Council of the European Union

Brussels, 14 October 2022
(OR. en)

13323/22
ADD 1

Interinstitutional File:
2020/0322(COD)

CODEC 1452
SAN 553
PHARM 156
PROCIV 123
COVID-19 158

'I/A' ITEM NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee/Council
Subject:	Draft REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on serious cross-border threats to health and repealing Decision No 1082/2013/EU **(first reading)** - Adoption of the legislative act = Statements

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.