PANSOL

Advancing Equity in Medicine Access: The Case for a Pan-European Solidarity-Based Reimbursement Model (PANSOL)

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November 2025

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Key Features of the PANSOL Framework:

- **Solidarity-Based Model for Equitable Access**: The Pan-European Solidarity-Based Reimbursement (PANSOL) model is a proposed pan-European reimbursement model grounded in solidarity, equity, and efficiency, designed to ensure equitable access to essential innovative medicines in the EU, particularly addressing disparities faced by smaller and less wealthy member states.
- **Integrated and Streamlined Process**: It combines clinical evaluation, appraisal, pricing, and reimbursement into a single, centralized and smooth process, aiming to reduce bureaucratic delays and improve efficiency compared to fragmented models like the Joint Clinical Assessment (JCA).
- **Single EU-Level *Light-Touch* HTA and Negotiations**: The framework features a unified EU-level (or the level of a group of participating countries in an enhanced cooperation) health technology assessment (HTA) with an efficient 'light touch' process, centralized price negotiations and risk-sharing agreements, leveraging collective bargaining power to enhance affordability and access.
- **Accelerated Patient Access**: By unifying HTA, appraisal, and reimbursement into one streamlined efficient procedure, PANSOL substantially shortens the time from marketing authorisation to patient access.
- **Solidarity-Based Budgeting:** By pooling financial risk at the EU level, PANSOL safeguards timely access to high-cost and orphan medicines — especially in smaller or lower-income member states.
- **GDP-Proportional Financing**: Funding is based on contributions from member states proportional to their GDP, embodying the solidarity principle and ensuring wealthier nations support broader access.
- **Transparency and Predictability**: Transparency is a cornerstone, with predefined value drivers, methodological guidelines, clear criteria, and evidence requirements published in advance, fostering trust and predictability for stakeholders.
- **Real-World Evidence Integration**: It incorporates real-world evidence (RWE) alongside clinical trial data to strengthen HTA appraisals, particularly for ultrarare diseases where traditional data may be scarce, enhancing decision-making robustness.
- **Broad Stakeholder Engagement:** Early and structured consultation with patients, clinicians, payers, industry, and civil society strengthens legitimacy, relevance, and alignment with solidarity EU public health priorities.
- **Single Market Access Point for Industry**: PANSOL offers pharmaceutical companies a unified market entry pathway, reducing uncertainty and barriers, especially for therapies targeting rare conditions, potentially encouraging innovation in high-risk areas like gene therapies and other Advanced Medicinal Therapeutical Products.

Introduction

The European Union (EU) is committed to ensuring that its citizens have timely and equitable access to safe, effective, and affordable medicines. In 2023, the EU embarked on a reform of its pharmaceutical legislation, aiming to address multifaceted challenges ranging from accessibility and affordability to environmental sustainability and regulatory inefficiencies [1]. The overarching aim of the reform was to ensure that patients across the EU have timely and equitable access to medicines [2]. However, despite these commendable efforts, substantial hurdles persist. These include, but are not limited to, a lack of transparency in pharmaceutical pricing, inconsistencies in reimbursement policies across different national healthcare systems, and significant disparities in access to orphan and other highly specialized medicinal products, particularly within smaller member states. These issues collectively underscore the inadequacy of current strategies in achieving truly equitable access to essential innovative therapies.

In response to the fragmentation of health technology assessment (HTA) processes across the EU, the Joint Clinical Assessment (JCA) framework was developed. The JCA's primary intended aim is to standardise the evaluation of health technologies, thereby reducing redundant assessments and accelerating the adoption of novel medical interventions [3]. Its goal is to reduce duplication in assessments and accelerate the adoption of new technologies. The idea behind this design is to ensure a consistent approach to assessing clinical efficacy and potential effectiveness, allowing for rapid dissemination of beneficial treatments across the union [4].

