SUPPLY Project

Availability of IV/SC human normal immunoglobulins in the EU/EEA

EMA Amsterdam, 1 & 2 March 2023

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Background of the SUPPLY Project

- The need for plasma to produce plasma-derived medicinal products (PDMP) is increasing.
- Europe is increasingly dependent on plasma collected in the USA.
- Availability of PDMP is driven by a world-wide competitive market.
- Large differences in the usage of IgG between countries.
- COVID-19 pandemic and global political and economic developments have increased urgency to build in resilience in crisis situations
- Sufficient collection of plasma in a country does not automatically mean sufficient supply for its inhabitants.
- Therefore, increasing plasma collection by not-for-profit blood establishments will allow for increased overall resilience while safeguarding donor safety.

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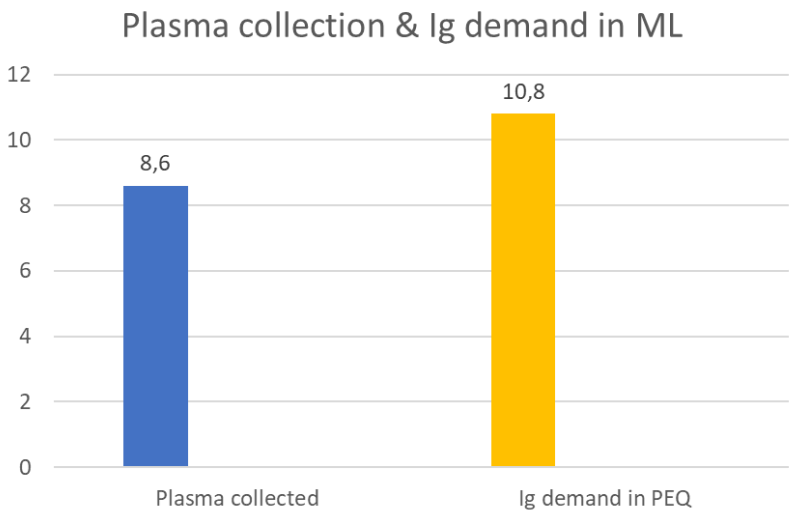
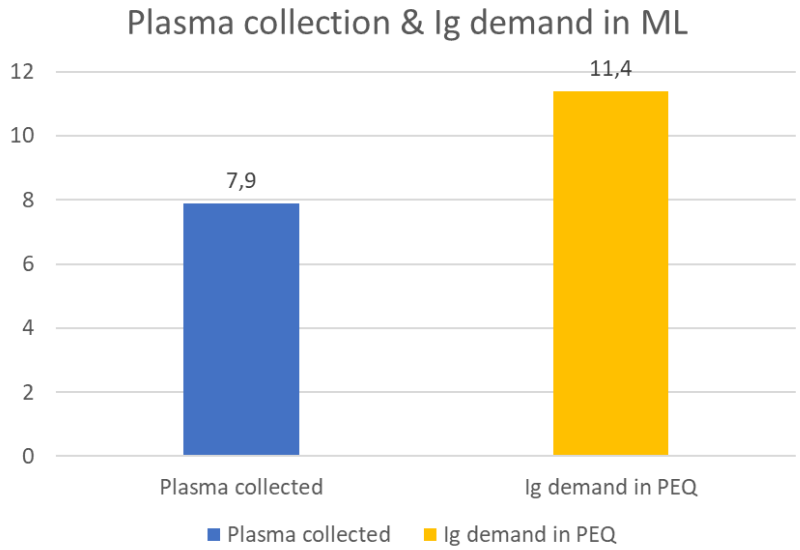
EU IgG demand

2019



2020



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Action, goals and solidarity

- The **SUPPLY** Project: Strengthening unpaid plasma collection capacity in Europe

- Goals:
  - Development of good practices by all project stakeholders and recommendations to strengthen and make more resilient unpaid plasma collection in Europe
  - Contribution to a more sustainable supply and increased access to essential PDMPs with mitigating actions to avoid disruption

