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MEETING DOCUMENT

From:	General Secretariat of the Council
To:	Working Party on Pharmaceuticals and Medical Devices (Medical Devices)
N° prev. doc.:	ST 11243/26, ST 11244/26
N° Cion doc.:	ST 16919/25 + ADD1
Subject:	Meeting of the Working Party on Pharmaceuticals and Medical Devices - Presentation by the Presidency

Delegations will find attached the presentation of the Presideny on the proposed Regulation to simplify rules on medical and in vitro diagnostic medical devices - clusters 3 and 4, blocks 1 and 2 - given at the Working Party on Pharmaceuticals and Medical Devices on 15 and 16 July 2026.

Uachtaránacht na hÉireann ar
Chomhairle an Aontais Eorpaigh 2026

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Irish Presidency of the Council of the European Union 2026

Working Party on Pharmaceuticals and Medical Devices
15th – 16th July 2026

MDR and IVDR

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Round 4

Classification

Clusters 3 & 4 – Block 1

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Classification

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- Clarification on the classification of blood bags
- Update of Rule 8 align with the concept of well-established technologies as defined elsewhere in the Regulation
- Further elaborated Rule 11 – Software
  - Software intended to generate an output to achieve a medical purpose
  - Enhanced alignment with IMDRF
  - Lay user Vs professional clinical oversight
  - Draws on situational risk: non-serious / serious / critical

Uachtaránacht na hÉireann ar
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Round 5

Round 5 - Conformity Assessment

Cluster 3 & 4 – Block 1

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Article 52a

Conformity assessment of breakthrough devices ~~and of~~**,** orphan devices**, and essential paediatric devices**

Article 52a

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3a. A device shall be considered an essential paediatric device if it meets all the following criteria:

(a) It is intended to be used exclusively for patients in the paediatric population, and

(b) it is expected to provide a significant positive clinical impact on patients or public health, for a life-threatening or irreversibly debilitating disease or condition, by either of the following:

(i) offering a significant positive clinical or health impact compared to available alternatives and the state of the art;

(ii) fulfilling an unmet medical need where there is an absence or insufficiency of available alternative options for that purpose.

Article 52a

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1. For the conformity assessment of breakthrough devices ~~and~~, orphan devices, ~~for which~~ **and essential paediatric devices, where the conformity assessment procedure requires the involvement of** a notified body~~, is involved in the conformity assessment,~~ the procedures laid down in Article 52 shall apply subject to the specific arrangements set out in this Article.

4. …**In addition, with the exception of devices covered by Article 54, upon a duly substantiated request by a notified body, an expert panel shall provide an opinion with respect to confirming whether the criteria set out in paragraph 7 of this Article are fulfilled.**

7. Notified body assessment of sufficient clinical evidence based on limited clinical data, benefit of immediate availability outweighs risk, benefit-risk-ratio is favourable.

Article 52a

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6. For a ~~confirmed~~ breakthrough device ~~or an~~ **,** orphan device, **or essential paediatric device, confirmed by the relevant expert panel**, as applicable, the notified body involved in the conformity assessment procedure set out in Article 52 shall **offer priority access to supports to the manufacturer throughout** ~~prioritise~~ the conformity assessment ~~of that device and apply, where appropriate, a rolling review with a view to reduce assessment timelines~~ **procedure**.

These supports may include, where appropriate:

(a) Reduced assessment timelines;

(b) Rolling reviews of technical documentation;

(c) Priority access, free of charge, to the dialogues outlined in Annex VII section 1.2.9;

(d) Proportionate reductions in related fees; and

(e) Deferral of payments of fees until the relevant conformity assessment activity is finalised.

…

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Article 59, 59a

Derogations

Article 59, 59a

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- “Limited (Defined) number of devices”
- Art 59. 1a. “use of the device”
- Conditions / limitations
- Expert panel opinion

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Regulatory Sandboxes

Definitions - Article 2(74), (75), (76)

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- Prospective manufacturer
  - AI Act – “Prospective Provider”
    - Numerous references
    - Reg. sandboxes
    - EU Database
    - MS Activities
  - Pharma Reg – not used

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Article 59b

Regulatory Sandboxes at National Level

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National - Article 59b

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1. Member States, on their own initiative or upon a substantiated request by a manufacturer ~~or a prospective manufacturer~~, may establish one or more regulatory sandboxes to which the application of certain requirements of Chapters V or VI or of Annexes I, VIII, IX, X, XI, XIV or XV would not be appropriate **from a technical or scientific viewpoint, and that, with regard to those requirements, every precaution has been taken to protect the health and safety of patients, users, and other persons. …**

…

1a. Regulatory sandboxes shall not involve investigational devices or the placing on the market or putting into service of devices which do not comply with the requirements of this Regulation other than those that are not applicable pursuant to paragraph 1.