While the JCA represents a step towards greater harmonisation, its proposed implementation at the European level presents several challenges. These could inadvertently compromise the efficient allocation of public funds for pharmaceuticals. Indeed, while the JCA is intended to expedite patient access to innovative medicines, its *heavy-touch*[1] approach risks exacerbating existing barriers to innovation, potentially leading to increased delays, higher burden on public institutions, rising costs and complicating reimbursement pathways.

This paper introduces the Pan-European Solidarity Reimbursement List (PANSOL) as a new model. PANSOL is designed to fundamentally enhance access to medicines through a solidarity-driven reimbursement system that integrates resource pooling, centralised decision-making, and streamlined negotiations. This

[1] *Heavy-touch approach* – refers to a comprehensive, resource-intensive model in which the HTA agency assumes primary responsibility for data analysis, methodological decisions, and evidence generation. Clinical evaluation is separated from appraisal and reimbursement decisions across multiple institutional levels, as exemplified by the JCA framework. While this model ensures scientific rigour, transparency, and accountability, it is characterised by significant bureaucratic oversight, multiple evaluation stages, and complex procedures. These features often result in extended timelines, duplicated efforts, and delays in patient access to medicines, while also increasing barriers to innovation due to its fragmented and administratively burdensome nature.

framework aims to transcend the limitations of current mechanisms by fostering a collective responsibility among member states, leveraging the collective purchasing power of the EU (or at least countries participating in an enhanced cooperation), and ensuring that all European citizens, irrespective of their national economic standing, can benefit from timely access to life-saving and innovative treatments. The subsequent sections will elaborate on the conceptual underpinnings, structural components, and anticipated impact of the PANSOL framework, alongside a comparative analysis with existing models and a discussion of the challenges and opportunities for its implementation.

Conceptualising PANSOL: A solidarity-based reimbursement framework

PANSOL is conceptualised as a pan-European solidarity-based reimbursement model based on voluntary collaboration or via enhanced cooperation among EU Member States. It expands on the idea of joint HTA, but advances further by enabling collective reimbursement decisions, pooled financial contributions, and centralised negotiations. A critical distinction between PANSOL and the existing JCA framework lies in their scope: while JCA deliberately separates clinical assessment from the broader value judgment of health technologies, PANSOL proposes an integrated model that seamlessly incorporates both rigorous evaluation and comprehensive appraisal of clinical *and* non-clinical criteria at the EU level. This holistic approach is designed to provide a more cohesive and efficient pathway from clinical evidence to patient access.

The implementation of PANSOL may follow several feasible paths, each offering distinct advantages and potential for synergistic development. One potential approach is for the European Commission to issue a regulatory manifesto recommending changes to national P&R policies. This manifesto could include targeted proposals to enhance the competitiveness of national pharmaceutical sectors and promote alignment in policy direction across the EU. Within this framework, PANSOL could be introduced as a recommended – but not mandatory – initiative. This approach would empower Member States to voluntarily adopt PANSOL's mechanisms, thereby integrating them into a more harmonised European policy landscape while respecting national competences.

Alternatively, or concurrently, PANSOL could be established through the enhanced cooperation mechanism as described in the Treaty on the European Union [5]. In this model, a group of interested Member States, particularly those with smaller populations or more constrained healthcare budgets, could lead the creation of PANSOL on a voluntary basis. This path allows for early adoption and practical experimentation, potentially serving as a proof-of-concept for wider EU integration at a later stage. The success of such a pioneering group could demonstrate the tangible benefits of PANSOL, thereby encouraging broader participation. A necessary condition for such an enhanced cooperation is that the interested Member States may differ in their level of Gross Domestic Product (GDP) per capita, hence providing opportunities for solidarity (see further).