- The SUPPLY Project is an excellent example of solidarity: many stakeholders from different Member States working together to improve the lives of EU citizens.
  - EBA
  - IPFA
  - Blood establishments
  - EHA
  - EDQM
  - Professionals (hospitals, medical centres, etc.)
  - Member State health authorities/competent authorities
  - Patients
  - Donors
  - Regulators, legislators and technical bodies
  - Press

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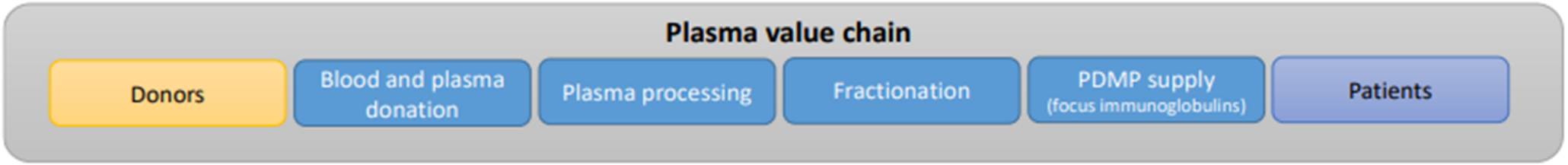

WP2: Donor recruitment and retention best practices

WP3: Plasma collection and processing best practices

WP6: Clinical programme on appropriate/prioritized use of PDMPs

WP4: National and EU infrastructures, policy, legal framework for plasma collection and PDMPs supply

WP5: Plasma donor protection best practices

WP7: Dissemination and Communication

WP1: Project management

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Road to solutions

- For not-for-profit blood establishments in various Member States, it is a challenge to collect sufficient plasma for their patients mainly due to the lack of (sufficient) plasmapheresis programs or high costs of plasmapheresis programs in combination with low selling prices of plasma and increasing use of PDMPs.

- We see several roads to a solution:

  - **awareness**: recruit and retain sufficient plasma donors by raising awareness

  - **efficiency**: making donor recruitment and plasmapheresis programs as efficient as possible and determine the appropriate use of PDMPs

  - **plasma economics**: optimize the cost structure of the total value chain from plasma to PDMPs

  - **education**: educate stakeholders in Member States on the plasma market and tender models and how to take ownership of the plasma as a strategic resource

- In Member States where health authorities and/or competent authorities are more involved in the plasma chain, blood establishments are more likely to initiate plasmapheresis programs.

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Current status

- The SUPPLY project website and the dissemination plan have been approved by the European Commission. The website is live.
- The SUPPLY survey on common EU policies was sent out to EU competent authorities. With a response rate of approximately 90%, the final report is expected in April 2023.
- Overviews of a “European” plasma manufacturing process and steps and guidelines for opening new plasma centers are being finalized.
- Report on best practices in plasma collection is expected in April 2023.
- Expertise was exchanged on the quality of collected plasma with certain fractionators. Data on plasma quality parameters has been extracted from a broader data base and is being analyzed. Results from that analysis are expected soon.
- Surveys on donor protection practices (blood establishments) and usage of PDMPs (hospitals) are in the process of being finalized and circulated.

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SUPPLY

Work Package 4

Survey on plasma collection and PDMPs production from national plasma in EU - Analysis of preliminary results

Fabio Candura and the CNS SUPPLY Staff

Amsterdam - March 1-2, 2023

Co-funded by the European Union

This report is part of the project “101056988/SUPPLY” which has received funding from the European Union’s EU4Health Programme (2021-2027). The content of this report represents the views of the author only and is his/her sole responsibility; it can not be considered to reflect the views of the European Commission and/or the European Health and Digital Executive Agency (HaDEA) or any other body of the European Union. The European Commission and the Agency do not accept any responsibility for use that may be made of the information it contains.

Disclosure

I hereby declare that I have neither financial nor nonfinancial relationships related to any of the products or services described, reviewed, evaluated or compared in this presentation.

