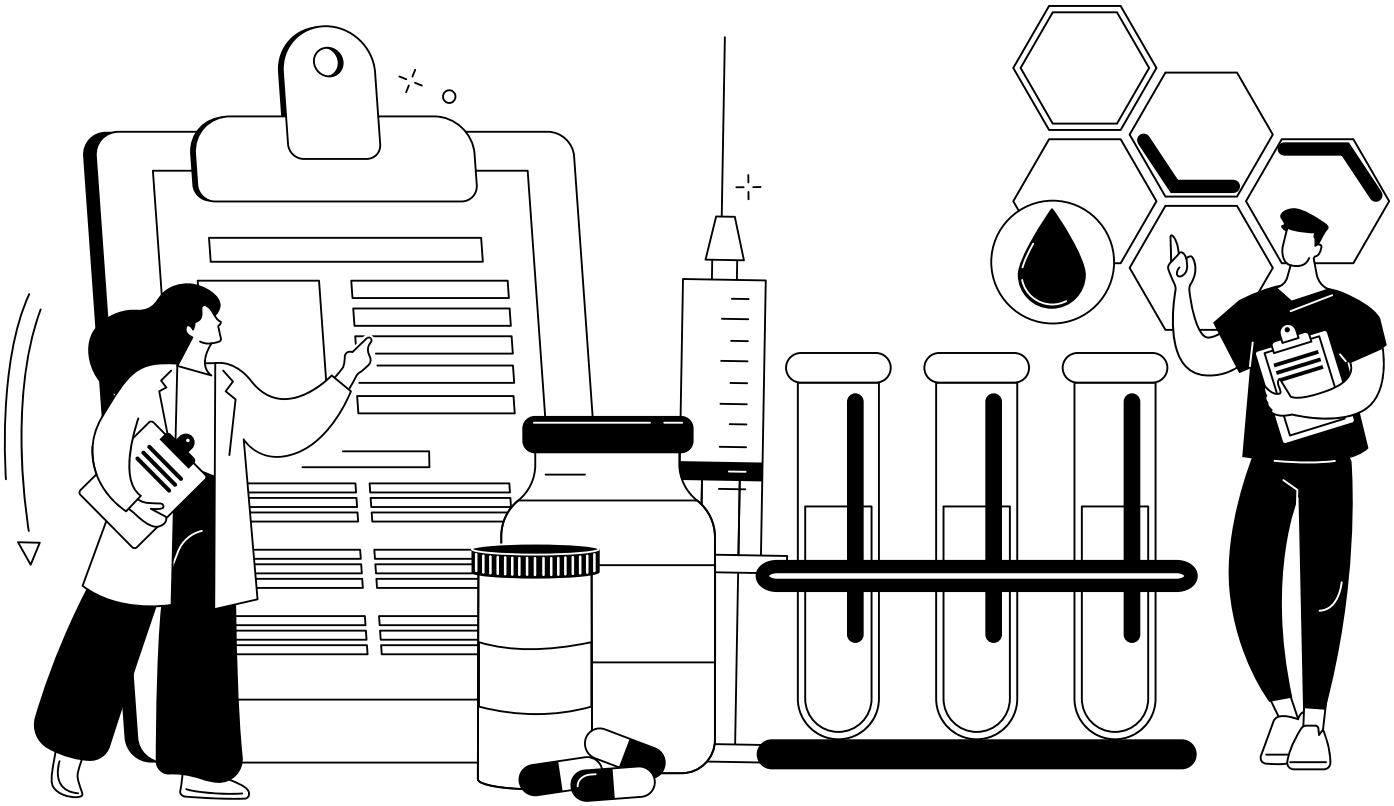
# Exempting PDMPs from cost containment measures

***Exempting PDMPs from national cost containment measures*** *is a policy paper that is supported by CSL.*

*The research for the policy paper was led by Lluís Alcover and Prof. Dr. Dr. med. Kai Zacharowski with support from APCO and the contribution of Dr Gisela Ernst. Lluís Alcover and Prof. Dr. Dr. med. Kai Zacharowski bear sole responsibility for the content of this policy paper. The findings and views expressed in this policy paper do not necessarily reflect the views of the sponsor.*



CSL

# National measures require alignment with European policy priorities for security of supply of critical medicines such as PDMPs

## Europe needs to ensure an appropriate ecosystem for critical medicines such as Plasma Derived Medicinal Therapies

The sector remains a cornerstone of Europe's economy, driving employment, growth, innovation and scientific progress[i]. The European Union (EU) has a pivotal opportunity to safeguard the sustainability of this vital sector[ii] while ensuring patients have timely access to essential medicines.