The two described pathways are not mutually exclusive. In fact, their parallel pursuit could create a synergistic effect, fostering both top-down encouragement through EU institutions and bottom-up momentum from willing national governments. This combined impetus could accelerate the adoption and successful implementation of PANSOL across the continent. Although the Pharmaceutical Package was adopted by the European Parliament in 2023 [6], and some concerns remain that its provisions may inadvertently restrict access to

innovative medicines, Member States still retain the sovereign authority to implement more robust local pricing and reimbursement measures to counterbalance any such adverse effects [6].

Empirical data underline the urgency of addressing disparities in access. Research indicates that pharmaceutical companies tend to prioritise product launches in wealthier EU countries with higher GDP per capita and larger patient populations [7, 8]. This market-driven behaviour exacerbates existing inequalities, leaving smaller or less wealthy nations at a disadvantage. It highlights the need for a collective and equitable solution, such as PANSOL, that ensures all European citizens benefit from timely access to innovative medicines regardless of their country's economic status, hence strengthening European solidarity.

PANSOL structure and core principles

PANSOL is envisioned as a centralised, pan-European solidarity-based reimbursement fund intended to ensure equitable access to innovative therapies across participating countries. The core principles underpinning this model are solidarity, equity, and efficiency. Under the proposed financing scheme, EU Member States would contribute to the PANSOL fund in proportion to their GDP per capita and population size. This funding mechanism ensures that wealthier nations provide greater absolute contributions, thereby embodying the EU's principle of solidarity. In return, patients across all participating countries – regardless of their national income levels – would enjoy equal access to the therapies listed under the PANSOL framework.

The equitable structure of PANSOL would be particularly transformative for lower-income and smaller Member States, which often face delayed or restricted access to high-cost, life-saving treatments. By strategically pooling financial risk at the European level, PANSOL would also address the persistent challenges associated with the reimbursement of orphan and other highly specialized medicinal products. Accordingly, the initial scope of the PANSOL list would likely prioritise treatments for ultra-rare diseases, where the unmet medical need is most acute and the economic burden on individual member states is disproportionately high. Over time, the list could be expanded to include selected oncological therapies, new antimicrobials, and high-risk medical devices, ultimately broadening its scope to encompass a wider array of therapeutic areas in alignment with European healthcare solidarity goals. Moreover, further externalities may arise from intensified co-operation between member states on HTA. For example, if infectious diseases (particularly drug resistant) are better treated in lower GDP-countries, then transmission to more affluent countries could be reduced and – vice versa – benefits and enhanced understanding of optimized treatment within the EU enhances the infectious diseases situation in those lower GDP-countries themselves.

Manufacturers of eligible drugs (market authorisation holders – MAHs) would have

a choice between two mutually exclusive reimbursement pathways: either apply to the centralised PANSOL mechanism or follow the conventional, often fragmented, process of submitting individual applications to each Member State. A MAH opting for the PANSOL route would not be permitted to pursue reimbursement for the same product through national-level submissions in parallel. This strict exclusivity clause is paramount; it ensures administrative clarity, avoids duplication, and reinforces the integrity and efficacy of the centralised model, thereby preventing forum shopping and ensuring a streamlined process.

The operational framework of PANSOL would include a single, EU-level health technology assessment conducted under a *light-touch*[2] model. Thereby, MAHs would be required to submit a comprehensive HTA dossier, including evidence relative clinical effectiveness and safety (which constitute the scope of the JCA [3] under the EU HTA Regulation), as well as cost-effectiveness, budget impact and medical need, and ethical, legal and social considerations. The task of the HTA body within PANSOL would then be restricted to evaluate the quality of those submissions (methodological soundness and data completeness) based on HTA guidelines, endorsed by all participating countries. Only high-quality submissions would advance to the appraisal phase, which would also occur at the EU level (or among countries participating in the enhanced cooperation). A dedicated decision-making body – either newly established or an extension of an existing EU institution – would oversee this process.

