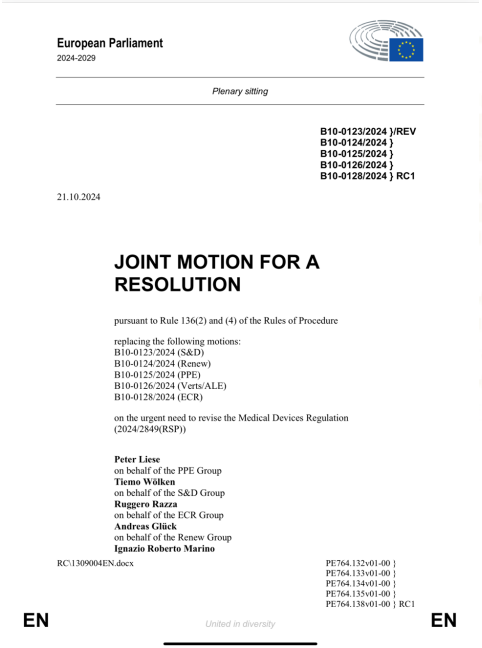


More things that manufacturers should do?

- Develop robust due diligence processes that involve regulatory from an early stage of the acquisition process so looming or pending compliance issues can be spotted early and vectored into the pricing / conditions
    - Insert regulatory expertise as counterweight for bankers and transactional counsel
    - Many companies that are for sale advertise an unrealistic or incorrect compliance profile
        - Remediation after acquisition or during acquisition is expensive (e.g. extended transitional services agreement)
- Prepare for article 10a MDR / IVDR implementation
- If legacy devices – have a plan for the way out

Recent developments

- Joint Parliament resolution on the urgent need to revise the Medical Devices Regulation of 22 October
  - Compromise of positions spanning the whole political continuum in Parliament
  - EPP input the most specific and far going as regards centralisation
    - Essentially implementation of Liese initiative



European Parliament
2024-2029

Plenary sitting

B10-0123/2024 }/REV
B10-0124/2024 }
B10-0125/2024 }
B10-0126/2024 }
B10-0128/2024 } RC1

21.10.2024

JOINT MOTION FOR A RESOLUTION

pursuant to Rule 136(2) and (4) of the Rules of Procedure

replacing the following motions:
B10-0123/2024 (S&D)
B10-0124/2024 (Renew)
B10-0125/2024 (PPE)
B10-0126/2024 (Verts/ALE)
B10-0128/2024 (ECR)

on the urgent need to revise the Medical Devices Regulation (2024/2849(RSP))

Peter Liese
on behalf of the PPE Group
Tiemo Wölken
on behalf of the S&D Group
Ruggero Razza
on behalf of the ECR Group
Andreas Glück
on behalf of the Renew Group
Ignazio Roberto Marino

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EN *United in diversity* EN

Parliament resolution

- Two step approach: Commission to propose
  - by the end of Q1 2025
    - delegated and implementing acts to the MDR and the IVDR to address the most pressing challenges and bottlenecks in the implementation of the legislative frameworks
  - ASAP
    - systematic revision of all relevant articles of these regulations, accompanied by an impact assessment, to be conducted as soon as possible

EPSCO Council non-paper

- Joint paper of Croatia, Finland, France, Germany, Ireland, Luxembourg, Romania, Malta and Slovenia on necessary reforms in MDR and IVDR: priorities / main points for 3 December 2024 EPSCO Council:
  - Reduction of administrative obligations of stakeholders
    - “Reporting obligations, validations tasks and inconsistencies in the conformity assessment process should be reviewed to avoid unnecessary formalities”
  - Centralisation of system management functions to the EMA
    - “greater involvement of the EMA in an integrated and structured way in the MD /IVD sector would be beneficial for a better implementation of the regulatory framework”
    - “setting up an EMA MDCG secretariat to support the practical applications and technical coordination of the system, development of MDCG guidance documents within a reasonable timeframe and transmitting certain administrative functions to the EMA”
  - Foreseeable and balanced certification procedures
    - “appropriate, transparent and predictable timelines for certification (including stop-the-clock-options) should be introduced”
  - Taking into account specific needs for medical devices intended for specific patient populations
  - Assuring a special pathway for innovations

Thinking, fast and slow during the first 100 days

- Commission EY fact finding exercise completed in November - results now awaited, input for impact assessment for targeted evaluation. Commission started another call for evidence ending end March 2025
- Some member states have been looking for bureaucracy reduction proposals
  - E.g. Germany in autumn 2024
- New Commissioner confirms short term low hanging fruit measures for Q1 2025 and longterm measures proposal for Q4 2025
  - E.g. eIFU regulation revision
- Notified bodies working hard to be more part of the solution and less of the problem by improving procedures

What is on the table?

