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**LIMITE**

**SAN 117**  
**PHARM 37**  
**AELE 21**  
**EEE 14**  
**N 14**  
**ISL 13**  
**FL 14**  
**MI 167**  
**IPCR 19**  
**COVID-19 8**  
**RECH 114**  
**COMPET 184**  
**PROCIV 28**  
**RELEX 379**

#### **LEGISLATIVE ACTS AND OTHER INSTRUMENTS**

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Subject: COUNCIL DECISION authorising the opening of negotiations with the Kingdom of Norway, Iceland and the Principality of Liechtenstein for one or more agreement(s) on health emergency measures in the area of medical countermeasures

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**COUNCIL DECISION (EU) 2025/...**

**of ...**

**authorising the opening of negotiations  
with the Kingdom of Norway, Iceland and the Principality of Liechtenstein  
for one or more agreement(s) on health emergency measures  
in the area of medical countermeasures**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 212, in conjunction with Article 218(3) and (4) thereof,

Having regard to the recommendation from the European Commission,

Whereas:

- (1) Council Regulations (EU) 2022/2372<sup>1</sup> and (EU) 2016/369<sup>2</sup> lay down rules regarding a framework for the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level, and the provision of emergency support within the Union, respectively. Pursuant to Article 46 of the Agreement on the European Economic Area (the ‘EEA Agreement’), Union measures in the field of the Economic and Monetary Union, other than non-binding information exchanges, are excluded from the scope of the EEA Agreement. Both Regulations are thus outside the scope of the EEA Agreement.
- (2) The Kingdom of Norway (‘Norway’), Iceland and the Principality of Liechtenstein (‘Liechtenstein’) expressed an interest in participating in all Union actions related to health emergency measures in the area of medical countermeasures, including, in particular, Regulation (EU) 2022/2372 and possibly Regulation (EU) 2016/369. They also expressed an interest in participating, to the extent possible, in the shaping of policy in this field.

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<sup>1</sup> Council Regulation (EU) 2022/2372 of 24 October 2022 on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level (OJ L 314, 6.12.2022, p. 64, ELI: <http://data.europa.eu/eli/reg/2022/2372/oj>).

<sup>2</sup> Council Regulation (EU) 2016/369 of 15 March 2016 on the provision of emergency support within the Union (OJ L 70, 16.3.2016, p. 1, ELI: <http://data.europa.eu/eli/reg/2016/369/oj>).

- (3) In light of the Union's close partnership with the EEA EFTA States and their partnership in the internal market, a coordinated approach to health emergency measures, in particular by means of economic cooperation, without prejudice to the autonomy of the Union's decision-making, is beneficial for both sides. The EEA Agreement already provides for the full integration of the EEA EFTA States in the internal market, whereby the four freedoms are homogeneously applicable and the legal framework of the EEA EFTA States is aligned to that of the Union. It can therefore be considered that, due to the special level of internal market integration achieved with the EEA EFTA States allowing for free movement of persons and goods, Union cooperation with the EEA EFTA States on health emergency measures, including those relating to medical countermeasures, will also benefit Member States. Health emergency situations increasingly have a cross-border nature and impact, and the effectiveness of health emergency measures therefore depends on the collective effort of all parties concerned.

- (4) Access to medical countermeasures plays a pivotal role in ensuring a timely and effective response to a health threat and reduces the impact of cross-border public health emergencies on the economic situation of the states concerned. The availability of the legal framework created by the EEA Agreement and a possible activation of the relevant measures laid down in that framework should ensure that appropriate medical countermeasures are accessible during emergencies. That would enable Member States and EEA EFTA States to protect European citizens from the first moment a public health emergency is recognised and would foster a global economic response to health emergencies, in accordance with the principles underpinning the Union's external action set out in Article 21 of the Treaty on European Union. The lack of a coordinated approach between Member States and EEA EFTA States, combined with a high level of dependency on third countries, disruptions in pharmaceutical supply chains, suboptimal production capacities linked with trade disruptions, and unanticipated demand surges, undermines the timely access to crisis-relevant medical countermeasures and the necessary level of homogeneity of health protection.
- (5) Negotiations should therefore be opened with a view to concluding one or more agreements concerning health emergency measures in the area of medical countermeasures, in so far as they are not covered by the EEA Agreement, with Norway, Iceland and Lichtenstein.

- (6) In accordance with Article 168(7) of the Treaty on the Functioning of the European Union, the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care, including the management of health services and medical care and the allocation of the resources assigned to them, are to be fully respected throughout the negotiating process.
- (7) This Decision is without prejudice to the division of competences between the Union and its Member States or to Member States' competence to participate in the negotiations in accordance with the Treaties,

HAS ADOPTED THIS DECISION:

### *Article 1*

The Commission is hereby authorised to open negotiations, on behalf of the Union, for matters which, in accordance with the Treaties, fall within the competences of the Union, for one or more agreements on health emergency measures in the area of medical countermeasures, in so far as they are not covered by the Agreement on the European Economic Area, with the Kingdom of Norway, Iceland, and the Principality of Liechtenstein.

### *Article 2*

The negotiations shall be conducted on the basis of the negotiating directives of the Council set out in the addendum to this Decision. Those directives shall be revised and further developed as appropriate depending on the evolution of the negotiations.

### *Article 3*

1. The negotiations shall be conducted in consultation with the Working Party on Public Health, which is hereby designated as a special committee within the meaning of Article 218(4) of the Treaty on the Functioning of the European Union (the ‘special committee’).
2. The Commission shall report to and consult the special committee on a regular basis. Whenever requested by the Council, the Commission shall report to the Council on the conduct and the outcome of the negotiations, including in writing.

*Article 4*

This Decision is addressed to the Commission.

Done at ..., ...

*For the Council*

*The President*

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