The establishment of a common PANSOL budget, informed by horizon scanning, will be fundamental to ensuring both equity and sustainability of the framework. Allocation of resources will be guided by criteria that are rational, transparent, and fully compliant with the EU Transparency Directives [9, 10], thereby safeguarding fairness in decision-making and reinforcing trust among Member States. This structured approach will enable consistent prioritisation of therapies while maintaining accountability in the use of shared funds. In practice, budget allocation could follow either a utilitarian approach, where treatments are ranked according to cost-effectiveness measures such as the incremental cost-utility ratio (ICUR), or an egalitarian approach, which prioritises access to therapies for rare or ultrarare diseases. A balanced combination of these approaches could maximise efficiency in resource allocation while upholding fairness for vulnerable patient populations, thereby ensuring responsible and accountable use of the shared budget.

[2] *Light-touch approach* – is a streamlined model that integrates clinical evaluation, value appraisal, pricing, and reimbursement into a single process, thereby reducing duplication and accelerating decision-making. Within this framework, the manufacturer bears primary responsibility for the quality, completeness, and methodological rigour of the reimbursement dossier, while HTA agencies focus primarily on verifying submissions rather than generating evidence. By placing the burden of proof on the applicant and minimising bureaucratic intervention, this model facilitates faster, more predictable, and more equitable patient access across participating countries. However, it also carries the potential risk of bias, as companies preparing HTA submissions may prioritise commercial objectives over patient outcomes. Without sufficient independent scrutiny, the evidence presented could disproportionately reflect the sponsor's perspective rather than an objective assessment of value for patients and health systems.

Under the PANSOL framework, the official and the net negotiated price for a medicine would be uniform across all participating countries, and paid via the PANSOL fund. This represents a significant advancement over existing fragmented pricing systems and promotes a more equitable pharmaceutical market throughout the Union. This approach, by leveraging the on solidarity-based budget and the collective purchasing power of the EU, is intended to promote cost-effective procurement and maximise the value of public spending. Furthermore, the use of a single appraisal and decision-making body would drastically reduce administrative delays and streamline market access, allowing for more timely patient access to new and innovative medicines. While prices would be uniform for medicines covered by PANSOL, participating countries would retain the autonomy to reimburse medicines or drug technologies[3] not covered by the PANSOL agreement from their own national budgets, ensuring national flexibility while benefiting from the centralisation of price negotiations and assessments. Wealthier nations, in particular, would benefit from PANSOL as the collective bargaining power of the fund would secure better prices than those achievable by any single country alone. This centralised procurement approach would enhance affordability without compromising incentives for pharmaceutical innovation. Additionally, the *light-touch* approach would significantly reduce administrative costs and bureaucracy for all participants.

By design, PANSOL enables a number of critical efficiencies. It systematically eliminates the need for multiple national HTAs and appraisals, removes the necessity for prioritisation (which can be prone to bias or political influence), and establishes a uniform, GDP-adjusted budget. Moreover, it consolidates these responsibilities into a single, efficient, and transparent pan-European HTA authority – either by establishing a new institution or by delegating the necessary functions to an existing EU body – thereby significantly reducing bureaucratic complexity. Importantly, the system guarantees proven, equal access to listed medicines across the EU and provides a far more effective framework for managing orphan and other highly specialized medicines, particularly from the perspective of small and medium-sized countries.

The unified approach facilitated by PANSOL would allow reimbursement decisions to be rendered quickly and on the basis of up-to-date, transparently defined evidence. With predefined value drivers and methodological guidelines published in advance, both MAHs and national authorities would benefit immensely from a more predictable and streamlined process. All reimbursement decisions issued under PANSOL would be legally binding and applicable across the entirety of the EU or participating countries, establishing a new standard for equitable pharmaceutical access across Europe.

