

IPFA-EBA SYMPOSIUM ON PLASMA COLLECTION AND SUPPLY

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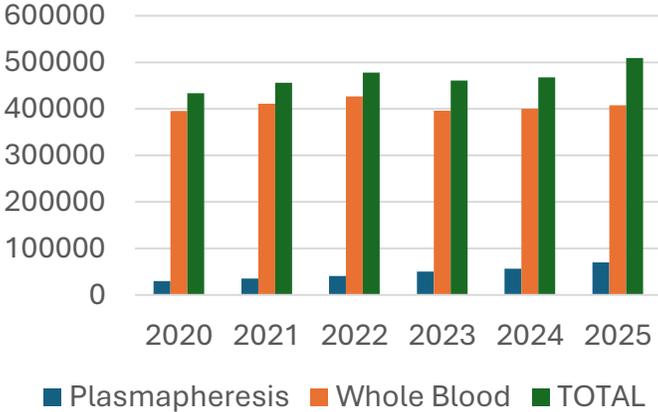
Spanish Scientific Committee For Blood Safety and Sufficiency



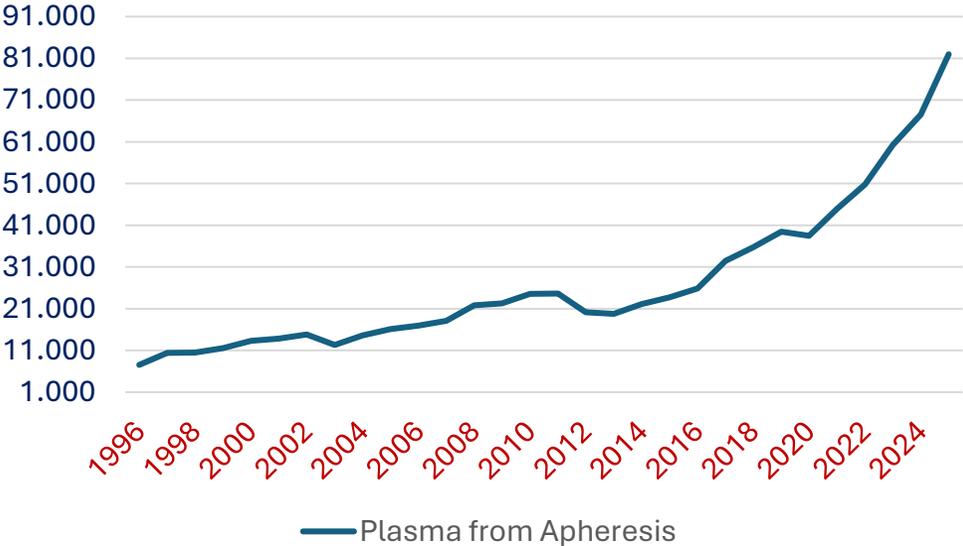
Where you are with your plasma collection vs meeting your PDMP demand. Spain



Plasma for fractionation



Plasma from Apheresis

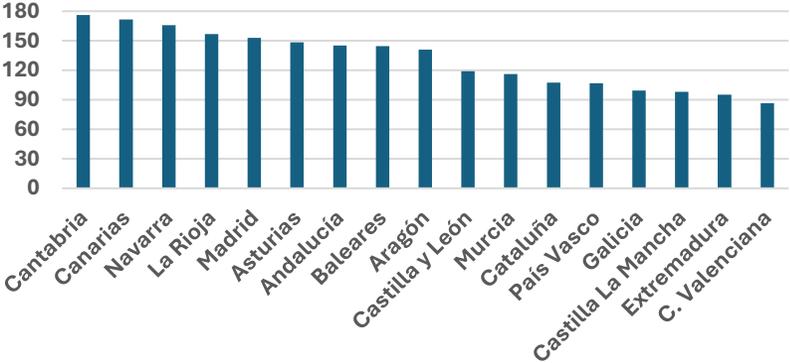


REGISTERED ACTIVE SOURCE PLASMA DONORS : 65.000

Where you are with your plasma collection vs meeting your PDMP demand. Spain



IgG CONSUMPTION BY AUTONOMOUS COMMUNITIES. 2025 X 1.000 hab.

