Adapting Global Frameworks: Insights from MDR/IVDR for African Regulators and Industry

MDR and IVDR: reliance and lessons learned

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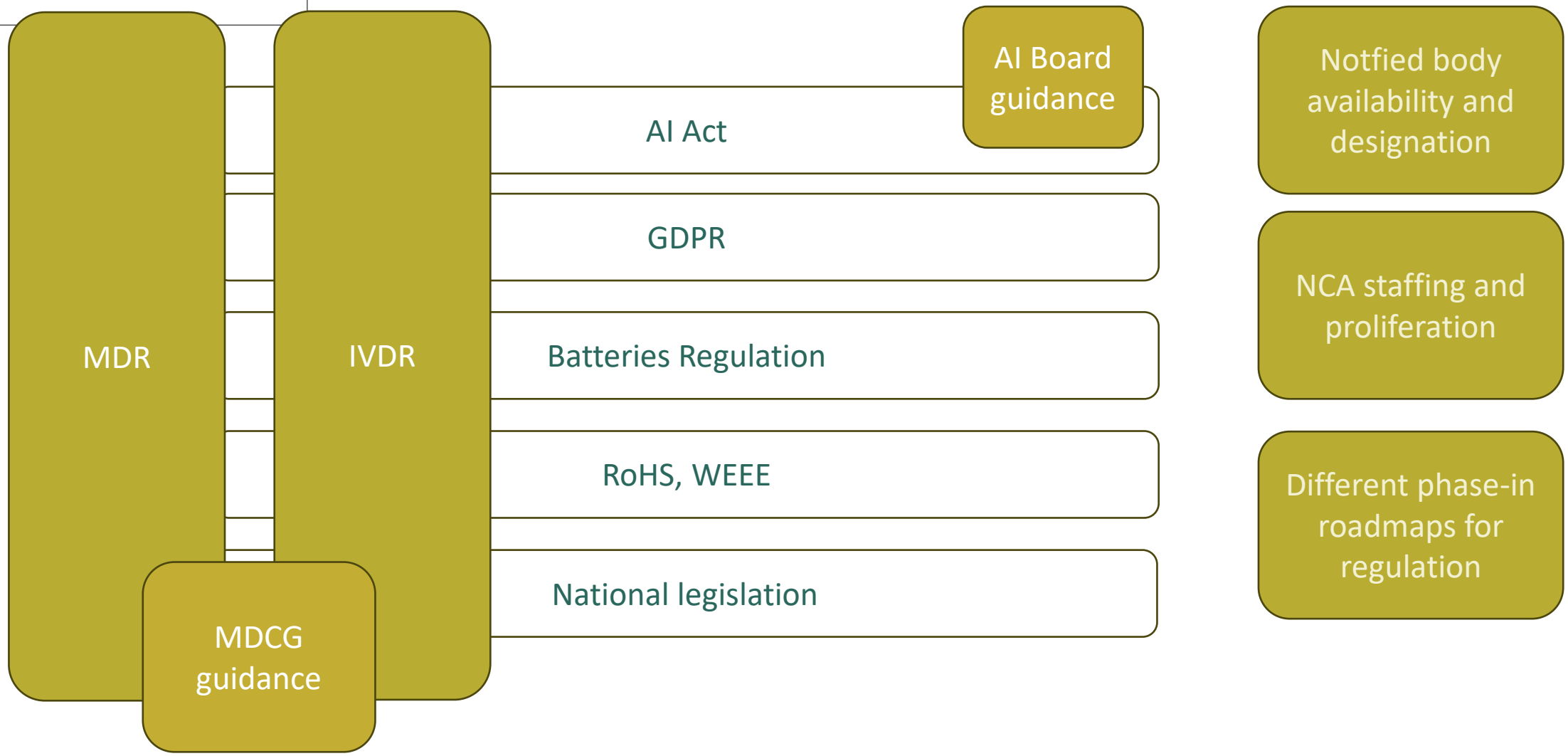
How should a system for medical devices international reliance work?

- Many good practices in WTO Good Practices in the Regulation of medical Products
- IMDRF Playbook for Medical Device Regulatory Reliance Programs
  - Worksharing
  - Abridged review
  - Recognition
- Existing recognition practices for CE in e.g. UK, various Asian countries (e.g. Malaysia, Singapore), Australia
  - The more mature reliance countries also publish local guidance about things like transitional periods for legacy certificates

How has the European system been built?

- European system is based on general product regulation, with a medical twist (clinical evaluation and clinical investigation /performance evaluation and performance studies)
- New Legislative Framework – system for CE marking logic across all product sectors
- Based on public-private cooperation
  - Notified bodies give market access based no pre-market conformity assessment
  - Competent authorities do market surveillance and remove non-compliant devices from the market and oversee notified body functioning
- Always keep in mind the dimension of harmonisation of national legislation as EU objective
  - Adds political complexity

European product regulation for medical devices



Good practices to transplant

- System with public-private cooperation for market access can be very efficient but not in transitional periods in which a lot must happen in short time
- Substance of the MDR and IVDR is very good (procedural framework needs improvement)
  - Methodology of review (conformity assessment) is complete and well-tuned for medical devices
  - Significant body of guidance available
- Well-trained clinical, technical and materials/biochemistry experts involved in review (don’t forget IVD experts)

Less productive practices to avoid

- Avoid “lasagna” – multiple sets of rules applying to a single product
- Don’t forget to ensure that the market for private conformity assessment keeps functioning
- Provide clear and standard documentation structure for applications
- Provide predictable timelines for review
- Resource competent authorities sufficiently
- Don’t treat medical devices like they are medicines
  - Clinical data requirements are different
  - Very diverse group of technologies
  - Ensure link up medicines and medicines authorities for coordination regarding combination devices

Reliance on EU system?

- Many countries are doing this already because EU is perceived to be a reliable international partner that observes international standards
- Evaluate existing legal framework of your country to identify any limits to implementing a reliance approach
- IMDRF Playbook for Medical Device Regulatory Reliance Programs
  - Blueprint for establishing a reliance program
  - What type of reliance will be appropriate?
    - Worksharing
    - Abridged review
    - Recognition
- EU system will change soon, watch these developments
- EU will increase its efforts to support international reliance in the future, through IMDRF and directly

Things to implement nationally

- Legal basis for recognition in national law
- Registration / notification procedure resulting in decision/license/certificate
- Clear and standard documentation structure for applications
  - List of documents to be submitted
  - Contact point to explain / answer questions
- Well-resourced approval process with links to other authorities (e.g. for medicines, animal tissues, cells, etc.
- Additional extended producer requirements, like collection of waste electronics
- Clear additional requirements that may have been not have been reviewed in Europe
  - E.g. halal requirements or contraceptives controls

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