EUROPEAN UNION

THE EUROPEAN PARLIAMENT **THE COUNCIL**

Brussels, 28 May 2024
(OR. en)

2024/0021(COD)

PE-CONS 54/24
COR 1

SAN 104
PHARM 28
MI 209
COMPET 215
CODEC 582

LEGISLATIVE ACTS AND OTHER INSTRUMENTS

Subject:	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, the obligation to inform in case of interruption or discontinuation of supply, and transitional provisions for certain *in vitro* diagnostic medical devices

On page 9, in recital 18:

For:

‘(18) This Regulation is being adopted in view of the exceptional circumstances arising from an imminent risk of shortages of *in vitro* diagnostic medical devices and the associated risk of a public health crisis, as well as the significant delay in the development of the electronic system on clinical investigations and performance studies of Eudamed. In order to attain the intended effect of amending Regulations (EU) 2017/745 and (EU) 2017/746 and to ensure the availability of such devices the certificates of which have already expired or are due to expire before 26 May 2025, to provide legal certainty for economic operators and healthcare providers, and for reasons of consistency as regards the amendments to both Regulations, this Regulation should enter into force as a matter of urgency on the day of its publication in the *Official Journal of the European Union*. For the same reasons, it is also considered to be appropriate to invoke the exception to the eight-week period provided for in Article 4 of Protocol No 1 on the role of national Parliaments in the European Union, annexed to the TEU, to the Treaty on the Functioning of the European Union and to the Treaty establishing the European Atomic Energy Community.’,

read:

‘(18) This Regulation is being adopted in view of the exceptional circumstances arising from an imminent risk of shortages of *in vitro* diagnostic medical devices and the associated risk of a public health crisis, as well as the significant delay in the development of the electronic system on clinical investigations and performance studies of Eudamed. In order to attain the intended effect of amending Regulations (EU) 2017/745 and (EU) 2017/746 and to ensure the availability of such devices the certificates of which have already expired or are due to expire before 26 May 2025, to provide legal certainty for economic operators and healthcare providers, and for reasons of consistency as regards the amendments to both Regulations, this Regulation should enter into force as a matter of urgency on the day of its publication in the *Official Journal of the European Union*.’.