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D4.6 Recommendations on plasma collection and PDMPs management

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Record of Changes

0 - 0.004	Draft versions		
0.005	Final draft to be circulated among WP4 beneficiaries		
0.006	Final draft after WP4 beneficiaries' revision		
0.007	Final draft to be circulated among SUPPLY beneficiaries		
DEF	Final draft after comments from SUPPLY beneficiaries		

List of acronyms

Acronym	Description
EU	European Union
IgGs	Immunoglobulins
PDMP	Plasma-derived medicinal product
SoHO	Substances of Human Origin
WP	Work Package

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Introduction

The SUPPLY project aims to increase and strengthen the resilience of plasma collection within the public sector in the European Union (EU) to enable a stable, appropriate, and sufficient supply of Plasma-derived medicinal products (PDMPs) for patients both in a general situation as well as in times of crises.

The initiative is providing recommendations, tools, and best practices to support national and EU efforts to define/improve common policies and legal frameworks to achieve a greater strategic independence in its needs for PDMPs.

The activities undertaken by Work package 4 (WP4) "National and EU infrastructures/policy/legal framework for plasma collection and PDMPs supply", and the associated Deliverables, provide a clear insight into current national and European policies/legal frameworks for (a) the strategic independence in collection of plasma for fractionation and (b) the management of PDMPs coming from national plasma collections.

This set of recommendations will contribute to the final SUPPLY recommendations for future actions and benefits from the information and conclusions included in key SUPPLY project surveys and reports including, *inter alia*:

- D3.3 Report on the results of the “characterization of the waste of recovered plasma and missed opportunities for plasmapheresis in European Union”;
- D3.6 Recommendations on plasma donation quality;
- D4.2 Analysis report: policies and/or legal frameworks on plasma collection and PDMPs management;
- D4.4 Position Paper on PDMPs distribution;
- D4.5 Assessment report on Plasma and PDMPs economics and tenders;
- D6.1 Report on the results of: “A comparative analysis on the current use of immunoglobulins in individual countries: A clinical programme”;
- Specific interviews with chosen EU and non-EU countries;
- Addressing medicine shortages in the EU.

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Main recommendations where common EU legal provisions can favour plasma collection and fractionation in a common EU framework

1) Legal provisions to consider / define plasma as a strategic resource.
Only a minority of Member States (MS) has implemented a legislative framework aiming at promoting in an active way, the collection and the use of domestic plasma for the production of PDMPs. This implies that until now the majority of the MS did not take into due consideration the necessity of designing defined legal frameworks to consider domestic plasma as a strategic resource as to make their supply of PDMPs more independent from the market. During the inception phase of the new regulation on Substances of Human Origin (SoHO), it has been clearly recognised that EU is vulnerable to the interruption of the supply chain of plasma and PDMPs. Therefore, it is now necessary to recommend the adoption of a common legislative framework in the EU in terms of principles aimed at defining plasma as a strategic resource for the European citizens.
In this sense, the European Commission's Communication from 24 October 2023 "Addressing medicine shortages in the EU" [1] sets a good foundation with a reference to a future "Critical Medicines Act" and the creation of a "Critical Medicines Alliance" to address shortages of medicines. As rightly identified by the 'Union list of critical medicines' published by the European Commission, the Heads of Medicines Agencies (HMA) and the European Medicines Agency (EMA)[2], many PDMPs match the definition of a critical medicine ("essential to ensure the provision and the continuity of quality healthcare, and to guarantee a high level of public health protection in Europe"). This particular attention to PDMPs in the legislative work of the EU on this matter should remain, wherein the plasma resource can be recognised as strongly linked to the security of the supply chain of these medicines.

2) Legal provisions favouring cooperation among different systems and models.
Public non-profit and private for-profit organisations play a role in collecting blood and plasma, both for transfusion and for manufacturing into PDMPs. Efforts must be made to avoid both competition between the operational models used, and competition for donors between the sectors in the collection of plasma for fractionation. Cooperation between the public non-profit and private for-profit sectors should be facilitated and enabled by means of appropriate and specific legislative interventions aimed

[1] European Commission. Communication from the Commission to the European Parliament, The Council, the European Economic and Social Committee and the Committee of the Regions Addressing medicine shortages in the EU EN. Brussels, 24.10.2023COM(2023) 672 final. Available at: https://commission.europa.eu/system/files/2023-10/Communication_medicines_shortages_EN_0.pdf. Accessed on December 08, 2023.
[2] European Medicines Agency. Union list of critical medicines - version 1. https://www.ema.europa.eu/en/documents/other/union-list-critical-medicines-version-1_en.xlsx. Available at: https://www.ema.europa.eu/en/news/first-version-union-list-critical-medicines-agreed-help-avoid-potential-shortages-eu. Accessed: December 12, 2023.

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at securing the contribution of both sectors to the fundamental goal of meeting national (or even European) demand for PDMPs in a sustainable and resilient way.

3) Legal provisions favouring cooperation among MS.
For-profit companies collect plasma in various European and non-European countries which is then fractionated after pooling only country by country, provided that the relevant collection centres are listed in the proprietary Plasma Master file (PMF). This is true also if plasma is collected by public facilities in the EU and then sold to both for-profit or non-for-profit organisations, which list the centres into their PMF as well. As a consequence, an EU MS collecting small volumes of plasma can sell the starting material to a fractionator only if the company is interested in including the collection facilities in its PMF. If this is not the case, this amount of plasma is wasted. Moreover, there are legal constraints in Europe against the toll-fractionation of domestic plasma together with plasma from EU or abroad which makes it impossible for a MS to enter into agreement with existing contract manufacture programmes of other MS. In order to share a common approach on the fractionation of domestic plasma and the production and the return of critical PDMPs, EU should support and facilitate all MS in creating legal environments that both eliminate any barrier against the pooling of plasma from different MS and promote the agreements among two or more MS (e.g., common toll manufacturing agreements or common tenders for selling plasma).

4) Legal provisions for the priority use of products coming from fractionation of domestic plasma.
Within MS national health systems, patients should have equitable access to safe and high-quality blood products and medicines derived from voluntary blood and plasma donations in the EU. Products derived from the fractionation of EU plasma should be primarily intended to meet the clinical needs of EU citizens. Thus, the collection of EU plasma should be supported by adequate legal provisions, including recommendations for such at national level, to guarantee that plasma collected inside the EU gives origin to products which are made available for the therapeutic benefit of EU patients in the first instance. These legal provisions, along with other measures designed to optimise the European plasma environment, will also better Europe's position to work with other global regions on ensuring patients there also have their PDMP needs met.

5) EU plans supporting the increase and improvement of plasma collection.
True Strategic Independence of plasma and PDMPs in the EU will have been reached when an equal or larger volume of plasma is collected (source and/or recovered plasma) in the EU than is required to meet the maximum estimated plasma-related requirements of EU Citizens, meeting these requirements is legislatively guaranteed, and the EU has the capacity to act autonomously - that is, without being dependent on other regions/markets.
In order to support national and EU efforts to achieve strategic independence from non-EU sources, EU should launch and fund programmes aimed at increasing the quantity and quality of plasma collected by public and not-for profit Blood Establishments throughout the EU and ultimately strengthening the resilience of plasma collection, also during emergency situations.

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