Analysing the Impact of EU5 Pricing Reforms

A Pathway to Adaptation in an Evolving Policy Landscape

HPR4

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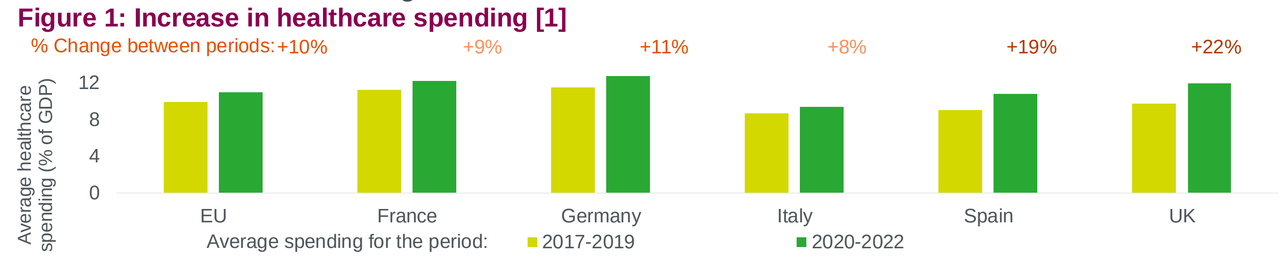
Background

- European countries experienced a 10% increase in healthcare spending as percentage of GDP when comparing the average spending between two time periods: 2017-2019 and 2020-2022 (**Figure 1**). While healthcare spending was in the high single digit pre-pandemic, this increased significantly post-pandemic. Among the EU5 (Germany, Spain, France, Italy, and the UK), Spain and the UK registered the highest increases in healthcare spending of 19% and 22%, respectively [1].
- An increased focus on healthcare budgets driven by newer high-cost innovative drugs and the COVID-19 pandemic led the EU5 countries to implement pricing policy reforms to support payers with increased pricing negotiation controls. This research analysed the commonalities and impact of recent EU5 pricing reforms on pharmaceutical industry market access strategies.

Methods

- Secondary research was conducted to analyse healthcare pricing policies such as laws, decrees, memorandums, guidelines promulgated by EU5 Ministries of Health (MoH) or Health Technology Assessments (HTA) bodies between 2019 and 2024 [2-12].
- Policies which have an impact on market access of pharmaceutical products were then grouped into three categories impacting: 1. Pricing negotiation, 2. Healthcare spending, 3. Access and manufacturing.

Figure 1: Increase in healthcare spending [1]



Results

- In response to the trend of increased spending and budgetary pressures [1], governments embarked on a series of pricing reforms [2-12]. The timelines of key reforms is highlighted in **Figure 2** and coincides with the rise in healthcare spending.
- Eleven key policies have been categorized, impacting three aspects of market access (**Table 1** and **2**):
  - **Pricing negotiations:**
    - GKV-FinStG act introduced price-volume agreements and reduced revenue thresholds for orphan drugs.
    - NICE updated review methodology to allow higher ICERs.
    - AIFA merged committees to accelerate pricing negotiations and JCA implementation.
  - **Healthcare spending:**
    - Increased "mandatory discounts", reduced free pricing to 6-months, and introduced a combination drug markdown.
    - Merger of CCGs into ICSs and adjusted VPAS rebates.
    - CEPS-LEEM agreement clarified originators and biosimilars discounts based on market share.
    - Reference Pricing Order introduced new reference groups for discounted rates.
  - **Access and manufacturing:**
    - MHRA plan expedited post-Brexit approvals
    - The IMF funded innovative medicines
    - Incentivised innovative medicines production and introduced the Direct Access Scheme.
    - Pricing decree permitted price increases and renegotiation incentivising manufacturing.

Figure 2: Timeline of pricing reforms in the EU5

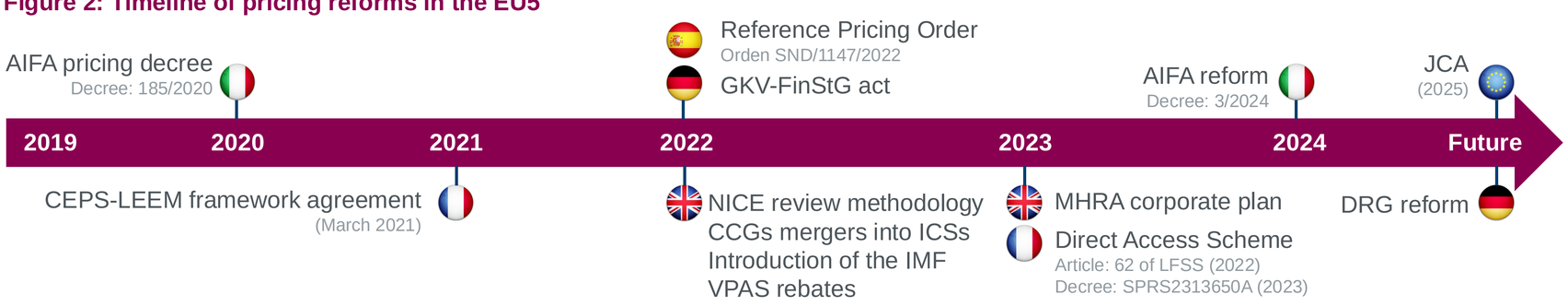


Table 1: Heatmap of key pricing reforms

Pricing reforms	Pricing negotiations	Healthcare spending	Access and manufacturing
Germany	4	3	2
France	1	0	1
Italy	1	0	1
Spain	1	0	0
UK	1	2	2

