EPF's recommendations for the ongoing Trilogues on the Critical Medicines Act (CMA)

February 2026

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Introduction

The European Patients' Forum (EPF) has been actively engaged in the topic of shortages and equitable access to affordable medicines in recent years. From everyday medicines and antibiotics to highly specialised products, patients across all Member States experience difficulties in accessing the medicines and treatments they need, leading to serious harm to patients' health and safety, quality of care, professionals' ability to deliver care, and health system functioning.

The Critical Medicines Act, with the appropriate tools and actions, can be an important step towards improving medicine security, as well as the availability, affordability and accessibility of medicines across the EU for all patients.

Following the adoption of the positions of the Council and the European Parliament, and as the EU institutions are engaging in trilogues, it is crucial for EPF to convey the patients' voice and re-state our key priorities.

As trilogue negotiations progress, and in light of an evolving geopolitical context that could affect the availability and affordability of medicines, EPF stands ready to work constructively with the European Commission, the Council, and the European Parliament to ensure that the final legislative text delivers tangible benefits for patients by improving equity and reducing access disparities across Member States.

Our 6 key demands for the Trilogue negotiations

1. **Stronger Patient Involvement:** Ensure meaningful, structured, and continuous patient involvement by including **two patient representatives as permanent members of the Critical Medicines Coordination Group → (Art.25)**

2. **Stronger Focus on Equal Access to Medicines:** Ensure that the CMA delivers better access to medicines by **safeguarding the EU Joint Procurement provisions and ensure that collaborative procurement can work in practice → (Art.23)**

3. **Stronger Public Procurement Policies:** Promote a genuine shift in public procurement criteria **away from price alone towards criteria that also prioritise quality, long-term security of supply, sustainability and resilience → (Art.18)**

4. **Stronger Safeguards for Public Funding Received: Include effective, proportionate, and dissuasive penalties in cases of non-compliance** with specific criteria for the strategic projects → **(Art.15 & Art.16)**

5. **Stronger Transparency: Create formal channels for ongoing engagement with patient representatives, publish regular public reports and monitoring results, and provide open access to information** on CMA implementation and associated activities → **(All Chapters)**

6. **Stronger Coordination: Facilitate structured dialogue on the implementation of the CMA within the Critical Medicines Coordination Group to enhance coordination between the EU and Member States; in addition, establish / maintain digital reporting systems providing real-time updates** on the status of national contingency stocks and stockpiles → **(Art.20 & Art.26)**

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Additional information: key recommendations by chapter

Chapter I - General provisions	
Ensure the CMA is driven by public health objectives, namely improving patient safety and medicines' availability (**Art.1**)	Maintain a targeted scope for strategic projects, focused on critical medicines only (**Art.2 and also Art.5**)
Ensure clear definitions to contribute to greater legal clarity and a better understanding of the scope of the Regulation (**Art.3**)	
Chapter II - Strengthening the Union's security of supply	
Support an inclusive approach to the implementation of the CMA, with meaningful involvement of patient organisations (**Art.4**)	
Chapter III - Enabling conditions for investment (Strategic projects)	
Ensure stronger coordination at EU level for the assessment and identification of strategic projects, with early involvement of the Coordination Group & adoption of EC guidelines (**Art.6**)	Promote communication and information exchange with organisations and social partners during the implementation of strategic projects and enable the publication of all final decisions on a single website (**Art 8 & Art.14**)
Strengthen project promoters' obligations, such as prioritising appropriate and continued supply to the EU market and adopting measures that contribute to availability and affordability, with effective, proportionate, and dissuasive penalties in case of non-compliance (**Art.15 & Art.16**)	

