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 call for evidence on the Critical Medicines Act

The Standing Committee of European Doctors (CPME) welcomes the opportunity to provide input to the ongoing preparation of the Critical Medicines Act.

CPME is concerned about the continuously urgent problem of medicine shortages and calls for concerted action at the EU level to secure medicine supplies. The Critical Medicines Act could help addressing supply chain vulnerabilities of critical medicines and reduce Europe's dependencies to strengthen the supply of critical medicines.

The availability of medicines has been a long-standing challenge in the EU. However recently, 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.

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 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.

Beyond that, The Netherlands and Germany 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) 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. EMA launched recently 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.

We underline that when needed, stockpiling of medicines should take place at producers level. Since the act should complement the future revised pharma legislation, we consider the provisions related to safety stocks, in the proposal for the revision, related to safety stocks insufficient and we call for introduction of mandatory stocks at the producers level, examples of which already exist in some Member States. Such stocks should be coordinated at the EU level. Following the good example of some Member States, it is highly recommended to introduce an obligation for marketing authorisation holders to establish and maintain safety stock of finished medicinal product sufficient to meet two-month long demand in a Member State. The obligation should apply to critical medicinal products selected in accordance with this Regulation.

We stress that national stockpiling should only be introduced when not endangering neighbouring countries, regions or health care facilities with patients in need of the stockpiled medication. To prevent a shortage, stockpiling for essential medicines should be introduced lasting at least two to three months in wholesalers' inventories (CPME Policy on medicines shortages). Also, dynamic stocks could improve medicines availability and prevent waste, and this should be reflected in the Critical Medicines Act.

Finally, we call on the European Commission that any evaluation of most vulnerable medicines should be closely aligned with the existing Union list of critical medicines and duplication of existing structures should be avoided.