



## Generic v/s Branded Drugs: Marketing Strategies and Market Dynamics

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### ABSTRACT

There is a striking structural and economic divergence developing in the pharmaceutical industry between the large innovator branded drugs on one hand, and the rapidly expanding simple generic competitors on the other. In the branded sector, significant R&D investments are followed by fierce lifecycle management, high-end patient support programs, and aggressive on-target physician detailing. In the generic industry, high volume and low margin are key. Generics must establish scientific sameness, outsmart regulatory complexities, and overcome a “cheaper is inferior” consumer mindset. We describe the Generics Competition Paradox: brand prices often either remain unchanged or even increase post generic entry. Authorized generics and patent thickets have become a tool of exclusivity. We examine the increasingly important intermediary role of Pharmacy Benefit Managers (PBMs), particularly in light of their growing vertical integration with insurers, and how this leads to higher pricing and greater out-of-pocket expenditures for patients. Our review the impact of socio-economic forces like consumer perceptions of bioequivalence, and the rapidly spreading use of international reference pricing. Finally, we conclude that the pharmaceutical industry's future rests in its successful segmentation into commodities (simple generics) versus highly valued, highly complex offerings (complex generics and biosimilars).

**Keywords:** Pharmaceutical Marketing; Generic Drugs; Branded Drugs; Market Dynamics; Patent Cliff; Bioequivalence; Pharmacy Benefit Managers.

### 1. INTRODUCTION

The distribution of pharmaceuticals to millions of people around the world daily presents a seemingly insurmountable conflict between stimulating innovative life-saving and life altering pharmaceuticals while maintaining a fair price point. At issue is the current relationship between branded (originator) pharmaceuticals and generic pharmaceuticals. Most branded pharmaceuticals undergo intense and expensive clinical trials to receive market approval and often take more than a decade in the works, costing over a billion dollars. To stimulate further development of life saving products, governments currently grant branded pharmaceuticals a time period of market exclusivity which can last anywhere from 7 to 12 years.<sup>[1]</sup> This time of exclusivity is often used to repay some of the development costs and grant the manufacturer a patent-backed monopoly on the pharmaceutical, protected by complex laws of intellectual property. However, once the exclusivity period expires, a sharp decline in profits often follows as generic producers begin to seek FDA approval to manufacture and market the same medication. In fact, generic and biosimilar medicines currently account for 90% of all prescriptions written in the U.S. in 2023, yet comprise only 13% of spending on medications and have saved the healthcare system \$445 billion in 2023 alone and \$3.1 trillion in the last decade.<sup>[2]</sup> Many feel that required levels of bioequivalence ensure that generic pharmaceuticals will have the same levels of absorption in the body and efficacy as the branded versions. However, the ‘marketing paradox’ means that generics may be viewed as inferior by patients and pharmacists because of minor cosmetic differences in dosage forms, allowing many off-patent branded products to retain large market shares and higher-than-necessary prices post-generic launch. While the Hatch-Waxman Act of 1984 paved the way for efficient entry of cost-effective generics by exempting copying of most contents of a branded submission from requiring duplicate clinical data, huge increases in generic market share, from 19% in 1984 to more than 91% in 2022, have shifted focus from simple generics to ‘complex generics’ and ‘biosimilars’ that can deliver greater profits for manufacturers.<sup>[4]</sup>

### 2. COMPARATIVE MARKETING STRATEGIES AND PROMOTIONAL APPROACHES

The strategic orientations of branded and generic pharmaceutical firms are diametrically opposed, reflecting their different roles in the product lifecycle. Innovators focus on differentiation and value-based medical necessity, while generic firms emphasize scientific sameness and economic value.



