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MEETING DOCUMENT

From:	General Secretariat of the Council
To:	Working Party on Pharmaceuticals and Medical Devices (Medical Devices)
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 1 and 2 - given at the joint Working Party on Public Health and Working Party on Pharmaceuticals and Medical Devices on 2 July 2026 and at the Working Party on Pharmaceuticals and Medical Devices on 3 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

2 July

MDR and IVDR

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Cluster 1

Scope and Definitions

Well-Established Technology Devices (WET)

Well-Established Technology Devices (WET)

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‘(72) ‘well-established technology device’ means a device that ~~belongs to a generic device group, which~~ fulfils **all** the following criteria:

(a) it ~~has~~ **is** simple **in its design, with a**~~, common and~~ stable ~~design~~ **manufacturing process and is characterised by a relative ease of use and operation by the intended user**;

(b) it ~~has not been associated with safety issues in the past;~~ **is part of a generic device group that is characterised by all the following:**

- it has a stable, acceptable, and well understood risk profile, with a demonstrable, favourable track record of safety;

- the clinical performance characteristics of the generic device group are acceptable, well-understood, and sufficiently documented based on relevant clinical and post-market surveillance data, taking into account the expected lifetime of the device and the state of the art;

- devices in the generic device group have been continuously made available on the Union market for at least ten years; and

- the characteristics of devices in the generic device group are stable, as demonstrated by no significant changes to the design or intended purpose over the past ten years.

~~(c) it has well-known clinical performance characteristics and comprises standard of care devices with little evolution in indications and the state of the art;~~

~~(d) it has a long history on the Union market;’;’~~

Well-Established Technology Devices (WET)

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Article 3

Amendment and implementation of certain definitions

1. The Commission is empowered to adopt delegated acts in accordance with Article 115 in order to amend the definition of well-established technology device set out in Article 2, point (72), in the light of technical and scientific progress and taking into account definitions agreed at Union and international level.

2. The Commission ~~may, by means of implementing acts, draw up non-exhaustive lists of devices that fall under, or of devices that do not fall~~ **shall, in consultation with the MDCG, develop dedicated guidelines to support national authorities in the determination of whether a device falls** under the definition of well-established technology device **as referred to** in Article 2, point (72). **Those guidelines shall include at least an indicative, non-exhaustive list of devices that are deemed to fall under the definition, and may include an indicative, non-exhaustive list of devices that are not deemed to fall under that definition. Those guidelines shall be published by [one year after publication of this Regulation in OJEU], and shall be assessed and updated regularly, as appropriate.**

~~Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).'~~

Uachtaránacht na hÉireann ar
Chomhairle an Aontais Eorpaigh 2026



Irish Presidency of the Council of the European Union 2026

Working Party on Pharmaceuticals and Medical Devices

3 July

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Cluster 2

Rounds 1 & 2

Cooperation and **Support**

MDCG, NBO, EMA, Expert Laboratories and Expert Panels

Approach

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- Reinstate and further elaborate the tasks of the MDCG
- Reinforce the establishment of MDCG subgroups
- Detail the role of NBO and its tasks
- Clarify the role of the EMA in providing centralised support on operational regulatory activities
- Further outline the governance and oversight of expert panels and clarify the potential activities of expert laboratories

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Irish Presidency of the Council of the European Union 2026

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