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**NOTE**

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| From: | Permanent Representatives Committee (Part 1) |
| To: | Council |
| Subject: | Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL laying a framework for strengthening the availability and security of supply of critical medicinal products as well as the availability of, and accessibility of, medicinal products of common interest, and amending Regulation (EU) 2024/795<br>- General Approach<br>- Statement by the Republic of Bulgaria |

Bulgaria has requested that the following statement be entered in the Council minutes.

**ANNEX**

**STATEMENT of the REPUBLIC OF BULGARIA**

**on**

**the proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL laying a framework for strengthening the availability and security of supply of critical medicinal products as well as the availability of, and accessibility of, medicinal products of common interest, and amending Regulation (EU) 2024/795**

Bulgaria considers the availability of affordable safe, effective and quality *medicines* as one of the key priorities of national health policy. This is the case also for treatments that are assessed as *critical* at European or at national level.

In that regard the ambition of European Critical Medicines Act to support the manufacturing of critical medicines in Europe is generally to be welcomed. However, **this ambition, claimed to be a common European goal, is not backed by a common European fund.**

We remain of the opinion that **the proposed legal basis – Article 114 TFEU is inappropriate and insufficient** in the light of the stated objectives of the proposal, namely, to strengthen the availability of critical medicinal products, and the availability and accessibility of "medicinal products of common interest" within the Union.

First, the measures proposed do not have the "establishment and functioning of the internal market" as their genuine object but appear to be aimed at safeguarding availability and accessibility of medicines, as part of health policies. Secondly, some of the envisaged measures are likely to result in limiting Member States' discretion on spending national healthcare budgets, thereby effectively circumventing the explicit prohibition of harmonisation set out in Article 168 (7) TFEU. Third, the general requirement set out in Article 114 TFEU to ensure high level of protection of health *inter alia*, does not constitute an objective in itself, but rather serves as a safeguard to prevent harmful impact on health, safety, environment etc.

The public procurement of medicines with public budgets constitutes an integral component of national health policies and should continue to be governed accordingly, in line with national priorities and resources available. The „critical“ status of certain medicinal products does not alter their inherent nature as medicines and treatments. Therefore, this characteristic alone cannot justify a replication of the legal framework applicable to various categories of critical products.

Overall, the choice of Art. 114 as a legal basis appears as an attempt to subordinate health policies to the logic of the internal market. This will predictably have negative consequences for the healthcare in Europe. **In the absence of an impact assessment, it remains unclear which "distortions" of the internal market are targeted by the proposed measures. At the same time, the actual impact of some of the measures will be** "**distortion" of national solutions at the core of health policies, as well as distortion of competition.**

Despite the good intentions, some measures, such as voluntary collaborative or joint procurements (Chapter IV, Section II) are not only incompatible with a harmonisation legal basis but will have a potentially disruptive effect on national health policies and healthcare budgets by resulting in single price for countries with different GDP, and limiting availability, accessibility and affordability in non-participating countries.

In our view therefore the current choice of legal basis does neither adequately respect the division of competences between the Union and the Member States, nor the conferral of powers principle. The *management of health services and medical care and the allocation of the resources assigned to them* includes the public procurement of medicines (critical or not) with public budgets. An erosion of national competences in the field of health remains undesirable, given that Member States' policies, priorities and budgets differ and must be adapted to the specific needs at national level – those closest to citizens and patients.

We remain convinced that by the end of the ordinary legislative procedure there is still time to choose a proper legal basis. Other legislative acts dealing with complex situations of interaction between internal market and health policies – mostly national competence, can serve as inspiration, such as the EU HTA Regulation ((EU) 2021/2282), which does have **a dual legal basis – Article 168 and Article 114 TFEU.**

Finally, we note that the implementabilty of Art. 18 (2) and Art. 19 highly depends on guidelines, that should be developed on time and in respect of Member States' competences in the area of healthcare.

We remain committed to constructively contribute to the upcoming trilogues, with the aim to achieve a reasonable, clear and legally robust regulatory framework.