PLUS
PLATFORM OF PLASMA PROTEIN USERS

Patients living with rare plasma related disorders, should have access to safe, efficacious, and high-quality Plasma Derived Medicinal Products (PDMPs) wherever they live

The following joint stakeholder statement was prepared as an outcome of the PLUS[1] Stakeholders Consensus Conference held on 23-24 January 2025.

Plasma-derived medicinal products (PDMPs) rely on healthy donors providing plasma through plasmapheresis or blood donation as a starting material for their production. Since PDMPs are sourced from human plasma, ensuring their safety with respect to the transmission of blood-borne pathogens is paramount. The combination of strict donor selection procedures, advanced serological and NAT screening, and modern industrial fractionation methods, all following good manufacturing practices, guarantees that PDMPs are safe and effective therapeutic products. In order to ensure the availability of these medicines, regulatory frameworks and guidelines should be based on the latest scientific evidence and harmonised globally.

PDMPs produced by fractionators licensed by leading reputable regulatory agencies, including the US FDA and EMA, adhere to stringent regulatory standards. They have not been associated with viral transmission since the 1990s.

However, regulatory capacity varies significantly across countries. Recently, alternative local or technological approaches to industrial fractionation have been proposed, particularly in low- and middle-income countries. Attempts to distribute falsified PDMPs[2] and plasma bags have also been reported in different countries. Similarly, the use of potentially unsafe and outdated therapies such as cryoprecipitate and pathogen reduced cryoprecipitate have been proposed for the treatment of bleeding disorders in spite of the existence of well-established, safe and effective therapies for such patients.

[1] PLUS is the Platform of Plasma Protein Users (PLUS) is a consortium of 6 patient organisations representing people living with treatable rare plasma related disorders. Its member organisations are: Alpla-1 Plus, the European Haemophilia Consortium (EHC), the GBS-CIDP Foundation International, the International Patient Organisation for Primary Immunodeficiencies (IPOPI), the ITP Support Association and the World Federation of Hemophilia (WFH).

[2] WHO Medical Product Alert nº3/2022: Falsified Intratect (Human normal immunoglobulin). Available at: https://www.who.int/news/item/27-05-2022-medical-product-alert-n-3-2022-falsified-intratect-human-normal-immunoglobulin

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These developments emphasize the urgent need for national regulatory agencies, particularly those with limited experience in overseeing plasma products, to ensure PDMPs under their jurisdiction meet the required safety, efficacy, and quality standards.

It is crucial that these vital medicines adhere to rigorous manufacturing processes, and that robust regulatory frameworks, grounded in current science, are put in place to guarantee their safety and effectiveness for patients.

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