



Deliverable D4.4:

Position Paper on Distribution of PDMPs coming from EU/national plasma

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BACKGROUND



1. Position Paper. PDMPs Supply in Europe: **Where are we now?**

- **Decades** of Plasma Fractionation in Europe from Whole Blood and Source Plasma
- **Heterogeneity** of Plasma Fractionation Systems currently in place
- **Persistent Plasma Deficit**: Considering IgG global consumption, 25% of usage versus 15% of plasma contribution
- Uncertainty of exact **contribution** of European Plasma to IgG global availability (Higher IgG content in EU plasma source)
- A more **integrated** european policy could be of help to achieving the Independence strategic
- This Position Paper **focuses** on:
 - Degree of **commitment** in obtaining plasma for fractionation
 - Level of **collaboration** amongst all stakeholders
 - Modes of **supply** of available products from national and European plasma



BACKGROUND



2. Position Paper: **Overview**

- Analysis report: policies and/or legal frameworks on plasma collection and PDMPs management (D4.2)
- Assessment report on plasma and PDMPs economics and tenders (D4,5)
- A comparative analysis on the current use of Immunoglobulins in individual countries: A clinical programme (D6.1)
- Characterization of the waste of recovered plasma and missed opportunities for plasmapheresis in European Union. (D3.3)
- Recommendations on plasma donation quality (D3,6)
- Specific interviews with chosen EU and non-EU countries



BACKGROUND



3. Position Paper: **Factors influencing the availability of PDMPs**

- Role of regional, national and european Authorities in defining legal frameworks for national plasma **procurement** translated into **practical arrangements**: needs assessment, resources allocation, surpluses management....Essential for **transmission to citizens** to implement efficient apheresis plans
- The types and volumes of PDMPs obtained depend on the **characteristics** of tenders and agreements in every country, which are managed by a range of different bodies (Only in a few cases BEs are significantly involved in their management). Far from all PDMPs are **returned** to the country of origin of the plasma (When they are, albumin and Immunoglobulins are always included, and some other PDMPs may be added).
- Factors related to their **use**. There are numerous local initiatives but very few agreed as regional and national **guidelines**. In those countries where a **close relationship** exists between the prescribers on immunoglobulins and other stakeholders, there is a **better management** and insight on its use, which is important in achieveing **sufficiency and sustainability**.

TENDER MODELS



1. Position Paper. **DIRECT SALES MODEL**

GOALS:

- Defining a **Price for the sale** of plasma
- Defining, in some cases, the **price for the purchase** of the PDMPs and the **percentage of return** of PDMPs from the original local plasma

STRENGTHS:

- Single and **quick** model
- Plasma is **not wasted**
- Financial **support** for BEs

WEAKNESSES:

- Without a link to return of PDMPs, a positive impact on national / european availability is **not ensured**
- **Loss of public control** of a critical / essential material
- Difficulty to **explain** to donors and citizens
- It might have a **negative impact** on purchase prices
- Lack of inclusion of relevant **stakeholders**



TENDER MODELS

2. Position Paper. **TOLL FRACTIONATION MODEL / CONTRACTED SERVICE MODEL**

GOALS:

- Payment for fractionation of domestic plasma and the subsequent **return** of PDMPs obtained

STRENGTHS:

- Frequently reported as a high value model. Return of PDMPs to the región or country of origin
- **Traceability** is ensured
- Useful to **motivate** citizens to donate plasma
- Positive impact on **social cohesion** (Transparency)
- Positive impact on **sustainability** (savings, market prices...)

WEAKNESSES:

- **Difficulties** for smaller countries or regions (Low plasma volumes)
- **Limited availability** of some PDMPs and surplusses management
- Additional **work** for BEs, additional management resources required, risk of litigations...



Challenges

TENDER MODELS

3. Position Paper. CHALLENGES COMMON TO TENDERS

- A more effective **participation** of relevant stakeholders: BEs, Clinical Practitioners...will optimize the **efficiency** of tenders and agreements
- **Litigations** can delay the award of contracts, increase the costs and the risks for the availability of local products.
- Legal uncertainty due to the different interpretation of certain Court cases, such as **competition** within the free market should disappear
- Tenders and agreements should take into account important factors such as **protein yields or recovery** percentages.
- The allocation and use of IgG based on **best practice evidence and real world experience**
- A **closer relationship** between PDMPs prescribers and other stakeholders

EUROPEAN STRATEGIC INDEPENDENCE

1. Position Paper. AN ACHIEVABLE GOAL IN THE SHORT TERM

- Historical and significant, but **uneven**, contribution of European Plasma to the availability of PDMPs. A certain **detachment** has been recognized in some countries from playing an appropriate role in the supply of PDMPs
- A strong and **effective VNRBD** system has become a routine behaviour for many millions of european citizens, really proud of it, for decades. More than 20,000,000 Whole Blood donations / year **have guaranteed the self-sufficiency** for decades (It could be in contradiction with the frequent statement that only a remuneration-based donation system can guarantee the continued supply and sufficiency of PDMPs)
- Our **historical** evolution, and different national **experiences**, concerning blood components and plasma donation show that a high degree of sufficiency to get the strategic Independence for PDMPs through VNRBD is **achievable**



EUROPEAN STRATEGIC INDEPENDENCE

2. Position Paper. UNDERSTANDING REGIONAL AND NATIONAL DIFFERENCES

- According to the Marketing Research Bureau, **5,7 million L of plasma / year** are required by Europe (4,5 million L by the 27UE) based on current IgG usage
- National commitment to collect sufficient volumes of plasma through EU legislative framework which enables European strategic Independence is of critical importance. That commitment is **currently variable but insufficient** (range between 1.5 and 23 L / 1000 inhabitants / year). This commitment should be accompanied by control over the plasma-PDMP-Patient chain, ideally through legislative guarantees, to ensure the needs of the population are met
- European countries should implement **active plasmapheresis** programmes (17 European Countries have not done it yet); and plasma from whole blood should be more efficiently managed.
- Absolute priority of increasing the collection of plasma:
 - Positive willingness to donate by the citizenship
 - Transparency informing citizens about the terms and conditions of tenders and agreements
 - BEs should receive the necessary support from their Authorities
 - The Document by the Presidency of the EU: Resilient EU2030: **“A future oriented approach to reinforce the EU’s Open Strategic Autonomy and Global Leadership”** , in which plasma is considered as a critical product

POSITION PAPER. CONCLUDING REMARKS

1. To increase the **donation of plasma** of public origin to achieve the strategic Independence for PDMPs provision.
2. Plasma as a **critical medical raw material** and a **public resource** that requires a legal estrategic management
3. Provision of **legal clarity** and **transparency** to the agreements and for the **conditions of return** of PDMPs to the country itself
4. European Countries should offer **equitable health services** to citizens. Participation and responsibility of medical proffesionals should be supported to contribute to sustainability and to avoid prescription differences.
5. Plasma collected domestically must be linked to the **usage** of products manufactured from this plasma by the **Public Sector**
6. Agreements in public - private collaboration **avoiding dangerous competition** that help to establish procedures to guarantee the timely distribution of these products in a fair way for both parts.
7. The **donor base** should be increased by facilitating plasma donation in a similar way to any other types of donations.
8. Transparency when it comes **to inform** and recruit plasma donors about any **private-public agreements**.
9. **Ensuring the return** of PDMPs to the National or European scenario can have a positive impact on **citizen's willingness** to donate plasma.



**THANKS ROME
AND COLLEAGUES
OF WP 4 !!!!**