## 2.1. Branding Tactics and Consumer Loyalty Programs for Originator Drugs

For branded prescription drugs, the marketing mission is to create a "long-term medical identity." Medical marketing is no longer just about products; rather, it has evolved to an "experience-led" model. Customer Experience (CX) and Customer Experience Management (CXM) have become crucial drivers of competition in the industry.<sup>[18]</sup> Creating meaningful experiences and managing those experiences with patients, providers, and payers, will be crucial to building long-term loyalty and adherence in the years after patent expiration.<sup>[18]</sup>

In addition to the other strategies, Patient Support Programs (PSPs) are the most advanced approach to removing clinical and financial barriers to treatment. Going beyond mere call centers, they are sophisticated, integrated systems designed to support patients throughout their journey from diagnosis to treatment continuation.<sup>[20]</sup> In terms of the wide array of services offered, such as reimbursement assistance, support from a nurse educator and/or clinical case manager, and access to digital health solutions like patient adherence apps/SMS (e.g., MyWay), branded companies can map a patient's path to develop insights into all of the moments of truth that distinguish between continuation and discontinuation of prescribed therapy.<sup>[18]</sup>

**Table No. 2.1: Case Study Campaigns: Therapeutic Focus, Marketing Strategies, and Outcomes**

| Case Study Campaign                  | Therapeutic Focus              | Primary Marketing Strategy                                                     | Key Outcome                                                                            |
|--------------------------------------|--------------------------------|--------------------------------------------------------------------------------|----------------------------------------------------------------------------------------|
| "Depression Looks Like Me" (Janssen) | Depression in LGBTQ+ Community | Targeted inclusivity and directory access for friendly HCPs. <sup>[22]</sup>   | 23% conversion rate from campaign hub to website. <sup>[22]</sup>                      |
| "KnowPlanGo.com" (Pfizer)            | COVID-19 (Vaccines/Antivirals) | Unbranded public health awareness and high-risk planning. <sup>[22]</sup>      | Humanized brand through celebrity stories; served public health goals. <sup>[22]</sup> |
| Adalimumab PSP (Canada)              | Immunology                     | Proprietary clinical case management and financial assistance. <sup>[21]</sup> | Reported positive patient-reported outcomes (adherence, persistence). <sup>[21]</sup>  |

We develop programs that build a "moat" around branded medications by increasing the friction of switching to a generic, making the loss not only of revenue but also of a valuable service program. Our research has found that HCPs are twice as likely to prescribe a drug from a company that excels in Customer Experience due to the positive impact it has in boosting physician confidence and transparency. With digital support, we create meaningful engagement touchpoints with the patient breaking the traditional doctor-patient-pharmacist silo.<sup>20</sup>

## 2.2. Pricing Strategies and Cost-Effectiveness Positioning for Generic Alternatives

Generic drugs build their value proposition on price. The main hurdle that Generic manufacturers face is the psychological "cheaper is inferior" bias which connects lower price to lower quality<sup>[5]</sup>. In order to combat these Generic strategies, emphasize on creating trust and transparency through education of bioequivalence and also highlight the fact that many Generic medicines are made in same manufacturing facilities as Branded medicines.<sup>[5]</sup>

But even as a generic loses its market exclusivity — the typically 10-year or so patent protection afforded the original developer — the process of price reduction happens fast, and is accompanied by still more entrants. Industry practitioners distinguish between "pure generics" that are often dispensed under the chemical name of the medication (e.g. atorvastatin) as opposed to "branded generics" that retain a proprietary name as a transitional strategy to come down in price more gradually. Companies using the "branded generic" label typically are targeting big B2B customers such as chain drug wholesalers and Group Purchasing Organizations, or GPOs.<sup>[5]</sup>

The "First-to-File" (FTF) window is the single most important period in time in which a generic can make money. That window occurs at the time of the first generic to file a Paragraph IV challenge against a brand's patent. That generic receives 180 days of market exclusivity. During this period of time generic prices are only 30% to 39% below the brand list price generating large margin for the generic. After that the market experiences a "precipitous race to the bottom."

