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Generic Launch Market Entry Study

Pharmaceutical Care Management Association

Written By
David Walters, ASA, MAAA
Matthew Sauter, ASA, MAAA

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EXECUTIVE SUMMARY

This report examines the market dynamics of the market for an individual drug in the short and intermediate terms after a small molecule brand drug's patent expires (herein referred to as the Exclusivity Phase for the short-term period and the Post-Exclusivity Phase for the intermediate-term period). The study divides the launch types into "Major" and "Other" generic launches, based on average monthly spend for the brand drug in the period immediately preceding the launch.

The generic drug's success in the market is measured by the generic penetration for the generic alternatives and the achieved point-of-sale discount of the generic alternatives compared with the average price of the brand drug in the period immediately preceding the generic launch. Both metrics are measured separately by launch type and the results of each are compared to one another. The study also reviews the relationship between the generic alternatives' achieved penetration and the point-of-sale generic discounts.

The generic penetration analysis demonstrates: 1) remarkably consistent results between the Major and Other launch types, and 2) generic drugs win about half of the market in the first six months of the launch and corner a supermajority of the market after the first six months/exclusivity phase of the launch concludes. The consistency of results for the penetration analysis is evidenced in all of the relevant measurements with respect to penetration. All averages, minimum, and maximum penetration measurements for both phases and both launch types are within a few percentage points. The average penetration is particularly consistent between the launch types, with the average penetration between 49% and 50% in the exclusivity phase and between 70% and 75% in the post-exclusivity phase. The overall ranges show more variance, but still the large ranges of penetration outcomes for individual launches is mostly consistent between the launch types by phase for the period of study.

The generic point-of-sale discount analysis likewise shows mostly consistent results by phase between the Major and Other launch types. Measured against the pre-launched average brand price, the average calculated discounts in the exclusivity phase are approximately 30% for both the Major and Other launch types and increase to just over 50% and 40%, respectively, for Major and Other launches after the exclusivity phase.

Finally, this report finds a positive correlation between generic penetration and point-of-sale discounts. The correlation coefficient between generic drug penetration and generic drug discounts demonstrates that higher generic penetration tends to drive higher cost savings for therapies with new generic alternatives.

DATA

Pharmacy Claim Data

The two primary pharmacy claim data sources for this analysis are Merative MarketScan (MarketScan) and Wakely Affordable Care Act (WACA) de-identified data sources. These datasets represent an average of approximately 20 million large group lives and 4.3 million Affordable Care Act (ACA) lives. For this study, only pharmacy claim data were used (i.e., enrollment data were not employed)—as this study focuses on the impact of patent expiration and emerging generic competition in the pharmacy marketplace.

The WACA dataset includes pharmacy data for individual and small group plans available through the ACA marketplace for the full benefit years of 2019 to 2022. Membership within the span fluctuates from a low of 3.5 million members in 2020 to a high of 5.5 million in 2022, but all years have sufficient membership to be credible for this analysis. The pharmacy data contain details at the National Drug Code (NDC) and individual pharmacy claim level, and the data include allowed and paid cost information and script counts, quantity, and days' supply utilization information. The study uses allowed cost for cost impact estimates in the report, as ingredient cost information is unavailable.

The MarketScan Commercial database includes a large sampling of employer-sponsored plans, and contains data for active employees, early retirees, COBRA continues, and dependents insured by these plans. The MarketScan data are available for calendar years 2014–2023; as of 2023, the data represent approximately 20.8 million lives. For purposes of consistency with the WACA data, allowed cost is used for the cost comparisons between brand drugs and their generic drug counterparts, even though MarketScan includes ingredient cost and dispensing fee detail.

Together, the WACA and MarketScan data provide a five-year window of recent pharmacy data for examination of the market dynamics of generic launch drugs within the pharmacy landscape. Both datasets represent a credible amount of experience for the study; for years in which MarketScan data are unavailable, the WACA data are sufficient for the marketplace analysis in this report, and vice versa. For the years of overlap, when the full cycle of a generic launch is in both datasets, the MarketScan data is preferred given the significantly higher volume of lives and scripts contained in that dataset.

