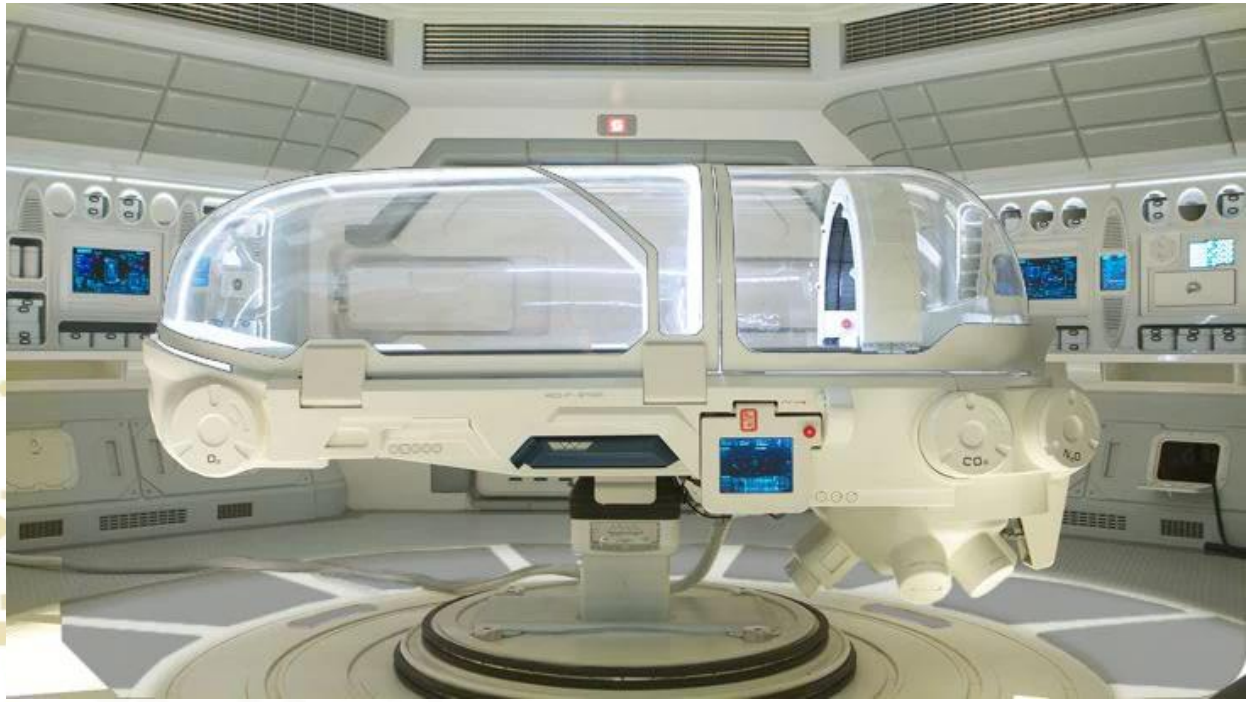
AXON
science based lawyers

AI in Action: Enhancing Clinical Decision-Making with AI

OSMA Spring meeting
23 April 2025

A regulatory conundrum

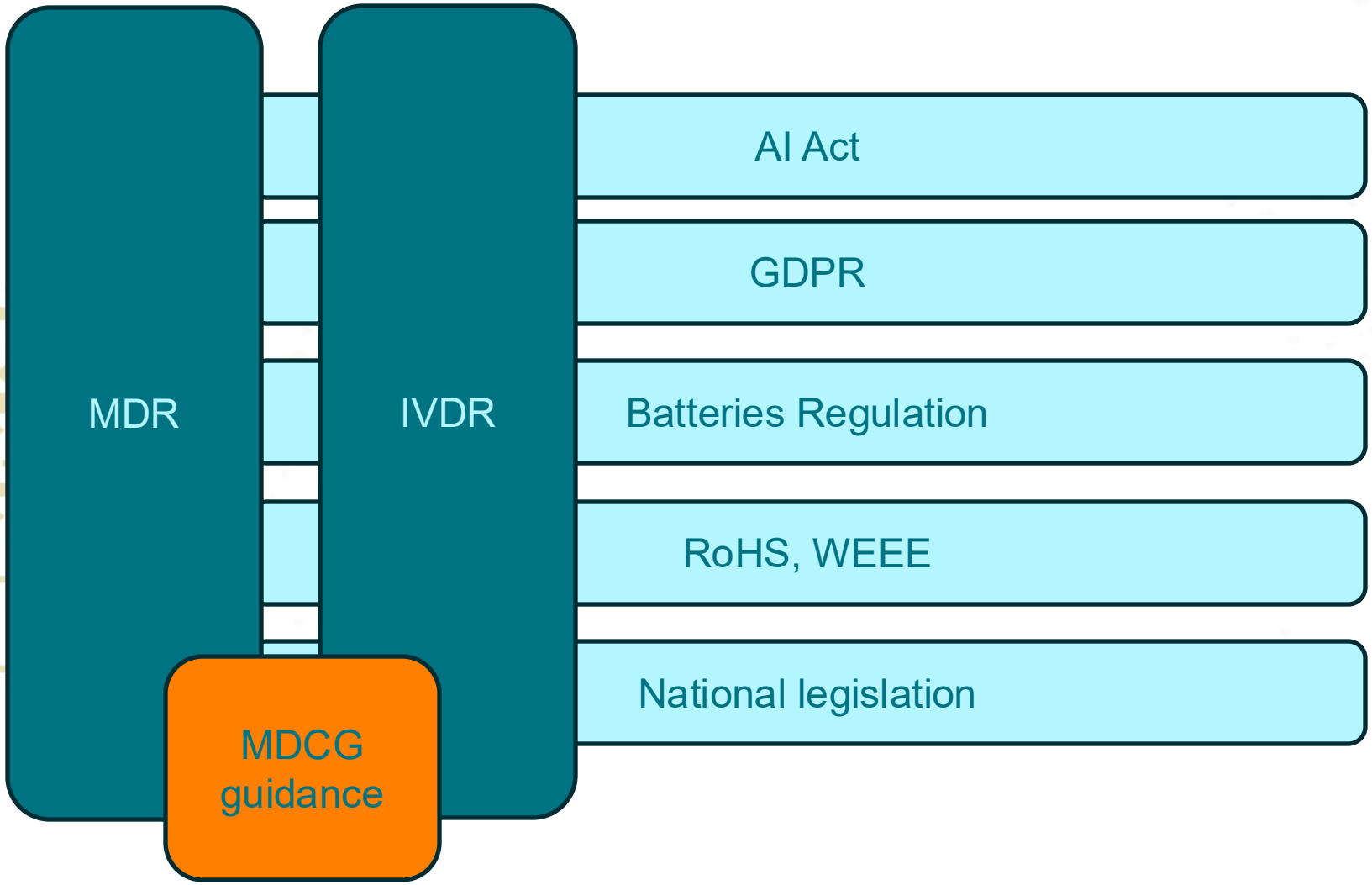


The Prometheus MedPod

- AI Act
- MDR (maybe IVDR too - wait what?)

- And then some
  - Batteries Regulation
  - RoHS
  - Machinery Regulation
  - GDPR / data regulations
  - Etc

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



Notified body availability and designation

NCA staffing and proliferation

Different phase-in roadmaps for regulation

Legal issues

Principle: AI Act applies on top of product regulation (art. 8 (2)) but AI Act compliance can be integrated in 'documentation procedures' under MDR/IVDR, such as technical documentation (art. 11) and in processes (such as PMS (art. 72)

Apart from having to comply with the AI Act as such it raises many legal issues:

- Interpretation of 'inference' under AI Act and IVDR
- Double CE marking
- Incoherent use of concepts defined both in MDR/IVDR and AI Act
- Economic operator obligations
- Requirement to declare conformity to GDPR
- Lots of need to course correct during implementation
- Phased introduction

AI systems and medical devices/IVDs

An AI system can qualify as (part of) a medical device or IVD if it is:

- An independent medical device or IVD (AI system itself has a medical purpose in scope of the definition of medical device or IVD)
- It is an accessory to a medical device or IVD without a medical purpose of its own

- A component or part of a medical device or IVD (which under IVDR includes a part of a kit);
- A part of a system under article 22 MDR; or
- A product under Annex XVI of the MDR (products without intended medical purpose) to which the MDR applies nonetheless.