Chapter IV – Section 1 - Demand side measures (Public procurement & Contingency stocks requirements)	
Encourage a shift away from price-only award criteria in public procurement by mandating the systematic inclusion of additional criteria such as supply-chain robustness and patient impact, and promoting multi-winner procurements (**Art.18**)	Mandate the establishment of national programmes to implement new public procurement rules, ensuring coordination among Member States and consultation of patient organisations prior to their adoption (**Art.19**)
Establish and maintain a digital reporting system providing real-time updates on the status of national contingency stock requirements and national stockpile as well as enhanced collaboration in cases of shortages (**Art.20**)	
Chapter IV – Section 2 – Collaborative Procurements	
Support Commission-facilitated cross-border procurement by clarifying the obligations of Member States and allow such procurement for medicinal products of common interest (**Art.21**)	Support the lowering of the threshold to initiate Commission-led procurement and joint procurement and provide greater legal clarity, while ensuring patient-centric implementation of regulatory flexibilities such as the use of electronic patient information (ePI) only in situations of urgency and/or shortages. (**Art.22-23**)
Call for patient involvement in procurement governance mechanisms with the consultations of patient organisations for the adoption of Union guidelines (**Art.24**)	
Chapter V – Critical Medicines Coordination Group	
Include two patient representatives as permanent members of the Group. Ensure structured stakeholder consultations and dialogue on the Group's decisions, in order to strengthen transparency, accountability, and democratic health governance (**Art.25**)	Expand both the scope and depth of the Group's tasks, in particular to enable more effective monitoring of the implementation of the Critical Medicines Act and the mandatory consultations of patient organisations to build trust and ensure transparency (**Art.26**)
Chapter VI – International cooperation	
Clearly state that strategic partnerships must fulfil the same requirements in terms of safety, quality and effectiveness. Include a clear reference to the need for an explicit assessment of the impact of imported medicines on affordability, in order to avoid increased out-of-pocket costs for patients (**Art.27**)	

Annex 1 – Explanations

Chapter I - EPF calls for the following during the Trilogues:

- ➔ **Recommendation n°1: Ensure the CMA is driven by public health objectives, namely improving patient safety and medicines' availability (Art.1)**
- ➔ **Recommendation n°2: Maintain a targeted scope for strategic projects, focused on critical medicines only (Art.2 and Art.5)**
- ➔ **Recommendation n°3: Ensure clear definitions to contribute to greater legal clarity and a better understanding of the scope of the Regulation (Art.3)**

Explanations

Objective of the CMA (Art.1): EPF supports the amendments introduced by the European Parliament which highlight patient safety and the availability of medicines as key objectives of the CMA. As medicines shortages have direct and serious consequences for patients, the CMA must be driven by public health objectives to ensure that it delivers meaningful benefits that meet patients' needs. While the Council's amendments to Article 1 focus on the need to improve the functioning of the internal market, we believe that patient safety and the reliable availability and accessibility of medicines should remain central to the CMA.

Scope of the CMA (Art.2): EPF is concerned about any expansion of the scope of strategic projects, in order to ensure that these instruments remain focused on critical medicinal products. In this context, we note that the European Parliament's position diverges from both the Council's and the European Commission by opening the possibility for medicinal products of common interest to benefit from strategic project status. **We are concerned that an expanded scope risks diluting the focus of the instrument and diverting resources away from where they are most urgently needed.** In times of budget constraints, the use of public funding must focus on addressing supply vulnerabilities of medicines most at risk of shortages.

Definitions (Art.3): We welcome the clarification of several definitions, which contributes to greater legal clarity and a better understanding of the scope of the Regulation. In particular, we support the explicit mention by the European Parliament of orphan medicinal products within the scope of medicinal products of common interest, as we believe that closer EU coordination, such as joint procurement mechanisms, can improve equitable access to these products. We also welcome the Parliament's and Council's inclusion of clearer definitions of national stockpiling and contingency stocks. These clarifications are important to ensure a common understanding of those mechanisms.

Chapter II - EPF calls for the following during the Trilogues:

➔ **Recommendation n°4: Support an inclusive approach to the implementation of the CMA, with meaningful involvement of patient organisations (Art.4)**

Explanations

Strategic objective of the Union (Art.4): EPF welcomes the European Parliament's amendment, which highlights the importance of including all relevant stakeholders, in particular patient organisations, in achieving the objectives of the CMA. As patients experience first-hand medicines shortages, patient organisations collect valuable information about vulnerabilities and supply issues affecting medicines used by their communities. Involvement of all relevant stakeholders improves the quality of the information collected and improves transparency. We also welcome the European Parliament's reference to the principle of **solidarity** between member states and the emphasis on **affordability** of critical medicines as a strategic objective of the Union.

