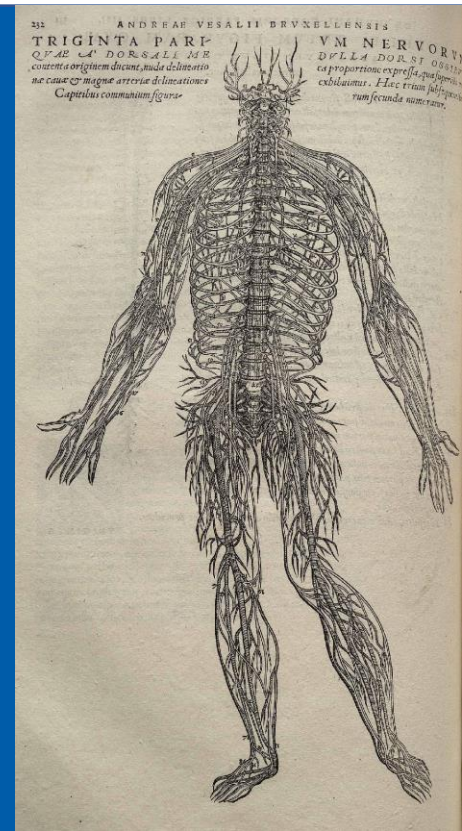


Situation among neurological diseases to meet need of immunoglobulins





Our
commitment



“EPODIN’s contribution aims, by mobilizing and strengthening the patient’s voice, to give each European citizen living with a rare immune-mediated peripheral neuropathy the opportunity to reduce the burden and inequalities due to the disease”.





The voice of patients

Plasma donation: Key proposals

- Full donors protection (minimum uniform protection throughout EU) / Full donors traceability.
- Principle of free donation with a clearer definition of the concept of compensation.
- Cohabitation between public and private collection systems under the authority of strict regulations both national and European.
- Priority to the country of origin of the plasma/blood collection to treat its own patient population.
- Common reflection on the concept of service of general interest for the subject of PDMPs.
- Multi-year European campaign for plasma donation.

L 33/30		EN	Official Journal of the European Union	8.2.2003
DIRECTIVE 2002/98/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC				
THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,				
Having regard to the Treaty establishing the European Community, and in particular Article 152(4)(a) thereof,				
Having regard to the proposal from the Commission (1),				
Having regard to the opinion of the Economic and Social Committee (2),				
Having regard to the opinion of the Committee of the Regions (3),				
Acting in accordance with the procedure laid down in Article				
			(4)	In respect of blood or blood components as a starting material for the manufacture of proprietary medicinal





Relationship, partnership...



Regular interactions



Member

Executive committee
Educational board
Peripheral neuropathies group



Immunoglobulins access in neurological disorders : where are we now?

At the European level

The pandemic highlighted:

- The fragility of the plasma collection and fractionation systems
- The need to work more collectively at least at the European level
- The heterogeneity of European health care systems and more than ever patients' needs





Many European countries are currently facing shortages of immunoglobulins IV and SC

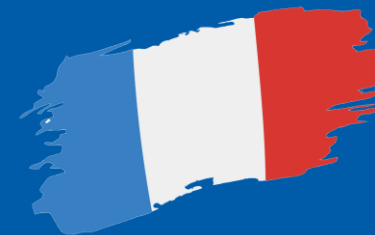
Three examples



ROMANIA



SPAIN



FRANCE





Romanian difficulties

- Romania does not collect plasma for fractionation
- Access is scarce throughout the country
- IG IV treatment is severely limited for acute patients and generally non existing for for chronic ones
- Far away from the international guidelines in several IMN e.g. Romanian health system budgets less than 180 gr / Chronical patient /year – While the average need is 600-1800g
- Lake of access to treatment causes invalidity and increase disability costs.





Patients' association survey / hospitals treating autoimmune neuropathies - 2021

- Suboptimal doses
- 2,2% received 4 or more doses in 2021 down from 8,5% in 2020 and 10,4% in 2019
- The pandemic affected access to care





- Romanian government stated that investing in its blood and plasma collection infrastructure is a priority / EU funds

But

- No strategy or action plan exists or is currently under development





Patient expectations

- Updating the Romanian legislation for collecting plasma and ensure return of derivatives for its patients
- Investment in blood and plasma collection infrastructure (including staff training)
- Strategic plan for digitalization, including donors and patients' registries, helping to ensure collection and access to treatment.





Spanish difficulties

- Strong shortages detected since at least September 2020
- Delays (in some cases up to 4 months)
- Reduced dosage
- Massive transfer to PE / shortage in albumin
- Forced treatment changes
- Strong disparities between large and small hospitals / contrast between several regions and cities
- Different fractionation contracts in each autonomous region
- No adequate Spanish regulatory or instrumental planning to respond to current and future needs for PDMPs.





Which responses?

