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# Pharmaceutical Pricing Policies and Price Evolution in European Countries: An Empirical Analysis

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## Abstract

This study investigates the relationship between pharmaceutical pricing policies, generic drug penetration, and consumer purchasing power on price evolution, as measured by the Harmonized Index of Consumer Prices (HICP). Focusing on eleven European countries from 2013 to 2023, the empirical analysis employs a balanced panel data sample. The natural logarithm of the HICP for pharmaceuticals serves as the dependent variable, while independent variables include generic market share (%), binary representations of pricing policies, and the logarithm of per capita GDP in Purchasing Power Standard (PPS).
Using Pooled OLS, Fixed/Random Effects, and Mundlak (Correlated Random Effects) models, the results reveal significant correlations. Specifically, Internal Reference Pricing (IRP) and Value-Based Pricing (VBP) show a strong negative correlation with drug prices, highlighting their effectiveness in cost containment. Conversely, External Reference Pricing (ERP) demonstrates a positive correlation, suggesting price convergence toward higher levels within the selected sample. Consumer purchasing power exhibits a dual impact; while within-country GDP growth correlates with higher prices, wealthier countries often maintain lower overall price levels through robust negotiation mechanisms. Notably, generic penetration alone did not significantly influence nominal price levels in this sample. Overall, the findings underscore the complexity of pharmaceutical price dynamics, which are shaped by a multifaceted interplay of regulatory mechanisms and macroeconomic conditions.

**JEL classification:** I11, I18, L65, C23.
**Keywords:** Pricing policies, Generic drug penetration, Purchasing power, Drug prices, Fixed Effects, Random Effects, Mundlak.

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# 1. Introduction

The determination of pharmaceutical prices in European countries has emerged as one of the most demanding and controversial policy and economic challenges of the 21st century. Unlike standard consumer goods, pharmaceuticals follow complex pricing rules, often involving the financial participation of national public health insurance systems. Each country establishes its own priorities regarding pharmaceutical pricing; some focus on rapid acquisition and equal access to new medicines, while others prioritize the reduction of pharmaceutical expenditures (Panteli et al., 2016).

The pharmaceutical distribution chain involves various points of price differentiation, from initial pricing by manufacturers to the setting of margins for pharmacists. Regulations vary significantly across the European Union (EU). For instance, hospitals often engage in direct negotiations and agreements with pharmaceutical companies to manage costs for inpatient care. Conversely, outpatient pharmaceutical prices are subject to much stricter administrative and legal approval processes in most EU member states (Panteli et al., 2016). Establishing fair institutional regulations is essential to prevent inequalities among EU countries and ensure that all citizens, regardless of income, have access to innovative and necessary treatments (Nemeth et al., 2022).

To manage these challenges, several pricing policies have been established. External Reference Pricing (ERP), which compares the price of identical drugs across selected countries, is perhaps the most popular mechanism (Kanavos et al., 2020). Internal Reference Pricing (IRP) is also widely used, setting a maximum reimbursement limit for groups of medicines with common therapeutic goals, primarily for off-patent drugs (Brekke et al., 2022). Value-Based Pricing (VBP) determines prices based on the clinical benefits offered to patients, such as Quality-Adjusted Life Years (QALYs) (Jommi et al., 2020). For highcost innovations, particularly in oncology, Managed Entry Agreements (MEAs) facilitate access by linking reimbursement to clinical performance or budget limits (Dabbous et al., 2020). Additionally, tendering processes allow large hospitals or national bodies to select the most competitive offers from manufacturers (Garattini et al., 2022; Petrou, 2016). While Cost-Plus Pricing was historically significant, it is now rarely used in developed EU states (Duncan et al., 2025). Beyond these policies, factors such as generic drug penetration and consumer purchasing power also significantly influence price levels (Zaprutko et al., 2017; Dylst and Simoens, 2011).

The motivation for this research stems from the fact that pharmaceutical markets do not follow standard supply and demand rules; instead, they are shaped by institutional mechanisms that vary by country. Despite the importance of these mechanisms, a large part of the existing literature remains descriptive or limited to a small number of countries (Panteli et al., 2016; Garattini et al., 2022; Dabbous et al., 2020). There is a clear need for an empirical framework that quantifies how these regulatory tools impact actual price dynamics across a broader European context using harmonized macroeconomic indicators.

This paper contributes to the academic and policy discourse by analyzing the interplay between pricing mechanisms, generic penetration, and purchasing power using a balanced panel of eleven European countries. By utilizing the Harmonised Index of Consumer Prices (HICP) for pharmaceutical products from Eurostat, this study bridges the gap between macroeconomic price data and specific health policy interventions. Furthermore, the findings offer strategic value for pharmaceutical executives in market access and pricing strategy, providing a clearer understanding of how regulatory environments affect price evolution over time.

The remainder of this paper is organized as follows. Section 2 provides a detailed literature review of pharmaceutical pricing policies and their determinants. Section 3 describes the methodology, data sources, and the econometric model. Section 4 presents the empirical results of the analysis. Section 5 offers a discussion of these findings in the context of current health policy. Finally, Section 6 concludes with policy implications and suggestions for future research.

# 2. Literature Review

The determination of pharmaceutical prices in Europe is a multifaceted process governed by a diverse array of regulatory and economic mechanisms. This section reviews the existing international literature regarding pricing policies, the impact of generic penetration, and the role of national purchasing power in shaping price dynamics across European markets. The literature highlights a complex interplay between health policy objectives, such as cost containment and patient access, and the economic incentives of pharmaceutical manufacturers.

## 2.1 External Reference Pricing (ERP)

External Reference Pricing (ERP), or international reference pricing, is one of the most widely adopted tools for regulating the prices of innovative, on-patent medicines. As these products often enjoy monopoly power due to patent protection, ERP serves as a benchmark to ensure that national prices remain within objective limits. The mechanism involves setting a drug's price based on its price in a "basket" of reference countries. For instance, Greece historically uses the average of the three lowest prices in the European Union (EU) for original products (Fontrier et al., 2019).

The effectiveness of ERP depends on several criteria, including the selection of reference countries, the calculation method (e.g., lowest price vs. average), the frequency of price updates, and adjustments for exchange rate fluctuations (Fontrier et al., 2019). However, ERP presents significant challenges. A major concern is the "spillover effect," where a price reduction in one reference country triggers a chain reaction of price cuts across other markets. This leads pharmaceutical companies to strategically delay or entirely avoid launching products in low-price markets to protect their global revenue (Remuzat et al., 2015). Furthermore, while ERP aims for price harmonization, significant variations persist; German prices have been found to be 27% higher than the European average, while Greek prices remained 32% lower, influenced by GDP and direct negotiations (Fontrier et al., 2019). Research suggests that broader reference baskets and the use of the "minimum price rule" lead to stronger price convergence (Gill et al., 2019; Toumi et al., 2013).

