Understanding Reimbursement and Access Policies for Immunoglobulins and Other Plasma-Derived Medicinal Products (PDMPs) Across Europe

HPR227

Why PDMPs Require Tailored Policy Frameworks: Lessons from European Access Models

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INTRODUCTION

- Plasma-derived medicinal products (PDMPs), particularly immunoglobulins (IgGs), play a critical role in treating rare and chronic conditions. Most of these therapies are life-saving and/or prevent severe disability and loss of quality of life.
- Due to their unique starting point (plasma donors) and a lengthy (7-12 months) and highly regulated manufacturing process, the PDMP value chain is exceedingly prone to disruptions and sensitive to any change in policy, reimbursement or procurement practices.

OBJECTIVES

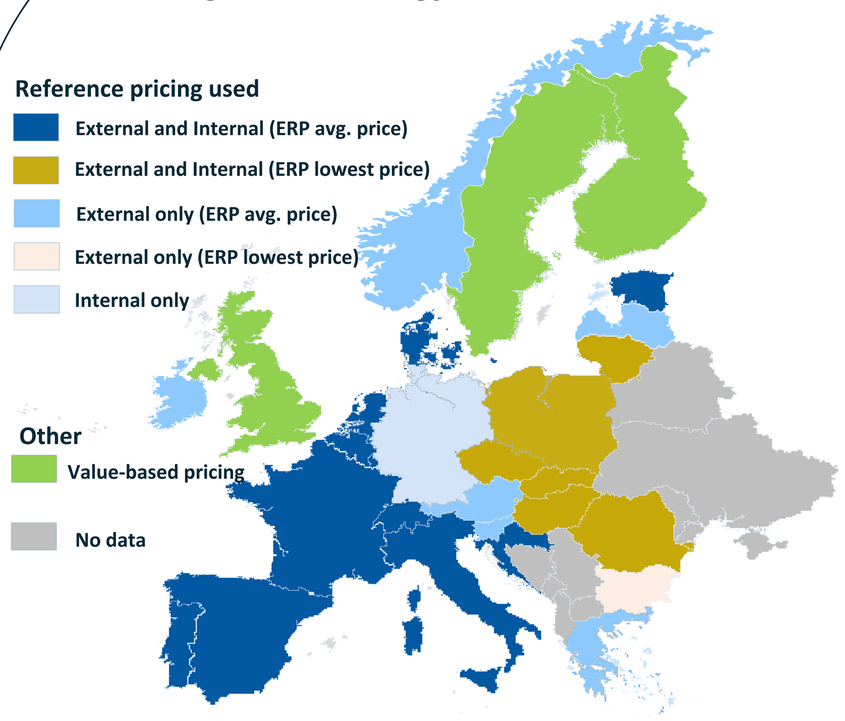
- Against the backdrop of ongoing EU-level initiatives to improve the availability of critical medicines and strengthen supply chain resilience, this study aimed to map the overall PDMP policy landscape and key access dimensions, including reimbursement coverage, cost-containment measures, and stockpiling policies across Europe.
- The in-depth analysis of national-level policies and frameworks applicable specifically to PDMPs allowed to identify common access barriers as well as transferrable best practices in alleviating these barriers and/or ensuring equitable access to PDMPs for all eligible patients.

METHOD

- Data was collected through a structured survey filled out by private sector stakeholders operating in the European PDMP markets.
- Responses were validated by independent multi-stakeholder third-party experts (policy-makers, HTA experts, national payers, patient groups) via structured interviews, to ensure accuracy.
- Research focused on categories identified as particularly relevant to access for PDMPs: national cost-containment measures (incl. external and internal reference pricing), stockpiling obligations, and reimbursement policies for Immunoglobulins (IgGs) as a case study.