We notice that prices are plummeting at an unprecedented rate, which makes generics portfolios overly exposed to the most mature oral solids. The next generation of generic manufacturers are actively seeking to shift into "complex generics" like respiratory devices (inhalers, nasal sprays), advanced parenteral products (pen fill finish products like auto-injectors), and biosimilars.<sup>[16]</sup>

**Table No. 2.2: Impact of Generic Competition on Drug Pricing and Market Strategy**

| Number of Generic Entrants | Price Reduction vs. Branded Price (Median) | Strategic Context                                                       |
|----------------------------|--------------------------------------------|-------------------------------------------------------------------------|
| 1                          | 31% – 39% <sup>24</sup>                    | High-margin window; often Paragraph IV challengers. <sup>25</sup>       |
| 2                          | 44% – 54% <sup>24</sup>                    | Shift to hyper-competitive battle; rapid margin erosion. <sup>25</sup>  |
| 3 - 5                      | 60% – 79% <sup>14</sup>                    | Commodity status; profitability requires efficient scale. <sup>14</sup> |
| 6 - 10+                    | 80% – 95%+ <sup>14</sup>                   | Prices approach marginal production costs. <sup>24</sup>                |

### 2.3. Direct-to-Consumer Advertising and Physician-Targeted Communication Channels

Pricing for medications beyond patent is often challenged by branded manufacturers that have lost protection from generic competitors in the past. The challenge is not as bad as it seems for branded manufacturers because Direct-to-Consumer Advertising (DTCA) allows them to build patient-driven demand, creating awareness for a brand that extends well after the generic counterpart has entered the market. In fact, research indicates that branded manufacturers should not stop promotion once the generic counterpart enters the market. In fact, many branded firms have found that they can make their post-generic promotion budgets go much further by re-allocation of just 10% of pre-generic budgets, on average falling to 57% of pre-generic detailing budgets.<sup>[26]</sup>



**Fig No. 2.3: Sustaining Brand Value Post- Patent.**

Using face-time with physicians is the number one activity of brands post-generic entry. In fact, by targeting the 24% of the physicians who are most loyal or the highest prescribers, these efforts have a higher ROI. Post generic entry, the per-dollar revenue ROI for physician detailing has increased by \$2.00 to \$3.00 per dollar spent, driving \$14.50 in 12-month incremental revenue for every dollar spent for those efforts. Thus, sustaining branded prescriptions can be profitable, and can be best achieved by targeting the right HCPs with the right information.

While manufacturers of generic pharmaceuticals do promote cost-effective and therapeutically equivalent treatment options to healthcare professionals, this is generally conducted by trained professionals or ‘academic detailers’ rather than sales representatives. These programs have been found to modestly increase the dispensing of generic medications (such as generic atorvastatin following distribution of free samples) in part because they are difficult to counter strong habits that health professionals have cultivated when dealing with expensive medications over many years, and the effects that years of innovative manufacturer marketing have had in creating physician affinity for particular branded products—often with the aid of samples from these same manufacturers.<sup>[28]</sup>

### 2.4. Distribution Styles and Retail Pharmacy Positioning Strategies

The distribution of pharmaceuticals in the US has increasingly moved away from direct relationships between manufacturers and

pharmacies, and more toward intermediaries that have taken on a role often compared to health plan managers: the Pharmacy Benefit Managers or PBMs. These companies manage formularies of drugs that are covered under a particular health plan as well as negotiate rebates with manufacturers in return for “preferential placement,” or where a branded product is listed over lower-priced alternatives on a PBM’s formulary.<sup>[29]</sup> Often, these formularies include special features such as four tiered co-pay levels and high rebates that are used to lower patients’ out-of-pocket cost-sharing as a means of driving sales volume.