## 2.2 Internal Reference Pricing (IRP)

Unlike ERP, Internal Reference Pricing (IRP) focuses on domestic competition by setting a maximum reimbursement limit for groups of therapeutically equivalent drugs. This policy is primarily applied to off-patent drugs where bioequivalent generics are available. The goal is to stimulate competition and reduce public expenditure. If a patient chooses a more expensive brand-name drug over the reference price, they must pay the difference out-of-pocket (Brekke et al., 2022).

Empirical evidence shows that IRP can significantly drive down prices. In Norway, the "Step Pricing" reform in 2005 resulted in a 57% reduction in generic prices and a 24% reduction for original drugs (Brekke et al., 2022). Nevertheless, IRP can lead to market exits or launch delays in smaller markets where prices are forced to unsustainable levels (Nemeth et al., 2022). Furthermore, market dynamics can sometimes produce counterintuitive results. In Portugal, research demonstrated that when reference prices for certain therapeutic categories were lowered, the prices of some branded drugs actually increased due to inelastic demand and weak competition, shifting the financial burden to patients while saving costs for the state (Costa and Santos, 2022).

## 2.3 Value-Based Pricing (VBP)

Value-Based Pricing (VBP) represents a shift from cost-based or reference-based pricing toward a model where prices are determined by the clinical benefit offered to patients. This includes metrics such as effectiveness, safety, and Quality-Adjusted Life Years (QALYs). The primary advantage of VBP is the alignment of price with actual therapeutic value, which incentivizes meaningful innovation (Jommi et al., 2020).

The implementation of VBP has enhanced the role of Health Technology Assessment (HTA) agencies, fostering transparency in disease management and resource allocation (Prieto-Pinto et al., 2020). However,

the definition of "value" remains subjective and varies across countries. In the United Kingdom, VBP is often linked to strict costeffectiveness thresholds, whereas in Germany and France, it is more indirect, influenced by population size and budget impact (Jommi et al., 2020). Critics argue that VBP allows manufacturers to set launch prices at the maximum threshold of cost-effectiveness, potentially straining healthcare budgets (Manders et al., 2025).

### 2.4 Managed Entry Agreements (MEAs)

Managed Entry Agreements (MEAs) are specialized contracts between payers and manufacturers designed to manage the uncertainty and high costs of innovative therapies, particularly in oncology. These agreements are categorized into Finance-Based Agreements (FBA) and Performance-Based Agreements (PBA). FBAs typically involve discounts, price-volume contracts, or expenditure caps, and are popular in France and the UK due to their administrative simplicity (Dabbous et al., 2020; Panteli et al., 2016).

PBAs link reimbursement to real-world clinical outcomes. While theoretically sound, PBAs face implementation hurdles, including high administrative costs and the need for robust clinical registries. In Italy, PBAs have been criticized for their complexity and the extensive human resources required to manage patient data (Dabbous et al., 2020). Evidence from Sweden further indicates that risk-sharing arrangements can support access to innovative treatments, although their effectiveness depends on agreement design, monitoring requirements, and the availability of real-world evidence (Andersson et al., 2020). A significant concern with MEAs is the lack of transparency, as confidential discounts in wealthier nations may disadvantage economically weaker countries that cannot negotiate similar terms (Dabbous et al., 2020; Panteli et al., 2016). Additionally, the lack of sufficient real-world evidence often complicates the evaluation of these agreements (Ardito et al., 2025).

### 2.5 Tendering and Cost-Plus Pricing

Tendering is a competitive bidding process used predominantly for hospital medicines and off-patent generics. Manufacturers submit bids, and the most competitive offer is selected, often resulting in significant savings for public health systems (Jalagam and Muddukrishna, 2021). While effective for cost reduction, "winner-takes-all" tenders can lead to market monopolies, the exit of suppliers, and drug shortages. Therefore, tendering must be supported by clear legal frameworks to ensure continuous supply (Vogler et al., 2017).

Cost-Plus Pricing (CPP), which sets prices based on production, R&D, and marketing costs plus a fixed profit margin, is largely obsolete in developed EU states. It is criticized for failing to account for therapeutic value and providing no incentive for innovation. The World Health Organization (WHO) generally advises against using CPP as a primary pricing mechanism (Manders et al., 2025).

### 2.6 Macroeconomic Factors: Purchasing Power and GDP

National economic conditions are critical determinants of pharmaceutical price levels. Research indicates that low GDP per capita is directly linked to limited economic access to medicines. In countries like Bulgaria, where incomes are significantly below the EU average, drug prices are sometimes comparable to or even higher than those in wealthier nations, creating a significant "affordability gap" (Zaprutko et al., 2017).

Conversely, an increase in GDP per capita often correlates with higher public pharmaceutical spending. Studies have shown that a 1% increase in GDP per capita can lead to a more than 1% increase in government pharmaceutical expenditure, as wealthier nations tend to prioritize access to newer, high-cost treatments (Shaikh and Gandjour, 2019). This highlights a structural issue in European pricing where institutional policies may not sufficiently account for macroeconomic imbalances between member states.

### 2.7 The Impact of Generic Penetration

Generic penetration is a vital factor in controlling pharmaceutical costs. High market shares for generics are generally associated with lower overall price levels, with some studies indicating price reductions of up to 43% in countries with robust generic competition (Dylst and Simoens, 2011).

However, this relationship is not always linear. In Denmark and Germany, high generic penetration did not always lead to expected price dropsa phenomenon known as the "generics paradox" (Kanavos, 2014). Competition is most effective when multiple producers enter the market; for example, in Sweden, the entry of an additional generic competitor was found to reduce original drug prices by 4-7% (Dylst and Simoens, 2011). Successful generic policies require not only price regulation but also incentives and education for physicians, pharmacists, and patients (Dylst and Simoens, 2011).

### 2.8 Synthesis and Research Gap

While the literature extensively describes individual pricing policies and their theoretical impacts, most studies are either descriptive or limited to a small selection of countries (Panteli et al., 2016; Garattini et al., 2022; Dabbous et al., 2020). More broadly, recent applied economics research has emphasized the importance of institutional arrangements, public policies, and macroeconomic conditions in shaping economic outcomes across sectors, including healthcare (Diarrassouba et al., 2025; Lee et al., 2026). Likewise, evidence from studies on inflation dynamics, economic growth, and policy effectiveness demonstrates the value of quantitative econometric approaches for evaluating the effects of regulatory interventions (Khinsamone et al., 2025; Bragoudakis and Krompas, 2025; Coulibaly et al., 2025). Nevertheless, there remains a notable absence of comparative empirical research that quantifies how different pharmaceutical pricing mechanisms interact with generic market penetration and purchasing power to influence pharmaceutical price evolution across a broader European context. This paper aims to fill this gap by providing an econometric analysis of the interplay between these regulatory tools and macroeconomic indicators.

