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NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee
Subject:	Regulation to simplify rules on medical and in vitro diagnostic devices *- Progress report*

I. INTRODUCTION

1. On 16 December 2025, the Commission adopted a proposal for amending the Medical Devices Regulation and the In Vitro Diagnosis Medical Devices Regulation[1] ("the proposal") as part of the health package. The proposal contributes to the Commission's objectives under the Competitiveness Compass, namely to simplify the regulatory environment, to reduce burden and to foster innovation, and is also consistent with the Commission's Strategy for European Life Sciences, which pointed out at the risks of losing competitiveness to other regions in areas such as medical devices.

[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, thus ensuring the 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 and withdrawal of critical devices from the market emerged. To tackle the issue of shortages in the short term, the transitional periods have been extended several times.

3. A thorough analysis of data gathered in the targeted evaluation of the existing regulatory framework, carried out by the Commission in 2024 and 2025[2], revealed underlying structural problems which remain unsolved by extensions of transition periods and which significantly affect the availability of devices, the competitiveness of EU manufacturers and innovation in medical technology. This, in turn, has a negative impact on healthcare quality and patient safety. The proposal addresses those shortcomings and is accompanied by a cost-savings analysis of the proposed changes[3].

4. The proposal seeks to make regulatory requirements more proportionate to the actual risk posed by devices, to reduce the administrative burden and to enhance the predictability and cost-efficiency of the certification procedure by notified bodies, while preserving a high level of public health protection and patient safety. While the proposal builds on a decentralised approach and the involvement of notified bodies in the conformity assessment procedure, it promotes further harmonisation and a more consistent application of rules through better coordination among national authorities, strengthened oversight of notified bodies and increased use of scientific, technical and regulatory expertise. Since the key features of the existing EU legislation remain unchanged, an impact assessment was not deemed necessary.

II. WORK AT OTHER INSTITUTIONS

5. The European Parliament designated the Committee on Public Health (SANT) as the responsible committee on this proposal and appointed Mr. Oliver Schenk (DE, EPP) as the Rapporteur. The Committee on Internal Market and Consumer Protection (IMCO) will submit an opinion for which the Rapporteur is Maria Guzenina (FI, S&D). The European Parliament is aiming to vote on its position early 2027.

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[2] ST 16919/25 ADD3-4
[3] ST 16919/25 ADD2

6. The European Economic and Social Committee adopted an opinion[4] on 29 April 2026.

7. The Italian Chamber of Deputies adopted an opinion[5] on 22 April 2026. The French Senate adopted an opinion[6] on 13 May 2026.

III. PROGRESS OF THE WORK DURING THE CYPRUS PRESIDENCY

8. The Commission provided a comprehensive overview of the proposal and its underlying objectives as well as the Staff Working Documents on the targeted evaluation and the estimate of cost-savings at the Working Party on Pharmaceuticals and Medical devices on 14 January, 13 February and 12 March 2026. The article-by-article examination in the Working Party started on 23 March 2026. Since then, the proposal was discussed in four full-day meetings, almost achieving a full read-through of the proposal.

9. Overall, delegations welcome the proposal and support its objectives of incentives for innovation, simplification, reduction of disproportionate burden and fostering more uniform practices of notified bodies. While examination of the proposal in the Working Party is still ongoing, it seems that additional work with a view to refining and complementing the proposal will be necessary to reach a General Approach, notably as regards the following aspects.

10. The Commission proposes to preserve the role of the Medical Device Coordination Group (MDCG), composed of representatives of the national competent authorities and chaired by the Commission, as the main governing body of the medical device regulatory framework. Delegations generally welcome the new role introduced for the **European Medicine Agency (EMA) to provide scientific, technical and administrative support as secretariat**, for the coordination among national competent authorities in several technical areas to strengthen coordination and cooperation on operational activities. However, several delegations consider that a clearer delineation of tasks and responsibilities and the relationship between the EMA and the MDCG should be defined.

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4 ST 9402/26
5 ST 8808/26
6 ST 9417/26

11. Delegations overall welcome the changes proposed by the Commission to improve **coordination among competent authorities regarding the qualification of a product or the classification of a device**. However, several delegations propose further streamlining of the procedures to avoid bottlenecks in EU level coordination and to enable more efficient and consistent outcomes at EU level.

12. The proposal broadens the role and the composition of **expert panels to provide scientific, technical, and regulatory advice** to the Commission, Member States, the MDCG, notified bodies and in certain cases to manufacturers or developers. Overall, delegations welcome the broader role of expert panels but consider that the conditions for their involvement should be further clarified to ensure efficient and streamlined procedures. In addition, several delegations stressed the competence of national authorities in regulatory matters.

13. Whereas most delegations welcome the introduction of a definition of '**well-established technology device**' which will be subject to more proportionate requirements, they also underline the need for further refinement and clarification of the criteria. There was general support for the **adapted pathway proposed for breakthrough devices and orphan devices** and some delegations would like to extend those pathways to other categories of devices, such as paediatric devices.

14. Overall, delegations welcome the strengthened and coordinated oversight of notified bodies to ensure uniform practices. However, several delegations remain cautious regarding the costs and resources needed for involving **Joint assessment teams** (JAT), composed of the national authority responsible for notified bodies, experts nominated by the Commission and by other Member States, in the monitoring of notified bodies and question the division of tasks within the JAT, especially the role of the national authority responsible for notified bodies. In addition, some delegations consider the mechanism proposed by the Commission for the settlement of disputes, between manufacturers and notified bodies, as being challenging as currently envisaged.

PUBLIC

15. The proposal makes the **involvement of notified bodies** in the conformity assessment and surveillance activities more proportionate to the risk of devices and introduces some elements of flexibility in the conduct and frequency of audits by notified bodies. In addition, the proposal introduces **changes to the reporting by manufacturers and broadens the type of evidence a manufacturer can rely on**. Overall, delegations are supportive of the changes proposed by the Commission regarding post-market surveillance, vigilance and generation of evidence. However, several delegations identify certain regulatory gaps and remain cautious regarding the cumulative impact of some of the simplifications proposed by the Commission. Delegations stress the need to find a careful balance between pre-market requirements, conformity assessment obligations and robust post-market monitoring of safety of medical devices and *in-vitro* diagnostic medical devices.

16. Whereas delegations support the aim of reducing the financial burden on micro, small and medium-sized enterprises, several delegations consider that the **reductions on the fees** to be paid by micro and small manufacturers for conformity assessment activities, may put at risk the financial sustainability of notified bodies, especially those that are SMEs themselves, and question the empowerment for the Commission to set the level and structure of notified body fees.

17. Delegations question several additional **empowerments** for the Commission to amend certain definitions, tasks and annexes, including requirements, through delegated acts. Those empowerments are subject to legal scrutiny.

18. The Commission proposes to introduce a new section on **international cooperation** to promote global regulatory convergence and reliance mechanisms. While most delegations support the aim of increased international cooperation in the field, they also recall the need to respect the procedures set out in the Treaties as well as the prerogatives of the Council.

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19. Several delegations are supportive of the Commission proposal to prevent overlaps and to create one regulatory framework for Artificial Intelligence (AI)-enabled medical devices by **limiting the application of the Artificial Intelligence legislation**[7] to medical devices. However, some delegations wish to complement the proposed implementing and delegated powers to lay down specific sectoral requirements regarding AI. The extent to which requirements from cyber-security legislation[8] should be reflected in the sectoral legislation is also a matter for further discussions.

III. CONCLUSION

20. Against this background, it is suggested that the Committee of Permanent Representatives invites the Council to take note of this progress report.

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[7] 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.

[8] 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.

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