RESULTS

Pricing Methodology applicable to PDMPs



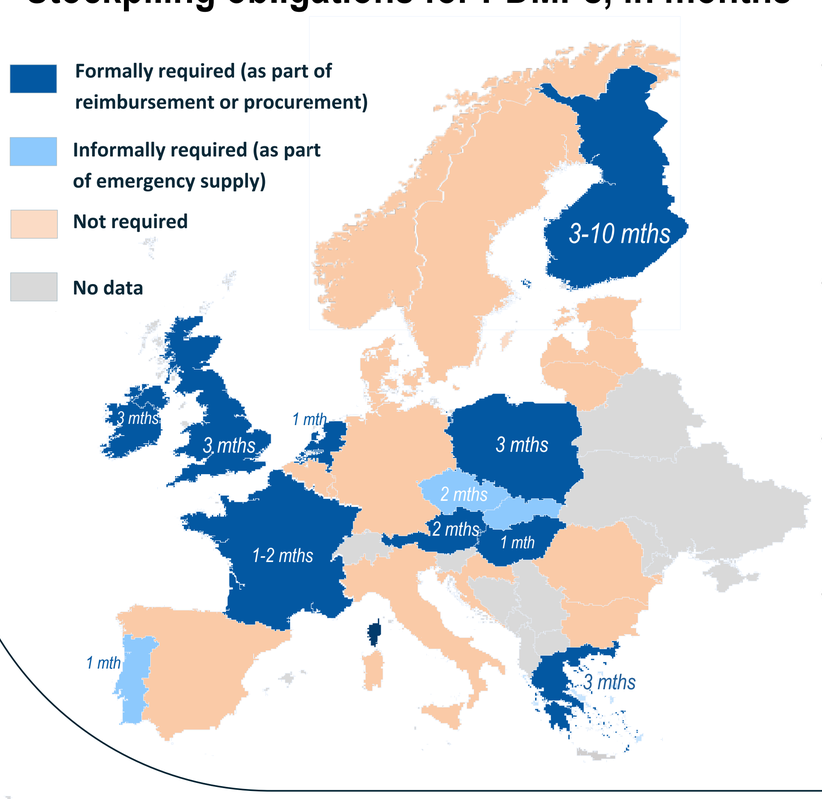
Reimbursement Coverage of IgGs in Europe, by Indication

Reimbursed by inidication | Reimbursed by class | No data

Indication	AT	BE	BG	HR	CY	CZ	DK	EE	FI	FR	DE	GR	HU	IE	IT	LV	LT	LU	MT	NL	PL	PT	RO	SK	SI	ES	SE	UK	NO
Primary Immunodeficiency (PID) associated with significant antibody defects	■	■	■	■		■				■	■	■	■	■	■	■	■	■			■		■	■		■		■	
Severe Combined Immunodeficiency (SCID)		■	■			■				■	■			■		■	■	■					■						
Secondary Immunodeficiencies (SID) associated with significant antibody defects	■	■	■	■		■				■	■	■	■	■	■	■	■	■					■	■		■		■	
Acquired hypogammaglobulinaemia in haematological malignancies or post-stem cell transplantation	■	■		■		■				■	■	■	■	■	■	■	■	■			■		■	■		■		■	
Specific antibody deficiency (SAD)		■														■	■	■			■							■	
Immune Thrombocytopenic Purpura (ITP)	■	■		■		■				■	■	■	■	■	■			■			■			■		■		■	
Alloimmune thrombocytopenia (FMAIT NAIT)				■		■				■								■										■	
Acquired von Willebrand disease (vWD)										■							■	■										■	
Haemophagocytic lymphohistiocytosis (HLH)																	■											■	
Guillain-Barré Syndrome (GBS)	■	■	■	■		■				■	■	■		■	■			■			■		■	■		■		■	
Chronic inflammatory demyelinating polyneuropathy (CIDP) (IgG, IgA associated)	■	■		■		■				■	■	■	■	■	■			■			■		■	■		■		■	
Multifocal Motor Neuropathy (MMN)	■	■		■		■				■	■	■		■				■			■		■	■		■		■	
Non-infective Autoimmune Encephalitides (AIE)										■								■			■							■	
Myasthenia Gravis Crisis (MC)	■					■				■	■				■			■			■					■		■	
Inflammatory Myopathies-Dermatomyositis (DM)/ Polymyositis (PM)		■								■	■							■			■							■	
Kawasaki Disease	■	■	■	■		■				■	■	■	■	■	■		■	■			■			■		■		■	
Autoimmune bullous dermatosis (AIBD) incl. Pemphigus Vulgaris (PV)	■	■								■								■			■							■	
Toxic epidermal necrolysis (TEN) incl. Stevens-Johnson syndrome (SJS)		■																■											

