Applied Health Economics and Health Policy
https://doi.org/10.1007/s40258-026-01054-2

CURRENT OPINION

The Price of National Pharmaceutical Pricing in the EU: A Proposal for "Common Procurement"

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Received: 17 November 2025 / Accepted: 8 June 2026

Abstract

Within the European Union (EU), pricing and reimbursement decisions for new medicines are the responsibility of individual Member States. The presence of many regulated prices for medicines within the EU single market drives strategic decisions by payers and manufacturers, resulting, among other things, in launch delays and unequal patient access across European countries. To increase equity in patient access, we propose strengthening collaboration on medicines procurement among Member States beyond emergency situations. Joint initiatives undertaken by groups of countries have demonstrated their potential to deliver benefits, and the need for common procurement initiatives has become apparent during the coronavirus disease 2019 (COVID-19) pandemic. We present our proposal within the context of the current European regulatory framework and the recently proposed "Critical Medicines Act", emphasising the key legislative provisions that can be invoked to support a common procurement initiative. We also provide relevant, actionable options for designing such initiatives. Strong political commitment and agreement on equity and solidarity principles would be needed for the successful implementation of the proposal.

Key Points for Decision Makers

The responsibility to set the prices of new pharmaceuticals in the European Union (EU) lies with the Member States. This increases the administrative burden on payers and manufacturers and triggers complex strategic responses that often result in delayed or denied patient access in some countries.

Strengthening collaboration among Member States in common procurement may reduce disparities and inefficiencies, increasing equity.

We propose to strengthen common procurement initiatives and explain how our proposal can be implemented within the current and upcoming EU legal framework.

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1 Background

New medicines play a crucial role in reducing mortality and promoting population health. To ensure safety and efficacy, they must undergo in-depth scrutiny by the entities responsible for granting marketing authorisation before reaching patients. In the European Union (EU), new medicines are usually centrally authorised by the European Medicines Agency (EMA). The EMA authorisation allows the product to be marketed throughout the EU. Manufacturers can also seek authorisation through a national route, but the centralised procedure is compulsory for certain areas and types of medicines. On the contrary, pricing and reimbursement decisions are the responsibility of individual Member States (MSs) {[1] Article (Art) 168 (7)}. This contribution aims to discuss the limitations of this allocation of responsibilities and to make a proposal to strengthen coordination in procurement and pricing within the EU legal framework.

Inequality in access to new medicines across the EU is acknowledged as a major policy issue [2]. According to an analysis by the European Federation of Pharmaceutical Industries and Associations (EFPIA) on market access of new products approved by the EMA between 2020 and 2023, as of January 2025, 156 products were included in the outpatient reimbursement list in Germany, but only 31 in Latvia, 28 in Lithuania, and 17 in Malta [3]. Reporting on two extremes within the EU in terms of launch delays, the

Published online: 01 July 2026

average time from EMA approval to national market launch for products receiving a centralised market authorisation in 2011 was virtually null in Sweden, but just under 4 years in Hungary [4].

There are several channels through which the decentralisation of pricing and reimbursement decisions contributes to this undesirable outcome [5, 6]. Firstly, to avoid overpaying for new medicines, most EU countries have adopted "external reference pricing" (ERP), which links domestic prices to those of a set of other countries. In response to the widespread use of this policy, manufacturers can postpone or avoid product launches in lower-price countries to prevent downward price externalities in other markets [7, 8], or they may increase prices in those countries that affect prices in a comparatively large number of other countries via the operation of ERP [9]. This is a key driver of delayed or forgone launches in countries with comparatively small markets, low income [10], or stricter policies [7]. To mitigate spillovers from ERP, manufacturers and payers frequently negotiate confidential discounts, further exacerbating cross-country inequalities, as higher-income countries often secure more favourable discounts [11]. Discounts are typically kept confidential (in Europe, Iceland represents an exception [12]), despite the fundamental right to access public documents [13]. In addition, other elements of the price-setting mechanism are also often confidential [14]. On the one hand, limited transparency constrains public scrutiny of government spending and weakens the accountability of reimbursement and coverage decisions [15], while preventing prescribers from making value-based decisions [11, 16]. On the other hand, confidential prices may result in more favourable net prices to payers and allow companies to implement price discrimination strategies across countries [15]. In recent years, calls for transparency in pharmaceutical prices, industry revenues, public funding of R&D, and the costs of inputs (including R&D and clinical trials) have emerged.[1] However, the (limited) literature on the impact of transparency on prices within countries yields mixed results [17], while the cross-country potential impact of transparency remains unexplored [15].

