Council of the European Union

Brussels, 11 April 2024
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Interinstitutional File: 2024/0021(COD)

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COVER NOTE

From:	Secretary-General of the European Committee of the Regions
date of receipt:	11 April 2024
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
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 *- Renunciation letter from the Committee of the Regions (CoR)*

Delegations will find attached a renunciation letter from the Committee of the Regions (CoR) regarding the consultation on file 2024/0021 (COD).

E-MAIL

IM 004178 2024
11-04-2024

COR 2024/1231 D - 09/04/24

European Committee of the Regions

The Secretary-General

Brussels, *date of official registration*
SGCab/DT/lv – D/2536 (2024)

Thérèse Blanchet
Secretary-General
Council of the European Union and European Council
Rue de la Loi / Wetstraat 175
1049 Bruxelles / Brussel

Dear Secretary-General,

On behalf of the President of the European Committee of the Regions (CoR), Vasco Alves Cordeiro, I would like to thank you for your referral request to the CoR, dated 19 February 2024, regarding the following dossier:

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 2024/0021(COD) – COM (2024) 43 final.

The CoR's Commission for Natural Resources (NAT) decided at its meeting on 22 March 2024 not to issue an opinion on this proposal (Rule 65 of the Rules of Procedure). The file is not sufficiently relevant for local and regional authorities. The proposal, across its 3 articles, provides some amendments to a couple of earlier regulations, extending some deadlines and defining provisional arrangements. The proposed changes do not affect subnational government competences in the field of in-vitro medical devices.

Should you require any further information, please do not hesitate to contact the NAT secretariat (nat@cor.europa.eu).

Yours sincerely,

Petr Blížkovský

Cc: Vasco Alves Cordeiro, President of the European Committee of the Regions
Didier Seeuws, Director-General, GIP – General and Institutional Policy, General Secretariat of the Council of the European Union

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Electronically signed by BLIZKOVSKY Petr on 08/04/2024 17:24