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MEETING DOCUMENT

From:	General Secretariat of the Council
To:	Working Party on Pharmaceuticals and Medical Devices (Medical Devices)
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Subject:	Regulation to simplify rules on medical and in vitro diagnostic devices - Commission presentation on cluster 6 - Interplay with the AI Act, dedicated IVD-specific discussion, final and transitional provisions

Delegations will find in annex the presentation by the Commission services at the meeting of the Working Party on Pharmaceuticals and Medical Devices on 3 June 2026.

MDR/IVDR revision
Commission Proposal



DG SANTE Unit D3, Medical devices

European Commission

#HealthUnion

Agenda – Cluster 6

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1. Interplay with the AI Act

- Topics: single procedure regarding AI medical devices under the MDR/IVDR Annex I to Regulation 2024/1689 (AI Act).
  (Legal references: MDR: Article 5(8), Article 36(1), 2nd subparagraph, Article 93(12); IVDR: Article 5(8), Article 32(1), 2nd subparagraph, Article 88(12))

2. Dedicated IVD-specific discussion

- Topics: Definition of 'companion diagnostic', PECP, performance evaluation, performance studies, PMPF, IVD kits.
  (Legal references: IVDR: Article 2(7), Chapter V, Section 2, Annex VII, Sections 3 and 4, Annexes IX, X, XI, XII, Article 29, Chapter VI, Annex II, Annexes XIII-XIV, Article 19a)

3. Final and transitional provisions

- Topics 1: delegated acts, grandfathering of legacy orphan devices, transitional provisions, evaluation (Legal references: MDR+IVDR: Chapter X);
- Topics 2: Entry into force and date of application of the amendments (Legal references: Article 5 of the proposal)



Interplay with the AI Act

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Context

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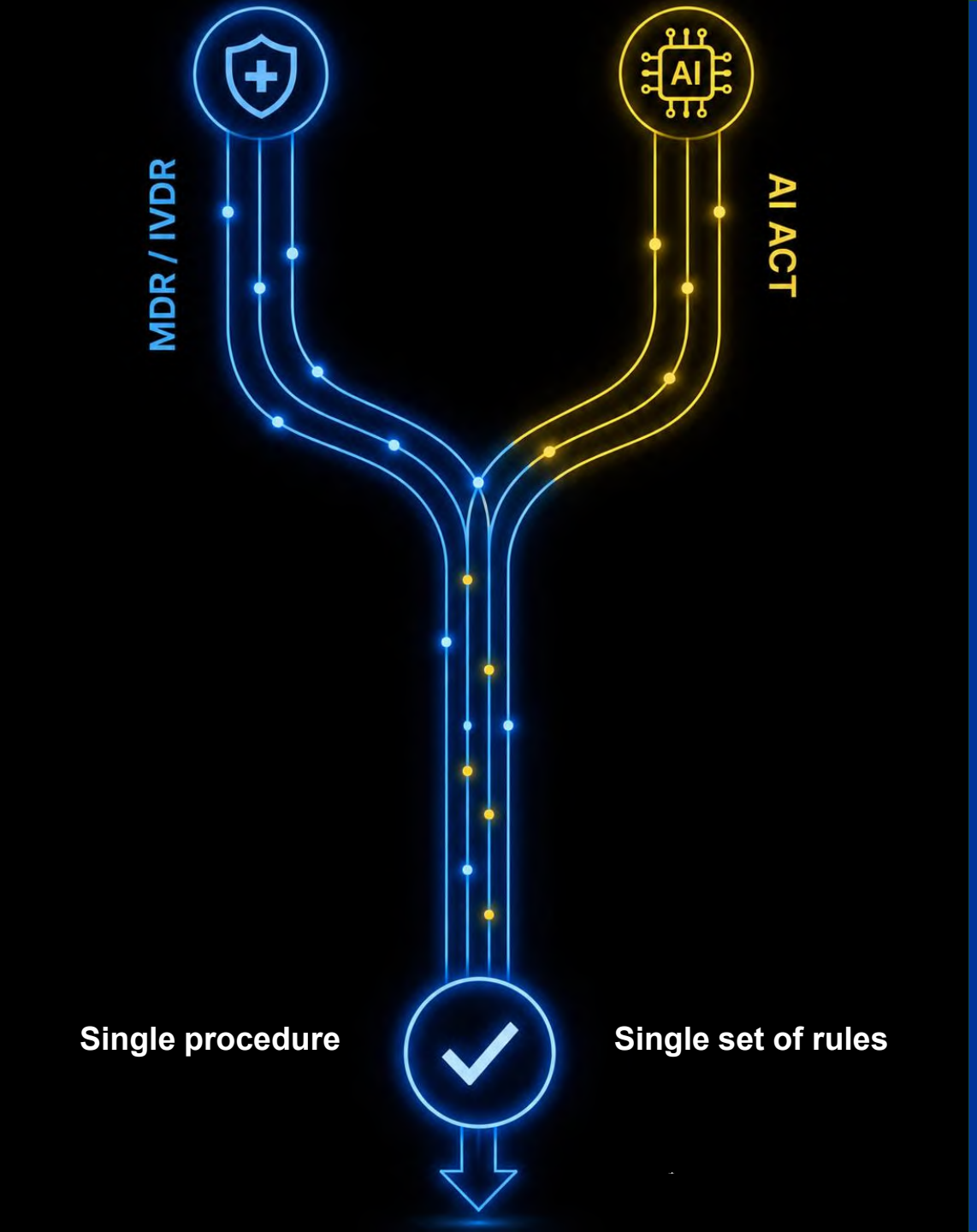
Medical devices and IVDs are already regulated through a **robust governance and risk-based framework** under the MDR/IVDR.

