SUPPLY

NEWSLETTER 1 - OCTOBER 2023

# SUPPLY: STRENGTHENING VOLUNTARY NON-REMUNERATED PLASMA COLLECTION CAPACITY IN EUROPE

EU4Health

## Welcome

Greetings from the SUPPLY consortium, and welcome to our first newsletter – together we represent the first united effort across the EU to develop good practices and recommendations to:
Increase the volume and resilience of unpaid plasma collection in Europe
and
Ensure safe and adequate access for EU patients to essential Plasma medicines.

- Daphne Thijssen-Timmer, Director Sanquin Blood bank, Leader of SUPPLY
- Peter O'Leary, EBA Executive Director, Coordinator of SUPPLY

## When & Who?

SUPPLY is a project co-funded by the European Union's EU4Health Programme. SUPPLY started on September 1 2022 and runs up to February 29 2024.

The SUPPLY Project is an excellent example of solidarity, with many stakeholders from different EU Member States working together to improve the lives of EU citizens. The SUPPLY Consortium includes Blood Establishments, Blood Donor Organisations, Ministries of Health, Universities, the International Plasma and Fractionation Association, and the European Hematology Association.

Co-funded by the European Union

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# What is SUPPLY?

The SUPPLY Project aims to increase and strengthen the resilience of plasma collection in the EU to enable a stable and adequate supply of Plasma-Derived Medicinal Products (PDMPs). The entire plasma-to-PDMP-to-patient chain is being assessed – from plasma donor recruitment, retention, and health, through plasma collection and processing, to procurement, demand, and use of PDMPs.

# How will we achieve that?

SUPPLY focuses on how Blood Establishments can improve and build up voluntary non-renumerated plasma collection programmes and make them more efficient, including the evaluation of current legal frameworks and policies in the EU on plasma collection and tender models. Emphasis is being paid to maintaining donor safety in a way that both benefits donor health and facilitates the plasma quality needed for optimal production of medicinal products.

The main project outcome is a set of recommendations and guidance for blood establishments (BEs), competent authorities, medical societies, and other professional stakeholders to support them in being able to increase plasma collection in the EU by the public health sector and achieve optimal availability of plasma medicines for patients both in a general situation as well as in times of crises.

# Why is SUPPLY needed?

Plasma is the yellow liquid suspending the cell components (red and white cells, platelets) in blood and contains a wide range of proteins essential to life. The medicines produced from plasma are referred to as plasma-derived medicinal products (PDMPs) and are used to treat over 50 different conditions including rare diseases, immune disorders, and genetic conditions. For many of the conditions that PDMPs treat, patients have no alternative treatment and many of these plasma medicines are therefore included in the WHO Model List of Essential Medicines.

A substantial part of plasma collection in the EU is conducted by the non-profit blood establishments (BEs) from voluntary non-remunerated donors. Currently, however, there is a global dependence on plasma coming from the US to manufacture these essential medicines. The Covid-19 crisis dramatically revealed the world's vulnerability in supply of PDMPs, particularly immunoglobulins, that also face shortages in Europe today. SUPPLY aims to address this global imbalance in the collection of plasma. By contributing to the EU becoming more strategically independent in its need for plasma medicines, SUPPLY aims to ensure safe and adequate access for EU patients to essential PDMPs.

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## WP1 – Project management and coordination

**Team Leader: European Blood Alliance (EBA)**

This WP will safeguard the effective execution of the proposed project and the delivery of quality results within time and budget. It will ensure appropriate liaison with the European Commission and with and between the external Advisory Board (quality assurance, risk, and ethical management), and the internal Project Management Board. We have been working to coordinate the work and progress in all WPs, ensure communication flows among partners and manage common consortium activities. It will oversee all administrative, financial, and contractual aspects of the project.

## WP2 – Donor recruitment and retention best practices

**Team Leader: University Hamburg (UH)**

Work Package 2 (WP2) focuses on "Donor recruitment and retention best practices" and has two main deliverables.
In our first deliverable, we developed a document to provide an overview of plasma collectors and their incentives in EU, non-EU and worldwide countries.
To compile this overview, we first gathered information through desk research, which was then validated by experts in each country. In total, we have information from 28 EU countries, 26 of which are validated by experts in the country.
With regard to the objective of the SUPPLY project, which is to increase unpaid plasma donations in the EU, non-monetary incentives are commonly used. The most popular non-monetary incentives are snacks (n= 21), small gifts and health checks (n= 14 each). Depending on the plasma organization, monetary incentives are used in 7 countries, namely Austria, Czech Republic, Germany, Hungary, Latvia, Lithuania and Sweden.

