



Unstoppable Generics:
A Guide for Manufacturers

Model **N**

It's All About Generics

The generic drug market in the U.S. continues to evolve at the mercy of scheduled patent expirations of branded drugs and treatments. Generic equivalent options offer the same results to patients, but cost significantly less for both payer and patient—around 80-85% on average. Payers pay a higher percentage of the cost of generics to encourage patients to take advantage of the savings while maintaining the same standard of care.

In the past several years, branded drug manufacturers have experienced what many are calling the “patent cliff”—a term that indicates revenue from branded drugs lost to patent expiration. In 2010, the year before a significant patent cliff took effect, generics accounted for 69% of all prescriptions dispensed in the U.S. By 2012, this number had grown to 84%.

The patent cliff peaked significantly in 2012. Drugs that went generic put \$52B in sales at risk—and ultimately, approximately \$37B was lost to generics. The next big cliff occurred in 2015, with 7% of the market, or approximately \$51B total sales at risk for brand manufacturers. Of that, only \$16B were picked up by generics, as many of expired drugs were biologics or large-molecule drugs, which are more difficult to replicate.

Did You Know?

In 2016, \$253B was saved through generic drug usage in the U.S.

— EvaluatePharma, 2018

Following 2015 until 2018, total sales at risk plateaued to an average of \$36.6B each year, or approximately 4.6%. That said, this plateau is expected to end as there will be approximately \$251B of sales at risk between 2018 and 2024, and more than 25% of those are in 2023 alone.

You Know What They Say... More Money, More Problems

Generics manufacturers must consider how to manage increased sales while maintaining compliance and avoiding revenue leakage. These manufacturers face a number of specific challenges that can make growth and profitability more elusive than for their branded counterparts.

Maintaining profitability while operating with razor-thin margins, achieving growth amidst intense downward pricing pressure, and ensuring compliance with evolving government regulations are concerns for any manufacturer. The risks of revenue leakage and government compliance are fears for many, but for generics manufacturers the landscape is much different.

Manufacturers rely on selling high volumes of low cost drugs in order to achieve their bottom line goals. Retail markup is low, so profit margins are thin. In order to keep costs very low for patients, manufacturers must keep their cost of developing and delivering quality generic drugs to a bare minimum.



It's a Jungle Out There

If you're in it, you know that the pharmaceutical industry is among the world's most competitive and is evolving at a rapid pace. The global population continues to rise and by 2020, people over 65 will outnumber children under 5, leading to increased demand for drugs and treatments that prevent, treat, and cure illness. On top of this, as brand patents continue to expire, more generic drugs will be in demand thanks to payers and patients looking to save money.

Competition will continue to increase as more manufacturers attempt to capitalize on the growing sales of generic prescriptions. Although generics have been a positive driver of growth, particularly between 2013 and 2015, it declined by \$5.5B in 2017 due to fierce competition. Consolidation within the industry has also been a method to continue growth and has led to major players like Teva Pharmaceuticals and Pfizer. With their massive portfolios, these companies can be more competitive on prices by undercutting the margin to gain and establish share.

To succeed in this evolving market, there are only so many things a generic manufacturer can do. Operating with such small margins, generics manufacturers cannot use marketing and advertising to the same extent as their

Did You Know?

Global generic drug sales are projected to account for 29.2% of total sales in 2022—a 1.2% increase from 2017 sales

— Deloitte, 2018

branded counterparts—it simply does not fit into the budget.

So what can manufacturers do to grow market share in this competitive environment? One place to start is by gaining better control over their contracts and contract lifecycle processes. Manufacturers also use tendering to compete in the global market and drive down healthcare costs by submitting bids to win a market's contract.

What may seem like pesky day-to-day roadblocks—like delays in contract approvals, missed milestones or errors in contract language—can, in fact, lead to serious consequences. Each issue can snowball from one or two missed deals to missed revenue targets and, possibly even worse, loss of existing customers. Losing deals and customers to competitors over mismanaged contracting is something generics manufacturers just cannot afford in the pursuit of growth.

Where is All of Your Money Going?

Generics manufacturers rely on creative pricing incentive agreements to drive market share and increase product profitability. But these types of complex, multi-tier, volume-based incentives come with risks.

The reconciliation processes for high volumes of incentives like chargebacks and rebates can add serious complexity to revenue management and require careful attention. When chargebacks or rebates are overpaid, inaccurately paid, or not paid on time (resulting in penalties), manufacturers suffer the financial consequences. A slow leak in revenue from the top to bottom line can occur and build up significantly over time.