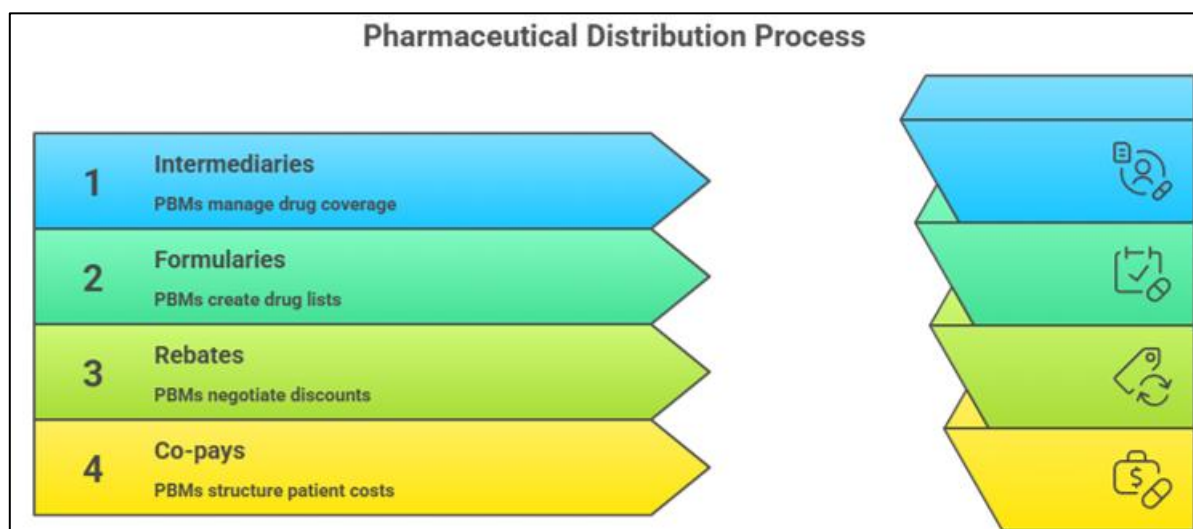


Fig No. 2.4: Pharmaceutical Distribution Process.

In the distribution of medications, another controversy has emerged: spread pricing. The PBM reimburses a pharmacy at one price, but bills the health insurer for a higher price — keeping the difference. However, this practice often is opaque, and does not reveal the true savings that generic medications provide. In Ohio, an audit uncovered that spread pricing on generics cost taxpayers \$208 million over a one-year period, with an average spread of 31.4%.<sup>[30]</sup>

With higher margins available to them when dispensing generic products versus branded equivalents, retail pharmacies have long developed strategies to efficiently provide generics to patients. In fact, the gross margin for generic prescription drugs has averaged 42.7 percent in pharmacies, compared with just 3.5 percent for branded drugs.<sup>[32]</sup> As the industry has consolidated and PBMs have reduced their reimbursement levels for prescription service, the issue has particularly affected independent pharmacies. Large mass retailers, like Walmart, in recent years began offering generic versions of dozens of key medications for \$4 each, prompting other pharmacies that want to retain customer traffic to accept a lower reimbursement or even sell some generic medications for less to turn a loss on some prescription sales.<sup>[32]</sup>

### 3. MARKET DYNAMICS AND COMPETITIVE LANDSCAPE

The pharmaceutical market is subject to unique forces that often decouple price from competition, creating a landscape that challenges traditional microeconomic assumptions.

#### 3.1. Impact of Patent Expiries and the Generic Competition Paradox

Introduction of Generics into a market typically results in a collapse in sales volume of the originator drug (in volume terms). However, the price of the originator drug is typically either stable or even increases. This phenomenon is known as the “Generics Competition Paradox”.<sup>[3]</sup> Economic theory suggests that in order to avoid entry by a potential competitor, a monopolist will resort to limit pricing, i.e. decreased prices in order to deter the competitor from entering the market. In reality, branded companies know that in spite of their strategy (price or non-price), they will inevitably lose the price sensitive customers to the Generics. Subsequently, the branded companies increase their prices of the original drug in order to extract the maximum surplus possible from the “hard-core” patients and their physicians who are brand-loyal and insensitive to price.<sup>[3]</sup>

Empirical evidence from both U.S. and European markets supports this paradox:

- After an eight-quarter average post Generic Entry (GE) period, 15 of 27 originator drugs remained over 70% of market share.<sup>[9]</sup>



- For several drugs, branded prices at pharmacies continued to rise at the same pace or a higher pace post-entry, whereas the prices of the generic versions dropped sharply to less than half of the initial price point.<sup>[3]</sup>
- Prescription generics saved American consumers \$338 billion in 2020, according to a recent report. But the biggest drug manufacturers, which lost billions as their patent protections expired like ticker time bombs, have continued to raise the list prices of their remaining patented medicines to pocket the revenue.<sup>[30]</sup>

### 3.2. Market Share Fluctuations and Volume-Price Ratios in Multisource Markets

The market for multisource drugs is unusual in that it has an extremely high volume-price ratio. Indeed, generic and biosimilar medicines represent approximately 90% of prescriptions written for in the U.S., but they account for only 13.1% of spending for medicines in that country.<sup>[7]</sup> That is, generic and biosimilar medicines do 90% of the work in medicine but receive only 13.1% of the industry's budget.