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WP4 - SUPPLY PROJECT

Leader: Italian National Blood Centre (CNS, Centro Nazionale Sangue)

Partners:

- Sanquin (**SQ**), The Netherlands
- International Plasma and Fractionation Association (**IPFA**), The Netherlands
- Servicio Vasco de Salud Osakidetza (**CVT**), Spain
- Etablissement Français du Sang (**EFS**), France
- Bloddonorerne I Danmark (**DBDO**), Denmark
- The Common Services Agency acting through its strategic business unit The Scottisch National Blood Transfusion Service (**SBTS**), UK
- Zavod Republike Slovenije Za Transfuzijsko Medicino (**BTCS**), Slovenia
- Instituto Portugues do Sangue e da Transplantacao IP (**IPST**), Portugal
- PHI Institute for Transfusion Medicine of RNM (**ITM**), North Macedonia
- Ministerio De Sanidad (**SCTS**), Spain

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WP4 – SUPPLY PROJECT

Ultimate goal

To formulate recommendations for the development of a proposal of common EU policies (or also legal framework) aimed to support national and EU efforts to achieve a higher degree of strategic independence from non-EU sources in the collection of plasma and its fractionation in PDMPs

- Gain clear insight into the current European national policies/legal frameworks for a) the strategic independence in collection of plasma for fractionation b) the management of PDMPs coming from national plasma collection.
- Assess the national demand for PDMPs, including pharmaceutical expenditure
- Assess the national needs of plasma for fractionation.
- Identify and compare the different tendering models for the choice of the fractionator.
- Gain a clear understanding and description of the state-of-the art of plasma economics which can be useful and educational for BEs in their interaction with the fractionators.

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TASK 4.1 SURVEY on *Plasma collection and PDMPs production from national plasma in EU*

OBJECTIVES

Investigate the presence and the effectiveness of different national legislation/policies aimed at promoting strategic independence in the public sector for PDMPs coming from national plasma.

Define the framework capable to mitigate the effects of the decrease in plasma availability (and consequently of PDMPs on the market) reported by pharmaceutical companies following the Covid-19 pandemic and, in general, in any crisis of plasma supply from outside Europe.

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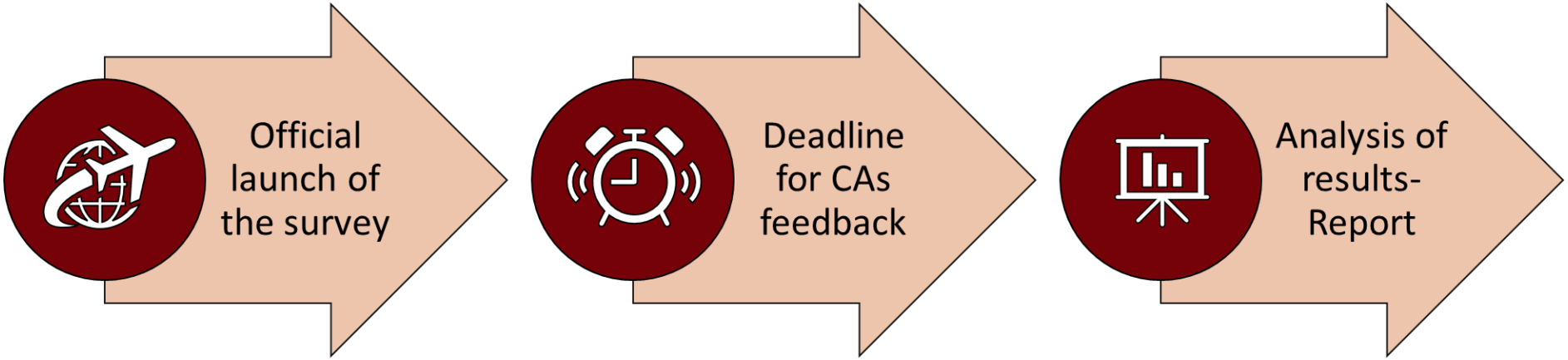
Official start on Sept. 1 2022

Action Plan Task 4.1



17/10/2022

* If needed, dedicated contacts with target Groups

30/11/2022

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TARGET GROUPS: Competent authorities for blood and blood components

YEAR: 2019 and 2020 Data

TOPICS:

