Acceptance Code: HPR34

Impact of the Inflation Reduction Act on Pricing, Reimbursement, and Market Access in the US

Kumar Sabbi T, Ahmed S, Patel K, Shah S

Background

The Inflation Reduction Act (IRA) passed in late 2022 includes provisions to lower Medicare prescription drug costs and reduce federal government spending. It includes the Secretary of the Department of Health and Human Services to negotiate prices, manufacturers to pay rebates if prices hike above the inflation rate, caps out-of-pocket costs for insulin at $35 per month, eliminating cost sharing of adult vaccines, and adjusting the out-of-pocket cap for Part D to $2,000

Objectives

The objective was to identify the effects of the IRA on market access, price, and reimbursement as well as possibilities and strategies that biopharmaceutical firms may adapt

Methodology

Secondary literature research was conducted to understand the impact of the IRA on innovators. A comprehensive analysis of public "pro" and "con" viewpoints is needed to capture the perspectives of all stakeholders

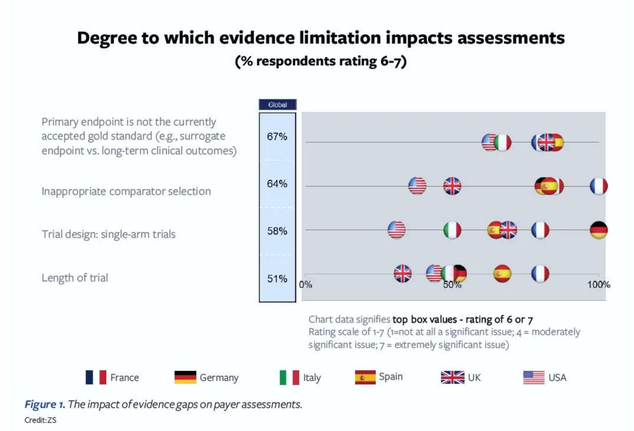

Figure 1. The impact of evidence gaps on payer assessments.
Credit: ZS

The FDA accepts surrogate endpoints of efficacy for drug approvals, so some treatments approved through the accelerated drug approval channel do not provide comprehensive proof of efficacy

Findings

The IRA grants Medicare the power to negotiate the amount it pays for certain prescription medications and to compel drug companies to abide by the law starting as early as 2023.

Provisions

- If the cost of a medicine grows faster than the rate of inflation, pharmaceutical firms will be compelled to pay rebates to Medicare
- Beginning in 2026, Secretary of Health and Human services (HHS) will negotiate prices for high-cost drugs (9-year-old small molecules or 13-year-old biologics); firms who refuse to negotiate will be subjected to a 95% sales tax on that medication
- Cost-sharing or out-of-pocket expenses for insulin and associated supplies are capped at $35 per month under IRA, and Medicare cost sharing for adult vaccines in Medicare populations is also removed
- Redesigning Medicare Part D by removing 5% cost sharing in the catastrophic stage and instituting a $2,000 out-of-pocket maximum beginning in 2025

Impact

The law will have a substantial influence on the pharmaceutical sector, affecting the profitability and market share of large drug firms that earn significant revenues from Medicare and the small molecule market.

- According to UBS, the impact is less than 3% of global biopharma sector earnings over a 10-year period
- Given the aforementioned, investors and other stakeholders may favor businesses with biologics over those with small-molecule pharmaceuticals
- The IRA's price-setting rules may hinder R&D across indications with larger Medicare populations (e.g., senior citizens) and small molecules

Opportunities of growth

Despite the fact that the IRA has created tremendous uncertainty for pharma manufacturers, there are still prospects for growth

- Undertaking portfolio evaluations and changes, as well as collecting additional value-based data and real-world evidence, offers a foundation for justifying price positions in negotiations
- Introducing cousin compounds for different indications at the same time reduces total drug spending and increases the portfolio for orphan indications
- Innovative pricing methods, such as optimal launch prices, pre-launch discussions, and aggressive pricing and pharmacy benefit circumstances, aid in market share gains

CMS intends to introduce a payment system for pharmaceuticals licensed under rapid approval to promote timely completion of confirmatory trials and enhance access to post-market safety and effectiveness data. This is due to a lack of supportive evidence for long-term effectiveness and safety concerns. clinical efficacy data development will receive increased focus, since it will be vital in pricing negotiations with the HHS

Conclusion

IRA has potential to significantly influence the US pricing, reimbursement, and market access space; subsequently creating downstream impacts toward manufacturer portfolios and decision making. Manufacturers must assess potential implications and optimize clinical development strategies to generate robust value-based evidence. Additionally, components of the IRA may decrease innovation among small molecules and/or therapeutic areas for the elderly population, due to incentivization towards launching biologics molecules and in younger adult/commercially insured patient populations

References:

1. https://www.lek.com/insights/ei/how-inflation-reduction-act-will-impact-biopharmaceutical-industry
2. https://www.zs.com/insights/inflation-reduction-act-what-biopharma-needs-to-know
3. https://www.pharmaceuticalcommerce.com/view/the-ira-is-industry-s-wake-up-call
4. https://www.kiplinger.com/investing/605063/ira-bill-a-blessing-in-disguise-for-drug-stocks
5. https://www.akingump.com/en/insights/alerts/the-impact-of-the-inflation-reduction-act-of-2022-on-pharmaceutical-innovation-patent-litigation-and-market-entry
6. https://innovation.cms.gov/data-and-reports/2023/eo-rx-drug-cost-response-report-summary

Poster presented at ISPOR 2023, Boston, MA, USA, May 7-10, 2023, | Presentation code: HPR34
Contact: Sandip Shah, Market Access Solutions LLC / LTD (MKTXS), Tel.+1-908-391-3398· Email: sshah@mktxs.com