**Table No. 3.2: U.S. Pharmaceutical Market Segments by Prescription Volume and Spending (2023)**

| Market Segment (US, 2023) | % of Volume (Prescriptions) | % of Spending         |
|---------------------------|-----------------------------|-----------------------|
| Generics & Biosimilars    | 90% <sup>[7]</sup>          | 13.1% <sup>[7]</sup>  |
| Branded (Innovator)       | 10% <sup>[32]</sup>         | ~86.9% <sup>[7]</sup> |

Dynamics of market share for generic drugs can vary depending on the size of the patient population. Large markets (greater than 15,000 users per month) are highly competitive, with an average of 10 labelers per drug, and have experienced the steepest price decreases.<sup>[14]</sup> Conversely, small markets (less than 5,000 users per month) are typically under-competitive with over 60% of generic drugs in these segments having three or fewer labelers. This lack of competition in small markets can lead to unstable prices and an increased risk of drug shortages.<sup>[7]</sup>

### 3.3. Effects of Pharmacy Concentration and Insurer Market Power on Pricing

The integration of PBMs into the supply chain with insurers and specialty pharmacies has changed the rules of play in the market. However, even with this shift, the three largest PBMs, CVS Caremark, Express Scripts, and OptumRx, are each still heavily integrated with major insurers (Aetna, Cigna, and UnitedHealthcare, respectively) and process approximately 80% of all prescription claims.<sup>[30]</sup>

Integration between PBMs and Medicare Advantage plans allows for the practice of “raising rivals’ costs,” where the integrated PBM can withhold rebates or otherwise provide inferior services to rival insurance plans.

A 2024 analysis of Medicare Part D national pharmacy claims found that patients enrolled in plans that were vertically integrated with a PBM paid an average of 48% higher out-of-pocket price for branded prescription medications than did patients enrolled in non-integrated plans. This effect reflects the additional bargaining power that the PBM claims as higher intermediary profit rather than lower cost-sharing for beneficiaries.

### 3.4. Influence of Authorized Generics on Brand Name Retention Strategies

An Authorized Generic (AG) is a product that is the same as the branded product but is relabeled and sold by the manufacturer of the branded product or by a subsidiary, such as a distribution arm or by a partner company. 8 Branded firms are increasingly using Authorized Generics as a counter measure to the 180-day exclusivity afforded the first filer of a branded drug.<sup>[23]</sup>

Since the brand manufacturer holds the original New Drug Application (NDA), they can launch an AG without separate FDA approval, and compete with the "first-filer" generic on day one of its exclusivity.<sup>23</sup> These changes can have a significant impact on both generic and brand-side profit.

- Revenue Reduction due to the Andegen Generic (AG): The first-filer generic's revenue is reduced by an average of 40% to 52% during the 180-day period due to the Andegen Generic (AG).
- Long-term Market Squeezing – by aggressive pricing a brand can “squeeze out” the expected generic Profits from challenging a patent.<sup>[38]</sup>
- Strategic Signaling: brand manufacturer internal documents reveal that AGs are intended to send a message as to the level of



competition the brand manufacturer is willing to tolerate, even that the brand manufacturer is “warmer” than on other products, thus deterring future generic filings of Paragraph IV certifications with respect to other versions of the branded product.<sup>[37]</sup>

Some argue that AGs benefit consumers by increasing competition leading to generic prices reduced by 7-14% at the wholesale level, while others see AGs as “predatory pricing” that destroys the very incentives for generic companies to challenge patents in the first place.<sup>[11]</sup>

#### 4. REGULATORY FRAMEWORKS AND SOCIO-ECONOMIC INFLUENCES

The lifecycle of a drug is governed by a complex intersection of intellectual property law, safety regulations, and public policy.