Disparities in timing and availability are further exacerbated by parallel trade, which also contributes to medicine shortages and increases the risk of falsified pharmaceuticals [18], undermining the European Commission (EC) goal of ensuring equal access to safe pharmaceuticals [19].

Against this background, we believe that enhanced coordination among MSs for the common procurement of new medicines in all areas, even beyond emergency situations, could play an important role.[2] This idea has been discussed within the EU [21] and endorsed by the World Health Organization's (WHO's) European Programme of Work [22, 23]. Likewise, the Draghi report mentions the need for common procurement rules "beyond those in response to cross-border health threats" [4] (p. 201).

We deliberately use the term "common procurement" as an umbrella term, to denote any form of collaboration among MSs (and, eventually, EU institutions) in the procurement of medicines. The term common procurement is also intended to convey the spirit of achieving better results through common efforts. Specific instances of common procurement include "joint procurement", the vertical collaboration between EU institutions and MS; "collaborative procurement", the terminology used in the Critical Medicines Act (CMA) (see Sect. 3.2 below); and the other forms of common procurement that are discussed in Sect. 3.

Section 2 reviews common procurement initiatives worldwide and discusses the role they could play. Section 3 details our proposal and assesses its feasibility within the current EU legal framework. We also consider its feasibility under the upcoming EU law (i.e. the CMA).

2 Common Procurement Initiatives

In many regions of the world, common procurement arrangements have been established to improve access to medicines and enhance equity [24]. Examples of common procurement mechanisms include the Pan American Health Organization fund for vaccine procurement, the Gulf Cooperation Council group purchasing programme, the Global Tuberculosis Drug Facility, and the United Nations Fund for Population Activities [25]. At the European level, voluntary collaborations on procurement and pricing among European governments seeking to enhance affordability include the Beneluxa Initiative, the Nordic Pharmaceutical Forum, and the Baltic Procurement Initiative [26]. Drawing conclusions about the impact of these collaborations that could be extended to other collaborations is difficult, given the still limited number of procurement processes undertaken and the specific characteristics of each collaboration. However, it has been noted that these experiences helped improve access to medicines and vaccines for the countries involved, but also showed some challenges, such as the presence of legal barriers, differences between national frameworks, and the possibility that some manufacturers are reluctant to be involved in joint negotiations [24, 26]. Interest in common procurement initiatives was further stimulated by the coronavirus disease 2019 (COVID-19) pandemic. At the global level, the COVID-19 Vaccines Global Access (COVAX) initiative was established, with the aim of ensuring the procurement of vaccines [27]. In Europe, the procurement of COVID-19

[1] See https://www.who.int/publications/m/item/wha72.8.

[2] The present proposal develops and extends some of the ideas originally included in a report prepared by three of the authors (Gamba, Magazzini, Pertile) for the European Parliament [20]. The opinions expressed in this article are solely those of the authors.

vaccines was, at the time, organised centrally for all MSs [28].

The idea of common procedures for the procurement of medicines is currently gaining recognition in the EU. In the "Pharmaceutical Strategy for Europe" [2], the EC mentions that it will support regional initiatives of "joint negotiation or joint tendering". In May 2024, the EC adopted a Communication on the European Health Union [29], under which the EC "supports cooperation projects to exchange on pricing, payment and procurement policies, in order to improve the affordability and cost-effectiveness of medicines and health system sustainability" and suggests the use of "Joint Procurement" for rare diseases. The European Parliament proposal for a revision of the pharmaceutical regulation includes the possibility of "Joint Procurement" for antimicrobials ([30] Art 39b), thus confirming that this is a feasible policy option. With the main objective to improve the availability, supply, and production of medicines in the EU, in March 2025, the EC proposed the CMA, another Regulation supporting collaborative procurement among MSs [31], which we cover in Sect. 3.

