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Plasma Supply Management Symposium
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Recommendations to Stakeholders

These recommendations were drafted by a working group consisting of members of the TS093 Plasma Supply Management Working Group, a subordinate working group of the European Committee on Blood Transfusion (CD-P-TS), and stakeholders' representatives during a meeting held the day after the Plasma Supply Management Symposium (list of participants as Appendix).

These recommendations represent actions, identified by the meeting participants, to be undertaken by different stakeholders in order to increase the availability of plasma for fractionation in Europe following issues discussed during the symposium on Plasma Supply Management. They are intended for any stakeholder who is in a position to contribute to increasing the volume of plasma available for fractionation in his/her specific field of activity.

The document was submitted to the stakeholders' representatives for comments and approval. Most comments were of an editorial nature and the text was amended accordingly.

Disclaimer

However, it must be clearly stated that these recommendations do not commit any of the stakeholders who participated in the meeting to undertake the actions listed.

GENERAL STATEMENT

- All stakeholders to prevent potential crowding-out competition between donors of whole blood and plasma

RECOMMENDATION TO THE EU COMMISSION

1. Donor vigilance

- Increase work on (whole blood and plasma) donor protection
- Request mandatory reporting of SARE (Serious Adverse Reactions and Events) in plasma donors
- Implement mandatory material vigilance reporting (equipment, e.g. citrate, bags, bowls)
- Harmonise donor vigilance reporting between member states
- Establish line of communication between haemovigilance and pharmacovigilance

2. Plasma collection (apheresis) support and strategic independence of plasma in Europe

- Develop and evaluate strategies for preventing disruption of access to PDMPs (Plasma-Derived Medicinal Product) for patients in the event of a shortage
- Ensure equitable access to treatment for PDMP-dependent patients

- Communicate on the need for strategic independence of plasma for PDMPs from third countries
- Improve legal framework in order to enhance/enable/safeguard strategic independence in PDMPs
- Promote awareness of rare diseases requiring PDMPs
- Evaluate impact of free market on topics such as equal access to PDMPs for member states and parallel trade
- Campaign for education of plasma donors and awareness of the need for plasma
- Evaluate impact of "plasma master file" procedure as a potential obstacle to access to recovered or source plasma

3. Legal framework concerning plasma donor and donation regulation

- Promote the use of the Good Practice Guidelines (see Commission Directive (EU) 2016/1214)

RECOMMENDATION TO THE EDQM / CD-P-TS / TS093

1. Data collection

- Collect data and publish reports and surveys on plasmapheresis, plasma and PDMPs

2. Guide revision (evidence-based criteria, transparency of updating)

- Adapt text of *Blood Guide* to highlight standards and allow a legal reference in the EU Directives
- Promote the use of the Good Practice Guidelines published in the *Blood Guide*
- Plan a new meeting with extended[1] TS093 working party to look at 21st edition
- Promote individualised donor assessment methods for plasma collection

3. Stakeholder meeting concerning immunoglobulin (IgG) use and rare disease treatment

- Organise conference with the whole chain for rare diseases in collaboration with other stakeholders (EU Commission, industry, patient and donor associations)
- Organise Kreuth-like conferences to discuss optimal use of IgG (off-label use) and rare diseases

4. Plasma collection-targeted activities

- Promote strategic independence of plasma in the Council of Europe member states (wider Europe)
- Organise awareness campaigns on the need for plasma to produce PDMPs

[1] See TS093 mandate : https://www.edqm.eu/sites/default/files/mandate-blood-transfusion-cd-p-ts-project-ts093-2018.pdf

RECOMMENDATION TO MEMBER STATES / NATIONAL COMPETENT AUTHORITIES

1. Plasma collection and sustainable PDMPs availability

- Heighten awareness in donor community and the general population of the need for increased collection of plasma
- Provide adequate funding to blood establishments not only for whole blood collection, but also for plasma collection
- Design national programme targeting plasma needs
- Monitor the PDMP inventory of individual companies in the event of shortages
- Provide report on annual collection of plasma and use of PDMPs
- Monitor (appropriate, off-label and inappropriate) use of PDMPs
- Develop contingency plans

2. Donor vigilance

- Enforce donor vigilance
- Consider international harmonised approach for the qualification of staff in blood establishments

RECOMMENDATION TO BLOOD ESTABLISHMENTS

1. Awareness of the need for increased plasma collection for PDMPs

- Communicate on the need for plasmapheresis
- Collect more plasma (by plasmapheresis)
- Build awareness in donor community of the need for increased collection of plasma
- Improve cost-effectiveness of plasmapheresis

2. Plasma donor recognition and donor safety

- Enforce donor vigilance
- Improve donor experience
- Donor recognition: express gratitude
- Publish data / experience /surveys on donor adverse events / donor vigilance

3. Collaboration with other blood establishments

- Share experiences
- Perform benchmarking
- Publish on plasma issues in order to ensure evidence-based decision-making

RECOMMENDATION TO PLASMA FRACTIONATORS

1. Collaboration

- Participate in Kreuth-like conferences to discuss optimal use of IgG (off-label use) and treatment of rare diseases

2. Data and knowledge-sharing

- Publish donor SARE and donor surveys
- Publish on plasma issues in order to ensure evidence-based decision-making
- Share knowledge
- Apply Good Practice Guidelines in blood establishments when procuring recovered plasma

RECOMMENDATION TO PATIENT ASSOCIATIONS

1. Collaboration

- Participate in Kreuth-like conferences to discuss optimal use of IgG (off-label use) and rare diseases
- Promote patients' voice

2. Data and knowledge-sharing

- Develop contingency plans
- Set up databases, registries

RECOMMENDATION TO DONOR ASSOCIATIONS

1. Awareness

- Build awareness in donor community of the need for increased collection of plasma
- Educate donors to support the collection of plasma

2. Data and knowledge sharing

- Share donor-recruitment best practices
- Promote donors' voice

RECOMMENDATION TO PROFESSIONAL SOCIETIES

- Participate in Kreuth-like conferences to discuss optimal use of IgG (off-label use) and rare diseases
- Contribute to the development of evidence-based guidelines

Appendix: List of participants

TS093 Core working party:

Name:	Affiliation:
Bigey Frederic	Etablissement Français du Sang, Strasbourg, FR
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Stakeholder representative:

Name:	Affiliation
Misztela Dominika	Plasma Protein Therapeutics Association (PPTA), Europe
Pergent Martine	International Patient Organisation for Primary Immunodeficiencies (IPOPI)
Simonetti Alice	International Federation of Blood Donor Organizations (FIODS)
Strengers Paul	International Plasma and Fractionation Association (IPFA)
Tiberghien Pierre	European Blood Alliance (EBA)
Van der Spiegel Stefaan	European Commission (DG Health and Consumer Protection)
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