## 3. Data and Methodology

This section details the methodological framework and the analytical approach adopted to investigate the relationship between pharmaceutical price dynamics and their primary determinants. The empirical analysis focuses on the interaction between national pricing policies, generic drug market penetration, and consumer purchasing power across a selection of European countries (Eurostat, 2024; OECD, 2024). By employing a quantitative research design based on balanced panel data from 2013 to 2023, the study aims to quantify how institutional mechanisms and macroeconomic conditions shape price evolution over time (Mundlak, 1978). The following subsections outline the research design, data sources, variable definitions, and the econometric specifications used to provide robust empirical evidence.

### 3.1 Empirical Framework and Sample Selection

The primary objective of this research is to empirically investigate the relationship between pharmaceutical price evolution and three key dimensions: national pricing policies, generic drug market penetration, and consumer purchasing power. The study utilizes secondary data at the national level, drawing upon theoretical insights from health economics to quantify how institutional mechanisms and macroeconomic conditions shape price dynamics (Eurostat, 2024).

The analysis focuses on the period from 2013 to 2023. This timeframe was selected to ensure the availability of updated, comparable data across all variables, particularly regarding generic market shares and specific pricing policy implementations (OECD, 2024). By examining this decade, the study captures the modern regulatory landscape of European pharmaceutical markets, characterized by increasing cost-containment pressures and the rising importance of innovative therapies.

This study employs a non-experimental, quantitative research design. Given that pharmaceutical pricing policies are determined at the national level and are not subject to manipulation by the researcher, an observational model is appropriate (Panteli et al., 2016). The methodology is designed to analyze price variations resulting from heterogeneous regulatory and political frameworks across different states.

The sample consists of a balanced panel of eleven European countries: Belgium, Czechia, Estonia, Finland, Italy, Latvia, Portugal, Slovakia, Sweden, and notably, Norway and Switzerland. Although the latter two are not European Union (EU) members, they possess advanced healthcare systems and pricing regulations

that are largely consistent with EU standards, thereby enhancing the cross-country variance of the study (Remuzat et al., 2015). The panel data structure allows for the observation of price fluctuations both between different countries and within the same country over time (Mundlak, 1978).

The empirical analysis relies on three primary internationally recognized statistical sources. Pharmaceutical price dynamics are captured using the natural logarithm of the Harmonised Index of Consumer Prices (HICP) for pharmaceutical products, sourced from Eurostat, which provides a harmonized measure of consumer price evolution reflecting the retail prices faced by patients (Eurostat, 2024). Data regarding the market share of generic drugs, expressed as a percentage of total pharmaceutical consumption volume, are obtained from the Organisation for Economic Co-operation and Development (OECD) and serve as a proxy for the level of competition within national off-patent markets (OECD, 2024; Dylst and Simoens, 2011). Finally, to account for macroeconomic heterogeneity, GDP per capita in Purchasing Power Standard (PPS) is utilized, also sourced from Eurostat, to control for the economic development and actual purchasing power of consumers across the sampled nations (Zaprutko et al., 2017).

The variables are defined at the country-year level to maintain consistency with the panel structure. The dependent variable is the natural logarithm of the pharmaceutical HICP, denoted as ln(HICP drug ). Because the raw Eurostat data is provided at a monthly frequency, an annual index was constructed for each country by calculating the simple arithmetic mean of the twelve monthly observations for each year. The logarithmic transformation is applied to reduce distribution asymmetry and to allow for the interpretation of coefficients as elasticities (Eurostat, 2024).

The core explanatory variables consist of five major pricing policies, represented as binary (dummy) variables, where a value of 1 is assigned if a policy is active in a given country during a specific year and 0 otherwise. These policies include External Reference Pricing (ERP), which benchmarks prices against a basket of other countries (Kanavos et al., 2020), and Internal Reference Pricing (IRP), which involves setting reimbursement limits based on therapeutically equivalent domestic products (Brekke et al., 2022). Furthermore, the model incorporates Value-Based Pricing (VBP) to link prices to clinical benefits and QALYs (Jommi et al., 2020), Managed Entry Agreements (MEAs) as specific contracts between payers and manufacturers (Dabbous et al., 2020), and Tendering (Tender), involving competitive bidding processes for drug supply (Garattini et al., 2022).

**Table 1: Definition and Measurement of Pharmaceutical Pricing Policies**

| Policy | Operational definition | Relevant dimensions not captured by the indicator |
|---|---|---|
| ERP | Domestic prices are set or revised using prices observed in a basket of foreign countries. | Composition of reference basket, calculation rule, revision frequency, exchange-rate adjustments, and treatment of discounts. |
| IRP | A common reimbursement ceiling is applied to groups of identical or therapeutically comparable medicines. | Definition of reference groups, reimbursement ceilings, patient co-payments, and substitution rules. |
| VBP | Pricing or reimbursement explicitly considers clinical benefit, therapeutic value, or cost-effectiveness. | Cost-effectiveness thresholds, assessment procedures, budget-impact criteria, and institutional coverage. |
| Tendering | Public authorities or healthcare institutions systematically use competitive bidding for medicine procurement. | Hospital or outpatient coverage, award criteria, contract duration, number of suppliers, and procurement volume. |
| MEA | Payers and manufacturers use formal financial- or outcome-based agreements to manage cost or clinical uncertainty. | Agreement design, product coverage, expenditure caps, confidential rebates, and outcome measurement. |

**Notes:** Each policy variable equals one when formally implemented and operational in a country-year, and zero otherwise. The indicators measure policy presence rather than implementation intensity. Detailed country-level coding and sources are reported in Appendix Table 5.

The indicators capture the formal presence of each policy but not differences in policy design or implementation intensity. For example, ERP systems may differ in their reference-country baskets, price-calculation formulas, revision frequency, and treatment of confidential discounts. Similarly, IRP systems vary in how therapeutic groups and reimbursement ceilings are defined, while VBP, Tendering, and MEAs differ in scope, institutional coverage, and enforcement. Consequently, the estimated coefficients measure average conditional differences between countries with and without the relevant policy classification and should not be interpreted as the effects of a standardized or equally intensive intervention.

In addition to these regulatory mechanisms, the model includes control variables to account for macroeconomic heterogeneity and market dynamics. GDP per capita in Purchasing Power Standard (PPS) is included as ln(GDP pc) to capture the "ability-to-pay" effect and national income levels (Shaikh and Gandjour, 2019). Finally, Generic Penetration (GEN) is measured as a continuous percentage to assess the impact of competition on nominal price levels (Dylst and Simoens, 2011).

