HOW IVDR INFLUENCES PROCESSES IN TISSUE ESTABLISHMENTS

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Why is IVDR relevant?

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WHY IS IVDR RELEVANT

- Tissue banks depend on diagnostic tests and laboratory processes
- IVDR framework regulates those tests
- Influences availability, documentation, oversight, management of changes, responsibilities
- Affects safety, quality and continuity within tissue banks' operations
- Safe use following the intended purpose

RESPONSIBILITIES TISSUE ESTABLISHMENTS

- Make sure tests are performed by a qualified lab

- Make sure tests are CE certified or in same health institution

(donor screening tests, specific buffers, blood tubes, calibrators, controls)

- Follow the intended use

- Third party agreements

WHEN DO YOU FALL UNDER IVDR

IVDR applies when you:

- Use IVDs for:
  - donor screening
  - recipient acceptability
- modify / combine tests
- Develop your own methods

Are you:

- A user of CE-labeled IVDs
  OR
- A manufacturer of an in-house IVD?

This determines your regulatory burden

(in-house = RUO ≠ CE-modified)

IVDR = Additional layer and not a replacement of Directive 2004/23/EC and Directive 2006/17/EC

ARE QUALITY TESTS IVDR?

Our interpretation

For example: Viability assays, apoptosis assays, cell counts for SoHO-preparations

- Test is on donor samples and information will not be linked back to the donor
- It is not for a specific treatment or compatibility, safety for a potential recipient
- It is a quality test for a SoHO-preparation
- SoHO-preparation is regulated itself
- Case-by-case
- Ongoing discussion

HOW DOES IVDR IMPACT TISSUE ESTABLISHMENTS

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WHAT ARE THE PROBLEMS

Classification (class D)

- detection of the presence of, or exposure to, a **transmissible agent** in blood, blood components, cells, tissues or organs, or in any of their derivatives, in order to assess their **suitability** for transfusion, **transplantation** or cell administration;

Devices intended to be used for blood grouping, or tissue typing to ensure the immunological compatibility of blood, blood components, cells, tissue or organs that are intended for transfusion or transplantation or cell administration (following markers are class D)

— ABO system [A (ABO1), B (ABO2), AB (ABO3)]; — Rhesus system [RH1 (D), RHW1, RH2 (C), RH3 (E), RH4 (c), RH5 (e)]; — Kell system [Kel1 (K)]; — Kidd system [JK1 (Jka), JK2 (Jkb)]; — Duffy system [FY1 (Fya), FY2 (Fyb)];

WHAT ARE THE PROBLEMS

Class D requirements

- Compliance with common specifications
- European Union Reference Laboratory verification (EURL)
- Batch verification/ Batch testing
- Notified body

- General safety and performance requirements (GSPR, Annex I)
- Quality management system (QMS)
- Technical documentation
- Performance evaluation (scientific validity, analytical performance, clinical performance)
- Post market surveillance and vigilance

CE

Conformité Européenne

DONOR SCREENING

- Typically class D (HIV, CMV, Zika virus...)
- Commercial panels are often incomplete
  - Coverage may differ by:
    - donor type
    - specimen type
    - platform
    - post-mortem versus living donor setting
- Tissue establishments and laboratories therefore often need to combine assays, depend on limited local platforms, or develop in-house solutions when commercial coverage is incomplete.

DECEASED DONOR SCREENING

- validated post-mortem assays remain scarce
- appropriate sampling windows are not always well defined
- only a few manufacturers serve this area
- no single manufacturer covers all required assays
- commercial availability remains uncertain

TEST AVAILIBILTY ≠ PRACTICAL AVAILIBILITY

- A CE-marked assay may exist on the market
- But it may not be compatible with the laboratory's analyzer platform
- Many laboratories work with only one or two testing platforms
- This limits which donor-screening assays can actually be used
- As a result, market availability does not always equal practical availability

AMBIGUOUS GUIDANCE CREATES UNCERTAINTY

- requirements are not always translated into clear how-to guidance
- practical expectations may remain unclear
- room for interpretation with open wording such as:
  - when appropriate
  - such as
  - when applicable

- this makes implementation less predictable
- and creates uncertainty for both companies and health institutions
- Loss of time, additional costs, repeated discussions with authorities and notified bodies, rework, shortcomings

IVDR NOW

- Disappearance of essential niche devices
- Forced fallback to alternative solutions
- Disproportionate burden
- Innovation discouraged

PROPOSAL

- Commission proposal published: 16 December 2025
- Introduced to simplify MDR/IVDR and reduce burden
- Aims to improve availability, innovation and efficiency
- Keeps focus on patient safety
- Not finalised

PROPOSAL'S CHANGES

- 'No equivalent device on the market' is removed (not for MDR)
- The proposal also allows transfer of an in-house device to another health institution, where justified in the interest of public health, patient health, or patient safety

  This could make it easier for:
  - specialised labs to support other hospitals,
  - networks of health institutions to avoid duplicating the same niche test everywhere,
  - SoHO services to maintain continuity when local testing options are weak.

- Recognizing ISO 15189 accreditation as QMS basis
- the extra Class D-specific documentation requirement disappears, and
- the sentence allowing Member States to extend that requirement to Class A, B or C disappears too.

PROPOSAL'S CHANGES

- Flexible rules on acceptable evidence sources, regulatory sandboxes

- For class C and D IVDs, the proposal may make procedures more predictable.
  - The current IVDR performance evaluation consultation procedure would be removed.
  - Early expert-panel advice would be introduced for class C and D IVDs under IVDR Articles 48 and 56a.
  - This may reduce delays and late-stage disagreements.

- Article 10a MDR/IVDR may improve advance warning of device discontinuation.

CONCLUSION: PROBLEMS VS. PROPOSAL

- Donor-screening / Class D IVDs Partly resolved: procedure more predictable, but CS/EURL burden and class D remains.
- Deceased-donor screening Not resolved: scarce post-mortem assays, unclear windows, incomplete coverage.
- Test availability vs practical availability Resolved: equivalent on the market is not a problem.
- Ambiguous guidance Partly resolved: Article 5(5) IVDR clearer, but 'How to' questions remain.
- Disappearance of niche devices Partly resolved: six-month notice helps planning, but does not stop withdrawals.
- Forced fallback to alternatives Partly resolved: in-house IVD fallback easier; MDR/RUO/off-label burden remains.
- Disproportionate burden / innovation Partly resolved: ISO 15189, sandboxes and evidence flexibility help, but studies remain complex.

KEYPOINTS

- Companies and laboratories face a lot of problems, which may lead to discontinuation of IVDs
- Be careful with changing the intended purpose
- Every IVD is a case-by-case situation
- The proposal will simplify the process, but not solve all problems

THANK YOU

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Extra slides

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DEFINITION MEDICAL DEVICE

in vitro diagnostic medical device' means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, piece of equipment, software or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information on one or more of the following:

(a) concerning a physiological or pathological process or state;

(b) concerning congenital physical or mental impairments;

(c) concerning the predisposition to a medical condition or a disease;

(d) to determine the safety and compatibility with potential recipients;

(e) to predict treatment response or reactions;

(f) to define or monitoring therapeutic measures.

Specimen receptacles shall also be deemed to be in vitro diagnostic medical devices;