AI system as safety component

- In the case of high-risk AI systems that are safety components of devices, the product manufacturer shall be considered to be the provider of the high-risk AI system (art. 25)
- Overlapping conformity assessment (art. 43 (3))
  - Art. 9-15 apply additionally
  - Annex VII 4.3-4.5 and 4.6 5th indent

Legal hierarchy and framework (I)

- AI Act as horizontal legislation
  - Article 2: scope includes medical devices and IVDs
  - Article 6: high-risk classification → See annex I

- MDR is sectoral regulation → vertical contrary to horizontal AI Act
  - Contains clinical/performance data requirements
  - Safety and performance requirements

- MDR and IVDR are still not fully aligned with AI Act
  - AI Act does not override MDR/IVDR
  - AI Act sets additional requirements for AI systems that are also devices and whether placed on the market already or not
  - Combined compliance is necessary (but problematic)

Legal hierarchy and framework (II)

- MDR and IVDR set standards for clinical/performance evaluation, safety and performance of the device.
- Requires robust data collection for all medical devices and IVDs, including AI systems that are also a medical device
- AI Act focusses on transparency, quality and risk management
- Sets strict requirements on training and validation data
- Data is essential under all three regulations but not the focus of any of these regulations
    - Although AI Act requires DoC to declare conformity to GDPR
- AI Act says nothing about clinical/performance data, so it is essential to look at the interplay between the AI Act and the MDR/IVDR

Terminology and concept overlap and likeness

- The AI Act has been drafted based on the New Legislative Framework template
  - Has consequences for the ‘recognizability’ of the concepts of the AI Act.
    - Means that concepts as economic operators (operators in AI Act terminology), risk management systems, quality management systems are addressed
      - Similarity of concepts does not mean similar meaning!

        The AI Act and MDR/IVDR have significantly different purpose

Lots of overlap under AI Act

- CE marking related concepts
  - Meaning is not identical under MDR/IVDR vs AI Act
- Conformity assessment – overlapping technical documentation
  - Issue: MDR/IVDR conformity assessment has different purpose
- QMS – may be integrated in other QMS (article 17 (3) AI Act)
  - Issue MDR/IVDR QMS has different purpose (AI Act only compliance chapter III section 2 (AI risk management, human oversight, cyber, etc.)
- PMS / PMM overlap – under AI Act no requirement to look at patient data. AI PMM may be integrated in IVDR / MDR PMS plan and system, where approprate, provided that it achieves an equivalent level of protection (difficult)
- Incident reporting
  - Double reporting of same incident in different forms (MDR/IVDR and AI Act respectively)

Some of the big issues

- Clinical investigation / performance studies with AI
  - Real World Testing is really in real world, so not in controlled trial setting
  - This leaves sandboxes as regulatory option for clinical/performance study with AI
  - RWT outside sandbox only possible for Annex III AI systems – not MD/IVDs
- Grandfathering but not grandfathering (article 111 AI Act)
  - Significant change issue – implementation of significant change in brings legacy AI system in scope of AI Act
  - Relationship grandfathering clause AI Act (art 111(2) AI Act) and requirements concerning post-market surveillance MDR/IVDR is still entirely unclear
- Different risk management concepts
- Are AI Act specific obligations part of MDR/IVDR QMS?
  - E.g. AI literacy requirement for staff / users?

PMM vs PMS

- Article 5 (5) (h): the health institution reviews experience gained from clinical use of the devices and takes all necessary corrective actions
- It seems so nice (article 72 (4) AI Act): “[If AI system = MD/IVD then] providers shall have a choice of integrating, as appropriate, the necessary elements described in paragraphs 1, 2 and 3 using the template referred in paragraph 3 into systems and plans already existing under that legislation, provided that it achieves an equivalent level of protection.

  - Necessary elements are elements in Chapter III, Section 2
    - Risk management (find the delta) (art. 9)
    - Data and data governance (art. 10)
    - Life time record keeping (art. 12)
    - Transparency and provision of information to deployers (art. 13)
    - Human oversight (art. 14)
    - Accuracy, robustness and cyber (art. 15)
  - Will the template for PMM Plan of the Commission blend with the PMS plan in the MDR/IVDR?
  - GDPR compliance must be declared for AI Act process but not for MDR/IVDR process?

