Council of the
European Union

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'I' ITEM NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee (Part 1)
Subject:	Proposal for a Regulation of the European Parliament and of the Council amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and *in vitro* diagnostic medical devices *- Mandate for negotiations with the European Parliament*

I. BACKGROUND

1. On 6 January 2023, the Commission submitted a proposal to the Council and to the European Parliament for a Regulation amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and *in vitro* diagnostic medical devices[1].

2. The proposed Regulation aims to amend the Medical Devices Regulation (MDR) and the *In vitro* Diagnostic Medical Devices Regulation (IVDR) to mitigate the risk of shortages of medical devices on the market. It aims at extending the existing transitional period for medical devices covered by a notified body certificate or manufacturer's declaration of conformity issued before 26 May 2021, in a staggered and conditional manner until 31 December 2027 for higher risk devices and until 31 December 2028 for medium and lower risk devices.

[1] 5139/23

Furthermore, the proposal aims to introduce a transition period until 26 May 2026 for class III implantable custom-made devices, subject to the application of the manufacturer for a conformity assessment before 26 May 2024. The validity of certificates that were valid on 26 May 2021 is also extended. Finally, it is proposed to remove the "sell-off" date currently established in the MDR and IVDR.

II. WORK IN THE COUNCIL

3. The Commission presented the proposal to the Working Party on Pharmaceuticals and Medical devices on 17 January 2023. At that meeting all delegations intervening welcomed the proposal and no modifications were suggested as a result of the deliberations. Delegations also noted the importance of work to be done in parallel, such as guidelines to be issued by the Medical Devices Coordination Group (MDCG). DK and NL entered a parliamentary scrutiny reservation.

4. The Council Legal Service noted that the standard recital on proportionality and subsidiarity was missing from the proposal. This recital will be included in the final text for adoption as a legal-linguistic adjustment.

5. The Presidency concluded that delegations supported the Commission's proposal without substantive amendments.

III. CONCLUSION

6. In view of this, the Permanent Representatives Committee is invited to agree that the proposed Regulation as submitted by the Commission and set out in 5139/23 serves as a mandate for negotiations with the European Parliament.