Common procurement can enhance efficiency and the equity of pricing policies through several channels [20, 24, 28]. By relying on a single negotiation process, it would make ERP increasingly less relevant at the European level the larger the number of countries joining the initiative. This would, in turn, reduce the industry's incentive to define a strategic sequence for entering different markets depending on price levels and cross-references between countries. It has been argued that pooling MSs' purchasing power could also contribute to enhanced access by increasing the bargaining power of participating countries relative to a situation where they act independently of one another [11], although evidence on the ability of common procurement to reduce prices is mixed [32]. National regulators/payers could also see a significant reduction in the administrative burden of pricing and reimbursement decisions, for which they would be able to rely on a highly qualified central entity. From a different perspective, the industry could benefit from faster access to a larger consumer base and a reduction in transaction and administrative costs related to national market access procedures [32]. However, these gains may not materialise immediately, as additional organisational costs may arise during the transition to the new system.

Common procurement also presents significant challenges. Critics are concerned that large contracts are awarded to a single supplier or a few large multinational companies, which hinders competition and locks smaller companies out of the public market for a period [28]. This would only be relevant in off-patent markets, however, and may be addressed by negotiating multiple contracts jointly. Moreover, in some cases (e.g. orphan medicines), there is a single manufacturer anyway. The industry may also be reluctant to move away from national negotiations and the flexibility provided by confidential price reductions [33]. A further concern might be that common procurement could reduce incentives to invest in R&D, due to lower average prices. As mentioned above, it is not clear whether an increased size of the procurement authority would lead to lower prices in the context of the pharmaceutical market [32]. Furthermore, negative price effects could be partially or fully offset by positive volume effects associated with extended access.

3 A Proposal for "Common Procurement"

In this section, we outline a proposal for common procurement that could potentially involve all MSs and requires an active role for the EU institutions. Furthermore, it is intended to apply to any pricing and reimbursement decisions for new medicines, including those made outside emergency situations. Our proposal shares some features with the ideas proposed in [21, 33]. However, since the publication of these reports, the legislative framework has substantially changed, and a new EU legal framework is now available to implement common procurement initiatives, as outlined below.

3.1 A Two-Layer System

An ambitious initiative for coordination of pricing could be based on a two-layer system involving the definition of (1) a common price to be paid to the manufacturer by the central entity in charge of the common procurement, and (2) a country-specific contribution meant to finance the total payment to be made to the manufacturer while accounting for differences in the ability to pay of participating countries. The definition of the common price should be transparent and firmly grounded in explicit, evidence-based criteria. Relying on a centralised, highly specialised body could enable a wider and more consistent application of value-based criteria [34] across EU countries. This could also benefit from synergies with the centralisation of the assessment of relative clinical effectiveness and safety of new medicines carried out as part of the coordinated Health Technology Assessment (HTA) efforts under the HTA Regulation [16, 35].

As discussed in more detail below, the definition of the price could be managed by a European Union Authority, to operate in conjunction with a dedicated EU Pharmaceutical Fund. The common price should reflect the net amount the manufacturer receives for each unit sold. However, the price actually paid by each participating country could vary based on its ability to pay, for example, using per-capita gross domestic product (GDP) as a proxy [11]. This would result in differentiated, country-specific contributions that may be higher or lower than the established common price.

The EU Pharmaceutical Fund would serve as a financial intermediary, collecting contributions from MSs and making payments to manufacturers. To ensure the Fund's financial sustainability, the total expected payments to manufacturers must be carefully aligned with the total expected contributions from participating countries.

Combining a common price with country-specific contributions to the Fund would build on the benefits of the former by adding the desirable welfare properties of differential pricing [36].

3.2 Possible Legal Bases

To identify the appropriate legal basis, it is necessary to consider the rules that apply to all medicines and are not specific to emergency situations. The key provision we identify is Article 168 of the Financial Regulation [37], which also clarifies the terminology (and the reason why we opted for common procurement as an umbrella term):

- Its paragraph 1 ("interinstitutional procurement") applies to contracts of interest to EU institutions, such as EU agencies (horizontal, EU level), but not MSs.
- Its paragraph 2 ("joint procurement") applies to contracts of interest to various EU institutions and MSs (vertical).
- Finally, paragraph 3, which can be entitled "procurement procedure on behalf of the MSs", is of interest for our proposal (also horizontal, but at national level).