##### 4.1. Intellectual Property Rights and Strategic Patenting Interventions

The issue for pharmaceutical companies is to extract as much commercial value as possible from their intellectual property (IP) before it expires through a practice called ‘evergreening’. This technique is most commonly used by changing the formulation of a medicine in some minor way, such as by altering the form of the active drug from liquid to sweet-tasting pellets, or by making some minor clinical claim for the same active agent when delivered in a different way, even though the new form or claim is medically marginal or unnecessary, so as to garner a further ‘secondary’ patent. Such tactics produce ‘patent thickets’. A patent thicket is a densely interconnected web of patents which serve to deter any potential competitors by providing an array of potentially victorious lawsuits should they attempt to enter the market. The combined effect of these legal safeguards can easily add years to a successful drug’s effective monopoly.

**Table No. 4.1: Pharmaceutical Evergreening Strategies: Mechanisms and Notable Examples**

| Evergreening Strategy   | Mechanism of Action                                                                                                             | Notable Examples                                                                                                 |
|-------------------------|---------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------|
| <b>Product Hopping</b>  | Switching the market to a new, patent-protected formulation (e.g., IR to ER) before the original patent expires. <sup>[2]</sup> | <b>Viramune ER</b> (launched 1 year before generic entry); <b>Namenda XR</b> . <sup>[2]</sup>                    |
| <b>Device Patenting</b> | Patenting the delivery device (inhaler, pen) separately from the drug. Device patents outlast drug patents. <sup>[2]</sup>      | <b>Advair Diskus</b> ; <b>EpiPen</b> ; <b>Combivent Respimat</b> (monopoly potentially 58 years). <sup>[2]</sup> |
| <b>Chiral Switching</b> | Patenting the more effective enantiomer of a previously racemic drug. <sup>[2]</sup>                                            | <b>Prilosec to Nexium</b> ; <b>Prozac to Sarafem</b> . <sup>[2]</sup>                                            |
| <b>Patent Thickets</b>  | Filing dozens or hundreds of patents on manufacturing, dosing, and indications. <sup>[4]</sup>                                  | <b>Humira</b> (over 100 patents extending protection to 2034); <b>Ozempic</b> (154 patents). <sup>[4]</sup>      |

For biologic drugs, the thicketing effect is even more pronounced, with an average of 22.7 patents per drug compared to 3.8 for small-molecule drugs.<sup>[39]</sup> The median number of additional years of protection provided by device patents alone is 4.7 years.<sup>[2]</sup>

##### 4.2. Bioequivalence Standards and Quality Regulation Impacts on Market Entry

A very important term when we speak of generic substitution is the word "bioequivalence". The FDA defines bioequivalence as the rate and extent of absorption of a drug and its corresponding generic product in the body. A generic product is not released into the bloodstream any faster or more slowly than the product it is duplicating. To establish the AUC (Area Under the Curve) and Cmax (Peak Concentration) values for a brand-name drug and its corresponding generic, the FDA creates a ratio of the generic drug to the brand name. For the FDA to state that two drugs are bioequivalent, the 90% confidence interval of this ratio must fall within the range of 80 to 125%.

So why do we rely on a 20/25 rule which seems to give brand drugs a very wide berth? According to a recent article in Forbes, the average difference between a brand product and its generic competitor is about 3.5%.<sup>[5]</sup> What’s even more astonishing is that even though hundreds of 12-year bioequivalence studies were reviewed for the article, there were no ‘failures’ (i.e. no product found to be outside the acceptable 20/25 rule margin).<sup>[12]</sup> However, the process of demonstrating bioequivalence for so called “complex generics” is far more difficult, particularly for respiratory and dermal products such as metered dose inhalers where robust clinical endpoint studies may be required rather than simply a simple pharmacokinetic study.<sup>[16]</sup> This increases significantly the cost of generic development – arguably beyond the means of many generic manufacturers other than the largest players.<sup>[1][7]</sup>



### 4.3. Government Price Controls and Reference Pricing Mechanisms

Several countries use so called External Reference Pricing (ERP) or International Reference Pricing (IRP) when controlling spending on pharmaceuticals. IRP measures the price of a drug in one country in relation to the prices in a defined basket of so-called reference countries. The Netherlands uses four reference countries, while Austria for example uses the prices of an average of 26 countries as reference for its pricing decisions.