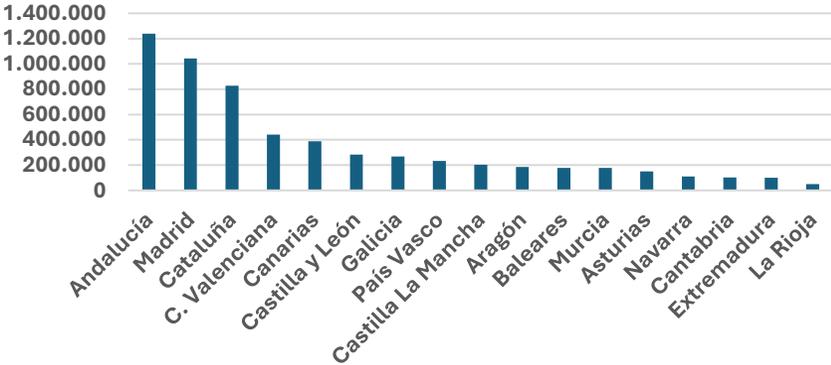


**Estimated Spanish Average Use 2025:
135 Gr x 1.000 Inhabitants.**

**REGIONAL SUFFICIENCY LEVEL:
20%-40%**



GLOBAL IGIV CONSUMPTION BY AUTONOMOUS COMMUNITIES. 2025



**Estimated Global Use 2025:
6.500.000 GR**

Where you are going within the coming years



1. Continue with the development of the **National Strategic Plan for Plasma Self-Sufficiency** prepared in 2021.
2. Increase our levels of sufficiency to ensure our **strategic independence**. As a reference we consider, reasonably urgent, moving to a minimum regional sufficiency level close to **40-60%**, depending on its current starting level
3. To improve the conditions both, in terms of **yield** (mainly in the case for Immunoglobulins) and **portfolio of PDMPs obtained** (Fibrinogen, Sc Immunoglobulins...), from our national fractionation procedures.
4. **Increase source plasma collection** by expanding registered active donors (**minimum 100,000**) and encouraging them to a regular and frequent plasma donation (**maximum 12 donations/year**).

What are the key levers to get there?



1. We have changed the model of 17 regional contracts for a single **National Agreement** with identical economic and quality requirements for the fractionation of, at least, 450,000 litres of Spanish plasma.
2. This National Agreement has also generated greater **visibility and awareness** of the importance of plasma as **strategic resource**. It is already in force and is mandatory for all the Autonomous Communities.
3. A **new Division** has been created within the structure of the Ministry of Health to act as the **National Competent Authority** in the field of blood **working in close cooperation with the Regional Competent Authorities and the Blood Establishments**. It has increased its resources and presence in decision-making bodies.
4. One of the **priorities** of this Division is the **sufficiency of plasma and PDMPs and the management and monitoring of the National Fractionation Agreement**. It also supports the Autonomous Communities with additional economic resources to obtain plasma (So far: €15,700,000 for donor recruitment, plasma collection and / or facilities and equipment)

What are the key levers to get there?



Plasma as a Critical Product !!!



SoHO Regulation (a good opportunity to implement measures towards PDMPs Strategic Independence from VNRBD)

SPANISH AGREEMENT ON NATIONAL PLASMA FRACTIONATION

(main features)

- 1. PUBLIC TENDER (Spanish Ministry of Health, technically supported by /Spanish Committee for Blood Safety and Sufficiency and a Committee of Experts from Blood Establishments). Date of award and signature. March, 2025**
- 2. DURATION OF AGREEMENT: 2 YEARS + 2 YEARS (2025-2029)**
- 3. MANDATORY FOR ALL AUTONOMOUS COMMUNITIES**
- 4. AWARDED COMPANY: GRIFOLS**
- 5. ESTIMATED MINIMUM VOLUME OF PLASMA / FIRST YEAR: 450.000 L (SOURCE PLASMA AND WHOLE BLOOD)**
- 6. PDMPs INVOLVED: ALBUMIN, IV IgG, ALPHA1-AT,AT-III, FACTOR VIII, FACTOR IX**
- 7. PROCEDURE SUMMARY: Plasma collected is picked up by the awarded company at the Blood Establishments and sent to the facilities of the fractionation industry according to the defined program. After each fractionation established in the scheduled calendar, BE receive the products obtained in relation to the amount of plasma provided by each of them. BEs distribute these PDMPs to hospitals under their influence.**