This last situation applies when some MSs mandate an EU institution "to act as a central purchasing body to procure on behalf of those Member States or in their name".[3]

In addition to the existing rules, it is worth considering the proposed CMA [31], as a legislative procedure still ongoing at the time of writing. The CMA [31] proposes a more structured and centralised approach compared to the Financial Regulation [37] for the procurement of critical medicines and is built upon existing EU rules.[4] The CMA covers only two of the three types of procurement mentioned in the Financial Regulation, namely joint procurement and procurement on behalf of the MSs (Articles 22 and 23 of the CMA). Yet, the CMA introduces a third option related to the General Public Procurement Directive (Article 21 CMA; [38]). These provisions are entitled "collaborative procurements" (see Table 1).

3.3 The Most Appropriate Legal Basis

Among these options, of particular relevance for our proposal is Article 22 of the CMA ("procurement on behalf of or in the name of Member States"), which covers not only critical medicinal products, but also medicinal products of common interest.[5] Its scope is quite broad and is available for nine or more MSs.

According to [31] [Art 22(4)], the EC assesses the content (utility, necessity, proportionality) of the request as well as its coherence with the CMA's objectives. Any request can be feasible if it does not "constitute discrimination or restriction to trade or a distortion to competition" {[31] Art 22(4)} and is in line with the Financial Regulation {[37] Art 168(3)}. The specific aspects of our proposal could be managed as part of the definition of the procurement conditions by the EC {[31] Art 22(6)}. Likewise, the agreement between the MSs and the EC on the "practical arrangements governing the procurement procedure, liabilities to be assumed and the decision-making process" foreseen in the CMA {[31] Art 24(2)} is broad enough to be the basis for the definition of a common price, rooted in explicit, evidence-based criteria and in line with the HTA Regulation. These procurement conditions could and should also reflect general EU values ([39] Art 2) and health values, such as solidarity and equity [19, 40]. To this end, a concrete possibility would be to include the ability to pay (per-capita GDP) among the relevant criteria, as was done in other fields. For example, in the field of migration, the former European scheme for relocation and resettlement included population size and GDP among its criteria [41].

3.4 Institutional Implementation

Coordination among participants in the common procedure would be essential, and there are now different possibilities within the EC. The necessary coordination role may be assigned to the Health Emergency Preparedness and Response Authority (HERA) or another Directorate General (DG). We suggest having an "authority", i.e. an entity

[3] In this case, the request of the MSs determines the mandate of the EU institution, for example, the EC, which is entitled to then analyse "the utility, necessity and proportionality of the request of" the relevant MSs {[37] art. 168(3)(a)}.

[4] That is to say, the more specific CMA is primarily applicable instead of the more general rule (i.e. the Financial Regulation), which normally applies. In other words, the CMA is a special provision in relation to the Financial Regulation.

[5] The proposed CMA defines "critical medicinal product" as "a medicinal product for which insufficient supply results in serious harm or risk of serious harm to patients", and "medicinal product of common interest" as "a medicinal product, other than a critical medicinal product, for which in three or more Member States the functioning of the market does not sufficiently ensure the availability and accessibility to patients in the quantities and presentations necessary to cover the needs of patients in those Member States" (Art 3, para. 4 and 5).

Table 1 Collaborative procurement: Articles 21–23 of the Critical Medicines Act (based on the European Commission proposal; procedure pending as of 13 May 2026)