As HTA increasingly shifts toward patient-centred, value-based evaluation, the strategic integration of real-world evidence (RWE) has become essential. The PANSOL framework not only acknowledges the growing relevance of RWE, but actively

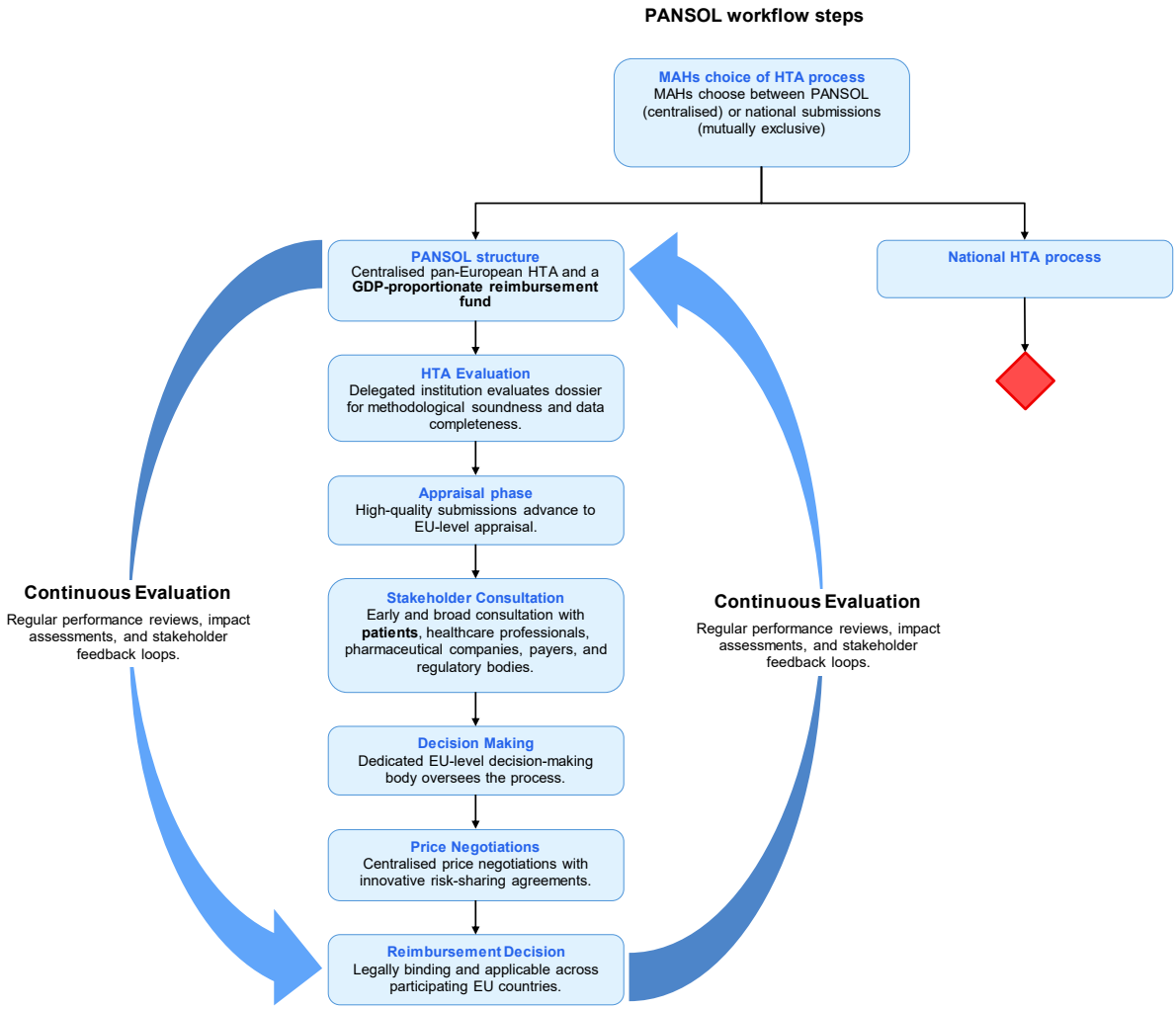
[3] *Health technology* is defined as an intervention in a given indication. Therefore, the same medicine used to treat three different medical indications creates three different drug technologies.