To translate EU commitments[iii] into tangible outcomes, European decision-makers and key stakeholders must work together to ensure that European nations remain economically attractive markets for innovation, support availability of life-saving medicines, and recognise the sector as the backbone of public health and societal productivity.

# Cost containment measures negatively impact European pharmaceutical competitiveness

Cost-containment measures, such as payback mechanisms or clawbacks, regular mandatory price reviews, may significantly hinder the economic viability of certain critical medicines.

- The Critical Medicines Alliance strategic report already recognized the economic viability of critical medicines as a relevant indicator for steady supply.
- The European Parliament draft report on the Critical Medicines Act rightly called on Member States to reconsider cost-containment measures to safeguard the economic viability of critical medicines, such as plasma therapies.

Plasma-derived therapies are an example that falls in this category, given the specific economic considerations in their value chain which results in fragile economic viability when measures like national clawbacks or mandatory price reviews are applied systematically over time.

Some EU Member States (Belgium, Greece, Spain) and the UK have already taken steps in this direction by lifting or decreasing the application of such measures to plasma derived therapies. However, these steps appear scattered and fragmented.

**Despite the Critical Medicine status of PDMPs, the steady supply of some critical medicines can be negatively impacted by disproportionate cost-containment measures across Europe and hinder the economic viability of these therapies.**

The EU has identified PDMPs as Critical Medicines[v] because of the seriousness of the diseases they address and the lack of suitable alternatives. Critical Medicine status, however, has not protected PDMPs from severe cost containment measures. The global trend towards increased clawbacks continues to affect IGs and PDMPs as a whole, while demand for IGs is set to grow over 6% annually in Europe.

Derived from human plasma,[vi] plasma derived medicinal products (PDMPs) are lifesaving treatments for rare and complex diseases. Many people rely on them – over 300,000 people in Europe[vii] – as the only effective treatment option for their condition, and there are often few or no alternatives.[viii] Currently, demand for PDMPs, especially immunoglobulins (IGs), is expected to increase[ix] due to improved diagnosis, new indications, obesity and ageing populations.

Strengthening the availability and security of supply of critical medicinal products, including PDMPs, is being addressed by the European Commission's March 2025 Critical Medicines Act (CMA) proposal.[x] To be effective, the CMA must be accompanied by nationaltlevel action to alleviate the burden of cost-containment measures on these medicines. EU Member States should explore exemptions for specific categories of critical medicines, such as PDMPs, from cost-containment mechanisms like clawbacks and rebates. Several Member States have already taken steps in this direction by lifting, delaying, or limiting the application of such measures to PDMPs, recognising their unique characteristics and value.

### PDMPs should be recognised as a unique category of medicines

PDMPs, including IGs, are clear-cut examples of Critical Medicines due to their unique economic model and the limited availability of plasma worldwide.

## A unique business model compared to traditional chemicals

Patient need for PDMPs, such as immunoglobulins (IGs), is increasing in the EU and globally, leading to an even wider gap between demand and supply. This is due to better diagnosis and a growing clinical demand (better diagnosis, more indications, obesity and ageing population). Thus, healthcare systems face growing challenges to secure sustainable patient access to PDMPs. Additionally, PDMPs require large numbers of human plasma donations, a scarce and a finite resource.

The systemic imbalance between the inherent limitations in plasma supply and the constantly growing demand for PDMPs is a unique challenge for this class of medicines. For example, IGs make up less than 12% of plasma proteins but 54% of global protein demand. Not all the proteins in every donation will be needed or used, but plasma manufacturers must fractionate them all to access in-demand proteins. Unlike other industries, plasma manufacturers do not benefit from economies of scale.

