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| From: | General Secretariat of the Council |
| To: | Delegations |
| Subject: | AOB for the meeting of EPSCO (Health) of 3 December 2024: Voluntary Cooperation of Member States on Joint Procurement of Medicinal Products - Information from Cyprus, Croatia, Denmark, Greece, Latvia, Malta and Slovenia |

Proposal for Voluntary Cooperation of Member States on Joint Procurement of Medicinal Products

Information note from Cyprus, Croatia, Denmark, Greece, Latvia, Malta and Slovenia

A significant number of Member States have been facing increasing challenges with respect to the accessibility, availability and affordability of costly innovative medicinal products.

The markets of the affected Member States are considered unattractive for the pharmaceutical industry to place products. As a consequence, many innovative products are not being launched, or are launched with significant delays in certain markets, causing inequalities amongst patients in the EU. In addition, these Member States have less negotiating power to secure a fair price mostly for innovative medicinal products, which results to pay higher prices. There were many relevant initiatives in the past on this issue, but none was successful in effectively resolving these problems.

It is pertinent to recall that the ongoing review of the EU pharmaceutical legislation (pharmaceutical package) aims, inter alia, to address the accessibility, availability and affordability of medicinal products. However, tangible results are only expected in the long term.

Based on the lessons learned from the COVID-19 pandemic and the successful joint procurement agreements for COVID-19 vaccines, we are confident that this cooperation could expand to other medicines, for example innovative medicines. We therefore, support changes to the existing legal basis for voluntary joint procurement of medicinal products, while also exploring possible solutions through the pharmaceutical package.

Moreover, and while awaiting the conclusion of the negotiations on the pharmaceutical package, we consider it important to promote a separate initiative in order to provide additional impetus towards the improved availability and accessibility of innovative medicinal products. This initiative should be sufficiently flexible and in line with EU legislation.

In view of the above, we propose to establish a **voluntary joint procurement cooperation mechanism** between Member States that face similar challenges in terms of availability and accessibility of innovative medicinal products.

We further propose that this cooperation initially focuses on the medicinal products that will undergo the Health Technology Assessment as provided by the HTA Regulation whose implementation will begin on the 1st of January of 2025, namely oncological products. The Joint Clinical Assessment performed under this framework will enable the cooperating Member States to further define their needs based on the scientific merits and the potential added value of these products.

The cooperation of interested Member States will strengthen our negotiating power with the pharmaceutical industry, thus reinforcing the security of supply in a timely manner and at fairer prices through, for example, equivalent Managed Entry Agreements.

As a step forward, the participating Member States will consider setting up an informal technical group that will, inter alia, work on specific issues, actual needs and mandates. This group could consist of one or two representatives from each interested Member State, who will then notify the relevant stakeholders and bodies in their respective countries.

Once the work on the modalities for the operation of this group are finalized, the industry could be invited to participate in joint procurement activities with the appropriate body(ies) appointed by the participating Member States, in order to negotiate and finalize agreements.

The ultimate goal of this proposal is to improve the viability and robustness of the collaborating Member States' health systems for the benefit of patients and the public health systems in general.

Therefore, Cyprus, Croatia, Denmark, Greece, Latvia, Malta and Slovenia invite Member States to initiate a dialogue in order to determine the best way forward on a voluntarily coordinated approach to joint procurement of particular pharmaceutical items. We also invite the Commission to reflect on this initiative and to provide concrete suggestions and guidance on how we can materialise this endeavour for the benefit of European citizens.
