



IPOPI welcomes the European Parliament rapporteur's draft report on the Critical Medicines Act

The International Patient Organisation for Primary Immunodeficiencies (IPOPI) welcomes the draft report on the Critical Medicines Act by MEP Tomislav Sokol, rapporteur on behalf of the European Parliament's Public Health Committee. We commend the report for its balanced approach, prioritizing a sustainable, secure, fair and equitable supply of critical medicines for patients across Europe.

MEP Sokol's draft rightly stresses the importance of reducing dependency on external sources for the development of medicines, raw materials, and supply chains. This is essential both for safeguarding uninterrupted access to life-saving treatments during times of crisis and for ensuring the long-term resilience of Europe's pharmaceutical sector. We also welcome the emphasis on the diversity of medicine supply chains. IPOPI considers important to recognise the unique characteristics of specific supply chains, such as those for immunoglobulin replacement therapies which are produced from donated human plasma. These treatments require particular attention, as outlined in the Strategic Report of the Critical Medicines Alliance¹, and should be assessed on their own terms.

IPOPI is pleased to see the rapporteur strengthen patient involvement in decision-making processes. The inclusion of two patient representatives in the Critical Medicines Group, the body responsible for coordinating actions across various sectors, is a positive step forward. MEP Sokol has also introduced specific key language around patient safety, meeting patients' needs, and safeguarding health, which is crucial to ensuring that patients' voices are heard and considered in the legislative process.

IPOPI also welcomes the consideration of orphan medicinal products and other medicinal products addressing specific public health needs as medicines of common interest. This inclusion goes into the right direction of ensuring that patients with rare diseases and other special needs have their needs of stable and reliable therapies addressed.

We look forward to further discussions on this vital Regulation and remain committed to working with the European Parliament to ensure that the Critical Medicines Act delivers tangible benefits across the European Union for individuals living with primary immunodeficiencies, an increasingly growing group of over 550 treatable rare immune disorders. .

¹ Strategic Report of the Critical Medicines Alliance, available at: https://health.ec.europa.eu/document/download/3da9dfc0-c5e0-4583-a0f1-1652c7c18c3c_en?filename=hera_cma_strat-report_en.pdf