Due to the least-prevalent proteins (IGs) being in the highest demand, the opposite is true. The manufacturing of IGs requires additional investment, compared to other PDMPs, and their commercial viability decreases as demand grows.

Meanwhile, cost-containment measures penalise the sale of additional volumes. This is particularly important considering the rising prevalence of life-threatening rare diseases that PDMPs/IGs treat.

Cost-containment and sub-optimal tender criteria significantly increase the vulnerability of IGs to supply disruptions, due to the unique market dynamics of the PDMP market.

# Good practices of European countries granted cost containment exemptions supporting a sustainable approach to PDMP development that focuses on availability for patients.

As part of these efforts, these countries have chosen to exempt PDMPs, or specifically IGs and albumins, from cost-containment measures such as mandatory rebates or clawbacks:

## The United Kingdom VPAG exemption

The UK controls the cost of branded medicines through two schemes: a statutory scheme established by legislation[xi] and the Voluntary Scheme for Branded Medicines Pricing, Access and Growth (VPAG), which is negotiated every five years between the Department of Health and Social Care (DHSC) and the Association of the British Pharmaceutical Industry (ABPI).[xii]

Most manufacturers supplying branded medicines to the NHS opt into VPAG, which applies across the UK and bases payments on sales exceeding allowed limits. Certain exemptions exist, notably for PDMPs[xiii], which are exempt from increased clawback payment rates which take the baseline 10% rate up to a possible 35%, reflecting long-term government-industry collaboration[xiv] on the uniqueness of PDMPs.[xv]

## Belgium exemption of all PDMPs

Belgium has had a clawback in place since 2001, which was enshrined in law in 2006.[xvi] It has been amended on several occasions since. All PDMPs, regardless of where the plasma is sourced, have been exempted from this clawback.[xvii]

According to the European Commission, the Belgian authorities estimated at the time that this would represent forgone revenue of around 4.5 million EUR a year, or 1.09% of the National Institute for Health and Disability Insurance (NIHDI) pharmaceutical supply budget allocation.[xviii]

Accounting for inflation, in 2025, this would be approximately 6.33 million EUR a year[xix] – reflecting the high impact of PDMP exemption at a low cost in relation to the pharmaceutical budget. For reference, the 2024 Belgian pharmaceutical budget sat at 5.85 billion EUR.[xx]