Whilst traditionally falling under 'NLF legislation', the MDR/IVDR provide for **a comprehensive and detailed total product lifecycle approach**, closer to the medicines framework than to other NLF legislation.

The AI Act, like the MDR/IVDR, also introduced a lifecycle governance framework. In most cases, this is for the very first time for products falling under Annex I Section A (e.g. Toys, Recreational Crafts, Pressure Equipment, Lifts).

The AI Act already recognises two approaches (Section A providing for direct application and Section B providing for integrated application). The recent Digital Omnibus on AI confirms that legislation previously under Section A can follow an integrated approach under Section B.

The aim is to ensure that MDAI continues to be regulated and relevant specific requirements introduced by AIA are applied and scrutinized and general principles applies, as appropriate, in a way that ensures **legal certainty, regulatory coherence, supervisory efficiency and consistency**.



MDR/IVDR proposal – the objective

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- Ensure that AI-specific requirements are applied to MDAI in a streamlined, proportional manner, avoiding risks of duplications and divergence
- Adopt a consistent approach on the interplay, similar to other health legislation (e.g. pharma) where specific requirements are included directly rather than in addition to existing requirements
- Build on existing highly developed MDR/IVDR regulatory framework and current experience with implementation (including on AI)

Amendments enabling **direct integration** of AI-specific requirements into the MDR/IVDR

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Amendments to Regulation (EU) 2024/1689

Annex I to Regulation (EU) 2024/1689 is amended as follows:

(1) in Section A, points 11 and 12 are deleted;

(2) in Section B, the following points are added:

'21. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices;

22. Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices.

8. When adopting implementing acts pursuant to paragraph 6 of this Article, delegated acts pursuant to paragraph 7 of this Article or Common Specifications pursuant to Article 9 of this Regulation concerning devices that are high-risk AI systems as referred to in Article 6(1) of Regulation (EU) 2024/1689 of the European Parliament and of the Council*, or that use high-risk AI systems as safety components, the Commission shall take into account the requirements set out in Chapter III, Section 2, of that Regulation.**

6. […] implementing acts to the extent necessary to resolve issues of divergent interpretation and of practical application of GSPRs […]

7. […] delegated acts in accordance with Article 115 to amend GSPRs in order to adapt them to scientific or technical progress […]

AI specific notified body requirements, enabling **direct integration**

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Current text

1. Notified bodies shall fulfil the tasks for which they are designated in accordance with this Regulation in the public interest. […]

[none]

Proposed text

1. Notified bodies shall fulfil the tasks for which they are designated in accordance with this Regulation in the public interest. […]

Notified bodies designated for conformity assessment activities relating to devices that are high-risk AI systems as referred to in Article 6(1) of Regulation (EU) 2024/1689, or that use high-risk AI systems as safety components, shall also meet the requirements set out in Article 31(4), (5), (10) and (11) of that Regulation.';