Examples of 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 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

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

Market surveillance

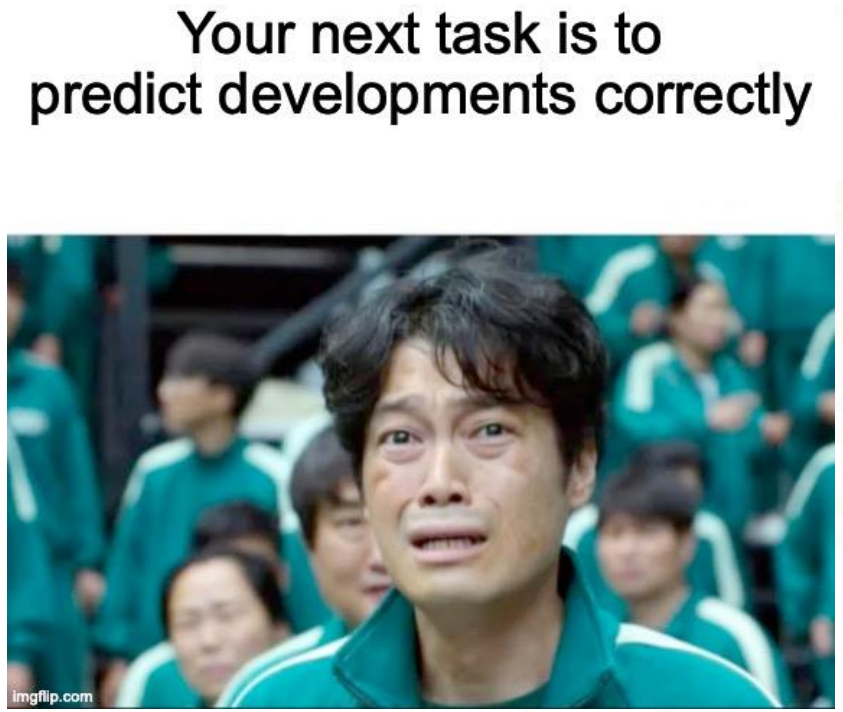
- MDR / IVDR NCA responsible for market surveillance (art. 74 (3)) but Member States may goldplate with another extra NCA
- MDR / IVDR market surveillance regime applies “where such legal acts already provide for procedures ensuring an equivalent level of protection and having the same objective” (art. 74 (4)

MDCG to the rescue for all incoherence?

- Will the MDCG save the day?
- It will require discussions with the AI Office
  - FAQ on Interplay between MDR/IVDR and AIA in the works, announced for Q2 2025
  - First meeting with AI Board subgroup on interplay took place in December 2024
  - Looks like this addresses article 5 (5) or amendment of MDCG 2023-1?
- Why not begin with the end in mind?

What could be next?

- MDR and IVDR may be amended in minor or major ways soon or in the mid term future
  - This may improve or complicate the AI Regulation interface
- Notified body crisis under MDR/IVDR
  - Compounded with AI code scarcity
- EHDS
  - Retrievability of data related to AI for sharing under EHDS
- Clinical research with AI?
  - Testing IRW outside sandbox requirements – real world testing plan vs trial protocol



AI and GDPR

GDPR interface

- GDPR applies but some interesting exceptions:
    - Article 10 (5): processing of personal data for bias detection and correction is allowed under conditions in AI Regulation
    - Article 59: further processing of personal data for developing certain AI systems in the public interest in the AI regulatory sandbox

