The Standing Committee of European Doctors (CPME) represents national medical associations across Europe. We are committed to contributing the medical profession's point of view to EU and European policy-making through pro-active cooperation on a wide range of health and healthcare related issues.

Statement on the European Commission proposal for a Critical Medicines Act

The Standing Committee of European Doctors (CPME) welcomes the opportunity to provide feedback to the recently published proposal to the Critical Medicines Act.

CPME welcomes the proposal from the European Commission through the act to address supply chain vulnerabilities of critical medicines and other medicines of common interest and reduce Europe's dependencies to strengthen the supply of medicines.

The availability of medicines has been a long-standing challenge in the EU. National medical associations have reported that the problem of medicine shortages has become systemic across seasons and types of medicinal products, which is impacting patient safety and the practice of healthcare professionals.

In this context, the Netherlands, Germany and France have registries for drug shortages. The Dutch websites (one for the marketing authorisation holders, which is linked to the EMA system, and the other for pharmacists from the national pharmacists association) that present not only the product on shortage, but also the available alternatives. Germany has a similar system of centrally collecting the information on shortages and the alternatives. Also, the French National Agency for the Safety of Medicines and Health Products has its own system to monitor the availability of healthcare products.

EMA recently launched the European Shortages Monitoring Platform (ESMP) which allows marketing authorisation holders and national competent authorities to directly report shortages of medicinal products. We highlight that the European system should be closely aligned with the national registries and avoid duplication.

Healthcare professionals are key partners in mitigating the negative impact of shortages on patient safety and health. Hence, there is an utmost need to ensure that doctors, pharmacists and other healthcare professionals have access to up-to-date information on actual shortages and available alternatives. Best practices already exist in some EU Member States, and we believe they could be easily implemented across the EU, e.g. in the context of electronic prescription tools. It is of utmost importance that doctors should be mandatorily informed of any shortage, with the software indicating the unavailable product and suggesting one or more suitable alternatives.

National Competent Authorities are responsible for provision of this information directly and in a timely manner to doctors and healthcare professionals regarding shortages with the best alternatives.

We stress the need to ensure that any public funding granted to pharmaceutical companies should go hand in hand with strong obligations regarding security of supply, affordability and transparency on the public money granted to companies. Any form of accelerated procedures applied by Member States' authorities (**article 7**) should follow this principle.

Currently, the majority of Active Pharmaceutical Ingredients (API) and medicines are produced outside of Europe in limited number of manufacturing sites. Distant location of factories makes it more difficult to inspect them and results in longer, less transparent and fragile supply chains[1]. Unforeseen disruptions or quality and production problems have far-reaching consequences. Moreover, at the production sites, delays in supply can also result from the shortages of raw materials[2] (CPME Policy on medicines shortages). Consequently, we support the broad definition of strategic projects to increase production capacities for medicinal products, active substances and the modernisation of manufacturing infrastructures in the EU (**article 5**) which includes raw materials. In this context, the obligation set out in **article 15(2)** for priorisation of supply of critical medicines to EU Member States, should consider that manufacturers who do not fulfill their obligation to prioritise supplying EU Member States and guaranteeing security of supply face sanctions (CPME position to the general pharmaceutical legislation revision), including mandatory repayment of aid received.

CPME supports **articles 18 and 19** of the proposed regulation and procurement of medicines should go beyond price and follow non-price criteria, such as security of supply, transparency throughout the supply chain and environmental criteria. However, **article 18(5)** should not allow Member States to generally deviate from applying security of supply criteria. Exceptions should

[1] R.E. Ferner, J. K. Aronson, et al., Crisis in the supply of medicines, BMJ 2019;367:l5841, October 2019, doi: https://doi.org/10.1136/bmj.l5841
[2] World Health Organization (WHO), Medicines shortages, WHO Drug Information Vol. 30, No. 2, 2016, pp. 180–181.

be limited to specific cases where the application of security of supply criteria would lead to disproportionate prices. Tenders who only have the lowest price as a rule could lead to shortages in the long-term, since there is dependency on only one or few suppliers who could either leave the market or increase the price.

Regarding stockpiling, we consider that the provision of **article 20** on Member States' contingency stocks is insufficient. Minimal safety stocks of critical medicinal products shall be sufficient to meet the two-month demand for that critical medicinal product in Member States where the medicinal product has been placed on the market (CPME position on the general pharmaceutical legislation). Also, dynamic stocks could improve medicines availability and prevent waste, and this should be reflected in the Critical Medicines Act. The obligation should apply to critical medicinal products selected in accordance with this Regulation.

We stress that stockpiling should not endanger other Member States, regions or healthcare facilities. Therefore, Member States should be obliged to notify any national stockpiling legislation in advance to the Commission and/or the Critical Medicines Coordination Group.

We also argue that, when needed, medicine stockpiling should take place at EU level (CPME Policy on Medicines Shortages).

Also, since medicine shortages can be caused by shortage of raw materials needed later in the process of pharmaceutical manufacturing, it could be worth asking manufacturers to stockpile raw materials. This could help mitigate logistical issues and ultimately prevent shortages of medicines.

We see as a positive development the proposal to facilitate joint procurement beyond crisis-relevant products (**articles 21 to 24**) on a voluntary basis which can ensure better patients access to the medicines they need not just in crises times. Joint procurement could lower costs and leverage bargaining power of Member States vis-a-vis pharmaceutical industry.

Finally, doctors and other healthcare professionals should have a seat at the future Critical Medicines Alliance Coordination Group (**article 25**).