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A missed opportunity to acknowledge EU's dependency on U.S. plasma

European Commission's "Study on medicine shortages" is a missed opportunity to recognise and address unmet needs for PDMPs

Brussels, 17 December, The Plasma Protein Therapeutics Association (PPTA) regrets that the publication of the European Commission report, "Study on medicine shortages," does not include plasma, which is a biological starting material for the manufacture of lifesaving plasma-derived medicinal products (PDMPs). PDMP availability is primarily dependent on volumes of plasma collected, which are currently insufficient to meet the needs of EU patients.

PDMPs are unique medicines that can only be made from human plasma donated by committed donors. More than 300,000 patients across the EU rely on these therapies to treat rare, chronic and life-threatening conditions such as immune-deficiencies (including cancer treatment-induced secondary immunodeficiency), immune-mediated peripheral neuropathies, Hereditary Angioedema, Alpha 1-antitrypsin Deficiencies, Hemophilia and other bleeding disorders. In many cases, PDMPs are the only treatment option for these conditions.

PPTA is concerned that, by not including all stakeholders in the consultation process, the report has not considered the unique aspects and challenges related to access to PDMPs. The EU currently has a shortfall of 3.8 million liters (or 30%) of the plasma needed to manufacture PDMPs for European patients, while clinical need for PDMPs increased 6%[1] per year. Whilst the COVID-19 pandemic has put a spotlight on the vulnerability of insufficient plasma collection in Europe, the European Commission seems to not take the issue seriously.

"Patient access to PDMPs is a key concern," remarked Maarten Van Baelan, Executive Director, PPTA Europe. *"The EU Pharmaceutical Strategy, the ongoing Structured Dialogue on security of medicines supply, the revision of the Blood Directive, and the revision of the EU Pharmaceutical legislation are all opportunities that the European Commission should embrace to introduce policy recommendations, practical approaches, and a new thinking on how more plasma can be collected in the future to address growing patient clinical need."*

About PPTA
The Plasma Protein Therapeutics Association (PPTA – www.pptaglobal.org) is the global industry trade association with a strong European presence representing the private sector manufacturers

[1] Report from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on the implementation of the Directives 2002/98/EC, 2004/33/EC, 2005/61/EC and 2005/62/EC setting standards of quality and safety for human blood and blood components.
https://ec.europa.eu/health/sites/default/files/blood_tissues_organs/docs/com_2016_224_en.pdf

of PDMPs and privately-owned plasma donation centres, including more than 160 centres in Europe. PPTA is steadfast in its mission to promote the availability of and access to safe and effective plasma protein therapies for patients worldwide.

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