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LIMITE

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From:	Presidency
To:	Delegations
Subject:	Recommendation for a COUNCIL DECISION authorising the opening of negotiations for one or more agreement(s) with the Kingdom of Norway, the Replublic of Iceland and the Principality of Liechtenstein on health emergency measures in the area of medical countermeasures <i>- Exchange of views</i>

Delegations will find below the draft Recommendation for a Council Decision by the Presidency on the above-mentioned subject to be examined in the Working Party on Public Health at its meeting on 17 March 2025.

EXPLANATORY MEMORANDUM**I. CONTEXT OF THE PROPOSAL****Reasons for and objectives of the proposal**

With this recommendation, the Commission invites the Council to authorise the opening of negotiations on an agreement(s) between the Union, on the one side, and Norway, Iceland and Liechtenstein ('hereinafter referred to as 'EEA EFTA States'), on the other, with regard to the participation of the latter countries in the work of the EU relating to health emergency measures in the area of medical countermeasures.

Pursuant to Article 218(3) of the Treaty on the Functioning of the European Union (TFEU), the Commission shall be nominated as the Union negotiator. Pursuant to Article 218(4) TFEU, the Council may address directives to the negotiator.

The purpose will be to negotiate an agreement with Norway, Iceland and Liechtenstein which would cover health emergency measures in the area of medical countermeasures in as far as they fall outside the scope of the European Economic Area (EEA) Agreement. The purpose of the agreement would be to ensure the availability and the supply of crisis-relevant medical countermeasures in the event of a public health emergency.

Consistency with existing policy provisions in the policy area

The Union framework on health emergency measures

In response to the COVID-19 pandemic, the Union has adopted several measures to strengthen the prevention, preparedness and response against serious cross-border threats to health. This includes Regulation (EU) 2022/2371 on serious cross-border threats to health¹, Regulation (EU) 2022/2370 amending Regulation (EC) No 851/2004 establishing a European centre for disease prevention and control ²[OBJ] and Regulation (EU) 2022/123 on a reinforced role for the European Medicines Agency³[OBJ]. These three legislative acts all have EEA relevance. The process of their incorporation into the EEA Agreement has been completed.

In addition, in September 2021, the Commission established the Health Emergency Preparedness and Response Authority (HERA)⁴ as a Commission service. Also, the Council adopted Regulation 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. ⁵

¹ Regulation (EU) 2022/2371 on serious cross-border threats to health and repealing Decision No 1082/2013/EU, OJ L 314, 6.12.2022, p. 26.

² Regulation (EU) 2022/2370 amending Regulation (EC) No 851/2004 establishing a European centre for disease prevention and control, OJ L 314, 6.12.2022, p. 1.

³ Regulation (EU) 2022/123 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices, OJ L 20, 31.1.2022, p. 1.

⁴ Commission Decision 2021/C/393 of 16 September 2021 establishing the Health Emergency Preparedness and Response Authority, OJ C 393I, 29.9.2021, p. 3.

⁵ Regulation (EU) 2022/2372 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.

Participation of EEA EFTA States in EU health emergency measures in the area of medical countermeasures

Preparedness and response to serious cross-border threats to health

Preparedness and response to serious cross-border threats to health is already covered by the current legislation incorporated under the EEA Agreement (notably Regulation (EU) 2022/2371 on serious cross-border health threats, as well as Regulations (EU) 2022/2370 and (EU) 2022/123 on reinforcing the mandates of the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA) respectively).

In particular, Regulation (EU) 2022/2371 on serious cross-border threats to health provides a comprehensive legislative framework to govern action at Union level on preparedness, surveillance, risk assessment, and early warning and response. Article 12(3)(a) of Regulation (EU) 2022/2371 specifically refers to the fact that participation in the joint procurement procedure is open to EEA EFTA States. Norway, Iceland and Liechtenstein are contracting parties” to the Joint Procurement Agreement to procure medical countermeasures.⁶ In addition, Norway and Iceland are associated to, and thus can benefit from, the Union programmes providing funding for actions carried out in the Union and in associated countries to address health emergency preparedness and response. This includes the EU4Health Programme⁷, the Horizon Europe programme⁸ and the Union Civil Protection Mechanism⁹. Their participation in these programmes, based on their financial contribution, is facilitated by the EEA Agreement (Articles 78 to 82).

⁶ Annex to Commission Decision C(2014) 2258 final on approval of the Joint Procurement Agreement to procure medical countermeasures pursuant to Decision 1082/2013/EU based on Decision No 1082/2013 (the latter was replaced by [Regulation \(EU\) 2022/2371](#)).

⁷ Agreement on the participation of Iceland and Norway signed in September 2021. The association and participation of Norway and Iceland (EFTA countries) to the EU4Health Programme is governed by Protocol 31 on cooperation in specific fields outside the four freedoms of the Agreement on the European Economic Area (OJ L 1, 3.1.1994, p. 3).-

⁸ Agreement on the participation of Iceland and Norway signed in September 2021. The association and participation of Norway and Iceland (EFTA countries) to the Horizon Europe programme is governed by Protocol 31 on cooperation in specific fields outside the four freedoms of the Agreement on the European Economic Area (OJ L 1, 3.1.1994, p. 3).