On the basis of Deliverable 2.1, we aim to evaluate donor preferences for the different incentives to derive a recommendation report and a transfer plan (Deliverable 2.2). A representative survey of blood, plasma and non-donors in Germany, Austria, France and the Netherlands was conducted for this purpose. The selection of countries is based on a matrix that characterizes the countries according to (1) the market situation of the plasma organization (monopoly vs. fragmented market) and according to the existence of financial incentives (cash incentives vs. no cash incentives). We are still collecting data from the countries and aim to have data from 200 respondents in each of the groups (blood, plasma and non-donors).

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# WP3 – Plasma collection and processing best practices

**Team Leader: Sanquin (SQ)**

Task 3.1, recommendations on plasma collection is still in progress. Task 3.2 & 3.4 focussed on the processing & manufacturing chain and plasma cost modelling. To come up with the most efficient processing chain a few sight visits were organized and with ten blood establishments an efficient processing chain has been developed. In addition, many recommendations are provided. The cost modelling is still in progress, but data has been gathered through a survey.

The aim of task 3.3 is to describe where plasmapheresis can be improved, with regards to quality management and regulation opportunities. We collected precise information on the volumes collected and not used, reasons why plasmapheresis plasma is not collected and why recovered plasma is not used for fractionation.Research allowed to highlight that 2% of currently collected plasma has been declared wasted, and that numerous technical quality practices lead also to unrecognised waste. Changes of practices, lead in a harmonised way will improve the volume of PfF collected by the not-for-profit sector. The absence of plasmapheresis collection of plasma for fractionation in some MS is mainly due to lack of funding and size of the country related potential volumes available for fractionators.

In task 3.5, the quality of collected plasma has been evaluated by analysing a dataset of 80,733 blood samples taken from donors directly before plasmapheresis. An assessment of influencing factors on IgG levels was conducted. The number of donations within defined timeframes turned out to be the single most relevant parameter.
IgG concentration in donors has a considerable impact on the IgG recovery yield during subsequent fractionation. IgG content in pools with different background in donation frequency could differ over 10% making IgG based compensation worth a discussion.

## WP4 – National and EU infrastructures / policy/legal framework for plasma collection and PDMPs supply

**Lead Beneficiary: Centro Nazionale Sangue (CNS)**

WP4 drafted and distributed among Member States Health authorities a survey on "Plasma collection and PDMPs production from national plasma in EU". The primary objective was to collect information on the current national legal frameworks, policies and/or programmes related to:

- the collection of plasma specifically intended for fractionation into PDMPs,
- the management of PDMPs coming from national plasma sources,
- the management of plasma collected in the Blood Establishments.

After a preliminary review of the answers/feedbacks and dedicated contacts with respondents for clarification, data analysis activities have been carried out. Answers were provided by 21 Member States. On the basis of the survey results, a comparative analysis of the different policies and/or legal frameworks regarding plasma collection and PDMPs management was conducted, resulting in the creation of the Analysis report and the Report on data set and calculation tool. The latter identified a common data set for assessing the national demand and pharmaceutical expenditure for PDMPs.

The current focus within the work package is on the preparation of a comprehensive report concerning plasma economics and tenders. To achieve this, the co-leader IPFA together with CNS and other WP4 members conducted an analysis on the existing information and available data on how tenders and agreements are established, including WP4 survey results. In order to gain deeper insights, specific interviews with national authorities and relevant stakeholders were performed.

During the first year of the project, WP4 team promptly collaborated with and contributed to the work of other WPs.

In the last months of the project, a Position Paper on the distribution of PDMPs and final recommendations on plasma collection and PDMPs management will be formulated. The collaboration between the WPs of SUPPLY has been truly excellent.

## WP5 – Plasma donor protection best practices

**Team Leader: AUH**
**Co- Leader: Sanquin (SQ)**

The objective of WP5 of the SUPPLY project is to facilitate evidence-based plasma donor protection practices. We have finalized the survey on the inventory of existing plasma donor protection practices. We received 18 complete responses, constructed a 'model' donation procedure based on the responses, and performed an analysis report. We have reviewed the literature to identify evidence on plasma donation safety and plasma donation-related adverse events. The scoping review is completed, and included literature is visualized in an evidence gap map (submitted for publication and published in preprint on medRxiv). We are now finalizing the systematic review and gap analysis report. Furthermore, we are finalizing the description of requirements for a tool to record donor vigilance data. Based on these finding, we will formulate recommendations on protection of plasma donors.