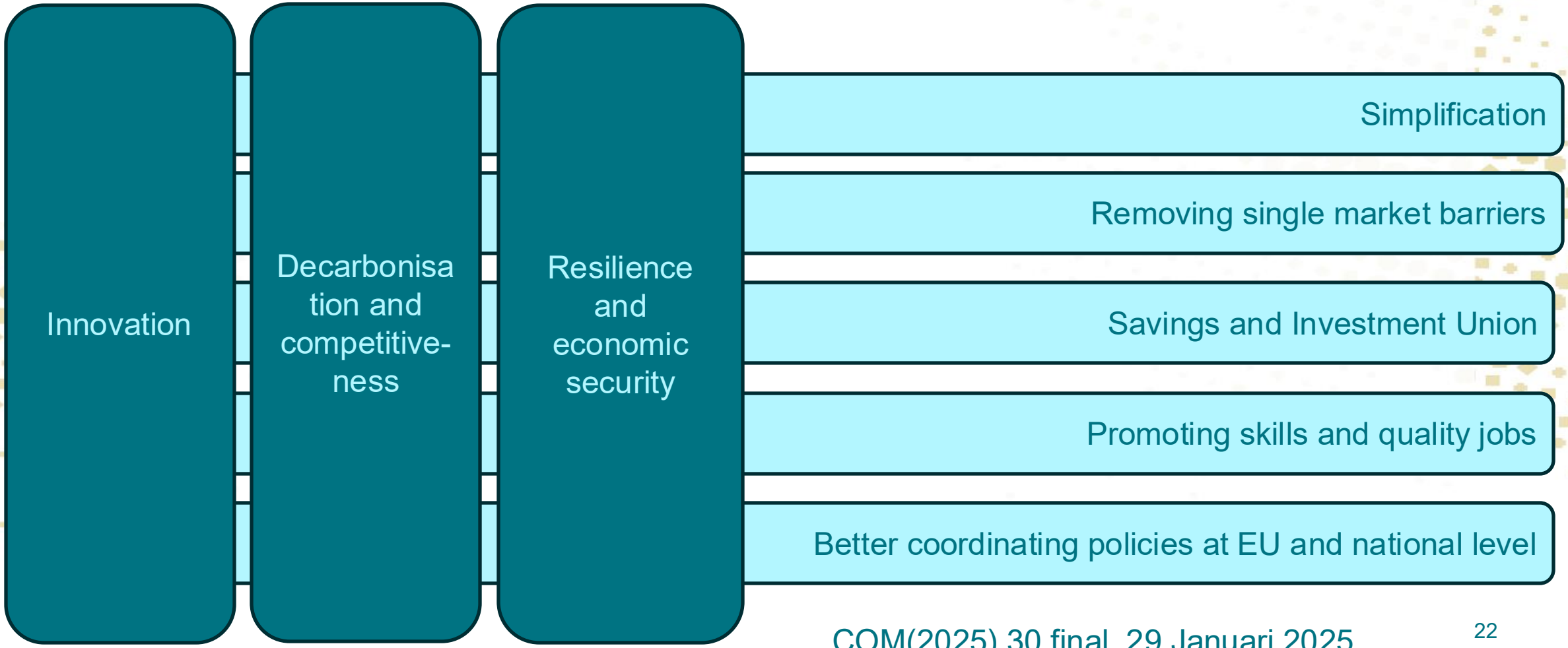
Some relevant things to note:

- GDPR generally leading
- Non-EEA data–escape routes closed-off
- Sourcing the data: EHDS Act?
- What about prohibition on automated processing?
- Is consent workable?
- How to inform the data subject?

GDPR interface

- DoC for AI Act must declare conformity to GDPR (Annex V sub 5)
  - But how to work with exceptions / divergence?
  - How to work with the open standards of the GDPR?
- But how does this work in a stacked DoC for a medical device or IVD?
  - You have a device that is an AI and declare conformity to GDPR
  - Can the notified body audit you for GDPR compliance?