⁹ The association and participation of Norway and Iceland (EFTA countries) to the Union Civil Protection Mechanism is governed by Protocol 31 on cooperation in specific fields outside the four freedoms of the Agreement on the European Economic Area (OJ L 1, 3.1.1994, p. 3).

Health emergency measures in the area of medical countermeasures

While preparedness and response to serious cross-border threats to health is covered by the legislation already incorporated under the EEA Agreement, health emergency measures in the area of medical countermeasures involve policy mechanisms within the economic and monetary sector of the Union which, pursuant to Article 46 of the EEA Agreement, is largely excluded from the scope of the EEA Agreement.

Council Regulation (EU) 2022/2372 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 currently does not apply to EEA EFTA States. At present, EEA EFTA States cannot become members of the Health Crisis Board, which is to be established if the Council activates one or several emergency measures.

Similarly, Council Regulation (EU) 2016/369 of 15 March 2016 on the provision of emergency support within the Union does not apply to the EEA EFTA States. On the basis of that Regulation, which was activated and amended through Council Regulation (EU) 2020/521 of 14 April 2020 activating the emergency support under Regulation (EU) 2016/369, the Commission concluded Advance Purchase Agreements with individual vaccine producers and secured the right to buy a specified number of vaccine doses in a given timeframe and at a given price in order to address the COVID-19 pandemic.

Depending on the type of procurement mechanism (in particular if the Commission acts on behalf of EU Member States), the EEA EFTA States may currently not be able to be involved in such procurements or in other health emergency measures.

II. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

Legal basis

Article 218(3) TFEU provides that the Commission shall submit recommendations to the Council, which shall adopt a decision authorising the opening of the negotiations and nominate the Union negotiator. Under Article 218(4) TFEU, the Council may address directives to the negotiator.

Considering the type of initiative (opening of negotiations for international agreement) and its limited scope, an impact assessment and a public consultation were not considered necessary. However, later in the process (during the negotiations), as envisaged in the draft mandate, the Commission intends to prepare the necessary analytical documents, including the analysis of the potential impacts, to serve as basis for the negotiations.

Later in the process, the Commission also intends to consult and gather feedback from relevant stakeholders.

Budgetary implications

The EEA EFTA States will need to make a significant financial contribution to the Union budget to cover the expenses related to health emergency measures.

III. OTHER ELEMENTS

The Commission will conduct the negotiations in accordance with the negotiating directives set out in the Annex to the Decision.

The Commission will conduct the negotiations in consultation with the special committee designated by the Council.

The Commission will, in a timely manner, keep the European Parliament fully informed of the progress in the negotiations.

Recommendation for a

COUNCIL DECISION

authorising the opening of negotiations for one or more agreement(s) with the Kingdom of Norway, the Republic of Iceland and the Principality of Liechtenstein 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) 2022/2372¹⁰ and (EU) 2016/369¹¹ 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. Apart from non-binding information exchanges, Union measures in the field of the Economic and Monetary Union are excluded from the scope of the EEA agreement pursuant to Article 46 of the EEA Agreement. Both Regulations are thus outside the scope of the Agreement on the European Economic Area (EEA Agreement).
- (2) Norway, Iceland and Liechtenstein expressed interest to have access to 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 wish to participate, to the extent possible, in the shaping of the policy in this field.

¹⁰ 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>).

¹¹ 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 the light of the Union's close partnership with EEA EFTA States and their partnership in the internal market, a coordinated approach to health emergency measures, **notably by means of economic cooperation**, is beneficial for both sides, **without prejudice to the autonomy of Union's decision-making**. The EEA Agreement already provides for a full integration in the internal market, whereby the four freedoms are homogenously applicable and the legal framework is ~~dynamically~~ aligned to the EU (see ~~Articles 1 and 102 of the EEA Agreement~~). It can therefore be ~~presumed~~ **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, the Union cooperation with those states on health emergency measures, including those relating to medical countermeasures, will also ~~automatically~~ benefit Union Member States. Health emergency situations increasingly have a cross-border nature and impact and the effectiveness of health emergency measures therefore depend on the collective effort of all parties concerned.
- (4) Access to medical countermeasures plays a pivotal role in ensuring 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 and a possible activation of the relevant measures laid down in that framework should ensure that appropriate medical countermeasures are accessible during emergencies, enabling the Member States and EEA EFTA States to protect European citizens from the first moment when a public health emergency is recognised **and fostering a global economic response to health emergencies, consistently with the principles of Union external action set out in Article 21 of the Treaty on the European Union**. A lack of 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 homogenous level of health protection.
- (5) Negotiations should therefore be opened with a view to establishing 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.

HAS ADOPTED THIS DECISION:

Article 1

The Commission is hereby authorised to negotiate, on behalf of the Union, one or more agreements on health emergency measures in the area of medical countermeasures, in so far as they are not covered by the EEA Agreement, with the Kingdom of Norway, the Republic of Iceland, and the Principality of Liechtenstein.

Article 2

The negotiating directives are set out in the Annex.

Article 3

1. The negotiations shall be conducted in consultation with ~~with the Working Party on Public Health, which is hereby designated as the special committee within the meaning of Article 218(4) TFEU.~~
- ~~1.~~ **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.**

~~name of the special committee to be inserted by the Council].~~

Article 4

This Decision is addressed to the Commission.

Done at Brussels,

For the Council

The President