Chapter III - EPF calls for the following during the Trilogues:

➔ **Recommendation n°6: Ensure stronger coordination at EU level for the assessment and identification of strategic projects, with early involvement of the Coordination Group & adoption of EC guidelines (Art.6)**

➔ **Recommendation n°7: Promote communication and information exchange with organisations and social partners during the implementation of strategic projects and enable the publication of all final decisions on a single website (Art.8 & Art.14)**

➔ **Recommendation n°8: Strengthen project promoters' obligations, such as prioritising appropriate and continued supply to the EU market and adopting measures that contribute to availability and affordability, with effective, proportionate, and dissuasive penalties in case of non-compliance (Art.15 & Art.16)**

Explanations

Assessment and determination of strategic projects (Art.6): We welcome the European Parliament's proposal to strengthen coordination and prevent duplication of strategic projects across the EU, while ensuring that all relevant information is systematically shared with both the European Commission and the Critical Medicines Coordination Group. In particular, **we support the amendment requiring prior notification to the Critical Medicines Coordination Group of a Member State's intention to designate a strategic project**. **We also strongly support the adoption of clear guidelines by the European Commission** to ensure a consistent, coordinated, and transparent approach across the Union to the assessment of strategic projects.

Transparency of information regarding strategic projects (Art.8 & Art.14): EPF strongly supports the European Parliament's efforts to enhance transparency in the governance of strategic projects. We welcome the amendment to Article 8, **which would enable Member States' authorities to strengthen**

communication and information exchange with organisations and social partners during the implementation of strategic projects. **We also support the Parliament's amendment to Article 14, requiring that all final decisions related to a strategic project be made publicly available on a single website.** Transparency is essential to ensuring accountability and maintaining public trust. **We are concerned about the Council's proposal to remove this transparency provision (deletion of Article 14), as this undermines democratic health governance and stewardship of public funds**.

Safeguards and accountability mechanisms (Art.15 & Art.16): EPF strongly encourages the European Commission and the Council to align with the European Parliament's amendments to Articles 15 and 16 regarding the conditions attached to financial support provided by Member States and the EU. We support the European Parliament's strengthening of beneficiary economic operators' obligations, including the necessary **adoption of measures that contribute to the affordability and accessibility of critical medicinal products and medicinal products of common interest**. **EPF also calls for the inclusion of robust accountability mechanisms, as proposed by the European Parliament**. **These should include effective, proportionate, and dissuasive penalties in cases of non-compliance**.

Additional considerations:

- ***EU funding for strategic projects under the upcoming Multiannual Financial Framework (MFF):*** The European Parliament proposes the establishment of a "*Critical Medicines Security Fund"* within the framework of the 2028–2034 MFF to support the implementation of strategic projects. As negotiations on the next MFF have started, **EPF stresses the importance of maintaining strong and ring-fenced EU health funding in the next MFF, ensuring that such funding is not reduced to an instrument for industrial policy alone. EU health funding should continue to support core public health objectives, including access to healthcare, prevention, and patient safety, while also ensuring adequate and sustainable support for health NGOs, in particular patient organisations**. Patient organisations require sustainable, accessible, and transparent funding mechanisms, such as operating grants, to enable their meaningful contribution to the design, implementation, monitoring, and evaluation of public health policies. The successful implementation of the CMA will only be possible if all stakeholders, especially patients, are meaningfully involved.