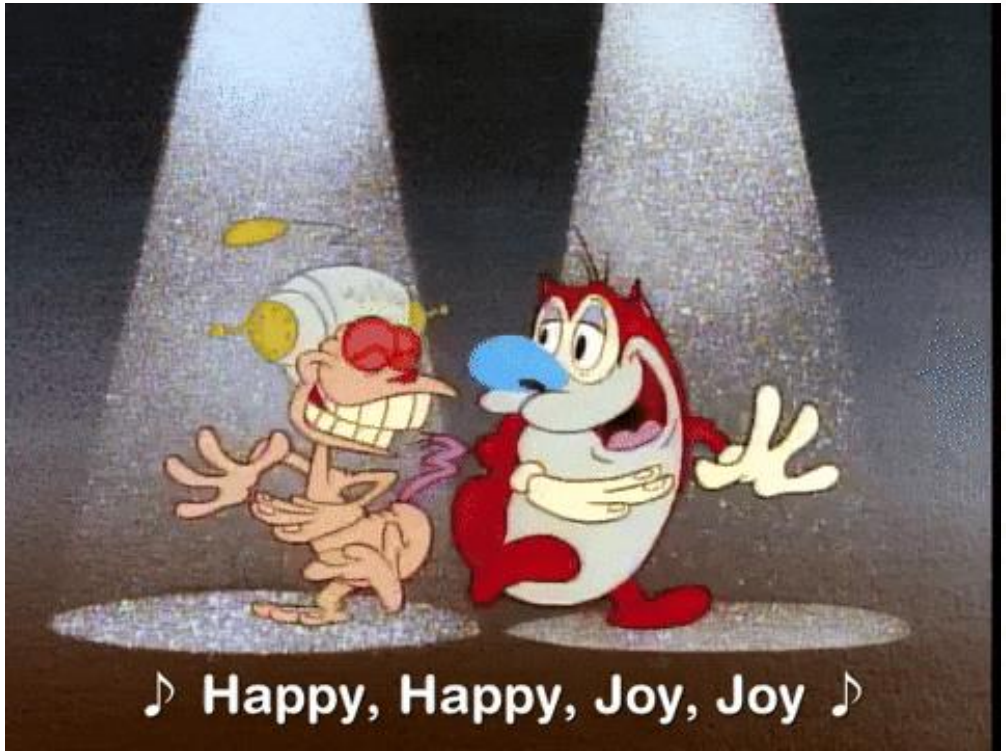
EU Competitiveness Compass



COM(2025) 30 final, 29 Januari 2025

What will (not) change?

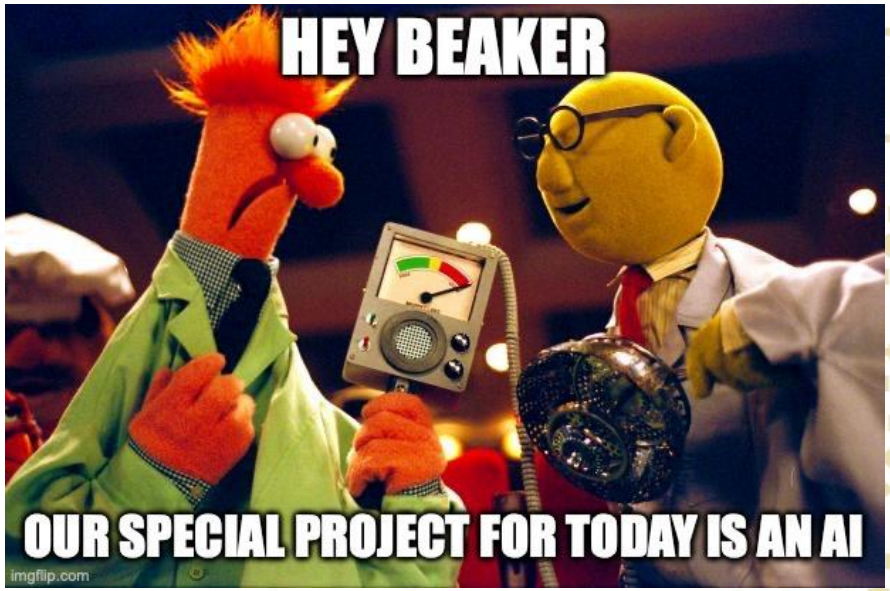
- Cumulative application of horizontal legislation to the same device
    - Although amended MDR, IVDR and AI Act may contain a better concurrence mechanism
    - Manufacturers will still need to work with phase in agenda of AI Act, Batteries Regulation and REACH SVHCs
- Conformity assessment by notified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



AI in the clinic

AI system – in-house produced device

- RUO exemption (recital 25) – RUO AI is out of scope
- MDCG 2022-10: assay is not RUO just because it is used in a reasearch setting
- BUT: not in-house produced devices exemption
    - Article 5 (4) MDR / IVDR: in-house produced = put into service
    - Put into service means: AIA applies and AI System/Model in scope of AIA
        - BUT: in-house produced device is not high-risk (article 6 (2) (b) AIA) so high-risk AI obligations do not apply?
        - Is this good? No – contrast with article 5 (5) MDR/IVDR enormous because that does treat IHPDs as high-risk