The reliance on manual processes and homegrown or outdated systems is typically the culprit. When individuals are manually collecting and entering data, like incentive parameters or invoice information, the potential for error is high. Human error is a major risk when it comes to managing spreadsheets or any data entry-based task—it is just too easy for mistakes to occur, and small mistakes can lead to big losses over time.

In the past four years, manufacturers have paid an average of \$7.35 million in a single overcharge penalty

For generics manufacturers, of course, things can be even more complex. They operate within razor-thin margins. Managing the intricacies and complexities of incentive reconciliation processes can be difficult even with large budgets, and for manufacturers of generics, it can add significant administrative burden on staff resources. When employees are overworked, errors are more likely to be made. Many transactions get processed without attention, overlooked, or even intentionally skipped due to time constraints.

15% of global revenue loss occurs due to price erosion

— Public Citizen,
Model N internal analysis

With strained resources and outdated processes and systems, manufacturers have limited ability to execute the complicated price and rebate terms necessary to be competitive and drive share growth. It is essential to minimize revenue leakage in order to maintain profitability under tight margins. The critical starting point is getting the right systems in place to ensure adherence to and accuracy of price and rebate incentive programs.

Healthcare Reform

Government regulations in the pharmaceutical industry are strict, and manufacturers must have the proper systems in place not only to ensure and maintain compliance with rules and regulations, but to be able to prove compliance as well. Penalties for non-compliance or lack of positive proof of compliance can be quite severe. Given the thin margins for generics manufacturers, a hefty fine could cripple their operations.

ADAPTING TO REGULATORY CHANGES

The election of Donald Trump and his administration's plan to eventually repeal and replace the Affordable Care Act (ACA), colloquially known as Obamacare, has led pharmaceutical manufacturers to prepare for a variety of scenarios. With the ACA, manufacturers have been scrutinized much more closely for compliance and this is expected to continue for as long as the ACA is in effect.

While the repeal of the ACA is still underway, a number of other regulatory changes have been already been passed. A tax reform passed at the end of 2017 gives manufacturers greater incentive to bring overseas earnings back to the U.S, with a new corporate tax rate of 21%, down from 35%. With more cash in hand, this may lead to an increase of mergers and acquisitions or greater spending in research and development, therefore prompting even more movement in the industry.

Additionally, Trump's 2019 budget proposal outlines methods to reduce high drug prices by increasing market competition. One aspect of the plan is to change the generic review process, making it more efficient and therefore expediting application approvals. The FDA is also fostering more competition by putting policies in place that will promote generic alternatives to complex drugs, which can be more difficult to replicate.

Furthermore, more emphasis has been made into pricing transparency at the individual state level, with California taking the lead in signing a law in early 2018 that requires manufacturers to clearly define cost components.

Outside of the U.S, the United Kingdom's exit from the European Union, known as Brexit, will lead to future market access changes. The exit, official as of March 2019, can result in any number of regulatory and trade challenges, leaving manufacturers to prepare for multiple scenarios depending on the decided upon exit scenario.

Regardless of potential changes to the ACA, manufacturers must make sure their systems are ready and able to adapt to any of the expected global market access and regulatory changes. For some, this may mean minor updates, but for others, it could mean a full system upgrade or even the addition of new solutions.

Generics manufacturers need to get their ducks in a row quickly. Manufacturers will need to comply—or pay the price.

The Solution: Integrated Contract and Revenue Management

The key to continued success for generics manufacturers will be taking a proactive and integrated approach to managing contracts, revenue, and compliance. As contract volumes grow, so does the diligence required to execute effective strategies for managing contract lifecycles, reimbursement and incentive strategies, processes and compliance.

A system that integrates and unifies each of these disciplines will streamline processes throughout the entire business. It will ensure accuracy of reimbursements and automate compliance functions—vital steps to ensure profitable growth. The manufacturers who will succeed as the market evolves are those that have proper systems in place to support new contract and pricing structures, changing relationships with Medicaid, GPO, IDN and local hospitals, and increased visibility into all aspects of revenue management.

This integrated approach includes automated contract creation and execution, tools for handling multi-tier pricing incentives and complex revenue structures, compliance solutions to meet commercial, financial, and industry regulations, and analytics to report on past performance and model future success.

However, there are serious things to consider. Generics manufacturers need proper systems in place, but are operating with constrained resources—tighter budgets and slimmer margins—and thus, they need solutions with minimal administrative burden, within budget, and that are flexible enough to grow.