- ***EPF regrets the absence of an impact assessment,*** which could have more clearly identified the impacts of strategic projects on reducing the European Union's dependencies and improving security of supply for critical medicines. Similarly, there is no clear evidence on the impacts of these projects, and of selected relocation of pharma manufacturing to the EU, on the overall cost of medicines. We are concerned that increased production costs will result in increased out-of-pocket payments for patients. **We therefore call for adequate scrutiny, ongoing monitoring and strong safeguards to ensure that measures and instruments adopted under the CMA do not penalise patients in the short or long term.**

Chapter IV – Section 1 - EPF calls for the following during the Trilogues:

➔ **Recommendation n°9: Encourage a shift away from price-only award criteria in public procurement by mandating the systematic inclusion of additional criteria such as supply-chain robustness and patient impact, and promoting multi-winner procurements (Art.18)**

➔ **Recommendation n°10: Mandate the establishment of national programmes to implement new public procurement rules, ensuring coordination among member states and consultation of patient organisations prior to their adoption (Art.19)**

➔ **Recommendation n°11: Establish and maintain a digital reporting system providing real-time updates on the status of national contingency stock requirements and national stockpile as well as enhanced collaboration in cases of shortages (Art.20)**

Explanations

Incentivising resilience, sustainability and positive social impacts in public procurement procedures (Art.18): While the European Commission, the European Parliament, and the Council broadly agree on the need to move beyond price-only procurement for critical medicines, their level of ambition and patient safeguards varies significantly. **EPF strongly supports transparent and resilience-oriented public procurement as a key tool to prevent shortages and strengthen supply chains. We call for a clear and sustained shift away from single-winner tenders and price-only award criteria, including the systematic inclusion of criteria related to supply diversification, robustness, and patient impact, and a strict limitation of exceptions.** We therefore support the European Parliament's amendments, which provide clearer criteria, stronger safeguards, and better protection for patients. EPF recalls that **patient organisations must be strongly involved in procurement decisions as they directly affect the availability of critical medicines for the communities they represent.**

National programmes to support the development of public procurement procedures (Art.19): We support the European Parliament's strengthening of coordination mechanisms and **involvement of patient organisations in the development of national programmes on public procurement procedures**. This ensures better coordination and transparency at EU level, facilitates the sharing of best practices and, most importantly, guarantees stronger governance through meaningful patient involvement.

Policies around national contingency stock requirements & national stockpile (Art.20): In its original proposal, the European Commission introduces minimum safeguards to avoid negative consequences of national contingency stock requirements on other member states, but the proposal leaves the details largely to Member States. We welcome the Parliament's additional provisions related to EU-level notification, Union guidelines setting common standards, consideration of waste and environmental impacts, mechanisms for redistribution of national stocks as last resort, **and a digital reporting system for better monitoring of the status of national stockpiles. EPF welcomes provisions that strengthen oversight and promote equitable access to medicines across Europe**. We recall that strong, coordinated governance as well as effective and sustainable management systems are needed to ensure that national measures do not disrupt existing supply chains. They must complement in a pragmatic way manufacturers' obligations to supply the market and maintain contingency of stocks. **We therefore strongly encourage the EU institutions to support the amendments tabled by the European Parliament.** Regarding the proposed Union coordination mechanism and the establishment of a Union Stockpile, presented as last-resort mechanisms, **EPF recognises their potential value in situations where all other measures have failed, especially during times of crisis, as experienced during COVID-19 with the European reserve of emergency medical equipment.**

Chapter IV – Section 2 - EPF calls for the following during the Trilogues:

- ➔ **Recommendation n°12: Support Commission-facilitated cross-border procurement by clarifying the obligations of Member States and allow such procurement for medicinal products of common interest (Art.21)**

- ➔ **Recommendation n°13: Support the lowering of the threshold to initiate Commission-led procurement and joint procurement and provide greater legal clarity, while ensuring patient-centric implementation of regulatory flexibilities such as the use of electronic patient information (ePI) in situations of urgency and/or shortages (Art.22-23)**

- ➔ **Recommendation n°14: Call for patient involvement in procurement governance mechanisms with the consultations of patient organisations for the adoption of Union guidelines (Art.24)**

Commission facilitated Member States' cross-border procurement (Art.21): EPF supports the European Parliament's position on Article 21, **as it clarifies the obligations of Member States when engaging in Commission-facilitated cross-border procurement and strengthens legal certainty for all parties involved**. At the same time, EPF stresses that regulatory flexibilities should be used with caution. In particular, the use of electronic product information (ePI) should be limited to situations of urgency and / or shortages, as not all patients are currently able to access or use ePI effectively. **Finally, EPF does not support limiting Commission-facilitated cross-border procurement exclusively to medicinal products of common interest**. This mechanism should remain available for critical medicines, where it can provide clear added value in improving availability, equity, and security of supply for patients across the Union.