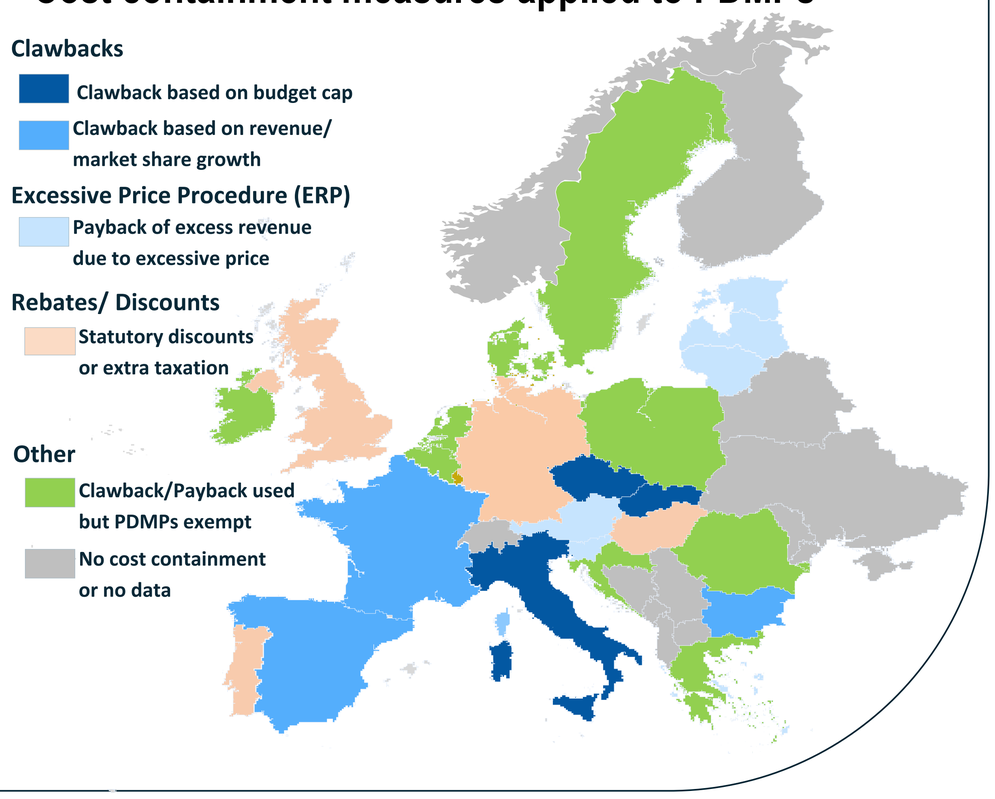
- **PDMP POLICY LANDSCAPE:** Is highly heterogeneous, with significant differences in reimbursement coverage, a wide variety of pricing methodologies, and rules concerning applicable cost-containment measures and stockpiling obligations. Some countries (e.g. Greece, Italy, the Netherlands, Poland, Romania, UK), **in recognition of the unique nature and high value of PDMPs, have a separate drug policy framework** applicable either to the entire class or to certain sub-classes (e.g. IgGs.
- **PRICING:** Despite the growing use of value-based frameworks for appraisal or re-appraisal of medicines in Europe, the pricing methodologies used for PDMPs (and most other medicines) are rarely value-based and most frequently are derived from External (ERP) or Internal (IRP) Referencing. When applied to high-value/ short-supply medicines, such as PDMPs, **reference pricing may lead to an unsustainable downward trajectory** (Incze et al. 2022).
- **REIMBURSEMENT COVERAGE OF IMMUNOGLOBULINS (IgGs):** In most EU countries is severely limited, with some countries reimbursing as few as 5-6 indications and only few extending reimbursement to 15-16 conditions. **Recent research (Kołtan et al., 2025) suggests that IgGs exhibit high effectiveness in as many as 27 indications**, accompanied by a favourable safety profile, thus suggesting a significant access gap across Europe. Additionally, even in countries with broad coverage, reimbursement does not always equal full patient access, especially when severe eligibility restrictions apply, meaning only a fraction of patients who could benefit from IgG treatment receive it in a timely and optimal manner.