### Greece exemption of IGs and Albumins

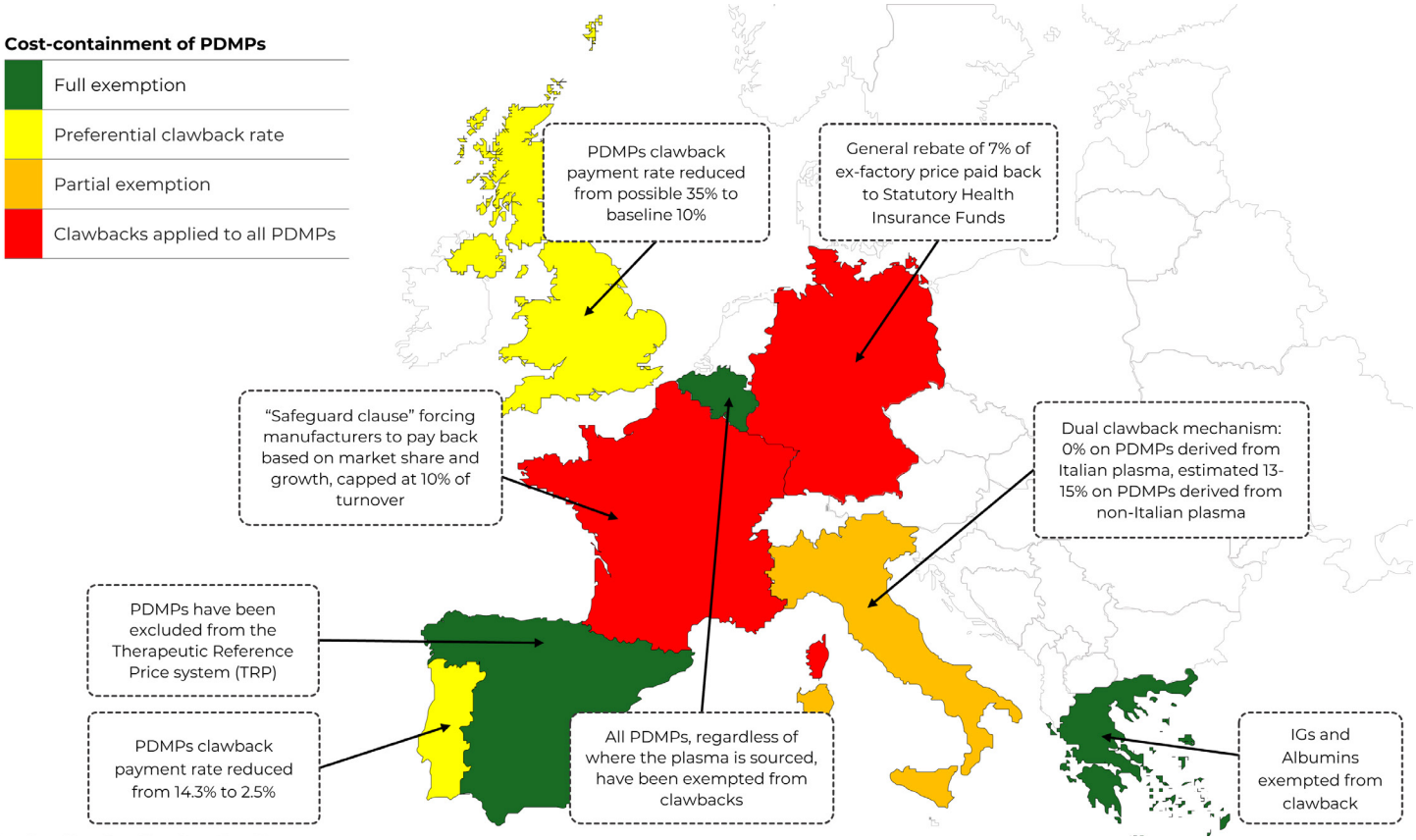
Greece has had a clawback since 2012 as part of the EU's financial assistance and adjustment package.[xxi] This was first introduced in the outpatient sector and was extended to the inpatient sector in 2016. Although their existing clawback presents challenges in supporting pharmaceutical innovation, the exemption of IGs and albumins is a marker of the specificities of PDMPs.[xxii] Since 2020 and 2022, they have been exempted from clawback contributions that could otherwise range from 40-70% (depending on the relevant budget channel). However, other PDMPs than IGs continue facing challenges to ensure sustainable economically viable access in this country.

### Spain PDMPs exclusion from Therapeutic Reference Price

Spain uses a local reference price group system to force prices down when new products with the same INN enter the market. PDMPs have been recently excluded from this system. This is a positive move towards considering the specificities of PDMPs when applying pharmaceutical policies. However, it must be ensured that clawbacks or other payback systems are not also applied to PDMPs.

## More is needed to make cost containment exemptions for PDMPs a standard practice across Europe

As of 2024, approximately 20 countries[xxiii] across Europe have adopted some form of clawback measures for pharmaceuticals. The landscape remains sub-optimal across Europe:




## The disproportionality of austerity measures for PDMPs

In Germany, France, and Italy, IGs only account for 1.2-2.0% of all clawback revenue.[xxiv]

In comparison, PDMPs constitute lifesaving treatments for over 300,000 patients in the EU, without which there would be a substantial increase in use of healthcare resources.

The marginal savings generated through cost containment measures for these products are not worth jeopardising access to these critical medicines by creating economically unsustainable conditions for manufacturers.

