

PLUS Consensus Principles on Strategies to encourage Blood and Plasma Donations in Europe

The Platform of Plasma Protein Users organised a Consensus Conference in Estoril, Portugal on 24-25 January 2019 bringing together different stakeholder organisations active in the field of blood and plasma collection and fractionation.

The following key principles were identified and endorsed by the stakeholders listed below during the meeting. This, with a view to inform future policy discussions in Europe around the collection of blood and plasma. These principles will also be helpful in the context of a potential revision of the EU Blood Directive.

- 1. Recognition that Plasma Derived Medicinal Products (PDMPs) are life-saving therapies.
- 2. Patient organisations representing the communities dependent on a stable supply of PDMPs should be involved in policy decision-making.
- 3. Patient organisations call for global sufficiency of PDMPs as the ultimate goal of any regional effort to collect more plasma.
- 4. Any measure or new policy aimed at increasing blood and plasma collection should ensure that it is both patient- and donor-centered, with the goal to meet growing clinical needs.
- 5. Education on health questions regarding blood and plasma should be promoted throughout Europe.
- 6. All measures and policies should respect and promote health and safety for patients.
- 7. All measures and policies should respect and promote quality, safety of blood and plasma collection, including donors' safety.
- 8. In the interest of transparency, blood and plasma donors should be informed about how their donation can be used.
- 9. Measures to increase blood collection may be different from the ones aimed at increasing plasma collection.
- 10. Plasma collection through plasmapheresis is key to ensure Europe can increase its supply of plasma for fractionation.
- 11. Avoiding wastage of recovered plasma is also important.
- 12. All manufacturers should be encouraged to use recovered and/or apheresis plasma.
- 13. Future European policies should take into consideration the differences between blood and plasma collection as well as between labile blood products and plasma derived medicinal products (PDMPs).
- 14. In doing so European policies should acknowledge the possibility of co-existence of both the public and private sector involved in blood and plasma collection.
- 15. Good Manufacturing Practices / Good Practices and testing requirements of the European Medicines Agency Plasma Master File should be implemented.



16. Clarification of terminologies / definitions in European legislation is required to support better coordination of blood and plasma collection.

Stakeholders endorsing:

- Alain Weill (World Federation of Hemophilia)
- Albert Farrugia (University of Western Australia)
- Bob Perry (International Plasma and Fractionation Association)
- Brian O'Mahony (Platform of Plasma Protein Users, European Haemophilia Consortium)
- Dominika Misztela (Plasma Protein Therapeutics Association)
- Frank Willersinn (Platform of Plasma Protein Users, Alpha 1 Global)
- Jan Bult (Plasma Protein Therapeutics Association)
- Johan Prevot (Platform of Plasma Protein Users, International Patient Organisation for Primary Immunodeficiency)
- Jose Drabwell (International Patient Organisation for Primary Immunodeficiency)
- Karl Petrovsky (Plasma Protein Therapeutics Association)
- Leire Solis (International Patient Organisation for Primary Immunodeficiency)
- Mark Brooker (World Federation of Hemophilia)
- Mark Skinner (American Plasma Users Coalition)
- Martin van Hagen (Rotterdam Erasmus Medical University Hospital, International Patient Organisation for Primary Immunodeficiency)
- Martine Pergent (International Patient Organisation for Primary Immunodeficiency, IRIS)
- Patricia Blomkwist (Guillain-Barré Syndrome/ Chronic Inflammatory Demyelinating Polyneuropathy, Multifocal Motor Neuropathy)
- Patrick Robert (Market Research Bureau)
- Paul Strengers (International Plasma and Fractionation Association)
- Saara Kiema (International Patient Organisation for Primary Immunodeficiency)
- Stephan Walsemann (European Plasma Alliance)