- strategic independence in collection of plasma for fractionation
- management of PDMPs coming from national plasma
- national demand for PDMPs, including pharmaceutical expenditure
- national needs of plasma for fractionation
- different tendering models for the choice of the fractionator
- state-of-the art of plasma economics which can be useful and educational for BEs in their interaction with the fractionators

MAIN ITEMS

- National legal framework/policies/programmes for the collection of plasma specifically intended for fractionation into PDMPs;
- National legal framework/policies/programmes concerning the management of PDMPs coming from national plasma sources;
- National policies, procedures or legal indications for the management of plasma collected in the BEs (sold to companies, fractionated in a toll manufacturing programme, other models); in all cases, the legal requirements used for the choice of the contracting pharmaceutical company will be identified;
- Quality of plasma for fractionation;
- Financial aspects

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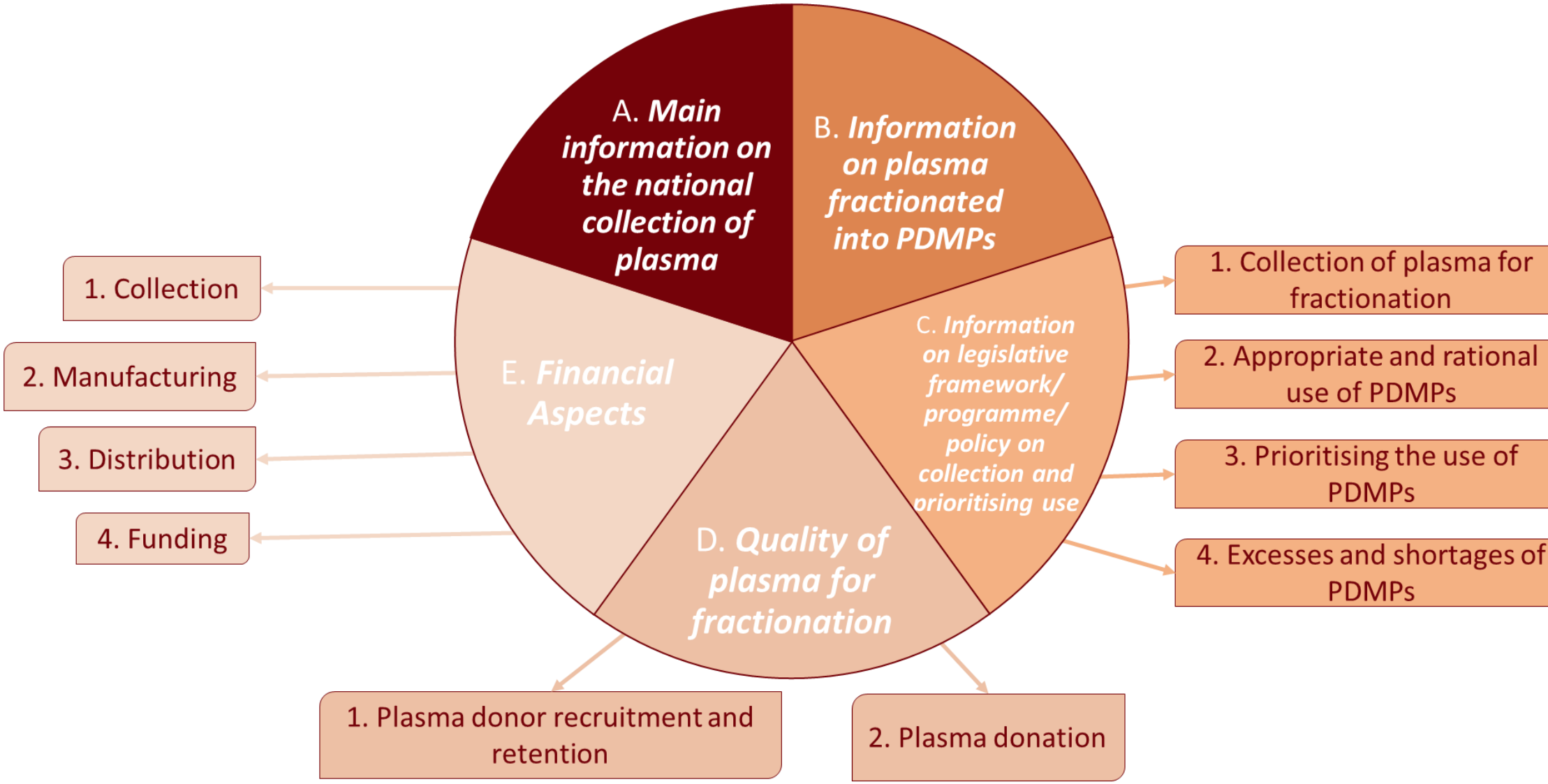
Sections



