EHC
Empowering the bleeding disorders community

European Haemophilia Consortium (EHC)
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EHC statement on EU Critical Medicines Act

We, the European Haemophilia Consortium (EHC), an international non-profit organisation representing 48 national patients' organisations for people with rare bleeding disorders from 27 Member States of the European Union (EU) and most Member States of the Council of Europe, are writing to you regarding the Critical Medicines Act.

We commend the European Commission's efforts to strengthen the resilience of Europe's pharmaceutical supply chains and ensure equitable access to essential medicines, particularly for patients with rare diseases, such as bleeding disorders. The COVID-19 pandemic has shown us the vital importance of such initiatives, especially in protecting vulnerable patient populations.

Patients with rare diseases are especially vulnerable to medicine shortages, as delays or disruptions in treatment can be life-threatening. Many of the medications these patients rely on are already produced in limited quantities, and shortages can have dire consequences, including worsening health conditions and, in some cases, death. For these patients, even a minor disruption in the supply of critical medicines can lead to significant, irreversible damage to their health. The Critical Medicines Act provides an important opportunity to address these challenges and ensure that the needs of these patients are met through stronger and more resilient supply chains.

However, despite the significant impact the Act will have on the lives of patients with rare diseases, we are concerned that the consultation on the draft strategic report of the Critical Medicines Alliance has not adequately represented patient groups. The short consultation timeline is insufficient for us to properly analyse the document, gather the necessary evidence, and provide meaningful input. As the strategic report will feed the Critical Medicines Act, we fear that this limited time will prevent us from offering comprehensive feedback that could enhance the Act's effectiveness for those most in need.

The Critical Medicines Act offers a crucial opportunity to fill existing gaps in the availability and distribution of essential medicines for rare disease patients. To ensure that the Act truly addresses these gaps, we strongly encourage the following:

1. A dedicated focus on rare diseases: We urge the European Commission to include in the Critical Medicines Act specific measures for ensuring the availability of critical medicines for rare disease patients. This could involve tailored strategies for addressing the unique challenges faced by these patients, including limited access to essential treatments produced in small quantities and the provision of mitigation plans.

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2. Increased representation of patient organizations: We call for a more robust representation of patient organizations in the consultation process, ensuring that the perspectives of those directly impacted by the Act—especially rare disease patients—are adequately included in decision-making.

3. Collaboration with all stakeholders: We strongly encourage ongoing collaboration between the European Commission, patient organizations, healthcare professionals, and the pharmaceutical industry to ensure that the Critical Medicines Act reflects the realities and challenges faced by patients with rare diseases.

In conclusion, while we fully support the European Commission's efforts to address medicine shortages and improve the pharmaceutical supply chain, we believe it is essential that the voices of patients with rare diseases are heard and integrated into the final strategy. We hope that the Commission will take the necessary steps to ensure the consultation process is inclusive, transparent, and fully reflects the needs of those who rely on these critical medicines. We stand ready to work together to ensure that the Critical Medicines Act fulfills its potential to safeguard the health and well-being of all patients, particularly those with rare and life-threatening conditions.