Aspect	Art 21 Critical Medicines Act	Art 22 Critical Medicines Act	Art 23 Critical Medicines Act	*Not covered in the Critical Medicines Act and not of relevance here*
Legal link to	Art 39 General Public Procurement Directive	Art 168, para. 3 Financial Regulation	Art 168, para. 2 Financial Regulation	*Art 168, para. 1 Financial Regulation*
Denomination	European Commission facilitated Member States' cross-border procurement	European Commission procurement on behalf of or in the name of Member States	Joint procurement	*Interinstitutional procurement*
Procurement in the interest of	Vertical (European Commission and Member States)	Horizontal (Member States)	Vertical (European Commission and Member States)	*Horizontal (EU institutions, etc.)*
Which products	Only for "medicinal products of common interest"	"Critical medicinal products" "Medicinal products of common interest"	"Critical medicinal products" "Medicinal products of common interest"	*Not covered here, as not relevant*
Role of the European Commission	Only facilitator (support and guidance)	Procurer on behalf of Member States	Joint contractor with Member States	
Contractor	National contracts by Member States (therefore, also no European Commission liability)	Centralised procurement	Shared parties European Commission and Member States	
Minimum number of Member States	3	9	9	

EU European Union

within the EC's administrative structure (a DG), rather than a distinct agency, as this would not require an EU regulation. In the case of those medicines that qualify as critical, the "Critical Medicines Coordination Group" ([31] Art 25) could also play this role. Amongst its various tasks, the "coordination of the strategic orientation of financial support for strategic projects" is particularly relevant in the context of our proposal {[31] Art 26(2)(a)}.

On the political ground, common procurement could strengthen the EU's role in ensuring equitable access to high-quality, affordable healthcare and enhance the EU's preparedness for future pandemics [28]. Strong political commitment would be needed, with all stakeholders agreeing on the principles of solidarity, transparency, and sustainability. This should help counter any resistance from high-income countries to paying higher contributions than low-income countries [11, 33] or from larger countries seeking advantages in bilateral negotiations [32].

The advantages of common procurement would increase with the number and stability of participating countries. Therefore, incentives for the sustained commitment of larger MSs should be strong enough, and there should be an appropriate balance between flexibility of participation and stability of the system. MSs should retain the flexibility to opt out of the common initiative—either entirely or on a product-by-product basis—as also allowed under the Joint Procurement Act (JPA) for medical countermeasures. In such cases, pricing and reimbursement decisions would continue to follow national procedures. However, the option to opt out should be available before the start of the process, but not after observing the negotiation outcome. The Financial Regulation allows for the introduction of rules meant to prevent countries from opting out of a single agreement after completing the negotiation process.

Being a breakthrough in the procurement of medicines within the EU, an experimental phase could be planned, limiting centralised procurement to a relevant number of products, to collect evidence on its effects.

3.5 Concluding Remarks

Could the same results be achieved through different reforms? As mentioned above, some existing voluntary initiatives involving cooperation between groups of countries have similar objectives to those of our proposal. However, coordinating this type of initiatives is likely to become more complicated as the number of countries involved increases. Conversely, the benefits of common procurement increase with the number of countries involved. In this sense, coordination at EU level through a specific entity could facilitate the implementation of a large-scale initiative. Another option for mitigating unequal access across countries could

be to abandon, or substantially reduce, reliance on ERP. However, individual countries may lack the incentive to do so unless other countries do the same, which would again call for coordination at a supra-national level.

In summary, having different prices for the same medicine in different EU countries creates several distortions, with negative implications in terms of delayed or missed access for patients, lost profits for the industry, and an increased administrative burden for national payers. In line with the growing consensus on the need to extend common procurement initiatives, we argue that allowing MSs to opt into a system involving a common price and country-specific contributions could be highly beneficial. This model could be implemented within the EU legal framework. However, even within the existing legal framework of the Financial Regulation {[37] Art 168(3)},[6] strong political commitment would be needed, with MSs adhering to the health values of equity and solidarity [19, 40]. From a policy perspective, it might obviously be more difficult to find a compromise in "normal times" than in times of crisis, as was the case during the pandemic. A reasonable implementation strategy would likely involve starting with a specific project as a pilot, then rolling it out more broadly.

Funding Open access funding provided by Università degli Studi di Verona within the CRUI-CARE Agreement.

Declarations

Funding None.

Conflict of Interest All authors declare no competing interests.

Availability of data and material Not applicable.

Ethics approval Not applicable.

Consent to participate Not applicable.

Consent for publication Not applicable.

Code availability Not applicable.

Author contributions All authors contributed equally.

[6] This provision addresses possible opt-ins and opt-outs, as well as rules for the allocations of the quantities between the participating MSs.

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