4. Notified bodies shall be independent […] independence and impartiality […].
5. […] shall (not) be directly involved in the design, development, marketing or use of high-risk AI systems, nor shall they represent the parties engaged in those activities. […] This shall, in particular, apply to consultancy services
10. […] professional integrity and the requisite […]
11. […] sufficient internal competences to be able effectively to evaluate the tasks conducted by external parties on their behalf. The notified body shall have permanent availability of sufficient administrative, technical, legal and scientific personnel who possess experience […]

Legal reference: Article 92(12)

Amendments enabling **direct cooperation** for of AI-specific requirements into the MDR/IVDR

Aim: clarify cooperation mechanisms between market surveillance authorities under MDR/IVDR and AI Act

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Current text

1. The competent authorities shall perform appropriate checks on the conformity characteristics and performance of devices including,

2. […]

[none]

Proposed text

1. The competent authorities shall perform appropriate checks on the conformity characteristics and performance of devices including,

2. […]

12. In respect of devices that are high-risk AI systems as referred to in Article 6(1) of Regulation (EU) 2024/1689, the competent authorities shall cooperate with market surveillance authorities of their Member State designated in accordance with Article 70 of Regulation (EU) 2024/1689.';

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Rationale to move to section B

Designation of notified bodies

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MDR/IVDR: already establish a mature and highly resource-intensive system for the designation and oversight of notified bodies.

AI Act: would introduce largely similar requirements for notified bodies, but important differences remain regarding the designation architecture and governance structure.



MDR/IVDR framework

- **Joint assessment** involving national authorities, Commission and other MS experts

  → **composition:** National MD authorities + COM

- **Existing designation** linked to technologies and conformity assessment activities
- **Continuous monitoring** and reassessment of NBs
- **Requirements** already cover competence, independence, resources, and QMS



AI Act framework

- **No joint assessment system**

→ **composition:**

  - **National AI designating authorities**
  - National MD authorities + COM

- **Similar scope-based** designation approach, according to new codes
- **Similar monitoring** obligations
- **Requirements** largely mirror MDR/IVDR

Pre-market certification / conformity assessment

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MDR/IVDR framework

Intended purpose, claims, and patient population

Risk classification and applicable conformity assessment route

Safety and performance requirements (GSPRs), inc. **information to users**

Quality & risk management systems

Technical documentation

Clinical/performance evaluation

Software lifecycle requirements, including development, validation, cybersecurity, maintenance

Benefit-risk assessment

Continuous lifecycle evidence generation through **PMS/PMCF/PMPF**

AI Act framework

For high-risk AI systems, the AI Act introduces requirements related to:

Quality & risk management systems

Data governance

Technical documentation + template

Logging and record-keeping

Transparency and human oversight

Accuracy, robustness and cybersecurity

Post-market monitoring

Post-Market Surveillance, Vigilance and Market Surveillance

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MDR/IVDR framework

Already establish a comprehensive lifecycle-based post-market system covering post-market surveillance, vigilance, and market surveillance, which include serious incident reporting, trend reporting, FSCAs/CAPAs, PMS plan, PSURs/PMSRs, PMCF/PMPF, and competent authority oversight.

MDR/IVDR authorities already oversee devices, manufacturers, importers and distributors to ensure compliance and risk mitigation, including through market surveillance measures.

Combines proactive and reactive oversight throughout the device lifecycle.

AI Act framework

Introduces post-market monitoring, serious incident reporting and a dedicated market surveillance framework for high-risk AI systems, notable inceptors that never had such requirements.

AI market surveillance authorities have a broader mandate, including oversight of deployers/users such as healthcare providers.

Additional horizontal oversight layer on top of existing MDR/IVDR obligations.