leverages it to complement data from randomised controlled trials, particularly in areas where clinical trial data may be limited – such as ultra-rare diseases, long-term treatment outcomes, and underrepresented patient subgroups. RWE can offer valuable insights into real-life effectiveness, safety, and treatment adherence, thereby enhancing the robustness and contextual relevance of HTA appraisals. To ensure consistent, scientifically credible assessment, PANSOL must establish comprehensive guidelines for the collection, submission, and evaluation of RWE. These standards should be harmonised across participating Member States, promoting transparency, methodological rigour, and regulatory alignment. In doing so, PANSOL would strengthen its evidence base and improve decision-making in complex or data-scarce therapeutic areas.

Given the dynamic nature of HTA processes and the PANSOL framework, and the fact that value and value for money are context-specific, with different willingness to pay thresholds for health gains in different countries, it is crucial to continuously evaluate the effectiveness, efficiency, and impact of these processed on patient access in the participating Member States. To achieve this, regular performance reviews and systematic impact assessments should be complemented by structured stakeholder feedback loops. By continuously measuring effectiveness, efficiency, and patient-access outcomes, the framework can pinpoint emerging challenges and opportunities for enhancement. This iterative cycle of assessment and adaptation will enable timely updates to both regulatory provisions and operational protocols, safeguarding PANSOL's relevance and effectiveness in an ever-changing HTA environment.

Early and broad stakeholder consultation is a cornerstone of the PANSOL framework, ensuring its design and implementation reflect diverse perspectives and needs across the EU. To achieve its goal of equitable medicine access, PANSOL must involve key stakeholders – such as patients, healthcare professionals, pharmaceutical companies, payers, and regulatory bodies – from the earliest stages of its development. This inclusive consultation process will promote transparency and foster trust in the decision-making framework. By prioritising regular, structured dialogue, PANSOL can align its reimbursement criteria and evaluation processes with real-world clinical and economic demands, particularly for addressing unmet needs in areas like rare diseases and oncology. Such stakeholder input is essential to shape robust guidelines and eligibility criteria, ensuring PANSOL's effective implementation and its ability to deliver equitable access to medicines throughout the EU. The full PANSOL structure is presented in **Figure 1**.

FIGURE 1. PANSOL WORKFLOW STEPS



EU: European Union; GDP: Gross domestic product; HTA: Health Technology Assessment; MAH: Market Authorisation Holder; PANSOL: Pan-European Solidarity.

Comparative evaluation: PANSOL versus JCA and other models

The PANSOL framework diverges fundamentally from the existing JCA model by uniting clinical evaluation, appraisal, pricing, and reimbursement into a single, streamlined process. This integrated paradigm stands in contrast to the JCA, which, by design, maintains a distinct separation between clinical assessment and the subsequent stages of value judgment and reimbursement. This inherent separation in the JCA risks to lead to protracted timelines and administrative inefficiencies, as each stage requires separate national processes following the initial EU-level clinical assessment. Under PANSOL's *light-touch* HTA approach, MAHs submit a full dossier to a designated EU authority, which first scrutinizes the methodological rigour and completeness of each submission. Only those dossiers meeting predefined quality standards proceed to a joint appraisal session conducted at the European level. Responsibility for these tasks could rest with a newly established pan-European HTA body or be formally delegated to an existing EU institution.

Under the current frameworks, price and risk-sharing negotiations remain decentralised, leading to fragmented and often underutilised bargaining power among Member States [11]. In contrast, under PANSOL, these negotiations would be conducted centrally, harnessing the full collective purchasing strength of all participating countries to achieve more effective and equitable outcomes. Furthermore, a key transparency feature of PANSOL is the pre-publication of its value-driver criteria and methodological guidance. This proactive disclosure provides MAHs and payers alike with predictable timelines and clear expectations, fostering a more transparent, reliable and efficient environment for market access. Reimbursement decisions issued under this unified framework would apply uniformly across the entire EU territory (or among the participating countries), effectively abolishing the current necessity for multiple, staggered national assessments, which are a significant source of delay and administrative burden.