## WP7 – Dissemination and communication

**Team Leader: European Blood Alliance (EBA)**

In WP7 we have reached our main objective to design and implement a 2-step dissemination, exploitation and communication strategy to raise awareness about the SUPPLY project and to disseminate its main results, while building up a long-lasting 'recommendations' identity. We have been focusing on how to target the relevant audiences and stakeholders, including policy makers.

The final users will be: Blood Establishments, medical and healthcare centres (e.g., hospital managers), Competent Authorities, donor associations, healthcare providers, scientific societies and academics as well as the general public to ensure maximum dissemination of the delivered recommendations across the EU.

In addition to collaborating with other EU4Health projects, we have been presenting on the SUPPLY project in various international conferences such as: ISBT, ECHDM, EHA conference, to name a few.

# WP6 Workshop

The SUPPLY WP6 multi-stakeholder virtual workshop started at 09:00 CET on September 6th by Robin Doeswijk welcoming the attendees and briefly going through the agenda. It was followed by presentations from Peter O'Leary (Introduction to SUPPLY), Syeldy Sasongko (Summary of doctor survey and expert interviews), Lucie Paulin (Summary of grey literature review), and Isabelle Durand – Zaleski (Deliverable 6.1 and our recommendations).

There were two breakout sessions regarding the topics of data collection and harmonization. All participants had 45 minutes in each room before switching to the other. Topics of discussion included (for example, in the harmonization room) off-label indications and how new indications could possibly added to the EMA's core SmPC but that the right procedures must be followed to continue monitoring Ig safety; and the importance of integrating prioritization recommendations into existing medical society-produced guidelines.

After the coffee break, all the participants came together again for the last part of the discussion and the conclusion. Several bullet points representing the main top takeaways from the discussions during the breakout sessions were presented.
In the data collection room, the main outcomes were to:

- Identify the existing data sources in every EU member state
- Identify what can be done in short term to provide information on Ig use by indication (not all indications but selected indications)
- Identify who will be doing what nationally (need better policy, better national regulations)

In the harmonization room, the main outcomes were that a harmonized prioritization or management plan would need to be a simple, universally recognized framework that includes criteria of:

- High medical need/unmet medical need
- Added benefit of Ig (also considering alternative treatments)
- Quality of evidence
- Quality of life for patients /patient involvement

The attendees were invited to discuss the two topics and/or if something was missing or should be considered that were not discussed during the breakout session. Additional comments included that to begin data gathering, the EMA/SPOC database on shortages could be used as a basis for the mapping of authorized Ig indications.

Participants were thanked for their attendance and informed that we would reach out to them in case of clarifications or specific input for our last deliverable.

# Dissemination

## Presenting SUPPLY

In the last year, you may have seen SUPPLY discussed or presented at recent forums:

- ECDHM,
- EMA multi-stakeholder workshop on shortages,
- EHA Congress,
- Conference in Madrid about SUPPLY (CCST from the Spanish government),
- as well as regular updates provided to the joint meetings of the National Competent Authorities for Blood, Tissues & Cells and Organs.

## Upcoming Meetings

**Meeting with Competent Authorities**
This will be an internal meeting with the SUPPLY Consortium and the Competent Authorities. This is a hybrid meeting in Leiden, the Netherlands on **February 6th, 2024.**

**Final Stakeholder meeting**
This will be a virtual meeting open to all interested in the SUPPLY project and sustainability of the project. This will be taking place on **February 16th 2024**.

If you are interested attending please send a mail to g.mori@europeanbloodalliance.eu so we can add you to the mailing list and provide updates.

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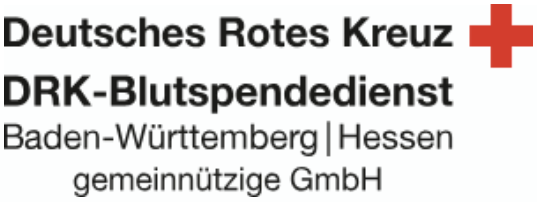



## SUPPLY Project

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