National - Article 59b

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2. (Sandbox plan) … **set out clinical, scientific and regulatory justification for the necessity to establish a** regulatory sandbox, **including at least:**

   (a) identification of the requirements of this Regulation referred to in paragraph 1, which, by way of derogation from this Regulation, are temporarily adapted in the regulatory sandbox;

   (b) justification that the application of those requirements is considered not appropriate and an explanation as to how potential risks related to the adaptation are controlled and mitigated;

   (c) recommendations for alternative or mitigation measures, where appropriate; and

   (d) identification of the reasonable duration of the regulatory sandbox necessary to achieve its objectives and the participants in the regulatory sandbox and their respective roles.

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Round 6

Round 6 – Clinical investigations

Articles 62(1), 74(1), 82

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Clinical investigations

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Work in progress

Article 82 – Reintroduced

Rationale for deletion

- Divergent application of A. 82 across EU
- National provisions
- Predictability, consistency
- Burden and costs associated with adapting to national provisions

Clinical investigations

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Current clinical investigations under A. 82

- Varies by MS
- Pre-market A. 82
  - Early academic, researcher-led
  - Prototypes
  - None
- Post-market A. 82
  - PMCF investigations **without** add. invasive/burdensome procedures
  - Independent, Researcher-led post-market clinical investigations not part of PMCF plan
  - Registry-based studies

Clinical investigations

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Article 62(1)

Current MDR:
Clinical investigations … where carried out as part of the clinical evaluation for conformity assessment purposes, for one or more of the following purposes:…

CION Proposal:
Clinical investigations … where they are carried out to assess an investigational device that has not been placed on the market or put into service in accordance with this Regulation and where carried out for one or more of the following purposes:

a) to **assess**, establish and verify that, under normal conditions of use, a device is designed, manufactured and packaged in such a way that it is suitable for one or more of the specific purposes listed in point (1) of Article 2, and achieves the performance intended as specified by its manufacturer;

b) to **assess**, establish and verify the clinical benefits of a device as specified by its manufacturer;

c) to **assess**, establish and verify the clinical safety of the device and to determine any undesirable side-effects, under normal conditions of use of the device, and assess whether they constitute acceptable risks when weighed against the benefits to be achieved by the device.

Clinical investigations

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Article 74(1)

- **Unchanged from CION proposal**

- CE Marked
- Within intended purpose
- Additional invasive or burdensome procedures.
- Part of PMCF plan

- **Not included:**
- PMCF investigations without additional invasive or burdensome procedures
- Independent, not part of PMCF plan

- Article 74(2) – outside intended purpose

Clinical investigations

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Article 82

(64) Article 82 is ~~deleted;~~ amended as follows

1. Clinical investigations, not performed pursuant to any of the purposes listed in Article 62(1) **or Article 74**, shall comply with the provisions of Article 62 (2) and (3), points (b) to (l) of Article 62(4), **Article 62(5)** and Article 62(6).

2. In order to protect the rights, safety, dignity and well-being of subjects and the scientific and ethical integrity of clinical investigations not performed for any of the purposes listed in Article 62(1) **or Article 74**, each Member State shall define any additional requirements for such investigations, as appropriate for each Member State concerned.

3. Article 80 shall apply for clinical investigations of devices conducted in accordance with this Article. Where the device already bears the CE marking in accordance with Article 20(1), the provisions on vigilance laid down in Articles 87 to 90 and in the acts adopted pursuant to Article 91 shall apply instead of Article 80.

Clinical investigations

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Decisions to be made regarding:

- **Article 82 retention**
- **How to reduce divergence and burden associated with Article 82**
- **Scope of Art 62(1)**
- **Expand scope of Art. 74 to include all PMCF investigations?**
- **Independent post-market investigations?**
- **Article 82 amendments to improve harmonisation?**

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Round 6

Round 6 – Clinical investigations

Other aspects

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Clinical investigations

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Other elements

- Clinical investigation vulnerable populations and emergency situations (Art 64-68)
  - CTR, IVDR, Dec. of Helsinki
  - Article 68

- Clinical investigation substantial modifications (Art 75)
  - Clock suspension

- Combined studies
  - Definition (MDR Art 2(73), IVDR Art 2(75))
  - Requirements for clinical investigation part (Art 79a)