Table 2: Expected impact of the reforms in the EU5

Reform name	Type of reform	Expected impact of the reforms
GKV-FinStG [2, 6]	Pricing and Reimbursement	Reduces free pricing period from 12 months to 6 months post-EMA approval
		Price negotiations will now consider price-volume components or prescription volume caps
		Provisions to sanction uneconomic package sizes
	Orphan drug AMNOG review	Orphan drugs require a full AMNOG process if projected annual revenue > €30 million (€50 million currently)
	Combination markdown	For new active substances used in a combination listed by the GBA, the health insurance funds will receive a markdown payment of 20% of the sales price
	Mandatory discount	Mandatory discount will increase from 7% to 12%
	Pharmacy discount	Increases contribution per package from 1.77 to 2.00 euros
	Price moratorium	Extends price freeze until the end of 2026 (exemptions may be applied)
	Local production	Strengthen local production by including it as an AMNOG evaluation factor
CEPS-LEEM framework agreement [8]	Biosimilars pricing	Price regulation for originator and biosimilar medicines varies by sales location and market share. Discounts differ between general pharmacies (40% biosimilar, 30% originator) and hospital pharmacies (30% for both). The biosimilar's discount decreases as the originator's market share increases
Direct access scheme [3]	Pricing to incentivize reshoring of innovative drugs	Price matching to European levels is allowed for drugs with low therapeutic value (ASMR IV) if they meet certain criteria: comparison to a drug with ASMR ≥III, cost-effectiveness dominance, limited comparators in its indication, novel antibiotic ingredients, orphan drug status, or new combination therapy drugs
AIFA pricing decree [4, 9]	Access and manufacturing	Prices negotiated with AIFA last 24 months, auto-renewing if not amended 60 days prior. Exceptional price increases may be allowed for low-cost drugs facing material shortages or rising production costs
AIFA reform decree [4, 9]	Pricing negotiations	Merging of clinical and economic evaluation committees into one single committee, and reducing the total number of members from 20 to 10
Reference Pricing Order [5]	Pricing negotiations	For inclusion within a specific reference group, medicinal products must have the same Level 5 ATC code and identical administration route
MHRA corporate plan [6, 10]	Access and manufacturing	Expediated regulatory approval post-Brexit and exit from the EMA processes
NICE review methodology [11]	Pricing negotiations	Inclusion of decision modifiers (e.g., disease severity, end of life criteria, etc.) to increase a product's QALY by a factor (1.2x to 1.7x), supporting higher costs and helping ICERs fall below recommendation thresholds (applies to product with an ICER ≤ £50,000)
Introduction of the IMF [11]	Access and manufacturing	Non-oncological therapy may be included in the IMF if it potentially addresses high unmet needs, offers significant clinical benefits, represents a step-change for patients and clinicians, and if new evidence could meaningfully reduce uncertainty
CCGs mergers into ICSs [12]	Healthcare spending	The 106 CCGs were merged into 42 ICSs in April 2022 to break down the barriers between healthcare and social care and improve population health
VPAS rebates [6, 12]	Access and manufacturing	VPAS and the statutory scheme regulate branded medicine prices in the UK. VPAS members' NHS paybacks increased from 5% of revenue in 2021 to 26.5% in 2023. The 2024 VPAS reset allows 2-4% annual growth in branded medicine sales by 2027. Older medicines will pay a 10-25% top-up rate

- While the search identified the main reforms impacting market access, the study did not identify the quantitative impact on drug prices due to the recent reforms and lack of publicly available data. Future research will allow for correlating the impact of these reforms on prices.

Conclusions

- Most identified policies (n=7) aimed to contain costs by increasing payers' negotiation and pricing controls, while 4 policies focused on optimising access to innovative treatments. With further policy reforms planned in Germany and Spain, and budgetary constraints weighing on healthcare spending across Europe, this observed trend of policies ensuring cost containment will continue.
- Considering the significant time and resources invested in the development of innovative therapies, it will be instrumental for pharmaceutical companies to monitor policy changes in Europe to understand local pricing drivers. This ensures aligned evidence development and commercial forecasts, optimizing market access for innovative therapies.

ABBREVIATIONS

AIFA: Agenzia Italiana del Farmaco; **AMNOG**: Arzneimittelmarktneuordnungsgesetz; **ASMR**: Amélioration du Service Médical Rendu; **ATC**: Anatomical Therapeutic Chemical; **CCG**: Clinical Commissioning Group; **CEPS**: Comité Économique des Produits de Santé; **DRG**: Diagnosis-Related Group; **EMA**: European Medicines Agency; **EU**: European Union; **EU5**: France, Germany, Italy, Spain and the UK. **GBA**: Gemeinsamer Bundesausschuss; GDP: Gross domestic product; **GKV-FinStG**: Act for the Financial Stabilization of the German Statutory Health Insurance System; **ICER**: Incremental Cost-Effectiveness Ratio; **ICS**: Integrated Care System; **IMF**: Innovative Medicines Fund; **JCA**: Joint Clinical Assessment; **LEEM**: Les Entreprises du Médicament; **LFSS**: Loi de Financement de la Sécurité Sociale; **MHRA**: Medicines and Healthcare products Regulatory Agency; **MoH**: Ministry of Health; **NHS**: National Health Service; **NICE**: National Institute for Health and Care Excellence; **UK**: United Kingdom; **VPAS**: Voluntary Scheme for Branded Medicines Pricing and Access.

REFERENCES

[1] World Bank. [2] German MoH. [3] France MoH. [4] Italy MoH. [5] Spain MoH. [6] UK MoH. [7] GBA. [8] LEEM; [9] AIFA. [10] MHRA. [11] NICE. [12] NHS

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