# Analogue critical medicinal products exempted from clawbacks

Other categories of therapeutics such as vaccines, antimicrobials, and generics have also faced unsustainable pressure and economic viability concerns. Across certain European countries, government intervention (e.g., favourable pricing & reimbursement models and exemptions from cost containment measures) have helped create a supportive environment conducive to sustainable production, ensuring patient access to those therapeutics. These include:

**In Italy**, the clawback does not apply to blood products, blood products from recombinant DNA, vaccines, and other medicines on the transparency list[xxv] of generic medicines with a retail price less than or equal to 5 EUR.[xxvi]

**In France**, the *Loi de Financement de la Sécurité Sociale* (LFSS) sets out how the clawback payment (known as the contribution M or safeguard clause) will work each year.[xxvii] Generics were exempt from the safeguard clause until 2019,[xxxviii] followed by a return to total exemption in the 2025 LFSS.[xxix]

Historically, the safeguard clause has included those medicines acquired by Santé Publique France with a view to building up a strategic stockpile in the event of serious health threats.[xxx,xxxi]

The LFSS 2024 clarified that medicines indicated for the treatment of COVID-19, as classified by the Ministers for Health and for Social Security, were excluded from the safeguard clause for stockpiled medicines in the year 2024.[xxxii]

# Exempting PDMPs or IGs alone from clawbacks and mandatory discounts can help achieve European health policy priorities

The regulatory instruments that apply to PDMPs - the CMA and the SoHO Regulation - are designed to enhance the EU's resilience in access to essential PDMPs[xxxiii] by promoting secure and ethically sound donation systems, by fostering European supply, and by incentivising investment into resilient production capacity. Any regulatory, financial, or contractual mechanism that undermines the economic viability of plasma collection or the sustainability of PDMP supply chains (for example, through clawback mechanisms) could counteract these explicit objectives.

This line of argument is reinforced by Article 35 of the Charter of Fundamental Rights of the European Union, which recognises the right of everyone to access preventive health care and to benefit from medical treatment under the conditions established by national laws and practices. Ensuring the availability and continuity of PDMP supply is therefore not only a matter of internal market efficiency but also part of the fundamental rights obligation of the Union and the Member States.[xxxiv]

Against this legal backdrop, policy coherence requires that both the CMA and the SoHO Regulation be implemented in a manner that avoids contradictory measures (one could argue that clawbacks would be contradictory in certain cases) which would weaken, rather than strengthen, the EU's resilience in securing plasma-derived therapies for patients.

Exemption of PDMPs from such clawback measures would help ensure policy coherence, and assist the EU and its Member States in meeting their health policy goals in the following areas:

## 1. Rare Disease

Member States[xxxv] and patient advocacy groups[xxxvi] have long called for an EU rare disease strategy to complement and update well-funded national rare disease plans and activities. Secure and timely supply is paramount for people living with rare conditions and who rely on critical treatments. Therefore, the EU needs a coordinated approach of existing policies (such as the Critical Medicines Act), complemented by national measures to significantly strengthen our collective capacity to ensure continued access to PDMPs for EU citizens.

## 2. Antimicrobial Resistance

Antimicrobial resistance (AMR) has also been identified as one of the top three health threats facing the EU[xxxvii] and is responsible for over 35,000 deaths every year in the EU/European Economic Area.[xxxviii] PDMPs play a critical role in reducing antibiotic use – and therefore reducing AMR risk – among people with weakened immune systems (e.g. cancer and organ transplant patients) by reducing the number and severity of infections they experience.[xxxix]

## 3. Security of medicine supply

With PDMPs listed by the EU as critical medicines due to how essential they are for the health of European citizens,[xl] securing their ongoing supply must be a top political priority to make sure PDMPs are consistently available to everyone who might need them. At a time when the Critical Medicines Act aims to support the security of supply of such medicines, national clawback exemptions for PDMPs can help ensure policy coherence between Member States.

## 4. Crisis preparedness

The European Union has also set out to build a Preparedness Union[xli] following on from the Niinistö Report[xlii] conclusions that civil and military preparedness require intensified national and European efforts. Such efforts are set to include an EU-wide stockpiling strategy and another to support medical countermeasures (in tandem with stockpiling measures under the Critical Medicines Act). PDMPs are critical for the military as well as for civilians. Uncontrolled haemorrhage remains the leading cause of preventable combat death[xliii], and PDMPs – especially fibrinogen concentrate and Prothrombin complex concentrate (PCC) in defined indications[xliv] – can help control bleeding. As such, security of supply for PDMPs is also a top priority for European security and strategic resilience.

