Council of the European Union
General Secretariat

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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 11246/26, ST 11249/26, ST 11961/26
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 3 and 4, and cluster 5, block 1 - given at the Working Party on Pharmaceuticals and Medical Devices on 27 and 28 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

1 July – 31 December 2026

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Background

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Objectives

- Achieve balance between a proportionate level of pre-market assessments and post-market oversight

- Adopt a targeted approach across the regulatory lifecycle including initial device certification, re-assessment, periodic monitoring, post-market surveillance and vigilance

- Employ risk-based principles

- Leverage a range of checks including single point assessments, self-checks and continuous monitoring activities

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Principles

- No maximum period of validity for “Quality Management System” certificates in principle

- Re-assessment of technical documentation to be conducted after an initial 5 years for certain risk classes

- Notified Body may limit the period of validity or impose conditions on certificates

- Monitoring to take place as part of risk based surveillance activities justified by Notified Body and periodic reviews

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Principles

- Selection of samples of technical documentation (where relevant) to be proportionate to risk and compliance history

- Notified Body to maintain a sampling plan including justification for selection

- Manufacturer to set criteria in Post-Market Surveillance Plan for update of post-market reports – compromise text includes minimum triggers per risk class

- Notified Body review of PSUR to be determined by risk and representative-based concepts

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Vigilance

- Maintain proposal for amended reporting timelines for serious incidents
- Emphasise the importance of exchange of vigilance information between authorities
- Clarify the role of the Notified Body in vigilance activities
- Market surveillance to be discussed in future CWP meetings