MDR in Section A

- Duplicative designation of NBs
- Two separate conformity assessments
- Single TD structure
- AI assessed outside clinical context
- Unclear integration of data /evidence
- Fragmented post-market system
- Legal uncertainty
- Bottlenecks

MDR in Section B

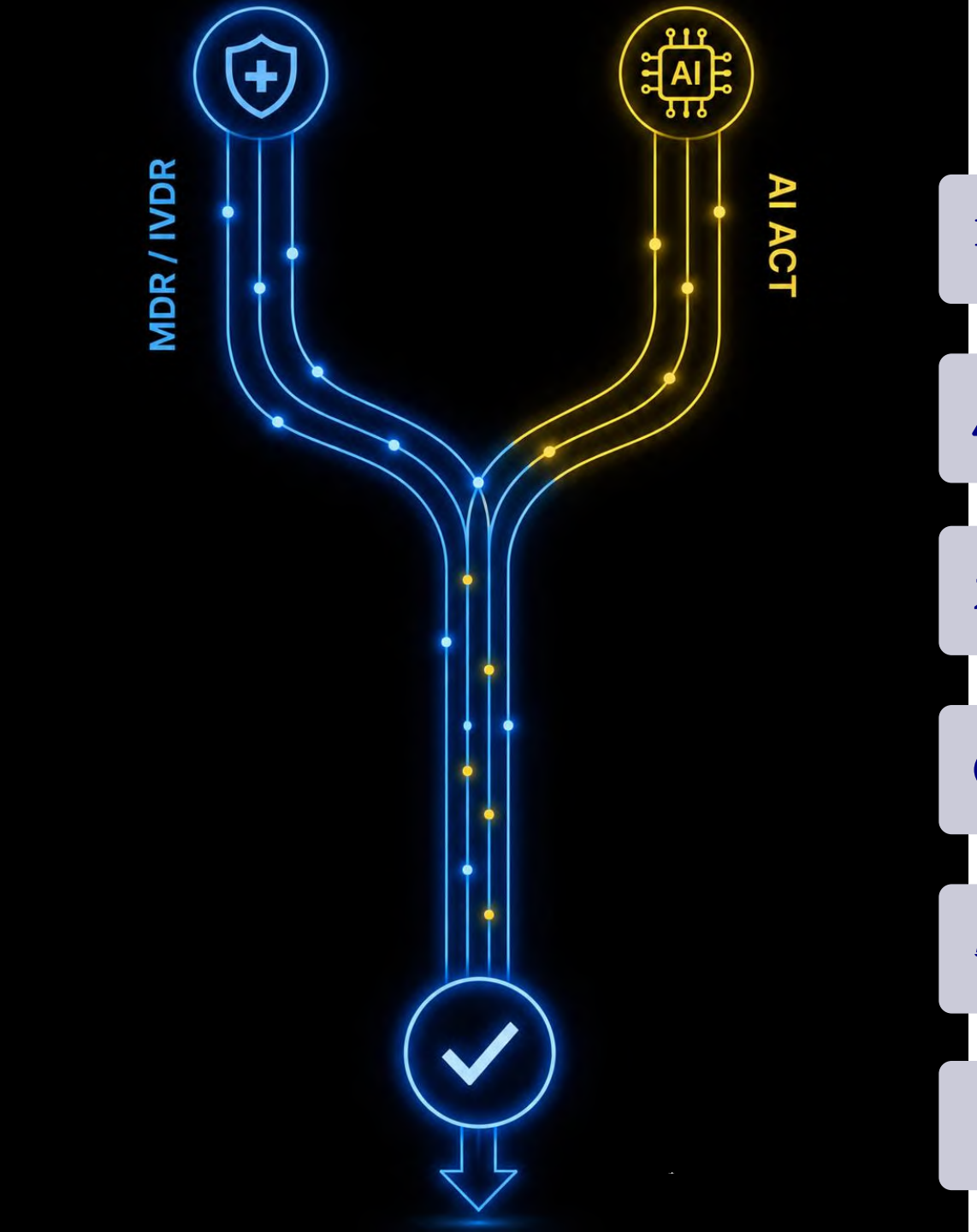
- Use existing MDR/IVDR NB infrastructure
- Integrated device certification
- Single TD structure
- AI assessed within intended medical purpose
- One set of evidence/data governance
- One lifecycle surveillance system
- Sectorial hierarchy
- Avoid additional MNF & NB burden

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All AI-specific requirements from AI Act will be integrated

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- **AI Act requirements:** still must be integrated within sectorial legislation, as appropriate. Notably, those which are AI-specific (e.g. human oversight, data governance, performance drifting, logging capability)
- **Prohibited AI practices under Article 5 continue to apply:** including prohibitions related to manipulative AI systems, exploitation of vulnerabilities, social scoring, certain biometric categorisation systems, emotion recognition in workplace/education contexts, and prohibited remote biometric identification practices.
- **Transparency obligations under Article 50 may apply** where the AI system: interacts directly with natural persons, generates synthetic/deepfake content, performs emotion recognition or biometric categorisation, generates AI-produced public-interest content.
  - In such cases, providers/deployers may need to ensure disclosure, labelling or user information obligations.
- **Fundamental rights safeguards remain relevant (as considered relevant & included):** particularly in relation to biometric systems, emotion recognition and law enforcement uses, including requirements linked to proportionality, human oversight, transparency and fundamental rights impact assessments.



