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NOTE

From:	General Secretariat of the Council
To:	Council
Subject:	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards simplifying and reducing the burden of the rules on medical devices and in vitro diagnostic medical devices, and amending Regulation (EU) 2022/123 as regards the support of the European Medicines Agency for the expert panels on medical devices and Regulation (EU) 2024/1689 as regards the list of Union harmonisation legislation referred to in its Annex I *- General approach*

I. INTRODUCTION

1. On 16 December 2025, the Commission adopted a proposal amending the Medical Devices Regulation and the *In Vitro* Diagnostic Regulation[1] ("the proposal") as part of the health package. The proposal is based on Article 114 and Article 168(4), point (c) of the Treaty on the Functioning of the European Union (TFEU) (ordinary legislative procedure).

[1] ST 16919/25 + ADD1

2. The aims of the proposal are coherent with the objectives of the existing EU legislation: safeguarding a high level of patient safety and public health and supporting the smooth functioning of the internal market, and ensuring a continued availability of safe and innovative devices for EU patients. However, with the entry into application of the existing EU legislation on medical devices, supply shortages emerged and critical devices were withdrawn from the market. To tackle the issue of shortages in the short term, the transitional periods have been extended several times. At the Council (EPSCO, Health) on 3 December 2024, several delegations called on the Commission to reform the existing EU legislation.[2]

3. The proposal seeks to address underlying structural problems which remain unsolved despite extensions of transition periods, and which significantly affect the availability of devices, the competitiveness of EU manufacturers and innovation in medical technology, with, in turn, a negative impact on public health protection and patient safety. Since the proposal builds on the key features of the existing EU legislation, an impact assessment was not deemed necessary. However, the proposal is supported by a targeted evaluation of the existing regulatory framework, carried out by the Commission in 2024 and 2025[3], and by a cost-savings analysis of the proposed changes[4].

4. The European Parliament designated the Committee on Public Health (SANT) as the responsible committee for this proposal and appointed Mr Oliver Schenk (DE, EPP) as the Rapporteur.[5] The European Parliament is aiming to vote on its position by the end of December 2026 or early 2027.

5. The European Economic and Social Committee adopted an opinion[6] on 29 April 2026.

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2 ST 15380/24
3 ST 16919/25 ADD3-4
4 ST 16919/25 ADD2
5 The Rapporteur for the opinion of the Committee on Internal Market and Consumer Protection (IMCO), adopted on 12 November 2026, is Ms Maria Guzenina (FI, S&D). The Rapporteur for the opinion of the Committee for budgetary assessment (BUDG), adopted on 5 November 2026, is Mr Hélder Sousa Silva (PT, EPP).
6 ST 9402/26

6. The Italian Chamber of Deputies adopted an opinion[7] on 22 April 2026. The French Senate adopted an opinion[8] on 13 May 2026. The Italian Senate adopted two resolutions[9] on 11 and 16 June 2026.

II. STATE OF PLAY

7. The Commission presented the proposal and the Staff Working Documents on the targeted evaluation and the cost-savings at the Working Party on Pharmaceuticals and Medical Devices on 14 January, 13 February and 12 March 2026. The Working Party on Pharmaceuticals and Medical Devices started its article-by-article examination on 23 March 2026. On 16 June 2026, the Council (EPSCO, Health) took note of a progress report submitted by the Cyprus Presidency[10]; several delegations highlighted the urgent need for reform and called for the negotiations to conclude as swiftly as possible.

8. Under the Irish Presidency, the text has been discussed in fifteen meetings. Based on those discussions and on comments from delegations, the Presidency has developed the following compromises:

   – Established sectoral rules for high-risk **artificial intelligence (AI)** system to facilitate the transfer of the medical devices framework from Section A to Section B of the AI Act[11], mandated the Commission to specify requirements relating to certain AI-enabled devices by July 2028, defined requirements for deployers and refined requirements for notified bodies and reporting obligations in relation to AI.

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7 ST 8808/26
8 ST 9417/26
9 ST 10876/26 and ST 11046/26
10 ST 9801/26
11 Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act), OJ L, 2024/1689, 12.7.2024.

- Reinforced the mechanism for the identification and communication of **interruptions in supply** that could result in serious harm to patients, as well as elaborating resilience requirements for devices on the Union list of such devices, including shortage prevention plans.
- Reformed the approach to the **reprocessing of single use devices** to ensure greater union wide harmonisation facilitated by the adoption of additional common specifications by December 2029, whilst also allowing Member States to introduce or maintain stricter rules, or prohibit reprocessing at national level.
- Tailored a regulatory **exemption for devices manufactured and used in-house** by health institutions, fostering innovation without undermining safety or creating undue distortions of competition.
- Strengthened the governance mechanisms of the regulatory system by clarifying the **decision-making roles and responsibilities** of the national competent authorities, the MDCG, the Commission and the European Medicines Agency.
- Further defined the **requirements to be met by notified bodies** and elaborated the role of the Notified Body Oversight subgroup of the the Medical Device Coordination Group ('MDCG') in the coordination and guidance of notified bodies with a view to ensuring greater harmonisation and more effective implementation of the Regulations.
- Further clarified the **roles of the authority responsible for notified bodies and experts** nominated by the Commission and by other Member States in the joint assessment of notified bodies.
- Ensured the **financial sustainability of the system** through fees, including reductions and deferrals taking into account the size and portfolio of notified bodies, as well as the size of manufacturers and the nature of orphan devices, cognisant of the challenges in bringing the latter to market.

