



Council of the
European Union

092059/EU XXVII.GP
Eingelangt am 02/03/22

Brussels, 2 March 2022
(OR. fr, en)

6335/22
ADD 1

SAN 101
PHARM 25
COVID-19 45
PROCIV 17

'A' ITEM NOTE

From: General Secretariat of the Council
To: Council

Subject: Recommendation for a COUNCIL DECISION authorising the opening of negotiations on behalf of the European Union for the conclusion of an international agreement on pandemic preparedness and response as well as for the negotiations of complementary amendments to the International Health Regulations (2005)

- *Adoption*
- *Statements by the Commission and the Bulgarian and Polish delegations*

Delegations will find attached statements by the Commission and the Bulgarian and Polish delegations on the abovementioned act.

Commission Statement no 1

The Commission considers it legally incorrect that a Council Decision authorising the opening of negotiations indicates a substantive legal basis.

The Decision authorising the opening of negotiations is premised solely on the existence of conferred powers of the Union and not on a determination of a specific competence. Its effect is limited to authorising the Commission or the High Representative, as the case may be, to use its prerogatives under the EU Treaties in order to start negotiations. The scope of these negotiations is therefore determined by the scope of the powers of the Union. Besides, the freedom of the envisaged treaty partner of the Union as regards the determination of the scope of the negotiations cannot be limited by the Council Decision authorising the opening of the negotiations. Thus, the precise legal basis for the future agreement can only be determined after the content of the agreement is known.

The Commission reserves all its rights in this regard.

Commission Statement no 2

The Commission considers that the Council may revise and further develop the negotiating directives laid down in the Addendum to the Council Decision authorising the opening of negotiations, as appropriate and necessary in the course of such negotiations, only on the basis of a prior new recommendation by the Commission, in compliance with the Commission's right of initiative under Article 218 (3) and (4) TFEU.

The Commission reserves all its rights in this regard.

Statement of the Republic of Bulgaria

The Republic of Bulgaria supports the efforts towards international cooperation in different sectors for improving global and national pandemic preparedness and response as part of the global health architecture.

Bulgaria considers that the French Presidency has improved substantially the initial text of the proposal for a Council Decision and the Directives for negotiations laid down in the Addendum to the Decision, and we are thus able to support the overall spirit of the Council Decision.

However, when it comes to the clear distinction between matters falling under national and Union competences, the text remains partially unclear, showing signs of fragility and ambiguity. While we understand that the scope of the Decision is to mandate the Commission to negotiate on matters falling within Union competence, we note with concern the unclear provisions in sensitive areas, thus leaving room for legal interpretation and potential difficulties for Member States at the stage of negotiations. For the avoidance of any doubt, we therefore consider it essential to highlight at the outset of this process several aspects, which have been thoroughly discussed and confirmed but are not explicitly reflected in the draft document:

Firstly, there should be a clear distinction in the negotiation process between matters that fall under national and under Union competences. When it comes to healthcare, in line with EU primary law, the division of competences between the Union and its Member States as defined by the substantive legal basis should be fully respected throughout the negotiation process. Therefore, we are grateful for the confirmation by the Commission and the Presidency that Member States reserve their right to negotiate on their own, based on their national positions on matters falling under exclusive national competences. This, according to Art. 168 (7) TFEU will cover all issues related to the organisation and delivery of health services and medical care and its financing, especially on matters that are likely to trigger financial obligations for Member States in the future.

Having in mind the persistent uncertainty with regard to the substance and content of the future international instrument on pandemic prevention, preparedness and response, the coordination mechanisms and in particular the reference to the International Health Regulations (2005), we consider such a clarification an indispensable safeguard for Member States and a confirmation of key principles such as subsidiarity, conferral of powers as well as good inter-institutional cooperation.

Secondly, we call for more caution when referring to a “legally binding instrument” and full respect of the text of the Decision adopted during the Special Session of the World Health Assembly. The hypothesis of a “legally binding instrument” presupposes Member States’ obligations and will be the subject of the negotiating process, and in this context, the Member States should remain free to make their final decisions. In its national capacity, Bulgaria considers that the development of new international treaties and partnerships needs a careful approach, with a clear added value to the already existing agreements, mechanisms and initiatives, e.g. International Health Regulations (2005), avoiding duplication of activities.

Last, but not least we consider that all references to financial commitments in the draft Decision concern only matters falling under EU competence. Commitments that concern national budgets are not covered by this Decision, as they are a matter of exclusive national competence. Given the lack of clarity on the possible content of a new international instrument and the resulting obligations for Member States, including of a financial nature, it is necessary to take into account the capacity of the health sector in-country to bear additional burden implementing a possible new international agreement.

In that context, taking into account in particular Art. 168 (7) of the Treaty on the Functioning of the EU, and since the leading role of the Member States is understandable but is not explicitly stated in the text of the Decision mandating the Commission to negotiate on matters falling within Union competence, Bulgaria will implement the Recommendation for a Council Decision within the Union competences as laid down in the primary law of the European Union. Our understanding is that it would in no way affect national competences in the field of health policy, including the positions Bulgaria may take within its national competences in the negotiation process on a future international instrument on pandemic prevention, preparedness and response.

We request for the inclusion of this statement in the minutes of the Coreper meeting and the Council adopting the proposed decision.

Statement of the Republic of Poland

Regarding the directives for the negotiation of an international agreement on pandemic prevention, preparedness and response contained in the Addendum to the aforementioned Decision Poland believes that any references to sexual and reproductive health and rights (SRHR) should not be included in the text of the directives.

The issue of SRHR is not the matter of the Union competence, but Member States', and such reference in the directives is contradictory to Article 168 (7) of the Treaty on the Functioning of the European Union, which clearly states that "Union action shall respect 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".

Furthermore, having the reference to SRHR in the directives is not in line with recital 6 and 7 of the decision itself, where full respect for Member States' competences and only auxiliary role of the Union is underlined.

For this reason we believe that having the reference to SRHR in the negotiating guidelines for the Commission is unjustified.