In a nutshell

MDR/IVDR already establish a **comprehensive lifecycle-based framework** covering conformity assessment, notified body oversight, PMS, vigilance and market surveillance.

Where MDR/IVDR already achieve the same regulatory objective through equivalent mechanisms, unnecessary duplication should be avoided.

Where requirements are only partially overlapping, additional legal clarity needs to be provided to ensure consistent interpretation and implementation.

AI-specific risks such as bias, robustness, and model drift are closely linked to clinical, performance and safety and should be assessed within the **MDR/IVDR framework as part of clinical evidence and GSPRs**.

Where genuinely new AI Act obligations exist, implementation should be proportionate and coherent with the existing sectoral framework.

The objective is to ensure **coherent and proportionate integration** of AI requirements within the existing sectoral framework while avoiding unnecessary burden and bottlenecks.



Dedicated IVD-specific discussion of topics not covered in other clusters

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Definitions and concepts

Legal reference: IVDR Article 2(7)

Companion diagnostics – definition

Aim: clarify that one CDx can be associated with more than one medicinal product – better fit with real-world developments

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Current text

‘companion diagnostic’ means a device which is essential for the safe and effective use of ~~a~~ corresponding medicinal product to:

(a) identify, before and/or during treatment, patients who are most likely to benefit from the corresponding medicinal product; or

(b) identify, before and/or during treatment, patients likely to be at increased risk of serious adverse reactions as a result of treatment with the corresponding medicinal product;

Proposed text

‘companion diagnostic’ means a device which is essential for the safe and effective use of **one or more** corresponding medicinal product**(s)** to:

(a) identify, before and/or during treatment, patients who are most likely to benefit from the corresponding medicinal product; or

(b) identify, before and/or during treatment, patients likely to be at increased risk of serious adverse reactions as a result of treatment with the corresponding medicinal product;

Legal reference: IVDR Article 29

SS(C)P – discussed in cluster 1

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Summary of safety and clinical performance (MD)

- Reduction of **scope** (only class IIb implantable and class III devices)
- SSCP should be written in a way that is clear to **intended user** (removal of reference to patients)
- **Removal** of dedicated notified body validation
- **Management** in EUDAMED entirely by manufacturer

Summary of safety and performance (IVD)

- Reduction of **scope** (only class D and class C CDx and self-tests)
- SSP should be written in a way that is clear to **intended user** (removal of reference to patients)
- **Removal** of dedicated notified body validation
- **Management** in EUDAMED entirely by manufacturer
- Removal of elements **duplicated in IFU** (IFU will be public through EUDAMED)

Technical documentation

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- Replace incomplete duplication of **intended purpose** elements in part 1.1(c) by reference to already existing list in Annex I section 20.4.1(c)
- Remove duplication and improve alignment of wording on **critical components**:
  - 1.1(g): the description of the components and where appropriate, the description of the ~~reactive~~ **critical** ingredients of relevant components such as antibodies, antigens, nucleic acid primers
  - 3(a): a description of the critical ~~ingredients~~ **reagents** of the device such as antibodies, antigens, enzymes and nucleic acid primers **not** provided ~~or~~ **but** recommended for use with the device
- For **integral IVD-MD combinations** with ancillary MD part, requirement to include results of Annex I assessment of that MD part or, if applicable, notified body opinion

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Conformity assessment

Conformity assessment - general

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- Streamlined drafting of Article 48 to remove duplication of provisions
- General conformity assessment procedures – addition to general principles already discussed for medical devices:



Class B – during initial conformity assessment, sampling of technical documentation of **one device** out of the manufacturer's portfolio instead of **one device per category**

