European Parliament
2019 - 2024

TEXTS ADOPTED

P9_TA(2024)0368

Gradual roll-out of Eudamed, information obligation in case of interruption of supply and transitional provisions for certain *in vitro* diagnostic medical devices

European Parliament legislative resolution of 25 April 2024 on the 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 (COM(2024)0043 – C9-0010/2024 – 2024/0021(COD))

(Ordinary legislative procedure: first reading)

The European Parliament,

– having regard to the Commission proposal to Parliament and the Council (COM(2024)0043),

– having regard to Article 294(2) and Article 114 and Article 168(4), point (c), of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C9-0010/2024),

– having regard to Article 294(3) of the Treaty on the Functioning of the European Union,

– having regard to the opinion of the European Economic and Social Committee of 20 March 2024[1],

– after consulting the Committee of the Regions,

– having regard to the undertaking given by the Council representative by letter of 21 February 2024 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,

[1] Not yet published in the Official Journal.

– having regard to Rules 59 and 163 of its Rules of Procedure,

1. Adopts its position at first reading hereinafter set out;

2. Calls on the Commission to refer the matter to Parliament again if it replaces, substantially amends or intends to substantially amend its proposal;

3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

P9_TC1-COD(2024)0021

Position of the European Parliament adopted at first reading on 25 April 2024 with a view to the adoption of Regulation (EU) 2024/... 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, the obligation to inform in case of interruption or discontinuation of supply, and transitional provisions for certain *in vitro* diagnostic medical devices

(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Regulation (EU) 2024/1860.)