### 3.2 Econometric Specification

The study aims to quantify the impact of the aforementioned factors on drug prices. The general functional relationship is defined as:

$$Price\_drug_{it} = f(gen_{it}, gdppc_{it}, erp_{it}, irp_{it}, vbp_{it}, tender_{it}, mea_{it}) \quad (1)$$

The empirical relationship is estimated using the following linear regression model:

$$ln(HICPdrug)_{it} = \beta_0 \& + \beta_1 gen_{it} + \beta_2\, ln(gdppc)_{it} + \beta_3 erp_{it} + \beta_4 irp_{it} + \beta_5 vbp_{it} + \beta_6 tender_{it} + \beta_7 mea_{it} + \varepsilon_{it} \quad (2)$$

Where:

- $i$ represents the country and *t* represents the year.
- $\beta_0$ is the intercept.
- $\beta_1$ to $\beta_7$ are the coefficients to be estimated.
- $\varepsilon_{it}$ is the error term, representing unobservable factors such as national health service operational frameworks or varying consumer habits (Mundlak, 1978).

The analysis initially considers Pooled OLS, Fixed Effects (FE), and Random Effects (RE) models. However, institutional policies (ERP, IRP, etc.) often exhibit low temporal variability within countries (time-invariance). While the Hausman test typically guides the choice between FE and RE, the FE model is unable to estimate these time-invariant dummy variables as they are dropped during the transformation process (Mundlak, 1978).

To overcome this, the study adopts the Mundlak (Correlated Random Effects) approach. This method allows for the estimation of time-invariant variables while controlling for the correlation between explanatory variables and unobserved country-specific effects. The Mundlak model decomposes the influence of variables into "within-country" effects (temporal changes) and "between-country" effects (structural differences) by including the mean values of time-varying variables ( M EAN_GEN and M EAN_LN GDP) as additional regressors (Mundlak, 1978).

The identification of the Mundlak Correlated Random Effects (CRE) model relies on different sources of variation for the time-varying and time-invariant regressors. For the time-varying variables, namely generic penetration and GDP per capita, the model includes their country-specific means and therefore allows the unobserved country effect to be correlated with the observed history of these regressors. Conditional on the Mundlak projection and the remaining covariates, the coefficients on the time-varying variables are identified from changes within each country over time and correspond to the withincountry estimates obtained from a Fixed Effects specification. The coefficients on the country means capture the difference

between the within-country and between-country relationships; consequently, the overall between-country association is obtained by combining the coefficient on the time-varying regressor with the coefficient on its country mean.

The identification of the pricing-policy coefficients is more limited. Because the policy indicators exhibit little or no variation within countries over the sample period, their coefficients are identified primarily from cross-country differences in policy regimes. Their interpretation therefore requires the additional assumption that, conditional on the observed regressors and the Mundlak controls, the policy indicators are uncorrelated with remaining unobserved country characteristics that also determine pharmaceutical prices. This assumption may be restrictive because policy adoption can respond to pre-existing price pressures, healthcare-system characteristics, or fiscal conditions. Accordingly, the reported policy coefficients should be interpreted as conditional cross-country associations rather than as causal policy effects. The CRE approach addresses correlation between the time-varying regressors and unobserved country heterogeneity, but it does not eliminate reverse causality, omitted-variable bias, or policy-selection endogeneity.

Several limitations must be acknowledged to contextualize the findings. First, data availability regarding generic market shares restricted the sample to eleven countries, which may limit the generalizability of the results to the entire European continent (OECD, 2024). Second, the HICP reflects retail prices and does not account for confidential rebates, manufacturer-level pricing, or hospital-specific discounts often found in MEAs or tendering processes (Eurostat, 2024; Dabbous et al., 2020).

Furthermore, the use of binary variables for pricing policies, while facilitating crosscountry comparison, does not capture the "intensity" or specific nuances of how these policies are implemented (e.g., the frequency of price updates in ERP or the specific reference groups in IRP). Finally, for a small percentage of generic penetration data (less than 3%), the Last Observation Carried Forward (LOCF) method was used to maintain a balanced panel, which assumes stability in market shares for those specific instances (OECD, 2024).

## 4. Empirical Results

This section presents the results of the econometric analysis concerning the relationship between pharmaceutical pricing policies, generic drug penetration, and GDP per capita on drug price evolution. The study utilizes a balanced panel of eleven European countries over the period 2013-2023, totaling 121 observations (Eurostat, 2024; OECD, 2024). The analysis follows a systematic approach, starting with descriptive statistics and proceeding through multiple panel specifications to identify the most robust correlations (Beck and Katz, 1995).

The descriptive statistics provide an initial overview of the dataset's characteristics and the variance within the selected variables. Table 2 summarizes the central tendencies and dispersion for the dependent variable, ln(HICPdrugs), and the primary independent and control variables. The pharmaceutical price index, expressed as ln(HICPdrugs), shows a mean of 4.63 with relatively low dispersion (Eurostat, 2024). In contrast, generic penetration exhibits significant heterogeneity, ranging from 16.5% to 77%, reflecting diverse national strategies toward off-patent competition (OECD, 2024). Regarding pricing policies, External Reference Pricing (ERP) is the most pervasive mechanism (90.91%), followed by Tendering (81.82%) and Managed Entry Agreements (72.73%). Conversely, Value-Based Pricing (VBP) is the least common, appearing in only 18.18% of the country-year observations (Kanavos et al., 2020; Jommi et al., 2020).

**Table 2: Descriptive Statistics of Main Variables (2013-2023)**

| Variable | Obs. | Mean | Std. Dev. | Min. | Max. |
|---|---|---|---|---|---|
| ln(HICPdrugs) | 121 | 4.63 | 0.07 | 4.46 | 4.86 |
| Generics (%) | 121 | 45.43 | 16.75 | 16.50 | 77.00 |
| GDP per capita (PPS) | 121 | 105.40 | 33.27 | 60.00 | 214.00 |
| ln(GDP per capita) | 121 | 4.61 | 0.30 | 4.09 | 5.37 |
| ERP (Dummy) | 121 | 0.91 | 0.29 | 0 | 1 |
| IRP (Dummy) | 121 | 0.64 | 0.48 | 0 | 1 |
| VBP (Dummy) | 121 | 0.18 | 0.39 | 0 | 1 |
| Tendering (Dummy) | 121 | 0.82 | 0.39 | 0 | 1 |
| MEA (Dummy) | 121 | 0.73 | 0.45 | 0 | 1 |

**Table 3. Comparison of Panel Specification Results (Dependent Variable: ln(HICPdrugs))**

| Variables | Pooled OLS | Fixed Effects | Random Effects |
|---|---|---|---|
| Constant (C) | 4.5343***<br>(0.1076) | 3.2242***<br>(0.6406) | 4.5343***<br>(0.1076) |
| GEN | 0.0034***<br>(0.0010) | -0.0003<br>(0.0017) | 0.0034***<br>(0.0010) |
| LNGDP | -0.0276<br>(0.0323) | 0.3079**<br>(0.1307) | -0.0276<br>(0.0323) |
| ERP | 0.0452***<br>(0.0169) | - | 0.0452***<br>(0.0169) |
| IRP | -0.0623**<br>(0.0252) | - | -0.0623**<br>(0.0252) |
| VBP | -0.0450***<br>(0.0138) | - | -0.0450***<br>(0.0138) |
| TENDER | 0.0649***<br>(0.0239) | - | 0.0649***<br>(0.0239) |
| MEA | 0.0347***<br>(0.0111) | - | 0.0347***<br>(0.0111) |
| $R^2$ | 0.3878 | 0.4602 | 0.3878 |
| Hausman test (p-value) | | 40.1438***<br>(0.0000) | |