(Re)certification cycle

International reliance, cooperation and harmonisation

IVDR specifics (e.g. scope of class B)

Centralisation / governance

Notified body procedure (time, costs, predictability, transparency, good administration)

Orphan devices / innovative devices / niche devices

SMEs / orphan / innovation friendly pathways

Reduce bureaucracy / standardisation of documentation

What are still the biggest issues?

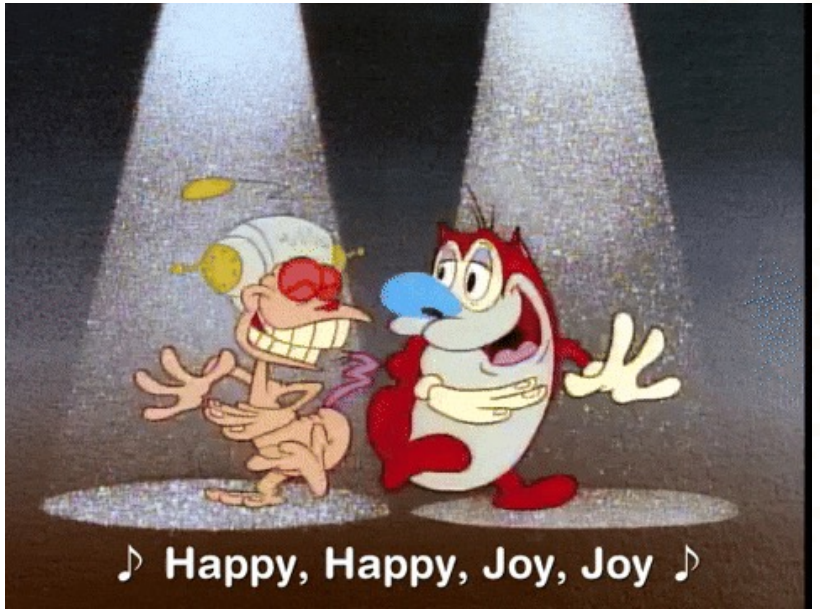
- Cost (long- and short term) and unpredictability:
  - While finding a Notified Body is less of an issue, uncertainty around costs, timelines, and predictability remains, risking Europe's attractiveness for innovative devices.
  - Rising costs in clinical evaluations, Post-Market Surveillance (PMS), and certification are challenging manufacturers, with variability across Notified Bodies complicating financial planning.
  - By the end of a five-year certification cycle, IVD manufacturers will spend 70% more on maintenance and re-certification, while MD manufacturers face a 50% increase.
- Conformity Assessment Efficiency: Over 50% of conformity assessment time is spent outside the actual review phase – condensing procedure could reduce total assessment time.