Not so fast on scope

- Did the legislator really want to exclude high-risk in-house produced devices from the scope of the AI Act?
    - Are the goals of the AI Act sufficiently served by these not subject high-risk AI system requirements (e.g. technical documentation, risk management, human oversight, cyber, accuracy, robustness and record keeping)?
    - Would comprise significant deregulation compared to product specific regulation (MDR and IVDR)
    - Competent authorities are not convinced that this is the right interpretation – best wait for EU or national level guidance
    - Article 46 (7) AI Act exemption is also option: circular reference to MDR/IVDR derogation from conformity assessment (“For high-risk AI systems related to products covered by Union harmonisation legislation listed in Section A of Annex I, only the derogations from the conformity assessment established in that Union harmonisation legislation shall apply.”)

Example of high risk in-house AI

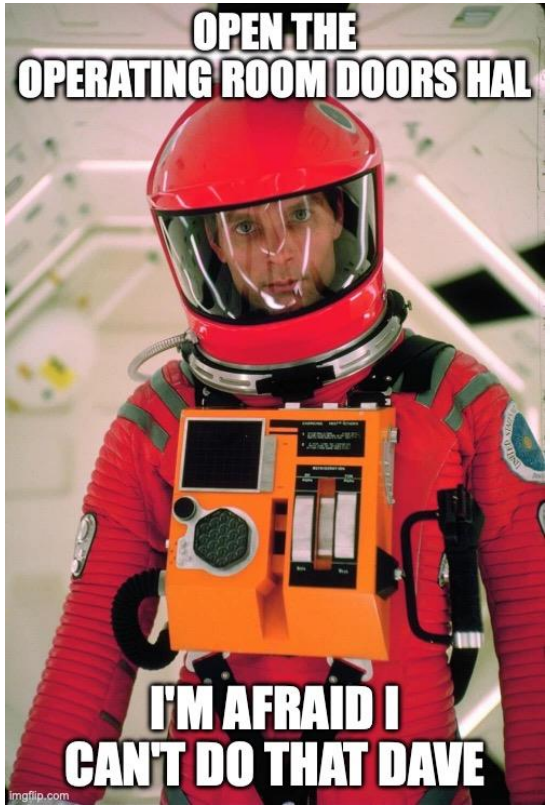
- In-house AI for diagnosis hypertrophic cardiomyopathy (HCM) trained on the patients of a speciific health insitution
- HCM presents differently in different ethnicities

- Does this AI meet the data quality criteria in article 10 (2) Ai Act, e.g.:
  - Has the data been prepared well?
  - Is this AI biased?
  - Are there data gaps?
  - Is the dataset suitable?

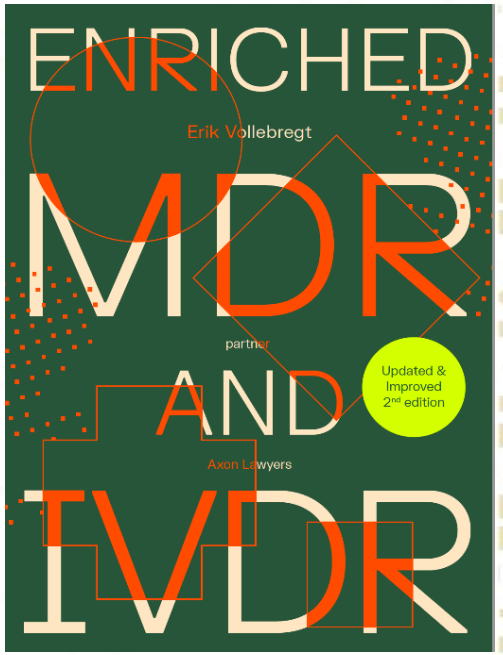
  - This only applies in case of high-risk AI systems

Health institution vs AI system provider

- Keep in mind that for use of article 6 (2) (b) AI Act all criteria of article 5 (5) must be met, which means crucially that the health insitution in which the AI is developed and used must also be the AI provider
- Article 5 (5) (c) – justification (as of 26 May 2028)
- Also, most of the obligations for high-risk AI must be met under article 5 (5) anyway: QMS, TD, PMS, series production, vigilance



Thank you and don’t panic!



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