**Notes:** ***, ** and * denote significance at the 1%, 5% and 10% levels. Values in parentheses below the coefficients represent the standard errors of the estimators. The results of the Random Effects model coincide with the Pooled OLS because the estimated random effects variance was found to be zero. Institutional variables (ERP, IRP, etc.) do not appear in the Fixed Effects model as they are time-invariant for the sample and are automatically excluded from the process. The Hausman test rejects the null hypothesis, indicating that the Fixed Effects model is the most appropriate for studying GEN and LNGDP.

The model was estimated using Pooled OLS, Fixed Effects (FE), and Random Effects (RE) specifications (see Table 3). To ensure reliability, standard errors were corrected for contemporaneous correlation and cross-sectional heteroskedasticity using Panel Corrected Standard Errors (PCSE) with Seemingly Unrelated Regressions (SUR) (Beck and Katz, 1995).

The Hausman test (p=0.0000) strongly rejects the null hypothesis, indicating that the Fixed Effects model is the most appropriate for interpreting time-varying variables like Generic Penetration (GEN) and GDP per capita (Mundlak, 1978). Under FE, ln(GDPpc) shows a positive and significant impact (0.3079), suggesting that domestic income growth correlates with price index increases, potentially due to higher uptake of newer treatments (Shaikh and Gandjour, 2019). However, institutional policies (ERP, IRP, etc.)

are omitted in the FE model because they are time-invariant within this sample, necessitating an alternative approach (Mundlak, 1978).

To estimate the effects of time-invariant pricing policies while maintaining the consistency of Fixed Effects, the Mundlak (CRE) model was employed. This model decomposes the effects of GEN and ln(GDPpc) into "Within" effects (temporal changes within countries) and "Between" effects (structural differences between countries) as Table 4 presents.

**Table 4: Mundlak Regression Results (Dependent Variable: ln(HICPdrugs))**

| Variables | Coefficient | Std. Error | p-value |
|---|---|---|---|
| Constant | 4.6355*** | 0.0850 | 0.0000 |
| GEN (Within) | -0.0003 | 0.0017 | 0.8686 |
| ln(GDPpc) (Within) | 0.3079** | 0.1291 | 0.0188 |
| MEAN_GEN (Contextual) | 0.0037* | 0.0019 | 0.0590 |
| MEAN_lnGDP (Contextual) | -0.3563*** | 0.1316 | 0.0079 |
| GEN (Between) | 0.0034*** | 0.0009 | 0.0001 |
| ln(GDPpc) (Between) | -0.0484** | 0.0245 | 0.0487 |
| ERP | 0.0425** | 0.0204 | 0.0393 |
| IRP | -0.0711** | 0.0274 | 0.0109 |
| VBP | -0.0501*** | 0.0125 | 0.0001 |
| Tendering | 0.0673*** | 0.0204 | 0.0013 |
| MEA | 0.0340** | 0.0147 | 0.0224 |
| $R^2$ | 0.4567 | | |
| Wald test (p-value) | 7.655*** | | 0.0008 |

**Notes:** The reported between-country coefficients are calculated as the sum of the coefficient on the time-varying regressor and the coefficient on its country-specific mean.. ***, ** and * denote significance at the 1%, 5% and 10% levels respectively.

The Wald test jointly rejects the null hypothesis that the coefficients on the country means of generic penetration and GDP per capita are equal to zero ( $F(2, 111) = 7.6554$, $p = 0.0008$). This result indicates that the Mundlak terms are jointly significant and supports the Correlated Random Effects specification over the conventional Random Effects model. In particular, it provides evidence that the observed time-varying regressors are correlated with unobserved country-specific heterogeneity.

The estimates reveal distinct within-country and between-country relationships between purchasing power and pharmaceutical prices. The coefficient on ln(GDPpc) is positive and statistically significant (0.3079, $p = 0.0188$), indicating that a 1% increase in GDP per capita within a country is associated with an approximately 0.308% increase in its pharmaceutical HICP, conditional on the other regressors. The coefficient on mean ln(GDPpc) is negative and statistically significant (-0.3563, $p = 0.0079$); however, this coefficient represents the difference between the between-country and within-country relationships rather than the between-country effect itself. Combining the two coefficients yields an estimated between-country association of:

$$0.3079 - 0.3563 = -0.0484$$

Thus, GDP growth within countries is positively associated with pharmaceutical prices, whereas countries with higher average purchasing power tend to exhibit slightly lower pharmaceutical price levels. The statistical significance of the latter association is evaluated using a separate linear-combination Wald test ($p = 0.0487$). This pattern may reflect, among other factors, the stronger bargaining capacity and more developed regulatory and negotiation frameworks of wealthier countries (Shaikh and Gandjour, 2019; Zaprutko et al., 2017).

The coefficients on the pharmaceutical pricing policies indicate statistically significant conditional cross-country associations with pharmaceutical prices. Internal Reference Pricing (IRP) and Value-Based Pricing

(VBP) are negatively associated with pharmaceutical HICP, with estimated coefficients of -0.0711 ($p = 0.0109$) and -0.0501 ($p < 0.001$), respectively. These results are consistent with the view that reimbursement limits based on therapeutic equivalence and pricing based on clinical value may contribute to pharmaceutical price containment (Brekke et al., 2022; Jommi et al., 2020). Conversely, External Reference Pricing (ERP) is positively associated with pharmaceutical HICP (0.0425, $p = 0.0393$), which is consistent with the possibility that reference baskets containing relatively high-priced countries may contribute to upward price convergence (Fontrier et al., 2019). Tendering and Managed Entry Agreements are also positively associated with the pharmaceutical price index, with coefficients of 0.0673 ($p = 0.0013$) and 0.0340 ($p = 0 .0224$), respectively. These positive associations may reflect the selective application of these instruments to expensive or innovative medicines, although the HICP does not capture confidential rebates or hospital-specific discounts commonly associated with such arrangements (Dabbous et al., 2020; Garattini et al., 2022).

