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'I' ITEM NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee (Part 1)
No. Cion doc.:	12884/21
Subject:	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulation (EU) 2017/746 as regards transitional provisions for certain <i>in vitro</i> diagnostic medical devices and deferred application of requirements for in-house devices - <i>Mandate for negotiations with the European Parliament</i>

1. On 15 October 2021, the Commission submitted a proposal amending Regulation (EU) 2017/746 as regards transitional provisions for certain *in vitro* diagnostic medical devices and deferred application of requirements for in-house devices to the Council and to the European Parliament.
2. The proposal aims at extending the existing transitional period for devices covered by a certificate issued under the current Directive 98/79/EC, to be replaced from 26 May 2022 by Regulation (EU) 2017/746, and to introduce tailored transitional periods for devices that have to undergo a conformity assessment involving notified bodies for the first time under Regulation (EU) 2017/746. Furthermore, the proposal also introduces a transitional period for the requirements for devices manufactured and used within the same health institution ('in-house devices'). In the absence of such transitional measures, the current shortage of notified body capacity would lead to a significant disruption in the supply of a multitude of *in vitro* diagnostic medical devices on the market both for health institutions and for the public.

3. The Commission presented the proposal to the members of the Working Party on Pharmaceuticals and Medical devices in an informal videoconference on 9 November 2021. At that meeting all delegations intervening on the substance welcomed the proposal. Given in particular the consequences of the COVID-19 pandemic and the associated public health crisis for the implementation of Regulation (EU) 2017/746, delegations considered it important to proceed with an accelerated legislative procedure in order to ensure a smooth transition to the new regulatory framework on *in vitro* diagnostic medical devices and to ensure the availability thereof on the EU market. DK entered a parliamentary scrutiny reservation.
4. The Presidency concluded that delegations broadly supported the Commission's proposal without substantive amendments.
5. It is noted that consultation of the European Economic and Social Committee and the Committee of the Regions is compulsory, as this proposal concerns public health. Both consultations must be finished before the proposed Regulation is adopted. Both Committees have been contacted with the aim of speeding up the consultation.
6. In view of this, the Permanent Representatives Committee is invited to:
 - confirm the agreement on the text of the Regulation amending Regulation (EU) 2017/746 as regards transitional provisions for certain *in vitro* diagnostic medical devices and deferred application of requirements for in-house devices, as proposed by the Commission;
 - authorise the Presidency to send a letter to the Chair of the ENVI Committee confirming that, should the European Parliament, in accordance with Article 294 paragraph 3 of the Treaty on the functioning of the European Union, adopt the Regulation as proposed by the Commission (subject to revision by the lawyer-linguists of the Council and the European Parliament) as its position at first reading, the Council would, in accordance with Article 294, paragraph 4 of the Treaty on the functioning of the European Union, approve the European Parliament's position and the act would be adopted in a wording which corresponds to the European Parliament's position.