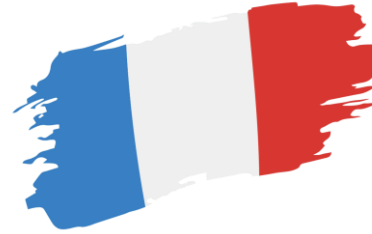
CONSENSO ESPAÑOL POR LA SUFICIENCIA DE PLASMA Y SUS TRATAMIENTOS DERIVADOS

Organization's consensus

- To improve the collection, management and administration of blood products
- To reduce the US dependency
- To meet the needs for patients

- Financial allocations for plasma donation campaigns by the central government
- Negotiations among the regions governments and manufacturers

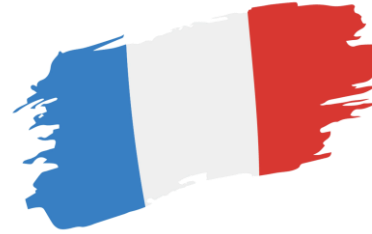




State of play

- Tensions that have persisted for several years worsened by the pandemic
- The national system is not self-sufficient / 50% of IG imported
- Patients with neurological diseases suffer from repeated shortages
- Because of scarcity of IG, physicians change their practices
- A French system (collection-fractionation) that has difficulty seeing its own flaws (*according to patient organizations*)
- A French drug agency very highly mobilized to meet the needs of patients





Immunoglobulin observatory OBSIG / A national patients' organization initiative

Objectives

- To assess the impact of tensions in the supply of polyvalent immunoglobulins (Ig-P) both IV and SC
- To show the impact on the clinical practice of prescribers

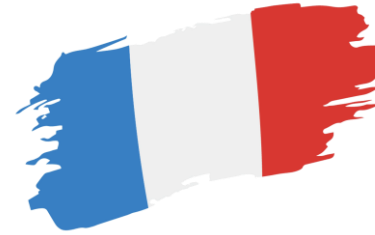
Target audience

- Patients with autoimmune peripheral neuropathies treated with Ig-P.

Methodology

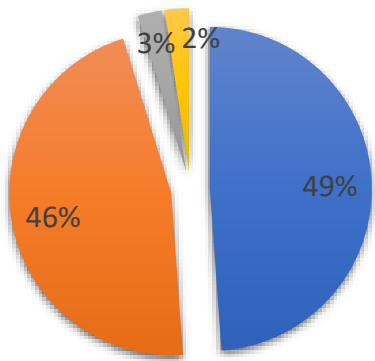
- Self-administered online questionnaire sent to a panel of patients identified by the French patients' organization (AFNP)





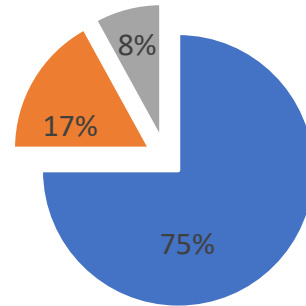
Key results

Care structure



■ Hospital ■ Home ■ Both HH ■ No answer

Injections modalities

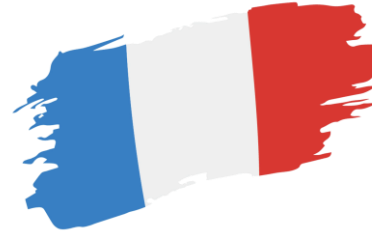


■ IV Ig ■ SC Ig ■ In transition

27.8% of patients have problems with the delivery of IG

38.8% Changes in treatment related to IG access difficulties





An example of mobilization in times of crisis 1/2

“The ANSM has been informed of upcoming tensions in human immunoglobulins (Ig), following a decrease in the supply capacities of laboratories. These tensions can be explained by the worldwide drop in blood and plasma collection in the context of Covid-19. The ANSM is mobilizing with all the stakeholders to guarantee the best possible coverage of patients' health needs”.



Scientific committee immunoglobulins (SCI)

- Clinician representatives
- Patient representatives
- Pharmacist representatives
- Ministry of health representatives



- Very strong mobilization of the SCI
- Exceptional recommendation measures/ IG SC for CIDP

- Since 2018, a prioritization document for the indications of polyvalent human immunoglobulins
- Text updated in 2021, in a context of persistent IG shortages

Key take-home messages



- ✓ Immunoglobulins shortages remains a problem for patients in many European countries. e.g. France, Spain and Romania.
- ✓ The drastic decrease in plasma collection worldwide during the Covid-19 pandemic has worsened the situation.
- ✓ In many European countries for years we have been questioning our dependence on US plasma and our capacity for self-sufficiency both at national and now European level .
- ✓ The choice of states to invest or not in a collection system remains an essential factor of success or failure.
- ✓ Today, public and private actors work closely together to meet the needs of patients.
- ✓ We must find an optimal articulation between all actors to meet this public health challenges of treating patients while respecting the health of plasma donors.



Thank you to all our national directors for their commitment throughout the year!



Q&A

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