Generic penetration does not display a statistically significant within-country association with pharmaceutical HICP (-0.0003, $p = 0.8686$). This suggests that increases in the generic market share alone are not systematically associated with reductions in the pharmaceutical price index within the countries considered. Overall, the results indicate that pharmaceutical price evolution is associated with a complex combination of macroeconomic conditions and regulatory arrangements rather than with a single determinant. Nevertheless, because the policy indicators exhibit little or no variation within countries over the sample period, their coefficients are identified primarily from differences across the eleven countries. They should therefore be interpreted as conditional cross-country associations rather than as causal effects or definitive evidence of policy effectiveness. The Mundlak specification helps distinguish within-country relationships from contextual cross-country differences, but it does not eliminate possible policy-selection endogeneity, reverse causality, or bias arising from omitted institutional characteristics.

# 5. Discussion of the Empirical Results

This section evaluates the empirical findings of the study, focusing primarily on the Mundlak Correlated Random Effects (CRE) specification. The Mundlak augmentation is useful in the present application because it distinguishes the within-country relationships of the time-varying regressors from the contextual differences associated with their countryspecific means. It also permits the inclusion of pharmaceutical pricing-policy indicators that exhibit little or no variation within countries during the sample period. Nevertheless, the estimated variance of the cross-sectional random effect is zero. Consequently, the fitted CRE model is numerically equivalent to a pooled specification augmented with the country means of the time-varying regressors. Moreover, because the policy indicators are identified primarily from differences across countries, their coefficients should be interpreted as conditional cross-country associations rather than as causal policy effects.

Internal Reference Pricing (IRP) is negatively and statistically significantly associated with pharmaceutical price levels. Its estimated coefficient is -0.0711 and is statistically significant at the 5% level ($p = 0.0109$). Because IRP is represented by a binary variable and the dependent variable is expressed in logarithms, the exact percentage association is calculated as $100[\exp(-0.0711) - 1]$, corresponding to approximately 6.9% lower pharmaceutical HICP levels in countries applying IRP, conditional on the other included variables. This finding is consistent with the economic argument that a common reimbursement limit for therapeutically equivalent products can promote price competition (Brekke et al., 2022). However, because IRP exhibits little or no within-country variation during the sample period, the estimate should not be interpreted as the causal effect of introducing the policy.

Value-Based Pricing (VBP) is also negatively and statistically significantly associated with pharmaceutical price levels. Its estimated coefficient is -0.0501 and is statistically significant at the 1% level ($p = 0 .0001$). The exact transformation of the coefficient indicates that countries applying VBP have pharmaceutical HICP levels that are approximately 4.9% lower, other factors held constant. This result is consistent with the proposition that linking reimbursement to clinical benefits and cost-effectiveness may constrain prices that cannot be justified by corresponding therapeutic outcomes (Jommi et al., 2020; Prieto-Pinto et al.,

2020). Nevertheless, as with IRP, this estimate represents a conditional cross-country association and does not establish that adopting VBP causes pharmaceutical prices to decline.

An important result concerns the different within-country and between-country relationships between purchasing power and pharmaceutical prices. The coefficient on the logarithm of GDP per capita is positive and statistically significant at the 5% level ( $\hat{\beta} = 0.3079, p = 0.0188$). As both the dependent variable and GDP per capita are expressed in logarithms, the estimate indicates that a 1% increase in GDP per capita within a country is associated with an approximately 0.308% increase in its pharmaceutical HICP, conditional on the remaining regressors. This positive within-country relationship may reflect an ability-to-pay mechanism whereby economic growth facilitates the adoption of newer and potentially more expensive treatments (Shaikh and Gandjour, 2019).

The coefficient on the country mean of the logarithm of GDP per capita, -0.3563, should not be interpreted as the standalone between-country elasticity. Under the Mundlak parameterization, it represents the difference between the between-country and withincountry coefficients. The complete between-country relationship is obtained as follows:

$$\hat{\beta}_{B,\ln \mathrm{GDP}} = 0.3079 - 0.3563 = -0.0484$$

The results therefore suggest a positive relationship between GDP growth and pharmaceutical prices within countries, but a modest negative relationship when countries with different average income levels are compared. One possible explanation is that wealthier countries possess stronger negotiation capacity and more developed regulatory institutions (Shaikh and Gandjour, 2019; Zaprutko et al., 2017). This explanation should, however, be regarded as a plausible interpretation rather than as a mechanism directly tested by the empirical model. The statistical significance of the combined betweencountry coefficient is evaluated using a linear-combination Wald test (p = 0.0487) based on the full estimated covariance matrix.

Contrary to its intended role as a cost-containment mechanism, External Reference Pricing (ERP) is positively and statistically significantly associated with pharmaceutical price levels. Its estimated coefficient is 0.0425, with a p-value of 0.0393. The exact transformation implies that countries applying ERP have pharmaceutical HICP levels approximately 4.3% higher, conditional on the other covariates. One possible explanation is that reference baskets containing relatively high-price countries may facilitate upward price convergence, particularly when the pricing rule does not rely on the lowest observed price or a sufficiently restrictive average (Fontrier et al., 2019; Remuzat et al., 2015). An alternative explanation is policy selection, since countries experiencing elevated pharmaceutical prices may be more likely to adopt ERP. The result should therefore not be interpreted as evidence that ERP necessarily causes pharmaceutical prices to increase.

The Mundlak results also clarify the relationship between generic penetration and pharmaceutical prices. The within-country coefficient on generic penetration is small and statistically insignificant ( $\hat{\beta} = -0.0003,\ p = 0.8686$). Thus, changes in the generic market share within a country are not systematically associated with changes in its pharmaceutical HICP during the sample period. This result suggests that increasing generic penetration alone may be insufficient to reduce retail price indices without complementary measures such as reference reimbursement, prescribing incentives, or substitution rules (Dylst and Simoens, 2011). The coefficient on mean generic penetration is a contextual effect and should not be interpreted independently as the between-country coefficient. The complete betweencountry association is:

$$\hat{\beta}_{B,GEN} = -0.0003 + 0.0037 = 0.0034$$

Consequently, countries characterized by higher average generic penetration also tend to have higher pharmaceutical HICP levels, conditional on the other variables. This positive cross-country association should not be interpreted as evidence that generic penetration increases pharmaceutical prices. It may instead capture differences in market structure, reimbursement arrangements, the composition of

pharmaceutical consumption, or other unobserved institutional characteristics. Its statistical significance is assessed through a linear-combination Wald test ($p = 0.0001$) using the full estimated covariance matrix.

Tendering is positively and statistically significantly associated with pharmaceutical HICP. Its estimated coefficient is 0.0673, with a p-value of 0.0013. The exact transformation implies an association with approximately 7.0% higher pharmaceutical HICP levels. This finding does not necessarily indicate that tendering is ineffective as a procurement mechanism. Tendering is employed predominantly in hospital procurement, whereas the HICP mainly reflects retail prices faced by consumers. Savings arising from competitive procurement and confidential discounts may therefore not be reflected in the dependent variable. Furthermore, tendering may be adopted more extensively in healthcare systems purchasing high-cost medicines, creating a positive policy-selection association (Garattini et al., 2022; Vogler et al., 2017).

