

Mandate from European Committee (Partial Agreement) on Blood Transfusion (CD-P-TS) for the TS093 Plasma Supply Management Working Group.

1. Background

In 2014, the CD-P-TS nominated a subordinate working group to focus on plasma supply management (PSM), given the steady increase in the need for plasma for fractionation to meet the demand for plasma-derived medicinal products, in particular immunoglobulin.

The issues of recovered plasma supplied for fractionation into plasma-derived medicinal products and the protection of plasma donors entering intensive plasmapheresis programs will need appropriate consideration by the working group.

2. Period of validity of the mandate

This mandate is valid by tacit renewal unless the CD-P-TS takes a different decision. The CD-P-TS verifies the appropriateness of the mandate every two years, and revises it when deemed necessary.

3. Objective and tasks

Collect data to establish trends and the latest available information on:

- Provision of recovered plasma (L/1000 inhabitants and total amount) for fractionation;
- Provision of apheresis (source) plasma (L/1000 inhabitants and total amount) for fractionation;
- Rough estimation of “plasma, unaccounted for”, i.e. theoretically available but not reported as transfused or fractionated.

Collection of additional data:

- Number of blood establishments/hospital blood banks with a license to supply plasma for fractionation;
- Number of blood establishments/hospital blood banks with a contract to deliver plasma for fractionation or a contract to return certain plasma products to the blood establishment/hospital blood bank after fractionation;
- Are plasmapheresis programs run by the blood establishment/hospital blood bank – and if so, which frequencies and volumes are allowed? What follow-up programs are established for the plasmapheresis donors? SARE reports for plasmapheresis/donors;
- Inventory of studies on the follow-up of plasmapheresis donors with respect to current acceptance of frequencies and volumes;
- Inventory of register data on plasmapheresis donors (SCANDAT, etc.) with respect to frequencies and volumes of plasma collection;

- NAT testing.

The outcome of the TS093 working group is expected to make a significant contribution to the revision of the content of the Guide, in particular with respect to recommendations for apheresis collection and donor protection by using evidence-based data and other adequate and relevant information sources (for example expert panels).

Evidence-based proposals for revision of the Guide should be submitted to the GTS working party in charge of the periodic revision of the Guide by the Chair of the TS093 working group. On the occasion of each GTS meeting, the Chair of TS093 submits a progress report on recent activities.

4. Working methods

The working group will use telephone conferences and face-to-face meetings, supported by e-mail exchanges, to facilitate work progress. Face-to-face meetings should ideally be planned in connection with CD-P-TS, GTS or other European meetings to avoid excessive travelling for members and to be cost-effective.

The working group is expected to undertake a monitoring of scientific progress and changes to the regulatory framework in the field of plasma supply management. If methodological approaches are chosen by the group for systematic evidence assessment (for example, GRADE approach, Delphi method) this should be communicated in a transparent manner.

5. Composition of the TS093 Working Group

The working group comprises a core working group and an extended working group.

The core working group is constituted of experts nominated by the CD-P-TS following proposals made by Delegations to the CD-P-TS. Membership of the TS093 core working group can be terminated by the CD-P-TS upon request of the Delegation that proposed the expert for nomination.

The extended working group is constituted of the core group and representatives of stakeholders involved in the field of blood transfusion and/or plasma-derived medicinal products, such as authorities, blood establishments, manufacturers and associations.

The TS093 Plasma Supply Management working group (core + extended) is currently chaired by Dr Johanna Castrén, member of the Finnish Delegation to the CD-P-TS.

It is anticipated that the format of the TS093 working group (core + extended) will provide a unique forum to ensure all active key players can contribute with their knowledge and data to the elaboration of adequate recommendations to be published in the Guide.

6. Communication structure TS093 – CD-P-TS

Regular progress reports will be made by the TS093 Chair during the CD-P-TS plenary sessions held in November of each calendar year.