Ancillary Pharmacy Informational Data

In addition to the pharmacy claim data sources, two supplemental data sources are employed in this report to:

- Determine brand/generic drug types
- Identify and group generic competitors of brands with recent patent expirations with the appropriate brand product
- Assign the pharmaceutical manufacturer for each NDC in the data
- Identify the drugs by molecule/launch type as a small molecule generic launch (this report excludes biosimilar launches).

The MediSpan database produced by Wolters Kluwer contains the proprietary Generic Product Identifier (GPI) and the manufacturer associated with each NDC. The GPI is a hierarchical classification code that provides a system to group NDCs into increasingly specific drug categories—from the broadest categories of therapeutic groups and therapeutical classes to the most specific level—which is at the chemical ingredient, dosage form, and strength level of specificity. This field groups generic drugs with their brand competitor products. MediSpan also includes the manufacturer for each NDC so that manufacturer competition for each launch can be quantified. Finally, the brand/generic assignment relies on the multi-source field in MediSpan to determine the drug type status within each brand launch.

The Comprehensive NDC SPL Data Elements (NSDE) file is used to differentiate between generic competition for small molecule brand drugs and biosimilar competition for biologic drugs. The NSDE file provides application type at an NDC level. Any drug approved via a New Drug Application (NDA) is considered a small molecule drug, whereas drugs approved through a Biologic License Application path are either biologics or biosimilars (depending on the Multi-Source field value in MediSpan).

METHODOLOGY

Summary and Categorization of Pharmacy Claim Data

Pharmacy claims from each source are summarized by NDC and incurred month for each drug in the data. The metrics summarized by NDC and month include allowed cost, script counts, quantity dispensed, and days' supply. The unit of measure to determine generic penetration by drug and launch phase is days supply. Generic launch penetration is calculated as the number of days that a member used the generic version of a drug out of the total number of days members utilized the generic or brand version. For this study, days supply is preferred to script

counts to avoid a potential biasing effect due to differentials in extended day supply scripts between the brand version and the generic version of a drug. Days supply is preferred to quantity to protect against potential variance in the population of the quantity field (e.g., an injectable populated with 500 milliliters in one script versus the same injectable being populated with one injection in another script).

After summarizing the drug data by NDC and month, the information from the MediSpan and NSDE tables are linked to the summarized data by NDC. From MediSpan, manufacturer name, drug name, GPI, and multi-source field are all assigned to every NDC. Manufacturer name and drug name stay with the drug without any additional changes or logic. Drug name is used throughout the study, and tables refer to specific drug launches, although actual launches are defined by a subset of the GPI value.

The multi-source field is used to assign brand/generic status for small molecule drugs. This study considers any drug with a "Y" indicator in MediSpan's multi-source field to be a generic drug; all other drugs are considered brands.

For the actual drug groupings to identify generic launches through the data, we use the MediSpan GPI field. The GPI is a 14-digit, hierarchical therapeutic classification system that increases in specificity every two digits. The broadest classification—therapeutic group—is identified with the first two digits. Therapeutic class is the next broadest classification and is represented by the next two digits of the GPI. Following therapeutic class is therapeutic subclass, followed by drug name, then drug name extension, then dosage form, and finally drug strength.

This report groups small molecule drugs at the GPI-12 level to identify the timing of a generic launch. While we acknowledge that some drug patents have different expiration dates based on the strength of the drug, most drugs will not vary in patent expiration beyond the dosage form level of specificity.

Calculation of Launch Timing, Generic Penetration, and Effective Discount

Timing of generic launch determinations are decided at the monthly level for all launches. As discussed previously, days supply is used as follows:

- To measure generic penetration. For small molecule drugs, generic launch is considered to have occurred in the first month that generic penetration crests 10%. Once the launch occurs, the study splits the generic launch into two phases—an exclusivity phase that is assumed to last for six months and a post-exclusivity phase that extends through the end of the range of data. Penetration and discount metrics

are separated by phase. The quantity field can be volatile and inconsistently populated, particularly for non-oral solid drugs, and script count may be inconsistent due to varying rates of extended day supply prescriptions.