Commission procurement on behalf of or in the name of Member States (Art.22): EPF supports the reduction of the threshold required to initiate a procurement request, **as this would make it easier for Member States to request the Commission to conduct procurement on their behalf or in their name**. EPF also welcomes the clarifications introduced by both the European Parliament and the Council **to improve the legal certainty of the mechanism**. At the same time, EPF stresses that **regulatory flexibilities should be used with caution**. In particular, the use of electronic product information (ePI) should be limited to situations of urgency and / or shortages, as not all patients are currently able to access or use ePI effectively. **Finally, EPF does not support limiting Commission-facilitated cross-border procurement exclusively to medicinal products of common interest**. This mechanism should remain available for critical medicines, where it can provide clear added value in improving availability, equity, and security of supply for patients across the Union.

Joint Procurement (Art.23): 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. One of the strengths

of joint procurement lies in its collective bargaining power, which is maximised when larger Member States participate and when the European Commission can be a contracting party / initiate the process, as demonstrated with COVID-19 vaccines. **We are therefore against deleting such an important mechanism.** At the same time, EPF stresses that regulatory flexibilities should be used with caution. In particular, the use of electronic product information (ePI) should be limited to situations of urgency and / or shortages, as not all patients are currently able to access or use ePI effectively.

Agreement concerning procedures under Articles 22 and 23 (Art.24): In the European Commission's proposal, this article sets out key steps to be taken by both the Commission and Member States to ensure the effective functioning of procurement procedures, including the sharing of relevant information and the provision of the necessary resources by Member States. The European Parliament strengthens this provision by requesting the Commission to issue Union guidelines establishing common standards for procurement mechanisms, developed in consultation with relevant stakeholders, including patient organisations. **This is particularly important for the patient community, as it would enhance transparency and help ensure that procurement practices better respond to public health needs.**

Chapter V - EPF calls for the following during the Trilogues:

- ➔ **Recommendation n°15: Include two patient representatives as permanent members of the Group. Ensure structured stakeholder consultations and dialogue on the Group's decisions, in order to strengthen transparency, accountability, and democratic health governance (Art.25)**

- ➔ **Recommendation n°16: Expand both the scope and depth of the Group's tasks, in particular to enable more effective monitoring of the implementation of the Critical Medicines Act and the mandatory consultations of patient organisations to build trust and ensure transparency (Art.26)**

Explanations

Establishment of Critical Medicines Coordination Group (Art.25): We support the European Parliament's proposal to include two representatives from patient organisations, two from healthcare professional organisations, and two from the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG), and by granting observer status to the Parliament. **The inclusion of patient representatives as permanent members is essential to ensure that the perspectives and real-life experiences of those directly affected by shortages and health inequities are fully taken into account, in line with the principles of patient-centred care and democratic health governance.** EPF further calls for clarification during the trilogue to ensure that patient representatives, like healthcare professionals, are explicitly recognised as "permanent members", as the current wording appears to result from a drafting inconsistency. **EPF also supports the amendment of the European Parliament requiring the Group to cooperate closely with patient and consumer organisations, healthcare professional organisations, and relevant marketing authorisation holders in order to fulfil its tasks.** This aligns with the principles of patient-centred care and democratic health governance. It also enhances transparency, accountability, and information-sharing regarding the implementation of the Critical Medicines Act.