## 5. A thriving and competitive pharmaceutical sector

Currently, the EU is reforming its pharmaceutical legislation[xlv] and taking various strategic actions to support European competitiveness and strategic autonomy.[xlvi] Ensuring the long-term competitiveness of the plasma sector is critical to maintaining a stable and resilient supply of PDMPs across Europe. Without appropriate economic conditions, manufacturers face an unstable and unpredictable market environment and may be forced to reduce or withdraw supply.

# Call to Action

We appreciate the steps taken by individual countries to exempt PDMPs from clawback mechanisms, recognizing the importance in maintaining secure supply and consistent availability of medicines. However, more action is urgently needed across Europe. In the absence of such action, the effects of cost-containment measures could lead to shortages and reduced medicine availability, ultimately impacting patients across Europe.

**We call on European governments with austerity measures in place to recognise the value of PDMPs and support sustainability and improved patient access by exempting PDMPs or IGs alone from harmful cost containment measures, including national clawback mechanisms, mandatory discounts and therapeutic reference pricing mechanisms.**

## References


[i] Draghi M. The future of European competitiveness. Available at: https://commission.europa.eu/topics/eu-competitiveness/draghi-report_en. Accessed August 2025.

[ii] Ibid.

[iii] European Commission. Commission launches new strategy to make Europe a global leader in life sciences by 2030. Available at: https://ec.europa.eu/commission/presscorner/detail/en/ip_25_1686. Accessed July 2025.

[iv] European Parliament. DRAFT REPORT on the proposal for a regulation of the European Parliament and of the Council laying a framework for strengthening the availability and security of supply of critical medicinal products as well as the availability of, and accessibility of, medicinal products of common interest, and amending Regulation (EU) 2024/795. Available at: https://www.europarl.europa.eu/doceo/document/SANT-PR-775742_EN.pdf. Accessed: November 2025.

[v] European Medicines Agency. Union list of critical medicines. 2024. Available at: https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/medicine-shortages-availability-issues/availability-medicines-during-crises/union-list-critical-medicines. Accessed: July 2025.

[vi] Laursen IA, Blou L, Sullivan JS, Bang P, Balstrup F, Houen G. Development, manufacturing and characterization of a highly purified, liquid immunoglobulin g preparation from human plasma. Transfus Med Hemother 2014; 41(3): 205-12.

[vii] Bonacker L. Open Strategic Autonomy for plasma therapies in the EU [Sponsored Content from CSL]. Politico, 2024. Avail-able at: https://www.politico.eu/sponsored-content/open-strategic-autonomy-for-plasma-therapies-in-the-eu/. Accessed: July 2025.

[viii] Plasma Protein Therapeutics Association (PPTA). Rare Diseases. Available at: https://www.pptaglobal.org/material/rare-diseases Accessed: July 2025

# References


[ix] Patrick, Robert: Plasma-Derived Medicinal Products (PDMPs) and Plasma Supply into the Future, European Blood Alliance and International Plasma and Fractionation Association (EBA-IPFA) Amsterdam, the Netherlands 14-15 January 2020. The Market Research Bureau (MRB). Available at: https://ipfa.nl/wp-content/uploads/2019/08/1_5_ROBERT-Robert_IPFA-EBA_January14_Dispatch.pptx-FINAL-READY-FOR-PUBLICATION.pdf. Accessed: September 2025.

[x] European Commission. Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL laying a framework for strengthening the availability and security of supply of critical medicinal products as well as the availability of, and accessibility of, medicinal products of common interest, and amending Regulation (EU) 2024/795. EUR-Lex. 2025. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52025PC0102, Accessed July 2025.

[xi] UK Government. The Branded Health Service Medicines (Costs) Regulations 2018. https://www.legislation.gov.uk/uksi/2018/345/contents/made. Accessed 2025.