Managed Entry Agreements (MEAs) also exhibit a positive and statistically significant association with pharmaceutical HICP. The estimated coefficient is 0.0340, with a p-value of 0.0224, corresponding to an exact percentage association of approximately 3.5%. One possible explanation is that MEAs are frequently used for innovative and high-cost therapies whose list or retail prices remain elevated even when confidential rebates, expenditure caps, or outcome-based payments reduce the net prices paid by public authorities. Because such confidential arrangements are not reflected in the HICP, the positive coefficient may capture the characteristics of the medicines covered by MEAs rather than the net cost-saving effect of the agreements.

The policy implications of the results must be interpreted in light of the specific information captured by the pharmaceutical HICP. The HICP is an index of changes in consumer-facing prices for pharmaceutical products and does not directly measure absolute price levels, manufacturer or ex-factory prices, public pharmaceutical expenditure, hospital procurement costs, or prices net of confidential rebates and discounts. It may also reflect changes in reimbursement arrangements, patient co-payments, indirect taxation, and the composition of pharmaceutical consumption. Consequently, a negative association between a pricing policy and the pharmaceutical HICP indicates slower growth or a lower evolution of observed retail prices within the harmonized index; it does not necessarily imply an equivalent reduction in the net prices paid by public purchasers or in total pharmaceutical expenditure. Similarly, the positive associations estimated for ERP, Tendering, and MEAs should not be interpreted as evidence that these policies necessarily increase the net cost of medicines, since their effects may operate through confidential discounts, hospital procurement, or access to high-cost innovative products that are not fully reflected in the consumer price index. The findings therefore provide evidence on consumer-facing pharmaceutical price dynamics rather than a comprehensive assessment of the fiscal effectiveness of each policy.

Overall, the findings demonstrate that pharmaceutical price evolution is associated with a combination of regulatory arrangements, market characteristics, and macroeconomic conditions. IRP and VBP are conditionally associated with lower pharmaceutical price levels, whereas ERP, Tendering, and MEAs are associated with higher price levels. These findings should not be interpreted as causal estimates because the policy indicators are identified primarily from cross-country variation and policy adoption may respond endogenously to existing price pressures, fiscal constraints, or healthcare-system characteristics. Although the Mundlak augmentation controls for correlation between the time-varying regressors and time-invariant country heterogeneity, it does not eliminate reverse causality, policy-selection endogeneity, or omitted-variable bias.

Additional limitations should also be considered. The model imposes common slope coefficients across countries and may therefore fail to capture differences in the intensity or design of policy implementation (Dabbous et al., 2020). Furthermore, the HICP does not incorporate confidential rebates, manufacturer-level discounts, or hospital-specific procurement prices, limiting its ability to measure the net prices paid by healthcare systems (Eurostat, 2024).

# 6. Conclusions and Policy Implications

This final section synthesizes the empirical evidence gathered throughout the study and outlines its broader implications for health policy and pharmaceutical management. The research utilized a balanced panel of eleven European countries from 2013 to 2023 to examine the interplay between pricing mechanisms, market dynamics, and macroeconomic conditions (Eurostat, 2024; OECD, 2024). By employing the Mundlak (Correlated Random Effects) approach, the study successfully differentiated between within-country temporal changes and between-country structural differences, providing a more nuanced understanding of pharmaceutical price evolution (Mundlak, 1978).

## 6.1 Summary of Key Findings

The empirical analysis revealed significant heterogeneity in the effectiveness of various pricing policies. Internal Reference Pricing (IRP) and Value-Based Pricing (VBP) emerged as the most consistent drivers of price containment. Both policies showed a strong negative correlation with the pharmaceutical Harmonised Index of Consumer Prices (HICP), suggesting that mechanisms promoting therapeutic competition and clinical evidence are vital for controlling costs (Brekke et al., 2022; Jommi et al., 2020). Conversely, External Reference Pricing (ERP) demonstrated a positive correlation with price levels in this specific sample, indicating that benchmarking against high-priced "baskets" can inadvertently lead to upward price convergence (Fontrier et al., 2019; Remuzat et al., 2015).

A critical insight of this research is the dual impact of purchasing power. While internal GDP growth within a country correlates with higher pharmaceutical prices due to the expanded "ability-to-pay" and the incorporation of innovative therapies, wealthier nations structurally maintain lower price levels through robust institutional negotiation and regulatory frameworks (Shaikh and Gandjour, 2019; Zaprutko et al., 2017). Furthermore, the study highlighted that generic drug penetration alone does not significantly influence nominal price indices without the presence of targeted regulatory support, such as IRP (Dylst and Simoens, 2011).

## 6.2 Policy and Managerial Implications

The results provide policy-relevant evidence regarding the conditional associations between regulatory arrangements and consumer-facing pharmaceutical price dynamics. IRP and VBP are associated with a more contained evolution of the pharmaceutical HICP in the countries examined. This finding is consistent with the view that reimbursement ceilings, therapeutic competition, and the systematic assessment of clinical value may contribute to moderating the growth of consumer-facing pharmaceutical prices. Nevertheless, because the HICP is a price index rather than a measure of comparable absolute price levels, and because it does not capture confidential net prices, hospital procurement costs, or total pharmaceutical expenditure, the estimates should not be interpreted as a comprehensive evaluation of the fiscal effectiveness of these policies.

The positive association between ERP and the pharmaceutical HICP suggests that the composition of reference-country baskets and the price-calculation rule warrant careful consideration. However, the result does not establish that ERP causes higher manufacturer prices, net medicine costs, or pharmaceutical expenditure. Similarly, the positive associations of Tendering and MEAs with the HICP may partly reflect their use for hospital medicines and high-cost innovative therapies, while the confidential discounts and procurement savings associated with these arrangements are generally not captured by the consumer price index. The findings therefore support cautious policy refinement rather than an unconditional ranking of pharmaceutical pricing instruments.

Within these limitations, policymakers may consider strengthening IRP and VBP as components of broader pharmaceutical cost-management strategies. Previous evidence indicates that IRP can promote competition among therapeutically equivalent medicines and reduce the financial burden on public payers and patients (Nemeth et al., 2022; Brekke et al., 2022). Similarly, VBP frameworks may help align pricing and reimbursement decisions with clinical benefits and cost-effectiveness considerations (Prieto-Pinto et al., 2020). The performance of these policies should nevertheless be evaluated using complementary indicators,

including consumer prices, manufacturer and net procurement prices, public and private pharmaceutical expenditure, patient access, medicine availability, and health outcomes.

Regulatory authorities should also exercise caution when designing External Reference Pricing systems. The effectiveness of ERP may depend on the composition of the reference basket, the use of average or minimum-price rules, the frequency of price revisions, and the treatment of confidential discounts. Inappropriately designed reference baskets may expose lower-income countries to benchmarks derived from higher-priced markets (Fontrier et al., 2019). Furthermore, the absence of a statistically significant withincountry association between generic penetration and the pharmaceutical HICP suggests that increasing the market share of generics alone may not be sufficient to moderate consumer price-index growth. Generic entry may need to be accompanied by appropriate reimbursement, prescribing, dispensing, and substitution incentives (Dylst and Simoens, 2011).