Critics of IRP — including the pharmaceutical industry trade group PhRMA — say it “outsources” the pricing of life saving and life altering medicines to countries that don’t place a proper value on innovation and cause patients to go without necessary medication for extended periods of time. But according to a series of reports published in 2011 by researchers Richard Hatch and Brian Grabowski, more than 89% of newly approved medications are currently available to American patients, compared to less than 50% available in France, and less than 46% available in Canada.

For multisource products, a different approach is used for managing the price in markets where multiple equivalent or interchangeable versions of a medicine are marketed. In this case, the manager sets a single reference price for the market, and any medicines priced above that reference price have to be borne fully by the patient. A so-called “Internal Reference Pricing” has been implemented in countries such as Germany, Italy and Poland. It has been extremely effective to foster the use of generics and to contain spending.<sup>[47]</sup>

### 4.4. Consumer Perceptions, Misconceptions, and Public Awareness Programs

A significant portion of consumers and physicians holds negative attitudes towards generic medicines, despite overwhelming scientific evidence for their equivalence. Although price is an important criterion for consumers when evaluating medicines, only 17% of a sample of Belgians was able to recognize the package of a generic medicine.<sup>[49]</sup> Many consumers associate lower prices with lower effectiveness. Insights are gained into the effects of “self-perceived seriousness of disease”.<sup>[51]</sup>

**Table No. 4.4: Stakeholder Perceptions and Drivers of Skepticism**

| Stakeholder Group  | Percentage with Negative/Skeptical View           | Primary Driver of Skepticism                                        |
|--------------------|---------------------------------------------------|---------------------------------------------------------------------|
| General Population | ~30% – 50%+ (varies by country) <sup>[49]</sup>   | "Cheaper = Inferior" bias; lack of education. <sup>[5]</sup>        |
| Physicians         | ~30% (India/Lebanon/Saudi Arabia) <sup>[49]</sup> | Preference for brand reliability; influence of reps. <sup>[6]</sup> |
| Pharmacists        | Generally, < 15% <sup>[53]</sup>                  | Concerns about patient confusion with packaging. <sup>[51]</sup>    |

Consumers are generally comfortable using generics for mild conditions like the seasonal flu but exhibit a strong preference for branded drugs for cardiological or oncology treatments.<sup>[54]</sup> To address this, experts recommend public awareness programs that highlight the name of the active substance on labels to reduce confusion and reinforce the message of therapeutic equivalence.<sup>[51]</sup>

## 5. CONCLUSION

The differences between generic and branded drugs are many faceted, and ultimately encompass aspects of chemistry, psychology, law, and economics. Branded pharmaceuticals that have reached the end of their patent life can maintain their market share through a combination of innovative features and defensive strategies such as product hopping, patent thickets, and authorized generics. The result is what the author calls the “Generics Competition Paradox,” in which the threat of generic competition does not necessarily translate into lower branded prices. The generic industry is at a crossroads. The “simple generic” market for oral solids is headed into a “commoditization death spiral” as the margins are getting too thin to sustain a robust supply chain. The future of the generic industry is in “complex generics” and “biosimilars” that have higher entry barriers and greater profitability. Biosimilars have seen remarkable growth with \$12.4 billion in cost savings in 2023, a 30% increase in savings from 2022. Policy makers now have two problems: One is to stop “evergreening” practices whereby innovators seek to extend the life of a patented drug beyond the socially optimal duration of market exclusivity. The second problem is to reform the behaviors of the PBM’s and insurer’s that stifle the flow of generic/ biosimilar savings to patients. Future research will also focus on the potential implications of the Inflation Reduction Act on long term R&D incentives as well as the early results from patent settlements that include “no-AG” clauses. It is essential to have both of the innovative types mentioned above, as well as a robust generic/biosimilar market, supplying huge volumes of low-cost products to the marketplace.



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