- A **lower risk class** that makes up **50% of the market** (e.g. MTE Facts and Figures 2025)
- Examples: general clinical chemistry tests (albumin, total protein, electrolytes), urinalysis dipsticks, cholesterol tests, pregnancy and fertility tests – typically **mature standardised methods**
- The proposal:
  - **maintains** some sampling, so there is still oversight
  - **reduces burden** in a low-risk area and therefore helps maintain diagnostic availability and diversity
  - supports **better use of notified body resources**, allowing them to focus on areas where their oversight matters most



Conformity assessment – special procedures

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Maintained

- **Self-tests and companion diagnostics** – individual technical documentation assessment
- **Companion diagnostics** – consultation of medicinal product authority (see later)
- **Class D devices** – EURL testing
  - Corrected copy error from MDR in Annex VII part 4.3.5 on notified body requirements as regards testing of products or product batches
  - In Annex IX 4.12 and XI 5.1, clarified legal basis for the notified body to conduct verification of batches by alternative means if no EURL designated

Removed

- **Class A sterile IVDs** – NB sterility assessment
- **Near-patient tests** – individual technical documentation assessment by NB
- **Certain class D devices** – performance evaluation consultation procedure by expert panel

Legal reference: Article 48 and Annexes IX 5.1, X(2) and (3)(j) and XI

Conformity assessment – special procedures

PUBLIC

Procedure	Rationale for removal
Class A sterile IVDs – NB sterility assessment	• A **small low-risk** product group (sterility is important, but these are still **class A** devices) • Sterilisation is a **standardised and mature** process, and requirements on manufacturer are **unchanged** • NB review adds limited safety value compared to the burden it creates
Near-patient tests – individual technical documentation assessment by NB	• These technologies are now **more mature** than at the time of the development of the IVDR, and are used by **health professionals** • They are **subject to the broader conformity assessment framework** including notified body assessment, according to their risk class and intended purpose • Automatic individual TD assessment is a disproportionate **burden** • Requirements on **manufacturer regarding usability** are intended to be maintained and can be verified by NB if file is sampled
Certain class D devices *(first certification of that device type if no common specifications)* – performance evaluation consultation procedure by expert panel	• A **"punishing" approach** – after manufacturer applied to NB • After 21 expert panel views, procedure is **hardly used** • The same device will also be **tested by an EURL** • A more constructive alternative is to offer expert panel advice to manufacturer **before** they finalise their documentation (see proposal in Art 56a) • Expert panels can always be **used ad hoc** to support development of novel devices or response to crisis based on Article 106, e.g. to input to common specifications

Legal reference: IVDR Annexes IX 5.2 and X 3(k)

Companion diagnostics – consultation [1/3]

Aim: reduce duplication of assessment between medicines authority and notified body

PUBLIC

Current text

The notified body shall, before issuing an EU technical documentation assessment certificate for the companion diagnostic and on the basis of the draft summary of safety and performance and the draft instructions for use, seek a scientific opinion from one of the competent authorities designated by the Member States in accordance with Directive 2001/83/EC or from the EMA, either of which to be referred to in this Section as 'the medicinal products authority consulted' depending on which has been consulted under this point, regarding the suitability of the device in relation to the medicinal product concerned.

Proposed text

The notified body shall, before issuing an EU technical documentation assessment certificate for the companion diagnostic and on the basis of the draft summary of safety and performance and the draft instructions for use, seek a scientific opinion from one of the competent authorities designated by the Member States in accordance with Directive 2001/83/EC or from the EMA, either of which to be referred to in this Section as 'the medicinal products authority consulted' depending on which has been consulted under this point, regarding the suitability of **the clinical performance** of the device in relation to the medicinal product concerned. **The assessment of the medicinal products authority consulted shall not repeat the assessment to be performed by the notified body in accordance with this Regulation.**

Legal reference: IVDR Annexes IX 5.2 and X 3(k)

Companion diagnostics – consultation [2/3]

Aim: make procedure more practical – introduce clock-stop to enable notified body and manufacturer to respond to requests

PUBLIC

Current text

The medicinal products authority consulted shall provide its opinion, within 60 days of receipt of all the necessary documentation. This 60-day period may be extended once for a further 60 days on justified grounds. The opinion and any possible update shall be included in the documentation of the notified body concerning the device.