[xii] Department of Health and Social Care (DHSC). Voluntary Scheme for Branded Medicines Pricing and Access (VPAG) 2024-2028. 2024. Available at: https://www.gov.uk/government/publications/voluntary-scheme-for-branded-medicines-pricing-and-access-vpag. Accessed: July 2025.

[xiii] Association of the British Pharmaceutical Industry (ABPI), How company payments are calculated under the 2024 VPAG. 2025. Available at: https://www.abpi.org.uk/value-and-access/uk-medicine-pricing/voluntary-scheme-on-branded-medicines/how-company-payments-are-calculated-under-the-2024-vpag/. Accessed: July 2025.

[xiv] Hogan Lovells. UK Pricing Exemption Report for CSL. 2025.

[xv] Department of Health and Social Care (DHSC). Annexes to the 2024 Voluntary Scheme for Branded Medicines Pricing, Access and Growth 2024-2028. 2024. Available at: https://www.gov.uk/government/publications/voluntary-scheme-for-branded-medicines-pricing-and-access-vpag. Accessed: July 2025.

[xvi] Gerkens S, Merkur S. Belgium: Health system review. Health Systems in Transition, 2010, 12(5):1–266. Available at: https://iris.who.int/bitstream/handle/10665/330331/HiT-12-5-2010-eng.pdf?sequence=5&isAllowed=y. Accessed: July 2025.

[xvii] European Commission. State aid: Commission endorses exemption from Belgian pharma levy for medicines made from blood. 2009. Available at: https://ec.europa.eu/commission/presscorner/detail/en/ip_09_1150. Accessed: July 2025.

[xviii] European Commission. Aide d'État N 105/2009 – Belgique, Exonération des médicaments plasmatiques de la cotisation sur le chiffre d'affaires. European Commission, 2009. Available at: https://ec.europa.eu/competition/state_aid/cases/230013/230013_1004134_36_2.pdf Accessed July 2025.

[xix] CSL Data on File.

[xx] SPF Chancellerie du Premier Ministre, Budget global 2024 des moyens financiers pour les prestations en matière de spécialités pharmaceutiques, news.belgium, 2024. Available at: https://news.belgium.be/fr/budget-global-2024-des-moyens-financiers-pour-les-prestations-en-matiere-de-specialites Accessed July 2025.

[xxi] Saionz,A. Clawbacks and Rebates in Greece: A Threat to Sustainability?. Pharma Boardroom. 2022. Available at: https://pharmaboardroom.com/articles/clawbacks-and-rebates-in-greece-a-threat-to-sustainability/. Accessed: July 2025.

[xxii] EY Parthenon, PDMPs (IGs): Pricing Policy Landscape Assessment & Payer Engagement Strategy [for CSL]. 2025

[xxiii] Moll. N. Make or break: The future of Regulatory Data Protection in Europe, EFPIA, 2024. Available at: https://www.efpia.eu/news-events/the-efpia-view/blog-articles/make-or-break-the-future-of-regulatory-data-protection-in-europe. Accessed July 2025.

[xxiv] IQVIA VIT Clawback Quantification. Country analysis. 2025.

[xxv] Agenzia Italia del Farmaco (AIFA). Transparency Lists. AIFA. 2025. Available at: https://www.aifa.gov.it/en/liste-di-trasparenza. Accessed July 2025.

[xxvi] Agenzia Italia del Farmaco (AIFA). DETERMINAZIONE 27 settembre 2006: Manovra per il governo della spesa farmaceutica convenzionata e non convenzionata. AIFA. 2006. Available at: https://www.aifa.gov.it/sites/default/files/2006_09_27_det_spesa_farmaceutica_convenzionata_e_non_0.pdf. Accessed July 2025.

[xxvii] Inbeeo. Clawbacks and Mandatory Rebates in Europe. Inbeeo. 2025. Available at: https://inbeeo.com/2025/05/06/clawbacks-and-mandatory-rebates-in-europe/. Accessed: July 2025.

# References


[xxviii] GEnérique Même Medicament (GEMME). L'avenir des génériques en France compromis par la clause de sauvegarde: Une menace pour l'accès aux médicaments essentiels . GEMME. 2023. Available at: https://medicamentsgeneriques.info/l-avenir-des-generiques-en-france-compromis-par-la-clause-de-sauvegarde-une-menace-pour-l-acces-aux. Accessed: July 2025.