- Developed **proportionate procedures for qualification and classification of devices** incorporating efficient coordination mechanisms and appropriate escalation pathways to ensure greater predictability and regulatory coherence.
- Further refined the definition of '**well-established technology devices**' and mandated the Commission to identify devices meeting this definition to support uniform application, while detailing proportionate requirements for these devices.
- Introduced a specific conformity assessment pathway for **essential paediatric devices**.
- Further specified provisions **on derogations** in the event of a serious cross-border threat and on the establishment of regulatory **sandboxes,** to ensure they are robust, effective and legally sound.
- Adpated the **clinical investigation** requirements to minimise disruption from the *status quo*, clarify the rules for post-market clinical follow-up investigations, update provisions for vulnerable populations in line with good clinical practice and established ethical principles, and preserve the ability for national requirements on certain clinical investigations such as independent, academic studies.
- Adpated the requirements regarding **clinical evaluations and clinical data** to ensure they are proportionate to the risk and characteristics of devices, while remaining robust and effective in confirming the device's safety and clinical performance.
- Detailed a carefully balanced approach for **equivalence** that allows for more flexible criteria and the removal of contractual obligations, while ensuring safeguards through sufficient access to the equivalent device's clinical data and through preventing inappropriate chains of equivalence leading to compounding reliance on a small volume of clinical data.

- Mandated the Commission to specify technical requirements relating to **cybersecurity** and integrated the reporting of cyber incidents into the vigilance system, making timelines consistent with the Cyber Resilience Act[12].
- Adapted **classification rules for software** in light of international guidance and recent technology developments.
- Refined the conditions for the appointment and conflict of interests concerning members of the **expert panels**, as well as the roles and responsibilities of those panels**.**
- Revised the **international cooperation** provisions to clarify fundamental aspects, including the Council prerogatives and the relevant procedures laid down in the Treaties.
- **Deleted or strictly framed empowerments** for the Commission to amend certain tasks and annexes through delegated acts.
- Introduced comprehensive **transitional provisions** with a view to mitigating the risk of bottlenecks during the transition to the revised regulatory framework and rewarding compliance with the existing legislation.

[12] Regulation (EU) 2024/2847 of the European Parliament and of the Council of 23 October 2024 on horizontal cybersecurity requirements for products with digital elements and amending Regulations (EU) No 168/2013 and (EU) 2019/1020 and Directive (EU) 2020/1828 (Cyber Resilience Act), OJ L, 2024/2847, 20.11.2024.

9. While recognising the overall aim of simplification, several delegations have raised concerns on the **cumulative impact of the Commission proposals on the safeguards in place** and the coherence of the regulatory framework. To address concerns raised by delegations while maintaining simplification as a key objective, the Presidency has adopted a targeted, risk-based approach across the entire regulatory lifecycle of the devices, including device conformity assessment, clinical evaluation, certification, re-assessment, periodic monitoring, post-market surveillance and vigilance. Under such an approach, proportionate measures for certificate validity and representative sampling of technical documentation by notified bodies are balanced within a package with a range of measures for post-market oversight to ensure that devices remain safe and perform as intended throughout their lifetime. This is a delicate balance between simplification and safeguards; changing a simplification element would necessitate a corresponding change to safeguard measures.

10. Under that approach, **only higher-risk devices are routinely subject to an initial certificate validity** of 5 years and a subsequent 'one-time' re-assessment of technical documentation. Those are typically life-supporting devices, or devices implanted for long-term use in the body, such as artificial heart valves, implantable defibrillators, paediatric spinal implants, coronary stents and breast implants. The certificate validity of other risk classes of devices remains unlimited as proposed originally by the Commission. In addition, transitional provisions will ensure that legacy devices certified under the current legislative framework may continue to be placed on the market with commensurate levels of assessment.

11. Along with a significant reduction of the regulatory burden, the compromise proposed by the Presidency also enables **significant savings related to re-certification costs**, estimated to amount to approximately 216 million EUR per year.[13] The cost savings that would result from a complete removal of re-certification as originally proposed by the Commission, are estimated at 227 million EUR per year. Both under the Presidency compromise and the Commission proposal, the removal of the quality management system certification remains the main source of savings, accounting for two thirds of the savings.

12. On 14 October 2026, the Permanent Representatives Committee broadly affirmed the overall balance achieved with the Presidency compromise text between **simplification and quality and safety safeguards**. The Permanent Representatives Committee also provided guidance to the Working Party on **support measures for micro and small enterprises** and highlighted **level playing field** considerations. In that respect, the Presidency has proposed to reduce the frequency of surveillance audits and assessments conducted by notified bodies in the absence of safety signals and where a manufacturer has previously demonstrated good levels of compliance, taking into account the complementary role played by competent authority market surveillance inspections as part of the overall oversight of the devices in the post-market phase.

[13] Source: Commission staff working document on costs savings (ST 16919/25 ADD2) and subsequent calculations. The compromise includes a single re-certification cycle for product certificates for higher-risk devices, which is assumed to reduce the savings calculated in the Commission proposal by 15%, hence the reduction in total savings in the compromise from EUR 227 to 216 million per year.

13. The Presidency considers the approach followed with the compromise text is risk-based, proportionate and well-balanced, and meaningfully reduces the burden on all actors within the system whilst retaining a high level of patient safety and effectively responding to the concerns expressed by the delegations. As such, the Presidency considers that the text both answers the Health Ministers' calls for urgent reform to benefit patients and healthcare systems and supports wider efforts to improve competitiveness.

14. At its meeting on 25 November 2026, the Permanent Representatives Committee examined the text set out in the addenda 16416/26 ADD1-2 and agreed to recommend that the Council reach a general approach.

IV. CONCLUSION

15. The Council is therefore invited to reach a general approach as set out in the addenda 16416/26 ADD1-2 to this note.