Proposed text

The medicinal products authority consulted shall provide its opinion, within 60 days of receipt of all the necessary documentation. This 60-day period may be extended once for a further 60 days on justified grounds. **When preparing its opinion, the medicinal products authority consulted may request the notified body, or the manufacturer, to provide within a specific time period additional information necessary for its assessment referred to in point (c). In case of such a request, the time-limit set out in this paragraph shall be suspended until the additional information requested is provided.** The opinion and any possible update shall be included in the documentation of the notified body concerning the device.

Companion diagnostics – consultation [3/3]

Aim: avoid burden from redundant procedures

PUBLIC

Current text

[none]

Proposed text

[The requirement for consultation] **shall not apply where the following conditions are met:**

(i) the companion diagnostic has the same intended purpose as another already CE-marked companion diagnostic for which a medicinal products authority issued a favourable opinion in accordance with point (d) or Section 3 of Annex X, point (k)

(ii) the manufacturer shows equivalent performance to that already CE-marked companion diagnostic

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Performance evaluation and performance studies

Performance evaluation – general

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- General provisions on performance evaluation and clinical evidence (Article 56 and Annex XIII) reworded to streamline and remove duplication
- Clear logical sequence of key principles in Article 56:
  - Performance evaluation to confirm the safety and performance of device
  - Including scientific validity, analytical performance and clinical performance
  - Data and conclusions shall constitute sufficient clinical evidence
  - Manufacturer to specify and justify the necessary level of clinical evidence
  - Performance evaluation is to be updated throughout life cycle of device
- 4 reports (scientific validity, analytical performance, clinical performance, post-market performance follow-up report) → one performance evaluation report

Legal reference: IVDR Article 56a

Advice from expert panels

PUBLIC

Aim: provide support to manufacturers as regards clinical performance of medium to high risk IVDs at an early stage

Current text

[none]

Proposed text

For class C and class D devices, a manufacturer may, prior to its performance study or clinical performance evaluation, consult an expert panel as referred to in Article 106 of Regulation (EU) 2017/745, with the aim of reviewing the manufacturer's intended strategy for demonstrating clinical performance or proposals for any clinical performance study. The manufacturer and the notified body involved in any future conformity assessment procedure shall, in the performance evaluation report and the performance evaluation assessment report, give due consideration to the advice of the expert panel, and where they do not follow that advice, they shall provide duly justified reasons.

Authorisation of certain performance studies [1/3]

Legal reference: IVDR Article 58(1)

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Aim: remove burden of authorisation for studies which involve only low-risk specimen collection procedures, e.g. capillary or venous blood sampling from non-vulnerable individuals

Current text

Any performance study:

~~**(a) in which surgically invasive sample-taking is done only for the purpose of the performance study;**~~

(b) that is an interventional clinical performance study as defined in point (46) of Article 2; or

(c) where the conduct of the study involves additional invasive procedures or other risks for the subjects of the studies

shall, in addition to meeting the requirements set out in Article 57 and Annex XIII, be designed, authorised, conducted, recorded and reported in accordance with this Article and Articles 59 to 77 and Annex XIV.

Proposed text

Any performance study:

(a) [none]

(b) that is an interventional clinical performance study as defined in point (46) of Article 2; or

(c) where the conduct of the study involves additional invasive procedures, **including high-risk procedures for collection of specimens,** or other risks for the subjects of the studies,

shall, in addition to meeting the requirements set out in Article 57 and Annex XIII, be designed, authorised, conducted, recorded and reported in accordance with this Article and Articles 59 to 77 and Annex XIV.

Accompanied by corresponding amendment of Art. 66(7) which provides for early start of studies under Art. 58(1)(a)

Legal reference: IVDR Article 58(2)

Authorisation of certain performance studies

Aim: remove (1) implementation ambiguity around CDx status and (2) administrative burden of notification

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Current text

~~**2. Performance studies involving companion diagnostics shall be subject to the same requirements as the performance studies listed in paragraph 1. This does not apply to performance studies involving companion diagnostics using only left-over samples. Such studies shall however be notified to the competent authority.**~~

Proposed text

[none]

Note: studies on companion diagnostics that are <u>not</u> done on left-over samples will continue to be subject to authorisation through Article 58(1)(b), as they are interventional performance studies