By consolidating HTA, appraisal, and pricing into one coherent procedure, PANSOL is projected to significantly reduce the time from marketing authorisation to actual patient access. Perhaps some Member States will question the possibly reduced input into the final decision but a single, comprehensive assessment under PANSOL would replace what currently duplicative and often inconsistent national reviews are. This not only translates into substantial reductions in public-sector administrative costs but also significantly lowers industry expenses associated with navigating disparate national systems. Moreover, the enhanced efficiency and collective bargaining power inherent in PANSOL's design could exert downward pressure on drug prices, ultimately benefiting patients and healthcare budgets across the Union.

Beyond efficiency gains, PANSOL's solidarity-based budget, which is pooled

and adjusted proportionally to GDP, is a cornerstone for promoting equitable access to high-cost therapies. This is particularly critical in therapeutic areas characterised by high unmet medical need, such as (ultra)-rare diseases, paediatric treatments, new generation antibiotics and oncology, where the financial burden on individual member states can be prohibitive. Small and lower-income Member States, which frequently struggle to secure timely launches of orphan medicines due to limited market size and negotiating power, would gain immediate and profound benefits from a pan-European reimbursement decision and shared financial risk. The centralised price-setting mechanism harnesses the EU's full purchasing power, thereby improving affordability without compromising the vital incentives for pharmaceutical innovation.

In essence, unlike the JCA's *heavy-touch* separation of clinical assessment and reimbursement [12, 13], PANSOL integrates all stages into a single, accountable process. This integrated approach is designed to set European priorities and to be free of bureaucratic fragmentation, which has historically characterised and often hindered the efficient and equitable access to medicines in Europe. By addressing systemic inefficiencies and access inequalities, PANSOL offers a robust and forward-thinking solution that transcends the limitations of the JCA and many existing national models [14], promising a more unified, equitable, and efficient pharmaceutical landscape for the European Union.

Impact on the pharmaceutical industry

The introduction of PANSOL would also offer substantial advantages to innovative biopharmaceutical companies. With one EU-wide reimbursement decision, companies secure market access across all participating States, removing the need for multiple national reimbursement submissions. This is especially relevant for therapies targeting ultra-rare conditions, where the limited patient population often renders national market entries economically unviable. PANSOL's rapid, consolidated pathway is designed to reduce uncertainty and substantially lower the barrier to launching such critical treatments, fostering innovation in areas of high unmet medical need.

PANSOL's framework is designed to address the significant disparities in drug pricing and access that currently exist between EU member states. For member states with lower GDP, PANSOL offers a crucial advantage by providing access to high-cost medicines at a price they would be unable to negotiate on their own. Under the current system, a new, expensive cancer therapy might be launched at a high price point in a wealthier nation, which has a large market and strong negotiating power. In contrast, a smaller, less affluent country might face a choice between accepting this prohibitive price, potentially bankrupting its public health system, or delaying patient access for years. PANSOL eliminates this dilemma by ensuring that all participating countries can access the same medicine at a single, collectively negotiated price, thereby promoting health equity across the Union.

To illustrate the potential price effects in concrete (theoretical) terms, consider a novel oncology therapy with a proposed manufacturer list price of €100,000 per patient per year. Without PANSOL, a wealthy country might leverage its significant market size and negotiating power to secure a final net (confidential) price of €60,000. Conversely, a lower-income Member State, with a much smaller market and less leverage, might struggle to negotiate a price below €90,000, and even at that price, it may only be able to provide the therapy to a very limited number of patients, restricting a target population. Under the PANSOL model, the collective bargaining power of all participating countries would be leveraged to secure a far better price, perhaps a single negotiated price of €55,000 for everyone, thereby accounting for effectiveness, medical need, cost-effectiveness and financial impact. This ensures that a patient in a lower-income country receives the same access and pricing benefit as a patient in a higher-income one, demonstrating PANSOL's role in advancing solidarity and equitable healthcare access across the EU. The pharmaceutical industry benefits as well since the negotiated price opens perspectives for a broader market, a quicker uptake and increased use, especially in the lower-income countries.

