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NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee (Part 1)
No. prev. doc.:	10570/22, 10570/22 ADD1
No. Cion doc.:	12972/20
Subject:	'Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on serious cross-border threats to health and repealing Decision No 1082/2013/EU <ul style="list-style-type: none">• <i>Analysis of the final compromise text with a view to agreement</i>• <i>Statements</i>

Commission Statement

The Commission welcomes the overall agreement reached by the co-legislators on the proposal for a Regulation on serious cross-border threats to health. This new Regulation provides for a strong health security framework in the EU and will strengthen EU-level protection, prevention, preparedness and response against cross-border health challenges.

The Commission regrets that the agreed text does not fully align the Regulation with the principle of one Commission and singles out one specific internal Commission service, whereas the Regulation will be implemented by the Commission (including other Commission departments) and other actors. Therefore, the agreement reached between the European Parliament and the Council on the provisions that refer to a specific Commission internal service is without prejudice to any future legislative texts.

Moreover, the Commission also regrets that the co-legislators agreed to include a review clause, which includes an assessment of the need to establish the European Health Emergency preparedness and Response Authority (HERA) as a distinct entity from the Commission. Such an assessment goes beyond the scope of the Regulation and should remain within the Commission's remit as HERA is a Commission service. Moreover, it duplicates the assessment

that is to be carried out under the Council 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.

Statement by Bulgaria

The Republic of Bulgaria supports the overall goal of the Health Union Package to improve the reaction of the European Union and its Member States to cross-border health threats.

For Bulgaria, protection of human health is of paramount importance, both in peace times and in times of crisis and emergencies. Hence, we reiterate our understanding, based on (Art. 168 TFEU, in particular paragraphs 5 and 7) that nothing in the Regulation on cross-border threats to health as part of the Health Union Package shall be interpreted as a limitation of Member States' sovereign actions to protect their population, including by procuring critical countermeasures in a timely manner and at affordable price, via all possible channels.

The provision of health services and medical care and the allocation of the resources assigned to them in times of crisis remains responsibility of Member states: an inherent part not only of national health policies but also a matter of national security.

Bulgaria also confirms its adherence to the precise text of the WHA Second Special Session Decision SSA2(5), which at this stage leaves open the matter about the legal nature of a future international instrument on pandemic prevention, preparedness and response. We note with concern the introduction of references in the EU internal legal order to ongoing international negotiations and attempts to prejudge their outcomes.

Finally, in terms of the envisaged reporting obligations and assessment of national crisis plans we commit to implement the Package, while bearing in mind the principles of subsidiarity, proportionality and conferral of powers, enshrined in the relevant provisions of the EU primary law. The national administrations and budget resources of Member States differ significantly - additional excessive burden can exhaust already limited resources and be counterproductive in crisis times.

Statement by Hungary

Hungary recognizes and promotes equality between men and women in accordance with the Fundamental Law of Hungary, and the primary law, principles and values of the European Union, as well as the commitments and principles stemming from the international law. Furthermore, equality between women and men is enshrined in the Treaties of the European Union as a fundamental value. In line with these and its national legislation, Hungary interprets the term 'gender' as reference to 'sex', in the Regulation of the European Parliament and of the Council on serious cross-border threats to health and repealing Decision No 1082/2013/EU.

Statement by Poland

Równość kobiet i mężczyzn została zapisana w Traktatach Unii Europejskiej jako podstawowe prawo. Polska zapewnia równość kobiet i mężczyzn w ramach polskiego krajowego systemu prawnego zgodnie z międzynarodowymi traktatami praw człowieka oraz w ramach podstawowych wartości i zasad Unii Europejskiej. Z tych powodów, wyrażenie "gender-sensitive" Polska będzie interpretowała jako wrażliwość na równość kobiet i mężczyzn, zgodnie z art. 2 i 3 Traktatu o Unii Europejskiej oraz art. 8 i 157 para 3 Traktatu o funkcjonowaniu Unii Europejskiej. W związku z powyższym, pozostałe wyrażenia zawierające termin "gender", Polska będzie interpretowała jako płeć ("sex"), zgodnie z art. 10, art. 19 para 1 oraz art. 157 para 2 i 4 Traktatu o funkcjonowaniu Unii Europejskiej.