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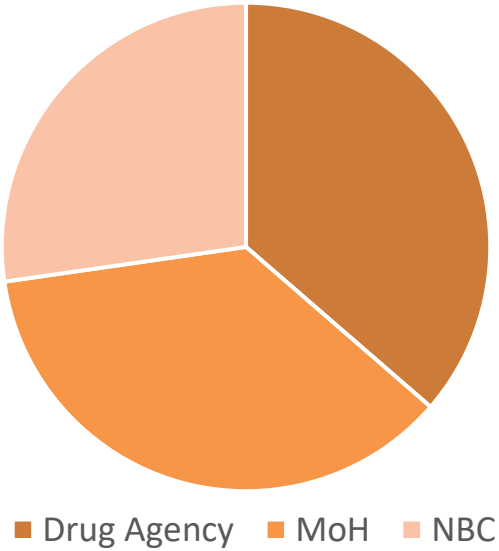
Survey on plasma collection and PDMPs production from national plasma in EU – General Overview

22 + 1 questionnaires received from MS CAs on Blood (tissues, cells, blood products, etc.)

representing countries for a total population of
412 M inhabitants
(out of 446 M – 92% of the total EU population)

6 NBC
8 MoH
8 Drug Agencies



Preliminary Data

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Section C.

Information on legislative framework/programme/policy on collection and prioritising use

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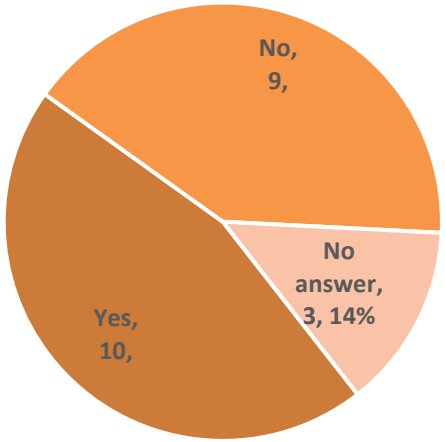
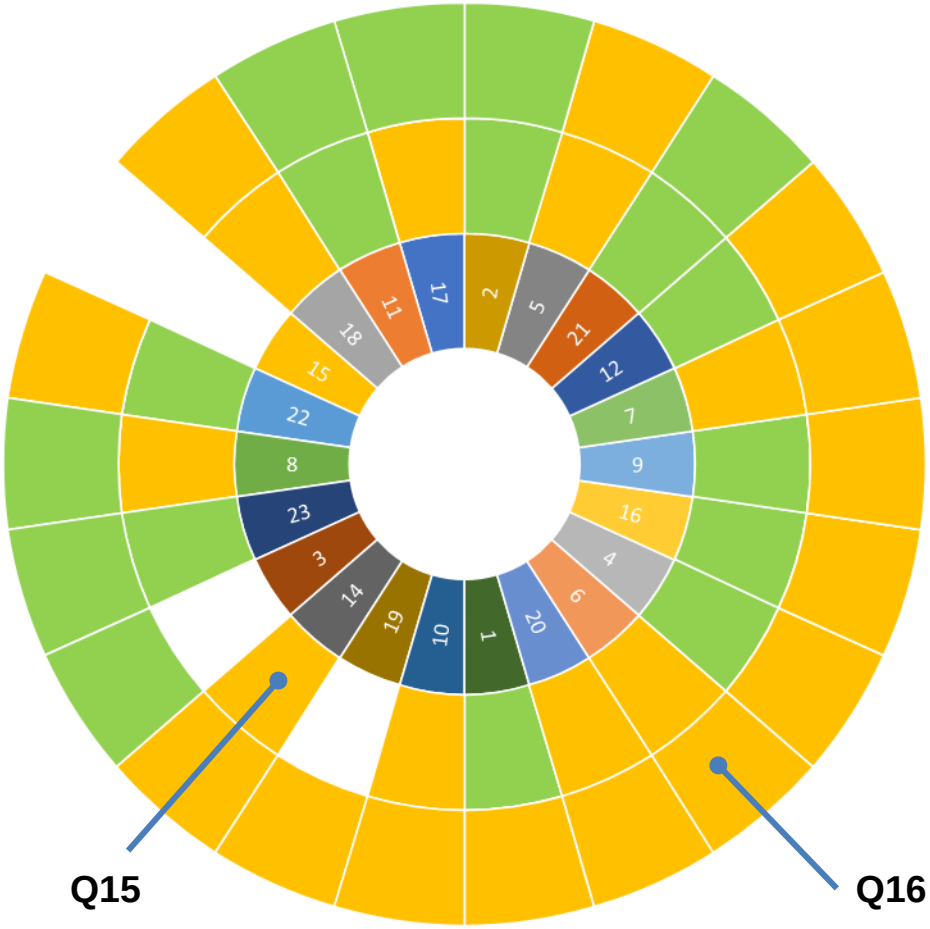
Section C. Information on legislative framework/programme/policy on collection and prioritising use

