How will recent pricing regulations impact the global pricing landscape?

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Background

While innovations have improved patients' health outcomes, finite healthcare budgets across the world are struggling to keep up with the volume and the demand for breakthrough medicines, making sustainable access to innovative medicines a source of growing concern. To curb the healthcare spending, law and policy makers, have started introducing country-level pricing regulations aiming to control increase in expenditure on pharmaceuticals. This research aims to identify current trends in the global pricing landscape by comparing recent regulations in the US (United States), Germany, and France.

Methods

- Using a thematic analysis approach, we investigated drug pricing measures in the IRA (Inflation Reduction Act) passed in the US (2022)[1], the Financial Stabilization Act of the German Statutory Health Insurance System (GKV-FinStG) passed in Germany (2022)[2], the LFSS (French Law on the Health Insurance Budget) (2022)[3], and the agreement between the pharmaceutical industry and the Accord-cadre (Economic Committee for Health Products in France).[4]
- We used a set of pre-specified criteria including overall regulation type, drug types concerned, and price control methods applied.

Results

- After successful passage of legislations, two new price control measures were introduced in the US, six in France, and five in Germany, as shown in Figure 1.
- The price control measures included price rebates (US, n=1; Germany, n=2; France, n=1), payback (France, n=1), price freeze (Germany, n=1), outcomes-based agreements (France, n=1), international reference pricing (France, n=1), reduction of free pricing period (Germany, n=1), stricter evaluation of orphan drugs (Germany, n=1), price stability measure (France, n=1), and negotiation termination procedure (France, n=1) (Table 1).[1,4,5]
- All the new measures were applied to drugs that are covered by national health insurance but have trickledown effect on private payers.
- The newly introduced rules targeted mainly high-cost, innovative and orphan drugs (US, n=1; France, n=3; Germany, n=1), combination therapies (Germany, n=1), and single-source branded drugs that lost exclusivity (US, n=1).[1,4,5] While measures in France, n=5/6 and Germany, n=3/5,[4,5] would have a direct impact on launch process, IRA in the US would have indirect impact to mitigate price negotiation / potential rebates later on.[1]
- As a result of price regulations, IRA in the US effectively shortens the average life cycle of top-selling drugs, incentivizes single indication over multiple, and puts the focus squarely on a post-launch evidence development strategy that demonstrates real-world value. As such, IRA in the US will have a broader indirect impact from clinical development, evidence development to portfolio optimization.

Figure 1: The timeline of new legislations passed and applied in the US, Germany and France.[1,4,5]

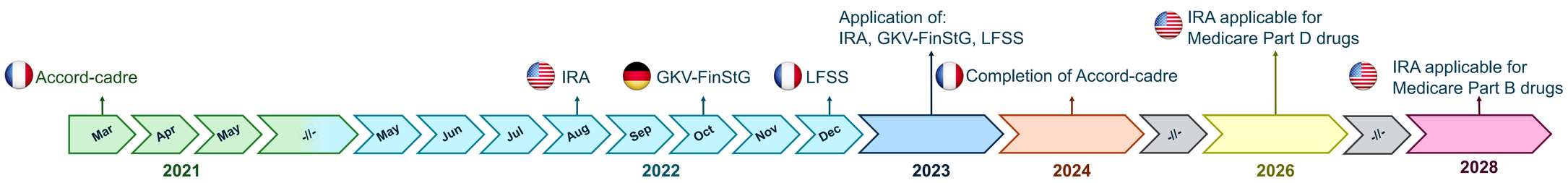

Table 1: The price control measures used in the USA, France and Germany after the application of the innovative pricing regulations.[1,4,5]

Price control measures			
Rebates linked to total spend and/or volume	• Inflation rebate: If the annual price increase of a drug is higher than the consumer inflation, the manufacturer will be required to pay back the difference to the federal government as a rebate • Maximum fair price (MFP): the provisions of IRA authorize the federal government to negotiate prices of selected high-spend drugs, aiming to establish MFP. The negotiations will be based on research & development costs (R&D), prior federal financial support for R&D, revenue/ sales volume data, and comparative effectiveness	• CEPS (Economic Committee for Health Products) to impose discounts for narrower indications compared to the label • Paybacks: The safeguard clause, payback if spending exceeds a certain limit • Outcome-based agreements: CEPS sets an outcome-based agreement that includes terms and conditions • Negotiation termination procedure for innovative drugs for which no agreement on price could be reached	• Temporary increase in rebate from 7% to 12% • Mandatory 20% markdown on the sales price will be applied for all new combination therapies listed by G-BA (Federal Joint Committee) • The sales threshold up to which orphan drugs are partly privileged and only subject to an abbreviated AMNOG (Pharmaceuticals Market Reorganization Act) process is set to be lowered from €50 to €30 million in annual revenues. If the revenue of an orphan drug exceeds this threshold amount, the drug will be subject to the full health technology assessment
Price stability/control measures	• IRA provisions allow the federal government to negotiate prices of branded drugs that have a) exceeded their exclusivity period and b) don't have a generic or biosimilar competition (expected discounts in a range of 25%-60%) • Excise tax on manufactures that do not comply with the negotiation process, starting at 65% of product sales, increasing by 10% every quarter to a maximum of 95%	• Price stability measures: Stability of list prices for up to five years for drugs produced in the EU (European Union) and France	• The free pricing period reduced from 12 to 7 months • Extension of the price moratorium/ price freeze until the end of 2026
Use of analogues/ international reference pricing	• International reference pricing (IRP) has been formally proposed	• IRP: ASMR (Improvement in Medical Benefit) I-IV drugs produced in France can set the list price at the level of the highest of EU4 list prices.	• Not Applicable

Conclusions

- **Price Control Mechanisms:** This research shows that in addition to price negotiations, which are an integral part of health technology assessments, EU employs specific drug price control mechanisms in the EU to reduce or stabilize prices. Implementation timelines of those mechanisms appear to be aligned, also with passage of IRA in the US and demonstrate policymakers' reliance on them as effective tools to manage drug prices.
- **Sequencing launch strategies**: As disincentives in some markets provide opportunities in others, these mechanisms will have ripple effect on how manufacturers consider launch sequence across markets. As such, drug manufacturers should consider additional matrix of factors and scenarios in their launch pricing strategies, including small versus large follow-on indications, price erosion due to legislative measures, and competitive dynamics as more low-price options emerge because of these pricing regulations.
- **Convergence:** As pricing mechanisms continue to evolve, there will likely be a convergence and "cross-walking" of parameters between the EU and the US. This implies that manufacturers will face the challenge of aligning their global pricing strategies with harmonized parameters across these regions, necessitating a thorough understanding of the changing landscape and its implications.

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