Legal reference: IVDR Article 58(5)(a) and others

Authorisation of certain performance studies

Aim: clarify in which Member State(s) the application is to be submitted

PUBLIC

Current text

the performance study is the subject of an authorisation by the Member State(s) in which ~~**the performance study is to be conducted**~~, in accordance with this Regulation, unless otherwise stated

Proposed text

the performance study is the subject of an authorisation by the Member State(s) in which **the specimens for the performance study are to be collected**, in accordance with this Regulation, unless otherwise stated

Note: for IVDs, “conducted” is ambiguous, as collection of specimens and their analysis can take place in geographically different locations

Legal reference: IVDR Annex XIII 1.2.3

Clinical performance – data sources

Aim: enable use of more data sources, similar to medical devices

Current text

Demonstration of the clinical performance of a device shall be based on one or a combination of the following sources:

– clinical performance studies;

– scientific peer-reviewed literature;

– published experience gained by routine diagnostic testing.

Proposed text

Demonstration of the clinical performance of a device shall be based on one or a combination of the following sources:

– clinical performance studies **of the device concerned or of a device for which equivalence to the device concerned can be demonstrated**;

– other studies published in scientific literature **on the device concerned or of a device for which equivalence to the device concerned can be demonstrated;**

– other clinical experience published in peer-reviewed scientific literature **with the device concerned or a device for which equivalence to the device concerned can be demonstrated;**

– clinically relevant information coming from post-market surveillance, in particular the PMPF;

– published experience gained by routine diagnostic testing

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Legal reference: Annex XIII section 2.3.2

Clinical performance – endpoints for combined studies

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Aim: facilitate combined studies of medicinal products and devices where endpoints are intrinsically linked

Current text

(l) parameters of clinical performance in accordance with point (b) of Section 9.1 of Annex I to be determined, with justification for any omission; and with the exception of studies using left-over samples the specified clinical outcomes/endpoints (primary/secondary) used with a justification and the potential implications for individual health and/or public health management decisions

Proposed text

(l) parameters of clinical performance in accordance with point (b) of Section 9.1 of Annex I to be determined, with justification for any omission; and with the exception of studies using left-over samples the specified clinical outcomes/endpoints (primary/secondary) used with a justification and the potential implications for individual health and/or public health management decisions; **for combined studies, endpoints reporting on the device and medicinal product together may be used**



Final and transitional provisions

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Final provisions MDR and IVDR

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Delegated Acts

- EP and Council scrutiny period 2 months (instead of 3 months) – Art. 115(6) MDR, Art. 108(6) IVDR
- Possibility to combine delegated powers in one delegated act – deletion of Art. 116 MDR, Art. 109 IVDR

Evaluation

- New evaluation of MDR/IVDR 5 years after date of application of amendments – Art. 122 MDR, Art. 111 IVDR

National databases

- Retrieval of data from Eudamed modules after mandatory use – Art. 123(3)(d) MDR, Art. 113(3)(f) IVDR

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Transitional provisions

- Grandfathering of ‘legacy’ orphan devices, i.e. no need for MDR/IVDR certification – Art. 120(14) MDR, Art. 110(12) IVDR
  - Expert panel opinion on orphan device status (renewal after 10 years)
  - No significant changes
  - No unacceptable risk
  - No CE marking
  - Information to users

- Pending NB conformity assessment procedures / surveillance activities – Art. 120(15) MDR, Art. 110(13) IVDR
  - Application of existing MDR/IVDR requirements subject to MFR/NB agreement until issuance/renewal of certificate

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Entry into force and application of the proposed amendments (Art. 5 of the proposal)

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Entry into force

- 20 days after publication in OJEU

Application

- 6 months after entry into force: all amendments
- Except for:
  - with entry into force: Art. 56 MDR/Art. 51 IVDR (NB certificates); Art. 120 MDR/Art. 110 IVDR (grandfathering of legacy orphan devices); Art. 58 IVDR (authorisation of performance studies); Art. 30 of Reg. 2022/123 (EMA ExPaMed Secretariat); Annex I AI Act (move of MDR/IVDR to section B)
  - 12 months after entry into force: Chapter IV MDR/IVDR (notified bodies)
  - 3 years after entry into force: Art. 87a MDR/Art. 82a IVDR (cybersecurity reporting)
  - 5 years after entry into force: Art. 17 MDR (single-use devices and reprocessing)

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