EUROPEAN PATIENT ORGANIZATION
FOR DYSIMMUNE AND INFLAMMATORY NEUROPATHIES

IMPACT STATEMENT

EDQM Stakeholder Conference on Plasma Supply Continuity

26th March 2025

Jean Philippe Plançon, EPODIN, President

AGENDA

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European Patients Organization for Dysimmune & Inflammatory Neuropathies

- Introduction EPODIN
- Treatment access and DIN patient needs
- EU plasma collection and DIN patient needs
- What to do from EPODIN perspective
- Outlook

OUR OBJECTIVES

EQUITABLE ACCESS SOLIDARITY

HEALTHCARE ADVOCACY

PATIENT ENGAGEMENT IMPROVING HRQOL

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- EPODIN to ensure equal access to expertise throughout Europe to reduce diagnostic delays and allow access to appropriate treatments for all European DIN patients in solidarity leaving no one behind.
- EPODIN to strengthen the patient's voice in European healthcare advocacy, and to reduce disease burden and inequalities regarding European patient living with dysimmune inflammatory neuropathies (DIN).
- EPODIN to facilitate and improve DIN patient's health related quality of life (HRQoL) by being involved in the process of improving European healthcare systems.

DYSIMMUNE AND INFLAMMATORY NEUROPATHIES (DIN)

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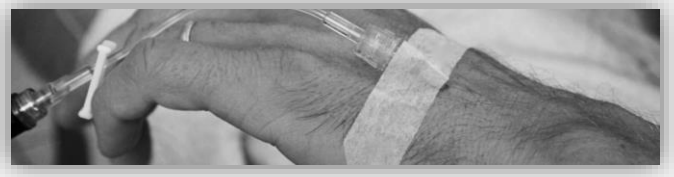
Rare auto-immune neurological disorders

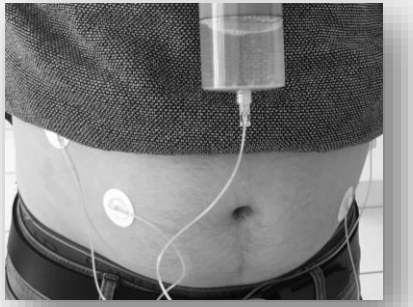
- Guillain-Barré syndrome
- Chronic inflammatory demyelinating polyneuropathy
- Multifocal motor neuropathy
- Lewis-Sumner syndrome
- Miller Fisher syndrome
- …

Debilitating diseases Acute - Chronic

- Weakness of 4 members
- Progressive / Rapid paralysis - Respiratory muscles
- Death (5% GBS)
- Loss of reflexes, loss of balance
- Loss of ability to walk, pain, tremor, fatigue…

Access to plasma-derived immunoglobulins (IG) is key and only option for most DIN patients
Decrease symptoms / Increase HRQoL





Treatment access and DIN patients needs
Where do we stand ?

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Immunoglobulins are Critical Medicines and figure as such in EU Critical Medicines' list

Patient usage and needs

- Between 2020-2023 immunoglobulins (IG) usage by DIN patients has grown in Europe around 4% (MRB)
- Important trigger was stronger usage of DIN patients, due also by increased diagnostic rates
- IG demand for DIN patients expected to grow at around 4,5 % per year from 2024-2030 (MRB)

European patient access to ig treatment

- Progress in few European countries (diagnosis progresses, improved access)
- In many countries low or restricted DIN patient treatment access due to supply tensions, low prices, or national market (in)attractivity
- Still huge inequalities across Europe, between East and West, and even in same country strong regional disparities

Treatment access of DIN patients

How to improve ?

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Access to IG as critical medicines will be influenced by NEW at the legislative level:

- provisions of EU Pharma pack and by proposal of EU Critical Medicines Act (of 11 March 2025), and
- on plasma starting material side, by implementation of EU SoHO Regulation & EDQM output

Need for balanced shortages prevention

- Avoid un-coordinated national excessive contingency schemes, able to put patients in neighbouring countries at supply risk (especially as to IG)
- But well-thought stockpiling schemes, coordinated by EU, to serve patients interests, with industry being able to execute

Need for more efficient public procurement / tender criteria

- Get away from "price-only", which reduces the ig product choice for patients and clinicians
- And application of wider criteria set, e.g. Most Economically Advantageous Tender (MEAT) including qualitative, technical, and sustainable aspects of the tender submission as well as price criteria by public procurement/tender authorities

Need for more performant reimbursement systems

- Facilitating better access to classical & innovative treatments, by ensuring adequate market attractivity

EU plasma collection and DIN patient needs

Where do we stand ?

- One CIDP patient needs 380 plasma donations for annual IG treatment
- Currently, around 9 million liters plasma are collected in the EU, with around 14 mio liters being needed for manufacturing IG medicines for European patients
- The current gap of around 5 mio liters EU plasma is covered by US imports
- 50% of the European plasma is collected in D/AT/CZ/HU, where public-private plasma collection models co-exist, or are operated in public-private-partnerships
- The remaining **23 EU countries** ensure 50% of the EU plasma needs
- Plasma collection « burden sharing » is thus very unequal

What to do from DIN patients perspectives ? 1-

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No more words, we need ACTION ! There is NO TIME to lose !

- EU/European plasma collection volumes are unacceptably low vs needs
- **Current GEOPOLITICAL RISKS could VERY negatively impact plasma supply, and put patients access to IG treatment at risk**
- Need for a well-thought **APPROACH SHIFT** combining pragmatism with rigorous science, and result-driven political will to move things fast
- Thus, EU SoHO Regulation national level implementation + EDQM work output, HAVE TO consider efficient pathways resulting in tangible plasma collection increases.

What to do from DIN patients perspectives ? 2-

No more words, we need ACTION !

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- **Donor safety ethics EQUALS Patient access to treatment ethics**
- Ensuring science-based plasma donor safety is key, BUT sametime patient access to appropriate IG treatments cannot be put at risk and **MUST** be ensured as well
- **Running plasma collection models have to be <u>driven not only by donor protection but also by efficiency and be held accountable</u> to generate tangible results**
  - Public sector (plasma) collection models have their historical « raison d'être » and an important role, but they must be more performant than by now
  - Where plasma collection is insufficient, and since **time is of essence**, best-practices from countries with successful & well-regulated models of co-existing public-private collection or public private partnerships should be considered

Outlook

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- Europe must be **bold and quick** in getting **strategic autonomy** in **plasma collection**
- Even more, since this is linked to manufacturing of the «**critical medicines» IGs**,

- **In short:** **EU plasma supply security**
  +
  EU « critical medicines » supply security (+EU defense security)

  = EU STRATEGIC AUTONOMY

- 11 EU Ministry of Healths consider EU critical meds supply security **as key as** EU defense security, and even propose to finance critical meds shortage prevention from new EU defense bucket..

- Importantly, EU plasma collection **needs to catch up the current gap in 5 years** !!!
- **DIN patients need change NOW in the very near future, not in 20 years !!!**


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THANK YOU !