- A consideration in the qualitative assignment of generic launches into a "Major drug" versus "Other drug" classification, with drug spend also being considered in the Major/Other classification.
- The basis of the effective discount achieved by the generic launch. To normalize cost, the allowed cost per day is calculated for each launch for the aggregated brand and generic scripts. The achieved discount of the new generic drugs is measured by both the change in cost per day from the pre-launch phase to after the launch (and the post-exclusivity phase), and by comparing the generic cost of the drug with the brand cost of the drug within each phase.

The decision to include a drug in this study—aside from the obvious constraint of the range of data, was determined by the annual level of spend for a drug in the year preceding its launch. Drugs that had less than $1 million in annual expenditures in either dataset were excluded from this study, to limit the effect of generic launch outliers due to the small size and competition for a particular drug market.

Finally, in the Results section, all averages are calculated via a straight average algorithm. While small molecule generic launches are separated into Major and Other categories, the weighting of each launch in the calculation of the averages is equivalent.

RESULTS

Generic Penetration

Within the parameters of the study, there were 31 small molecule generic launches that qualified for inclusion, with the criterion being:

- At least six months of data pre-launch
- At least four months post-launch data
- Either approximately $1 million of annual pre-launch spend in the WACA data or approximately $5 million of annual pre-launch spend in the MarketScan data)

These 31 launches were divided into "Major" or "Other" launches, with Major launches defined as launches with at least $2 million per month in allowed costs in the WACA data or $10 million per month in allowed costs in the MarketScan data. Table 1 shows the average, minimum, and maximum generic penetration for each category of launch in both the exclusivity and post-exclusivity phase.

Table 1. Generic Penetration by Launch Type

Launch Type	Phase	Count[1]	Average	Minimum	Maximum	Range
Major	Exclusive	7	49.5%	13.9%	75.9%	*62.0%*
Major	Post-Excl.	5	73.2%	31.1%	97.1%	*66.0%*
Other	Exclusive	24	49.1%	12.6%	79.4%	*66.8%*
Other	Post-Excl.	21	71.3%	28.7%	96.3%	*67.6%*

New generic launches gain approximately half of the market within the first six months of patent expiration, and close to three-quarters of the market in the post-exclusivity phase within the period of this analysis, although we note that, due to the limits of this study, the post-exclusivity phase is limited to less than two years in almost every launch.

There is only a minor difference in average penetration between the launch types in either phase of the launch. The outer ranges similarly demonstrate little difference in generic penetration. Within the exclusivity phase, the minimum penetration for both launch types is just under 15%, and the maximum penetration for both launch types is between 75% and 80%. After exclusivity, the range shifts to a minimum penetration of around 30% and a maximum penetration of greater than 95% for both launch types.

Perhaps most notable in these generic penetration results is the relatively equal generic market penetration between the Major generic launches and the Other generic launches. The Major drug launches (in terms of dollars) do not seem to attract more aggressive competition than the moderate launches, as measured by generic penetration. The alternate/opposing hypothesis—Major drug launches generating revenue sufficient to justify aggressive protections from the patent-holding manufacturer would be the more likely to show reduced generic penetration—is also shown to be insignificant in retaining market share for the more prominent brand drugs. It is possible that the contrasting motivators of increased generic competition for high-dollar products and the increased retention efforts from the Major brand manufacturers negate each other. Or, possibly, other dynamics are in play that in aggregate

[1] The change in launch counts from the Exclusivity to Post-Exclusivity phases is due to several drugs in the study that did not have sufficient data in the Post-Exclusivity phase to report.

result in a neutral outcome in terms of any relationship between generic launch size and generic penetration. The only certainty from the analytical comparison of Major to Other launches is that the generic penetration difference is essentially zero.