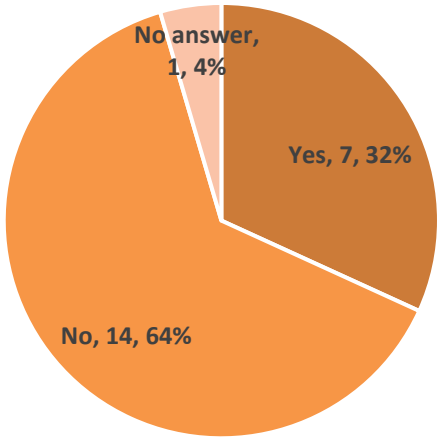
Q15 - Q16 Collection of plasma for fractionation

Q15: Does your Country have a **specific legislative** framework on the **collection of plasma** intended for fractionation into PDMPs?





Q16: Does your Country have a **national programme/policy** on the **collection of plasma** intended for fractionation into PDMPs?



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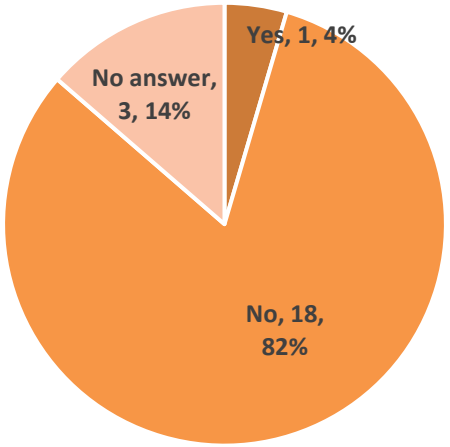
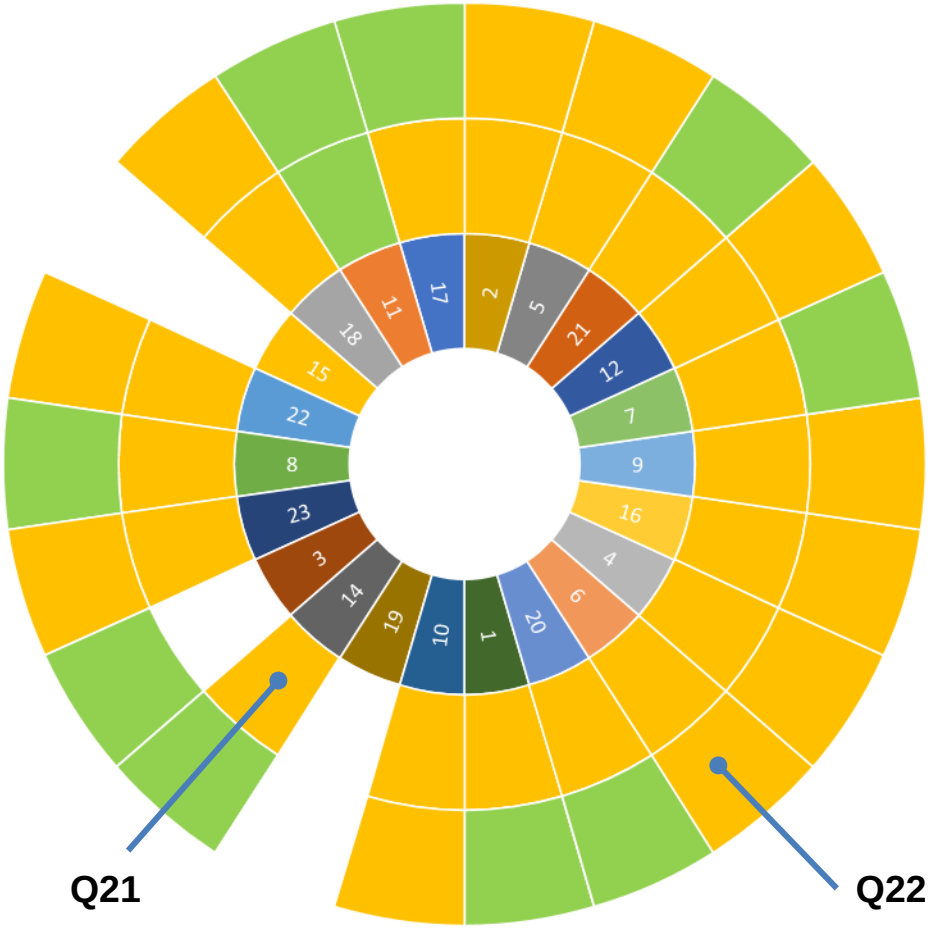
Section C. Information on legislative framework/programme/policy on collection and prioritising use

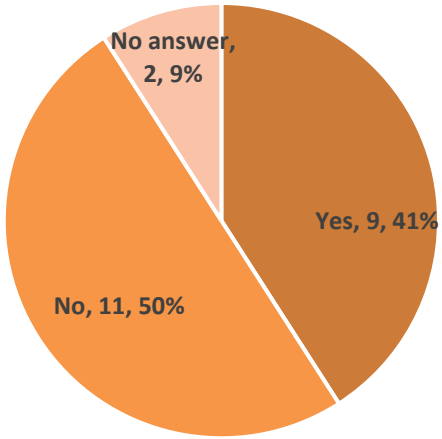
Q21 - Q22 Excesses and shortages of PDMPs

Q21: Does your Country have a **specific legislative framework/policy on exceeding** PDMPs?





Q22: Does your Country have a **specific legislative framework/policy** on PDMPs **shortage** (e.g. mandatory storage and/or contingency rules)?



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Main preliminary considerations

Main information on the national collection of plasma

The main objective of the section is to understand:

- the percentages of plasma for fractionation and for clinical use in both private and public sectors;
- the type procedures for collecting PfF ,
- the volumes of plasma collected in the years 2019-2020 (scattered and not 100% complete)
- the volumes of plasma discarded in the years 2019-2020

Information on plasma fractionated into PDMPs

The main objective of the section is to give an overview of Fractionation framework.

The preliminary analysis shows that about 1/3 of plasma is sold to different companies,
1/3 to one company on exclusive basis and 1/3 sold through toll manufacturing agreements

Information on legislative framework/programme/policy on collection and prioritising use

The report will demonstrate that there is a governance gap, because we do not have a full description of the European situation. Despite this, it should be taken into account that even no answers are in some ways answers and have an impact on the results. The report should outline that, in many cases, CAs do not have a clear overview of the situation in their Country.

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Thank You

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