For pharmaceutical executives and market-access specialists, the findings underline the importance of adapting pricing strategies to national regulatory and macroeconomic conditions. The positive within-country association between GDP per capita and the pharmaceutical HICP is consistent with the possibility that economic growth facilitates the uptake of newer and potentially more expensive treatments. It should not, however, be interpreted as direct evidence supporting an ability-to-pay pricing strategy. In markets characterized by well-developed Health Technology Assessment systems, pricing and market-access strategies are likely to depend increasingly on evidence concerning clinical outcomes, comparative therapeutic value, budget impact, and cost-effectiveness (Jommi et al., 2020; Persson et al., 2010).

### 6.3 Final Remarks and Future Research

The determination of pharmaceutical prices in Europe is an intricate process shaped by the collision of regulatory interventions, macroeconomic shifts, and corporate strategic choices. This study has demonstrated that the efficiency of a policy depends largely on its design and its interaction with a nation's economic status. While this research provides a comprehensive overview of the HICP dynamics, future studies should consider dynamic panel models to explore the long-term adjustments of prices. Additionally, incorporating more granular data on confidential rebates and hospital-specific procurement would further enhance our understanding of the true cost of medicines in the European landscape.

**Declaration of generative AI and AI-assisted technologies in the manuscript preparation process**

During the preparation of this work the authors used Gemini Notebook and generative AI assisted technologies in order to support the LaTeX formatting of complex econometric tables, the refinement of the manuscript's structure, and the linguistic processing of the research findings. After using this tool/service, the authors reviewed and edited the content as needed and take full responsibility for the content of the published article.

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## Appendix

### A Pharmaceutical Policy Coding and Data Sources

Table 5 reports the country-level coding of the pharmaceutical pricing-policy indicators used in the empirical analysis. The indicators are binary and take the value of one when the corresponding policy mechanism was formally applied in the relevant national pharmaceutical system during the sample period, and zero otherwise. The coding identifies the presence of a policy but does not measure its implementation intensity, institutional design, therapeutic scope, or frequency of application.

**Table 5: Country-Level Coding of Pharmaceutical Pricing Policies**

| Country | ERP | IRP | VBP | Tendering | MEA |
|---|---|---|---|---|---|
| Belgium | 1 | 1 | 0 | 1 | 1 |
| Czechia | 1 | 1 | 0 | 1 | 1 |
| Estonia | 1 | 1 | 0 | 1 | 1 |
| Finland | 1 | 1 | 0 | 0 | 1 |
| Italy | 1 | 0 | 0 | 1 | 1 |
| Latvia | 1 | 1 | 0 | 0 | 0 |
| Norway | 1 | 0 | 0 | 1 | 0 |
| Portugal | 1 | 1 | 0 | 1 | 1 |
| Slovakia | 1 | 1 | 1 | 1 | 1 |
| Sweden | 0 | 0 | 1 | 1 | 1 |
| Switzerland | 1 | 0 | 0 | 1 | 0 |
| Sample mean | 0.909 | 0.636 | 0.182 | 0.818 | 0.727 |

**Notes:** ERP denotes External Reference Pricing; IRP denotes Internal Reference Pricing; VBP denotes Value-Based Pricing; and MEA denotes Managed Entry Agreements. A value of 1 indicates that the policy was coded as formally applicable in the relevant national pharmaceutical system during the 2013-2023 sample period, while 0 indicates that the policy was not coded as applicable. The indicators capture the institutional presence of each policy and not its implementation intensity. Accordingly, they do not reflect differences in reference-country baskets, price-calculation rules, therapeutic coverage, procurement frequency, cost-effectiveness thresholds, contract design, or confidential discounts. Country-level coding was compiled from the Pharmaceutical Pricing and Reimbursement Information (PPRI) country profiles and briefs, WHO reports on pharmaceutical pricing and reimbursement policies, OECD publications, and the published comparative literature. When sources differed, preference was given to the most recent official national or PPRI source applicable to the sample period. Because the policy indicators exhibit little or no within-country variation during the sample period, they are treated as time-invariant in the empirical analysis. Their estimated coefficients are therefore identified primarily from differences across countries and should be interpreted as conditional cross-country associations rather than as causal policy effects.

The policy definitions follow the standardized terminology of the World Health Organization's guideline on country pharmaceutical pricing policies and the Pharmaceutical Pricing and Reimbursement Information network. Country-level classification was based primarily on PPRI Pharma Profiles, PPRI Pharma Briefs, and PHIS country reports, which provide information on national pharmaceutical pricing, procurement, and reimbursement systems. These reports are generally prepared by national pricing and reimbursement authorities or country experts and reviewed by the PPRI Secretariat. Comparative studies and reports from the WHO Regional Office for Europe, the OECD, and the European Observatory on Health Systems and Policies were used for cross-validation. Where conflicting classifications were identified, the most recent official source corresponding to the 2013-2023 sample period was given precedence.

**Table 6: Definitions and Operational Coding Rules**

| Policy | Definition | Operational coding rule | Main sources |
|---|---|---|---|
| ERP | Prices benchmarked against the same or comparable products in other countries. | 1 when external price comparisons are a formal systematic criterion. | WHO (2020); Remuzat et al. (2015); PPRI Network |
| IRP | Common reimbursement amount for identical, bioequivalent, or therapeutically comparable medicines. | 1 when formal reference-price grouping and a reimbursement ceiling are used. | WHO (2020); WHO Europe (2018); PPRI Network |
| VBP | Price or reimbursement linked to assessed clinical, economic, or societal value. | 1 when added value or formal cost-effectiveness has an explicit systematic pricing role. | WHO (2020); OECD (2008); PPRI Network |
| Tendering | Competitive procurement based on predetermined price and non-price criteria. | 1 when purchasers systematically use tenders for a relevant medicine category. | WHO (2020); PPRI Network; Vogler et al. (2017) |
| MEA | Payer-manufacturer agreement subject to financial, utilization, evidence, or outcome conditions. | 1 when financial-or outcome-based agreements are formally used. | PPRI Network; Dabbous et al. (2020); Panteli et al. (2016) |

**Notes:** The operational definitions are intended to support consistent binary coding across countries. A value of 1 does not imply that the policy applied to every medicine, payer, or healthcare setting. In particular, tendering may be concentrated in the hospital sector, while MEAs may apply mainly to selected innovative or high-cost medicines. HTA denotes Health Technology Assessment. Cost-effectiveness thresholds, therapeutic-benefit ratings, and budget-impact analysis may form part of a VBP framework, but the mere existence of an HTA agency does not necessarily imply that prices are value based.