From an operational perspective, the establishment of consistent HTA requirements, transparent appraisal standards, and centralised price and risk-sharing negotiations moreover translates into significant cost and time efficiencies

for manufacturers. The combination of robust clinical evaluation with EU-level purchasing power enhances the potential for favourable pricing outcomes and predictable reimbursement conditions—factors that are key to incentivising industry investment in areas of high unmet medical need.

In addition to lowering access barriers, PANSOL also offers pharmaceutical companies greater predictability and stability for long-term research and development (R&D) planning. By consolidating reimbursement frameworks and providing clear, harmonised market access criteria, PANSOL allows firms to allocate resources more confidently across development pipelines. This stability supports accelerated development timelines and encourages earlier engagement with academic and biotech partners. In turn, this may stimulate increased investment in high-risk, high-reward areas such as gene therapies and personalised medicine, which often require substantial upfront capital and carry considerable regulatory complexity.

Given the modest commercial impact of existing regulatory incentives under the Pharmaceutical Package [6] – such as supplementary protection certificates and data exclusivity extensions – the European Commission should envisage prioritising the implementation of PANSOL as a more impactful and direct mechanism for advancing pharmaceutical innovation. PANSOL's integrated, pan-European solidarity-based reimbursement framework offers a unified and predictable pathway for market access, significantly improving conditions for pharmaceutical developers while addressing the urgent need for equitable access to novel therapies, particularly in rare diseases and other high-need therapeutic areas. To further support the dual goals of innovation and equitable access, the Commission could complement PANSOL with a Reimbursement Model for Development (RMED, similar to RTR in Poland, *refundacyjny tryb rozwojowy (reimbursement development model*) – a performance-based incentive designed to promote pharmaceutical innovation and localisation within the EU. RMED rewards companies that meet defined thresholds in EU-based R&D, manufacturing, employment, and tax contributions with benefits such as preferential reimbursement, pricing advantages, and EU economic partnership status. Unlike traditional grants or tax relief, RMED offers repeatable and timely incentives, applicable to both innovative and generic medicines. Together, PANSOL and RMED provide a forward-looking strategy to boost competitiveness, strengthen supply chains, and position the EU as a global leader in medicine development and access.

Conclusion

PANSOL offers a compelling and robust framework designed to comprehensively address the persistent pharmaceutical access challenges within the European Union. By integrating a solidarity-based funding model – based on horizon scanning – with a streamlined HTA process, PANSOL promises improved equity, efficiency, and access to innovative medicines, particularly for rare diseases and underserved regions. Its advantages over the JCA framework – including substantially reduced bureaucracy, enhanced market access predictability, and the potential for more cost-effective pricing through collective negotiation along with a single risk sharing scheme – position it as a highly viable and superior alternative. However, political resistance, economic disparities, and implementation complexities pose risks to its adoption. Importantly, PANSOL's processes will need to accommodate the fact that medical need, value and value for money can be context-specific.

Given that the recent US pharmaceutical policy climate is likely to affect European pharmaceutical prices upwards, a solidarity based model seems to be needed more than ever [15].

The aim of this paper was to offer the overall principles of PANSOL, and not yet provide a guide to practical implementation. Future prospects hinge on pilot projects to test PANSOL's practical feasibility, refine its mechanisms, and build stakeholder support. Further research should explore its economic impact, optimal governance structures, and adaptability to diverse healthcare systems. If these hurdles can be navigated successfully, PANSOL has the potential to revolutionise European healthcare, fostering greater solidarity and ensuring equitable access to life-saving treatments across the EU.

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