[xxix] Ibid.

[xxx] Légifrance. Code de la sécurite sociale Article L138-10. Secrétariat général du Gouvernement. 2023. Available at: https://www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000041397395/2025-08-12/. Accessed: August 2025.

[xxxi] Légifrance. Code de la santé publique Article L1413-4. Secrétariat général du Gouvernement. 2022. Available at: https://www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000025104600/2025-08-12/. Accessed: August 2025.

[xxxii] Légifrance. LOI n° 2023-1250 du 26 décembre 2023 de financement de la sécurité sociale pour 2024 (1). Secrétariat général du Gouvernement. 2023. https://www.legifrance.gouv.fr/loda/article_lc/LEGIARTI000048670480/2025-08-12/. Accessed: August 2025.

[xxxiii] Recitals 24 and 64 of Regulation (EU) 2024/1938 on Substances of Human Origin ("SoHO Regulation") and Recital 12 of the Proposal for a Regulation on the Critical Medicines Act (COM/2025/102) ("CMA").

[xxxiv] See Recital 1 of the CMA and Recital 1 of the SoHO Regulation.

[xxxv] Rare Diseases Europe (EURORDIS). 21 Member States endorse Czech EU Presidency's Call to Action on rare diseases at EP-SCO Council Meeting. EURORDIS. 2022. Available at: https://www.eurordis.org/ms-endorse-czech-cta-rare-diseases/. Accessed: July 2025.

[xxxvi] EURORDIS. #30millionreasons for Europe to take action on rare diseases. EURORDIS. 2025. Available at: https://www.eurordis.org/rare-disease-policy/30-million-reasons/. Accessed: July 2025.

[xxxvii] Health Emergency Preparedness and Response Authority. HEALTH UNION: Identifying top 3 priority health threats. European Commission. 2022. Available at: https://health.ec.europa.eu/publications/hera-factsheet-health-union-identifying-top-3-priority-health-threats_en. Accessed: July 2025.

[xxxviii] European Centre for Disease Prevention and Control. Assessing the health burden of infections with antibiotic-resistant bacteria in the EU/EEA, 2016-2020. Stockholm: ECDC; 2022

[xxxix] Gathmann B, Mahlaoui N, Ceredih, et al. Clinical picture and treatment of 2212 patients with common variable immunodeficien-cy. J Allergy Clin Immunol 2014; 134(1): 116-26.

[xl] European Medicines Agency. Union list of critical medicines. 2024. Available at: https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/medicine-shortages-availability-issues/availability-medicines-during-crises/union-list-critical-medicines. Accessed: July 2025.

[xli] European Commission. Joint Communication to the European Parliament and the Council on the European Preparedness Union Strategy. 2025. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52025JC0130&qid=1743598660031. Accessed: September 2025.

[xlii] European Commission, Safer together: the path towards a fully prepared Union. 2025. Available at: https://commission.europa.eu/topics/defence/safer-together-path-towards-fully-prepared-union_en. Accessed: September 2025.

[xliii] TCCC, Damage Control Resuscitation CPG. 2025. Available at: https://tccc.org.ua/en/guide/damage-control-resuscitation-cpg. Accessed: September 2025.

[xliv] Rossaint, R., Afshari, A., Bouillon, B. et al. The European guideline on management of major bleeding and coagulopathy following trauma: sixth edition. Crit Care 27, 80 (2023). https://doi.org/10.1186/s13054-023-04327-7

[xlv] European Commission. Reform of the EU pharmaceutical legislation. https://health.ec.europa.eu/medicinal-products/legal-framework-governing-medicinal-products-human-use-eu/reform-eu-pharmaceutical-legislation_en. Accessed July 2025.

[xlvi] European Commission. Choose Europe for life sciences: A strategy to position the EU as the world's most attractive place for life sciences by 2030. https://research-and-innovation.ec.europa.eu/document/download/411698e8-6062-41af-96e5-af54474d70f5_en. Accessed July 2025.