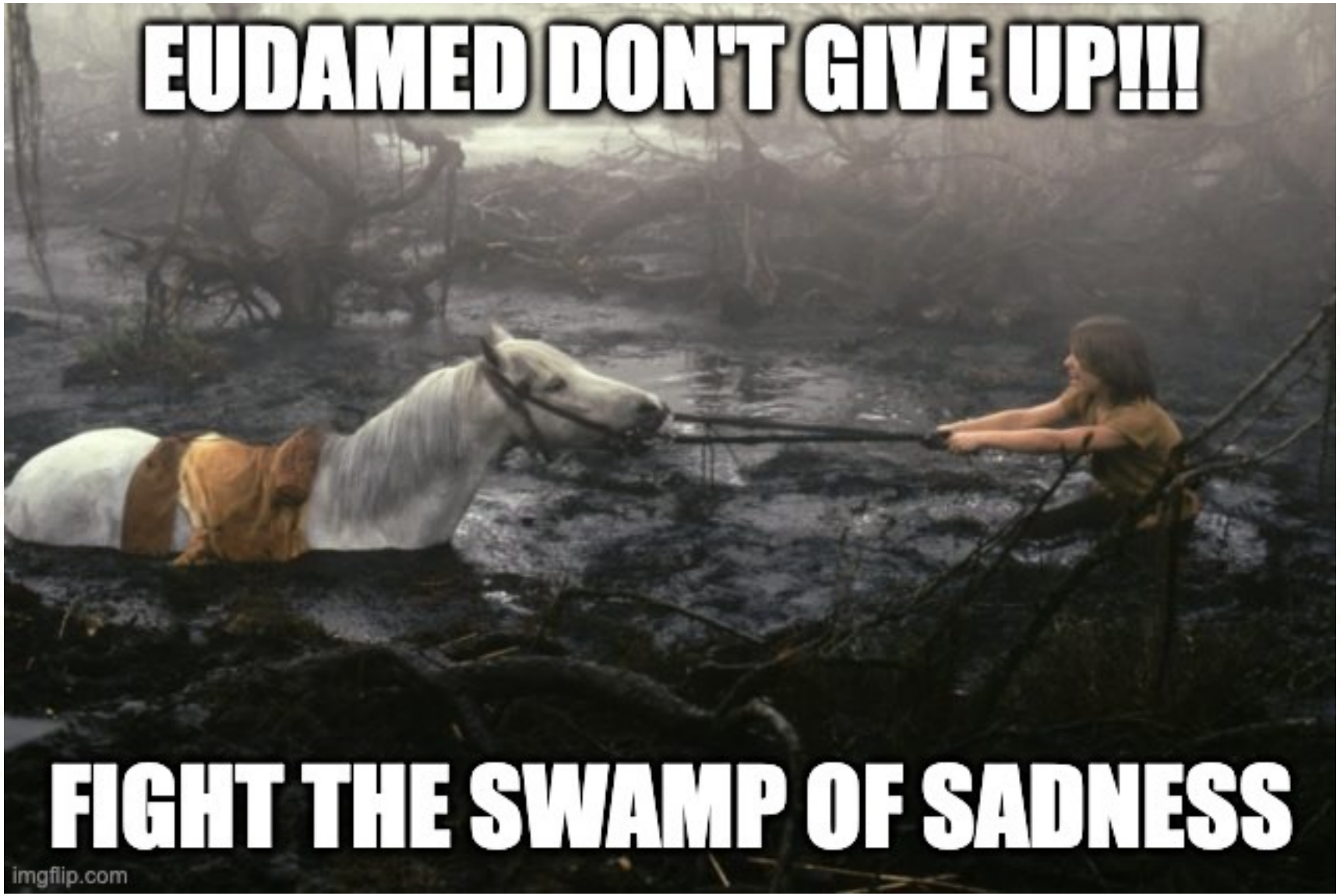
What would Brian Boitano do?

- There are several schools of thought at the moment:
  - Accelerate
    - European Parliament
    - Commission President
  - Contemplate but, yes action required
    - The clinical community
    - Commission
  - Procrastinate
    - Member states
  - Prepare for increased role
    - EMA

What will not change?

- Cumulative application of horizontal legislation to the same device
    - Although amended MDR and IVDR may contain a better concurrence mechanism
    - Manufacturers will still need to work with phase in agenda of AI Act, Batteries Regulation and REACH SVHCs
- Conformity assessment by notified bodies remains the default market access pathway but centralisation will make procedures more predictable and harmonised




EUDAMED DON'T GIVE UP!!!
FIGHT THE SWAMP OF SADNESS
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What other things to watch for in 2025?

- Implementation of specifics under MDR and IVDR
  - e.g. eIFU regulation
- Phase in agendas of horizontal legislation
  - Batteries Regulation
  - AI Act
  - Product Liability Directive
- Data, cyber and AI legislation
  - EHDS
  - GDPR
  - AI Act
  - NIS2

Thank you and don't panic!

Questions?

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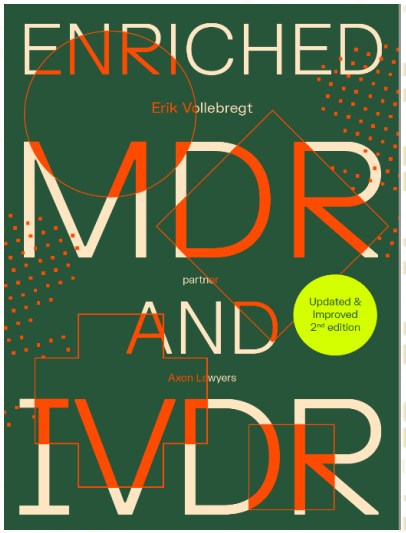

Erik Vollebregt
+31647180683
erik.vollebregt@axonadvocaten.nl
in/erikvollebregt