EPF's position on the report of MEP Sokol on the Critical Medicines Act (CMA)

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The European Patients' Forum (EPF) welcomes the publication of the report of MEP Sokol (EPP, Croatia) on the Critical Medicines Act (CMA). The report contains new recommendations to complement the European Commission proposal published in March, including some elements that EPF considers crucial to strengthen the proposal, providing a useful basis for upcoming discussions in the European Parliament. **However, we believe that some room for improvements remains**. In particular, further reflection is needed on the scope of strategic projects and EU joint procurement, to ensure that the final version of the text truly addresses patients' needs and upholds the fundamental objective of safeguarding public health in the EU.

Inclusion of patients in the governance of the system

EPF welcomes MEP Sokol's amendments to include patient representatives as permanent members of the new Critical Medicines Group, reflecting a key demand of the patient community.

The Critical Medicines Coordination Group would discuss strategic projects to be implemented at the national level, assess the possibility of EU joint procurement processes, as well as advise on prioritisation in the context of the vulnerability evaluation of critical medicines.

In the current version of the Commission proposal, only Member States and the European Commission could become members. However, the inclusion of patient representatives as permanent members of the Group **is essential to ensure that the perspectives, needs, and experiences of those directly affected by shortages of critical medicinal products are taken into account**.

Incorporating patient voices **supports the principles of patient-centred care and democratic health governance**, enhancing the transparency, accountability, and inclusivity of the Critical Medicines Coordination Group.

Increased accountability in the context of Strategic Projects

For EPF, it is essential to significantly strengthen the European Commission's proposal related to "Strategic projects" (Chapter III). EPF has consistently emphasised that any financial incentives or support provided by governments and public authorities must be accompanied by strict transparency requirements, robust obligations, such as supply commitments and equitable access, effective monitoring, and sanctions in cases of non-compliance.

We therefore welcome MEP Sokol's suggestions that any undertaking receiving financial support for a strategic project must fully comply with specific obligations, including supply and availability requirements for the national and EU market, and face financial penalties if failing to do so. This is crucial as transparency of EU and government action is key to ensuring public trust, especially at a time of public budget constraints.

However, we urge for a careful assessment of any expansion in the scope of strategic projects to include medicinal products of common interest. It is essential to ensure that public funds are used in the best interest of patients. The criteria for defining a strategic project should be also developed further to avoid legal uncertainty and ensure transparency.

Affordability is another key element to consider. Re-shoring production to the EU could lead to higher medicine prices and increased out-of-pocket payments for patients. A comprehensive assessment of this potential impact is therefore necessary.

Putting patients' needs at the heart of public procurement practices

EPF views transparent public procurement practices as a key tool to strengthen supply chain resilience and prevent disruptions in times of crisis. We therefore support MEP Sokol's proposal that Member States shall apply procurement requirements other than price-only award criteria, including criteria that take into account the diversification of supply sources, patient impact, and supply chain robustness.

We further call for **close coordination between the CMA and upcoming Commission guidance and legislative initiatives related to public procurement**.

However, any specific clauses or criteria relating to the guarantee of supply can only be assessed with patients' participation. This is essential to improve the transparency of public procurement practices and accountability of healthcare systems. **We therefore call for the European Parliament to support patient involvement in the definition of public procurement criteria to ensure public tenders truly meet their needs**.

Establishing joint procurement as an effective tool to improve patient access to critical medicines and medicines of common interest

We strongly support the Commission proposal to include joint procurement as a mechanism to improve patient access to vulnerable critical medicinal products and medicinal products of common interest under certain conditions.

The COVID-19 pandemic showed the relevance of a mechanism for joint purchasing at EU level **to ensure faster and simultaneous access to essential products across all EU member states, whatever their size and economic status**. Beyond crisis situations, EPF believes that joint procurement can address some market failures, including for generic medicines whose production is not economically viable for fragmented national markets or for highly innovative therapies that are unaffordable in the poorest EU countries.

We regret however MEP Sokol's additional restrictions on joint procurement procedures, namely that "*only countries in a similar epidemiological or economic situation*", could engage in such a mechanism. **We are concerned that this restriction would undermine the effectiveness of joint procurement and unduly limit opportunities for joint negotiations**.

One of the strengths of joint procurement lies in its collective bargaining power, which is maximised when larger member states participate, as demonstrated with COVID 19 vaccines. While we acknowledge the concerns of smaller Member States about potentially higher prices, we believe the benefits of joint

procurement depend on the specific context. **Therefore, we call for a flexible system that enables joint purchases at EU-wide level and among smaller groups of Member States, to be adapted based on patients and public health needs**.

Similar to procurement at national level, **we call for patient involvement in joint procurement governance mechanisms** to improve transparency and better address public health needs.

Positive steps on stockpiling and contingency stocks

MEP Sokol's report puts forward several recommendations related to national stockpiling and contingency stocks, notably by assigning the European Commission an enhanced role in monitoring, coordinating, and ultimately ensuring greater transparency of the system. **We welcome provisions that strengthen oversight and promote more effective and equitable redistribution**. This includes the establishment **and maintenance of a digital reporting system providing real-time updates on the status of national stocks.**

We recall that strong, coordinated governance as well as accountable and sustainable management systems and logistics are needed to ensure that national stockpiles do not result in waste and do not disrupt existing supply chains. They must complement in a pragmatic way manufacturers' obligations to supply the market and maintain contingency of stocks.

Regarding the creation of a Union Stockpile, described in the report as a "*last resort mechanism*", as well as granting the European Commission the authority to require Member States to redistribute medicines, **we recognise that such measures may be challenging to implement in practice, given political sensitivities and logistical complexity, regarding e.g. location of the stockpile, storage and maintenance.**

We strongly encourage continued discussions on this topic, **with the final objectives to promote solidarity and cooperation between EU member states**, to guarantee that all EU patients have access to critical medicines in times of shortages and crisis. **The same applies to the question of thresholds**. While we acknowledge the points raised by MEP Sokol behind the establishment of defined quantitative thresholds, we believe that enhanced collaboration, a better monitoring, and greater data exchange would provide a more effective solution than imposing strict rules, which may face resistance from Member States during the trilogue negotiations.

Uncertainty remains over future funding for the CMA

We still have major concerns about how the CMA will be financed in the short and longer term. In particular, we continue to call for a comprehensive impact assessment of the Act and of its ability to actually improve the situation for patients, contribute to more equitable access to medicines across the EU, and avoid unintended outcomes including increased out of pocket costs for patients.

In addition, we are concerned that the Act may further exacerbate existing inequalities among EU member states, as strategic projects require significant public investment. We understand that discussions on funding of the implementation of the Act may take place during upcoming negotiations for the 2028–2034 Multiannual Financial Framework (MFF). **We would like to re-state that only a robust health budget that prioritises investment in strong and resilient healthcare systems can support a comprehensive approach to addressing shortages and improving access to treatments for all patients across the EU. In times of**

budget constraints, it is crucial to direct public funds where they deliver the greatest value to those they should serve: the patients.

EPF previous positions on the CMA are available here.

ABOUT EPF

The European Patients' Forum (EPF) is an independent non-profit, non-governmental umbrella organisation of patient organisations across Europe and across disease areas. Our 80 members include disease-specific patient groups active at EU level and national coalitions of patients. To read about our vision, mission, and strategy, visit: www.eu-patient.eu