Tasks of the Critical Medicines Coordination Group (Art.26): EPF supports the amendment of the European Parliament which significantly strengthens Article 26 by expanding both the scope and depth of the Group's tasks. It reinforces the Group's role in coordinating national measures, overseeing strategic projects, monitoring the implementation of the Critical Medicines Act, and assessing national stockpiling strategies. The Parliament also mandates the Group to issue guidance on measures supporting availability and affordability and to ensure that public health and patient safety impacts are explicitly assessed in all relevant decisions. Importantly, it introduces stronger transparency and accountability requirements through structured cooperation and regular dialogue with key stakeholders, including patient organisations at both Union and national level. The Council also expands the Group's tasks by referring to exchanges of information and guiding principles on contingency stocks, but it adopts a more limited approach. Stakeholder consultation is mentioned in general terms, without clear specification, except with regard to industry, and without the structured transparency and patient involvement foreseen by the European Parliament. **EPF strongly advises supporting the European Parliament's position, as it would enable more effective monitoring of the implementation of the CMA and facilitate better harmonisation of decisions and the more systematic sharing of best practices across the Union**.

Chapter VI - EPF calls for the following during the Trilogues:

➔ **Recommendation n°17: Clearly state that strategic partnerships must fulfil the same requirements in terms of safety, quality and effectiveness. Include a clear reference to the need for an explicit assessment of the impact of imported medicines on affordability, in order to avoid increased out-of-pocket costs for patients (Art.27)**

Explanations

Strategic partnership (Art.27): While EPF supports the need to better understand, identify, and monitor strategic partnerships, we are concerned that none of the three institutions clearly require medicines sourced through such partnerships to meet the same standards of safety, quality, and effectiveness as those applied within the Union. Patients must be able to trust the medicines they use, and partnerships should not negatively affect patients in partner countries. EPF also calls for an explicit assessment of the impact of imported medicines on affordability to avoid increased out-of-pocket costs for patients.

Chapter VIII - EPF calls for the following during the Trilogues:

➔ **Recommendation n°18: Involve patient organisations in the evaluation of the CMA. Ensure that the evaluation assesses whether the CMA will contribute to achieving access to essential medicinal products by 2030, in line with United Nations Sustainable Development Goal 3.8.**

Explanations

Evaluation (Art.30): EPF supports the clarification of evaluation criteria by both the European Parliament and the Council and strongly welcomes the involvement of patient organisations in the evaluation process (which is currently happening for the evaluation of the HTA Regulation where patient organisations are involved in identifying KPIs). However, we further recommend that the evaluation explicitly include data related to the reduction of shortages, on the number and effectiveness of procurement procedures and their impact on access and affordability (in particular time-to-availability across Member States) as well as impact on out-of-pocket expenditure in order to assess whether the CMA contributes to achieving access to essential medicinal products by 2030, in line with the United Nations Sustainable Development Goal 3.8. The evaluation framework could also include measurable indicators related to reduction of shortages, time-to-availability across Member States, and impact on out-of-pocket expenditure, in order to assess the real-world effectiveness of the CMA.

Annex 2 – Definitions of CMA procurements

Commission facilitated Member States' cross-border procurement (Art.21): it refers to a mechanism where the European Commission, at the request of a group of Member States, acts as a facilitator to support cooperation between national contracting authorities conducting a joint or coordinated procurement procedure. Under such a tool, the European Commission provides logistical, technical, and legal support, including advice on applicable EU public procurement and pharmaceutical rules, but does not act as the contracting authority and does not assume legal or financial liability for the procurement or its outcome. Contracting and purchasing decisions remain fully under the responsibility of the participating Member States.

Commission procurement on behalf of or in the name of Member States (Art.22): it refers to a centralised procurement mechanism under which the European Commission, acting on the basis of a mandate from participating Member States, serves as the procuring authority and conducts the procurement procedure either on their behalf or in their name. In this framework, the Commission is responsible for organising and managing the procurement process in compliance with EU public procurement rules at the request of the Member States while the resulting contracts are intended to supply the participating Member States. Member States remain responsible for defining their procurement needs and for the implementation of the contracts at national level.

Joint Procurement (Art.23): It refers to a procurement procedure carried out jointly by the European Commission and participating Member States. Unlike other procurement mechanisms, the Commission acts as a contracting party. Besides, it is not only responsible for organising and managing the procurement process but may also initiate it.