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'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 health technology assessment and amending Directive 2011/24/EU **(first reading)** - Adoption of the Council's position at first reading and of the statement of the Council's reasons = Statements

Statement by Bulgaria

The Republic of Bulgaria supports the overall objective of the Regulation of the European Parliament and of the Council on health technology assessment amending Directive 2011/24/EU to contribute to a high level of human health protection. In this context Bulgaria also acknowledges the objective of establishing a framework to support Member States cooperation for the clinical assessment of health technologies. The Regulation should be an instrument contributing to access to safe, effective and affordable medical products for all.

However, the Republic of Bulgaria would like to stress upon the principles of subsidiarity and division of competencies in the context of the implementation of this Regulation. Pricing and reimbursement matters, as part of the organisation and delivery of health services and medical care remain exclusive national competence, as provided for in Art. 168 (7) of the Treaty on the Functioning of the European Union. The Union competences in this area remain limited to incentive measures for scientific cooperation and voluntary uptake of the joint clinical assessment in their clinical aspects, with no obligation for harmonisation of national health technology assessments.

The Republic of Bulgaria considers that certain provisions in the Regulation, in particular Art. 3, Art. 6d and Art. 8, lack sufficient legal clarity and certainty and could, thus, jeopardise the ability of the proposed system to balance different interests and to deliver from public health perspective to the benefit of all patients. Some of the arrangements in these provisions would impact adversely the inclusiveness of the process, the quality and usefulness of the joint clinical assessments for all Member States and patients. Thus, an implementation of the Regulation insensitive to these aspects, may result in pressure on national budgets for particular products, and lead to inequalities among different patient groups. Finally, the level of ambiguity and the legal uncertainty also put at risk the smooth and uncontested implementation of the act.

In view of these considerations, the Republic of Bulgaria cannot support the Regulation of the European Parliament and of the Council on health technology assessment amending Directive 2011/24/EU, and states that it will implement the Regulation within the Union competences as laid down in the primary law of the European Union. The Republic of Bulgaria will give due consideration to the joint clinical assessments to the degree required by law, while prioritizing the interests of all patients in the country.

Statement by Poland

The Government of the Republic of Poland supports efforts and actions aiming to promote the unification of assessment tools, publication of clinical data assessed by EMA or other clinical trials and the standardisation of clinical analysis methodology in the HTA processes across the EU, aiming to reduce duplication of workload between HTA institutions and the industry and to ensure that the results of joint work across the EU Member States can be used to a greater extent than currently foreseen.

Nevertheless, according to the Government of the Republic of Poland, the draft regulation does not clarify the needs associated with conducting joint work on the methodology and unification of the tools used and making clinical data available. Additionally it interferes with the refund procedures of individual Member States, thus obstructing their ability to adapt the scope of report to their national needs and restricting the possibility of obtaining the necessary current data, as well as analyses based on such data, from the MAH applying for a refund.

Moreover, in many areas, the proposed regulation remains unclear allowing for too broad legal interpretation. It is highly important that the regulation should not interfere with competencies

exclusively reserved for Member States. In our view the regulation impacts on national regulations of conducting HTA assesment and introduces ambuguity in the scope and range of data sumbmitted in national processes, thus may lead to the law disputes with the reimboursment applicants.

In view of the above, Republic of Poland was unable to support the final compromise text and therefore abstains in voting. We request for the inclusion of this statement in the minutes of the Coreper meeting and the Council adopting the proposed regulation.