Stockpiling obligations for PDMPs, in months



- **COST CONTAINMENT MEASURES:** Most countries use supply-side cost-containment tools (e.g., clawbacks, statutory discounts, ERP-based price caps), which can be highly punitive to PDMPs given their fragile supply chain. Some countries explicitly exempt PDMPs or subclasses, such as IgGs, due to their essential or critical medicines status and significant risk of short supply or shortages.
- **COST CONTAINMENT EXEMPTIONS:** Many of the countries with dedicated PDMP policy frameworks (e.g., the Netherlands, Romania, and Greece) also exempt PDMPs or certain PDMP sub-classes from cost containment measures, which are otherwise applicable to all other medicines.
- **STOCKPILING REQUIREMENTS:** Differ substantially, from no obligation for PDMPs to mandatory stockpiling linked to reimbursement status or to tender criteria, ranging from several weeks to 6 months (with Finland extending stockpile of albumins to 10 months).
- **OVERALL ACCESS CHALLENGES:** Combination of aggressive pricing coupled with additional cost-containment measures, as well as potentially excessive stockpiling requirements, jointly exert significant pressure on the fragile PDMP supply chain.

Cost containment measures applied to PDMPs



CONCLUSION & DISCUSSION

OVERALL: PDMPs, due to their high therapeutic value, unique nature, and fragile supply chain, have become the subject of dedicated policy frameworks in some European jurisdictions, promoting more equitable access across a large number of indications, and removing restrictive measures such as stockpiling requirements or cost-containment, which can otherwise severely affect overall sustainability and disrupt the value chain of these essential medicines

PRICING: PDMPs require an urgent restructuring of current pricing frameworks towards a more value-based approach, already used in several countries. The use of ERP/IRP in annual or bi-annual price re-assessments often leads to continuous price erosion for PDMPs, unsustainable in the medium to long-term, with overtly negative impact on access (Oldfield et al., 2025). Some countries have already recognised the need for a different pricing approach, introducing price freeze or even price increases to redress the imbalance caused by the past ERP/IRP.

STOCKPILING: Whilst there is currently no definitive research quantifying the impact of stockpiling on medicine shortages, many reputable associations (Medicines for Europe, April 2024) and governmental bodies (UK's Department of Health & Social Care, August 2025) have raised concerns that stockpiling requirements, especially when applied to short-supply medicines (e.g. PDMPs) may lead to unintended consequences, often directly contrary to building greater healthcare resilience: *"stockpiling, if not implemented strategically, can reduce agility in managing medicines shortages and has the potential to exacerbate [European] shortages where there is uncoordinated stockpiling across multiple countries at once"*. The recently formed SoHo Coordination Board is well-positioned to monitor and advise on limiting or optimising stockpiling as well as harmonising supply across Europe.

COST-CONTAINMENT MEASURES: When applied to short-supply critical medicines and vaccines can be cost-myopic and result in significant worsening of access instead of greater healthcare sustainability. This negative impact has been explicitly recognised by a number of European governments, who have temporarily or permanently exempted PDMPs from the practice. Instead of traditional cost-containment, PDMPs may require a better quantification of the actual medical need and, consequently, setting appropriate eligibility criteria, thus limiting costs associated with inappropriate use, and improving access for all patients who can benefit from the treatments. Additionally, if cost-containment co-exists with the widespread "price-only" procurement or tendering practices, this can further aggravate the situation and consequently diminish the already sub-optimal patient access.

REIMBURSEMENT: The reimbursement of PDMPs, especially IgGs, is currently suboptimal in many European jurisdictions. This is often caused by EMA's SmPC not covering all indications where IGs are a valuable therapeutic modality, or it is the result of national HTA or Regulatory bodies failing to re-evaluate and reimburse IgGs in many indications where there is robust body real-world evidence, supporting their superior effectiveness and safety. Countries may wish to benchmark their reimbursement coverage with the latest research (Koltan et al., 2025), alongside EMA re-assessing IgG SmPCs in line with the most up o date evidence.

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