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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 a gradual roll-out of Eudamed, information obligation in case of interruption of supply and the transitional provisions for certain *in vitro* diagnostic medical devices *- Mandate for the negotiations with the European Parliament*

I. BACKGROUND

1. On 23 January 2024, 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 a gradual roll-out Eudamed, information obligation in case of interruption of supply and the transitional provisions of certain *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 further mitigate the risk of shortages of medical devices on the market by:

   – extending the transition deadlines for IVDs under certain conditions;

[1] 5712/24.

– obliging manufacturers to inform competent national authorities in case of their intention to interrupt/withdraw the supply of certain critical medical devices and IVDs; and

– implementing in a step-wise manner the EUDAMED database, through mandatory use of those modules that have been audited and declared functional instead of waiting for the full platform to be operational.

II. WORK IN THE COUNCIL

3. The Commission presented the proposal to the Working Party on Pharmaceuticals and Medical devices on 30 January 2024. At that meeting, delegations intervening suggested no modifications to the text proposed by the Commission. In addition, delegations noted the importance of parallel non-legislative work for the implementation of the MDR and IVDR.

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

III. CONCLUSION

5. 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 5712/24 serves as a mandate for negotiations with the European Parliament.