Comparative Analysis of Launch Prices for Orphan Drugs in the US & EU3

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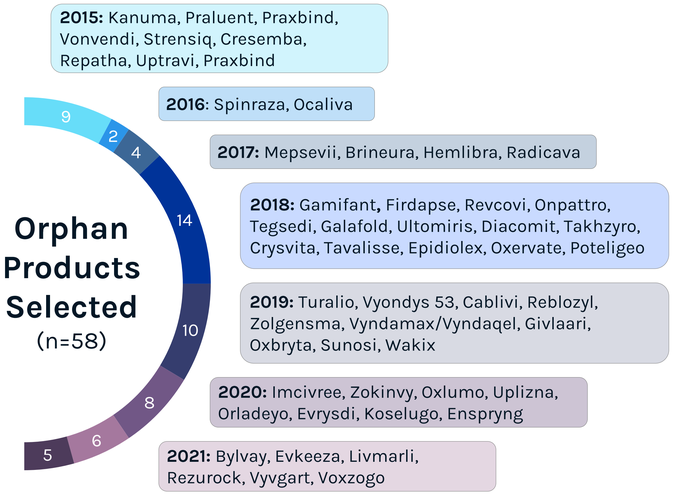
OBJECTIVES

Amidst the global concern over escalating healthcare costs, pharmaceutical costs have emerged as a pivotal focal point. Notably, the proliferation of orphan drug approvals, which may carry higher prices due to smaller patient populations, have intensified this discussion. Different markets have adopted distinct strategies to manage and regulate these pharmaceutical expenses. This analysis endeavors to assess the divergence in launch prices of orphan drugs between the United States (US) and EU3 (Germany (DE), France (FR), Italy (IT)) markets to understand the impact of each market's approach to managing pharmaceutical costs..

METHODS

The historical wholesale acquisition cost (WAC) pricing at launch of non-oncology orphan drugs in the US and EU3 markets from 2015-2022 was evaluated utilizing POLI, a global pricing database through GlobalData. The analysis compared WAC prices per pack across markets, employing consistent dosing assumptions. To ensure a meaningful evaluation of comparable costs, adjustments were made for variations in pack size, currency exchange rates, and the distinct free pricing period in Germany. Products launched or with available pricing only in one market were excluded. Following the collation of product pricing, the data was systematically juxtaposed to discern trends in launch pricing.



RESULTS

In total, 58 orphan product launches met the outlined criteria. From 2015-2022, orphan drug launches in the EU3 markets were introduced at 69.7% of the launch price observed in the US. Notably, there is a high degree of correlation across EU3 markets with Germany with the lowest at 64.6% and Italy the highest at 73.0% of US launch price. This is likely due to German prices being pulled after the free pricing period adjustment, where list price is typically lower reflecting national negotiations.

Over time, there was no discernible trends in relative launch prices, highlighting the influence of multiple factors that shape this pricing dynamic. Italy 2017 stands as an outlier with list launch prices exceeding US launch price likely due to most selected products having Innovative Status (i.e., Brineura, Hemlibra, Luxturna).

There are four products with average EU3 launch prices higher than US pricing (i.e., Givlaari, Oxlumo, Koselugo, Vyvgart), all of which have weight-based dosing. This trend may highlight population differences in payer assumptions during price negotiations. Additionally, all product except Koselugo have announced Value Based Agreements in the US that may indicate higher uncertainty in value due to variable dosing.

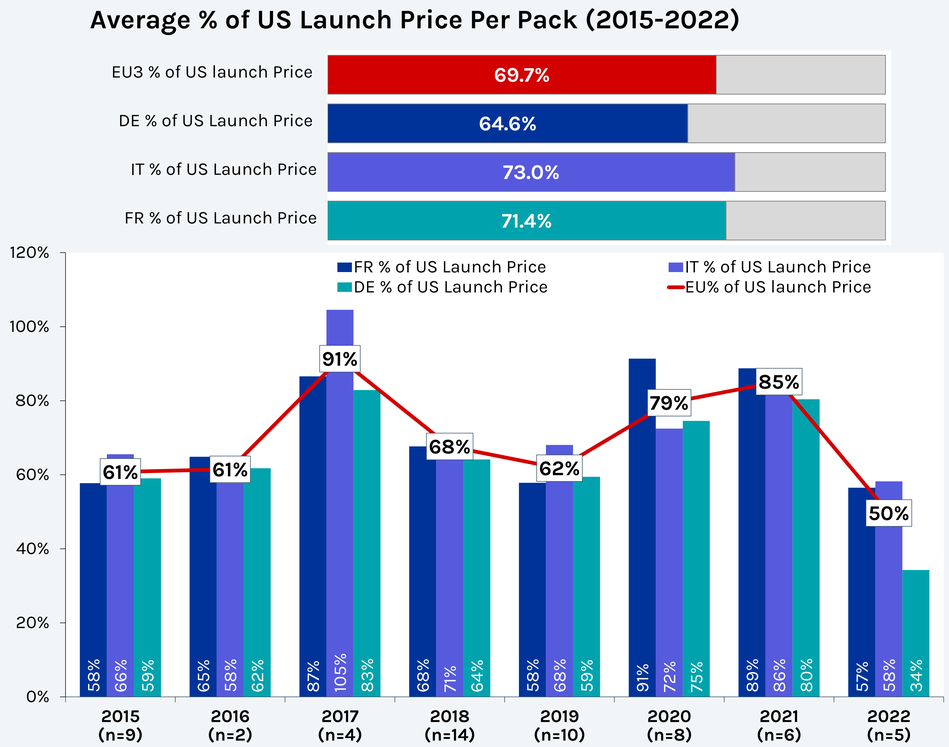


Figure 1: US: United States, FR: France, IT: Italy, DE: Germany, EU: Europe, ES (AVG): Estimated Average

DISCUSSION

The future trajectory of orphan drug pricing and market access will likely be influenced by legislative changes and regulatory interventions aimed at addressing healthcare affordability and promoting innovation. Potential reforms may include measures to enhance price transparency, foster competition among pharmaceutical manufacturers, and establish value-based pricing frameworks that align drug reimbursement with clinical outcomes and cost-effectiveness. One such legislative change is DE's lowering of the orphan drug revenue threshold to €30M in Dec 2022 as part of the GKV-FinStG, which may impact future launch pricing, while little-to-no orphan drug focused legislation is on the horizon that would impact launch prices in the US.

While high drug prices is of particular attention in the US, this research is limited in is understanding discounts from the list price and analyzing net pricing. In the US, discounts may vary based on an indications' competitive status, specific insurance plan, and product. In the EU, discounts are driven by national and regional pricing negotiations. When factoring in these discounts, overall trends seen in orphan drug pricing may change.

CONCLUSIONS

The analysis of orphan drug launch prices between the United States and EU3 markets underscores the complexity of pharmaceutical pricing dynamics amidst global concerns over healthcare costs. Our findings reveal a substantial variance in launch prices where the EU3 consistently introduces orphan drugs at a lower price relative to their US counterparts. Notably, while certain outliers such as Italy in 2017 reflect unique market dynamics, the overall absence of discernible trends over time emphasizes the multifaceted nature of factors influencing pricing strategies. As healthcare costs remain a pressing challenge worldwide, drug prices will continue to be criticized. Addressing these challenges requires a comprehensive understanding of the dynamics at play and collaboration among stakeholders to ensure equitable access to innovative treatments.

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