The lack of relationship between the size of the launch and the generic penetration presents on the individual launch level, as well with the two largest launches in the study. The launch with the highest pre-launch monthly spend in the study, Vyvanse, demonstrated higher-than-average generic penetration in the exclusivity phase, with 61.7% (data was not available for Vyvanse in the post-exclusivity phase). In contrast, the second-largest launch in terms of average pre-launch expenditures on the drug, Revlimid, had the second-lowest generic penetration of any of the launches (and the minimum for the Major launch category) in the both the exclusivity phase and the post-exclusivity phase, with 13.9% and 31.1%, respectively.

In summary, the notable results from the penetration metrics of the small molecule generic launch data are twofold: 1) the range of the success of the generic competitors to brand drugs with newly expired patents is both extensive in each phase of the launch process, and 2) the success of the market share gains of the generic competitors does not appear to vary by type of launch in either phase of the process.

GENERIC POINT-OF-SALE DISCOUNTS

The small molecule generic launch study also reviewed the point-of-sale discounts achieved by the generic competitors against the baseline Brand cost. The results of the price discount calculations of the generic alternatives to the brand drugs with recently expired patents illustrate similar themes to the generic penetration metrics. Table 2 below shows the results of the comparison.

Table 2. Generic Discounts by Launch Type, Compared to Brand Cost

Launch Type	Phase	Count	Average	Minimum	Maximum	Range
Major	Exclusive	7	31.0%	13.4%	61.3%	*47.9%*
Major	Post-Excl.	5	51.9%	11.8%	75.4%	*63.6%*
Other	Exclusive	24	30.5%	13.8%	70.4%	*56.6%*
Other	Post-Excl.	21	42.9%	18.7%	84.4%	*65.7%*

As seen in the generic penetration data, the range of discounts from the minimum to the maximum achieved discounts is wide for both launch types and in both phases. The minimum

discounts within the exclusivity phase are below 15%, while the maximum discounts are above 60% and 70% respectively, for the Major and Other launch types. In the post-exclusivity phase, the minimums (somewhat surprisingly) remain below 20% for both launch types (and even decrease for the Major launch), while the maximum discounts expectedly increase to 75%/85% for Major/Other launches.

For the discount average measures, in the exclusivity phase the achieved discounts between major launch types are very close, mirroring the penetration analysis data. Both launch types demonstrate an approximate 30% reduction in cost per day in the exclusivity phase. In the post-exclusivity phase, however, the average discounts show more separation by phase type than in any of the other pre/post data points. For the Major launches, the generic discount increases to approximately 52% in the post-exclusivity phase, while the Other launches show a discount of only 43%. The differential in averages between Major and Other launches may be due to the lower count of Major launch data points driving volatility in the measure, and with additional data points the average measures may converge. However, given that fewer data points for the Major launches does not resulting in differences in other measures, the break between Major launches and Other launches in the average discount measure may be meaningful.

RELATIONSHIP BETWEEN GENERIC PENETRATION AND DISCOUNTS

Less surprising is the correlation between penetration rates and generic discounts. Penetration rates demonstrate an r-squared correlation of greater than 0.50 with generic discounts off the brand alternative, meaning higher generic discounts are associated with higher generic penetration rates. Economically, this is sensible; the brand name value diminishes relative to a generic drug when the generic delivers a greater savings. Returning to the Revlimid example, anecdotally, the Revlimid generic holds to this relationship. Revlimid's generic alternative has the lowest penetration rate of any Major generic launch and demonstrates the least savings of any of the generic launches of *any* type. While there are occasional outliers within the forty-odd launches examined, overall, the correlation coefficient demonstrates the relationship between penetration and achieved discount through most of the study participants.

CONFLICT OF INTEREST

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DISCLOSURES AND LIMITATIONS

Responsible Actuary

David Walters is the actuary responsible for this communication. David is a Member of the American Academy of Actuaries and an Associate of the Society of Actuaries. He meets the Qualification Standards of the American Academy of Actuaries to issue this report.

Scope of Services

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