Revenue Management is a strategic asset, responsible for over 25% of a company's revenue

— Model N internal analysis

Get All Your Ducks in a Row

As the competitive landscape becomes more intense, only manufacturers who are agile enough to quickly adapt to changes in the market will gain the competitive advantage needed to succeed. It is essential to take the necessary steps and get the proper systems and solutions in place before major growth occurs.

First things first—it is critical for the organization to grasp the strategic importance of improved revenue management, rather than viewing the contracting process as just a series of tasks to complete, or boxes to check on a list. In fact, by implementing a revenue management strategy and automating every phase of the contract lifecycle, companies will improve end-to-end visibility into contractual relationships and performance outcomes while speeding the sales process and reducing risks. This is critical for success in the competitive and complex generics market.

So, what are the keys to contract management that drive success for generics manufacturers?

AUTOMATED WORKFLOWS speed contract review and approval processes. Automation prevents contracts from slipping through the cracks due to delayed approvals, lost deals, or missed milestones.

RESOURCES AT EMPLOYEES' FINGERTIPS enable companies to build and execute more effective and profitable contracts in a shorter period of time—including language libraries, legal-approved templates, terms and conditions, a central repository, e-signature functionality, and mobile access.

ANALYTICS TOOLS to evaluate past contract performance and provide invaluable insight. Visibility into past contract performance allows proactive sales executives to model new pricing structures and analyze effectiveness of contract terms in preparation for the next renewal or new deal.

Keep Your Hands on Your Money

No system will effect as much change for a pharmaceutical manufacturer as a comprehensive pricing execution engine. Companies seamlessly regain control over pricing and reimbursement processes—ensuring accuracy of outgoing payments. Many manufacturers don't even fully grasp the seriousness of their revenue leakage problem until a pricing system is implemented and bottom line revenue sees a major boost.

A system that is fully integrated with contracting and compliance applications as well as with internal systems like ERP and CRM can really make a serious impact throughout the organization. A pricing system that captures terms and conditions from the contract, then defines, processes, and executes chargebacks, rebates, discounts, and other incentives and passes off the data to the ERP system for payment reconciliation, will enable manufacturers to:

REDUCE INACCURATE PAYMENTS: Complex fee structures, customer and product eligibility and pricing calculations associated with rebate and chargeback agreements are executed automatically, ensuring accurate payments based on contract terms—thereby reducing revenue leakage and improving profit margins.

MINIMIZE COMPLIANCE RISKS: An integrated pricing system maintains auditability for regulatory, financial, and commercial compliance and contains solutions to lessen risk and streamline accurate compliance reporting.

OPTIMIZE CONTRACT PROCESSES: Increased visibility into financial performance will supplement future contract development, negotiation, and renewals.

Get a Good Night's Sleep

Generics manufacturers have always faced a plethora of compliance requirements. Ongoing healthcare reform measures will bring more rules to learn and requirements to satisfy. Companies managing compliance manually—such as with a spreadsheet-based system—are probably already pushing the limits of what their resources and systems can support, and the situation will only continue to get more complex.

With automated applications, achieving, maintaining and reporting on compliance with the 340B drug pricing program, Medicare, Medicaid, and other government health programs becomes easier. These systems enable manufacturers to be more adaptable to government requirements that know only one constant—change.

WHAT DO GENERICS MANUFACTURERS NEED IN A SYSTEM TO BE SUCCESSFUL WHEN IT COMES TO COMPLIANCE?

- Execution of government-compliant processes
- Automated and streamlined audit processes
- Sufficient reporting functionality to thoroughly prove compliance
- Out-of-the-box reports that meet government requirements with flexibility to configure according to specification from legal counsel



Relying on Model N

Model N's Revenue Cloud for Pharma provides a comprehensive suite of solutions that manage the most complex pharmaceutical contracts and pricing agreements. As an expert in the domain with a deep knowledge of the industry, Model N has been delivering these solutions to pharmaceutical companies for nearly two decades.

Model N provides powerful Revenue Management solutions delivered in the cloud, designed to bring agility, flexibility, and scalability to companies while enhancing performance outcomes and improving compliance—exactly what the doctor ordered for generics manufacturers in the 21st century.

Model N solutions integrate applications for contract management, pricing and reimbursement execution, and compliance automation—and deliver the suite on a single, strategic platform that provides agility and scalability and features advanced analytics to improve visibility.

Join the industry's leading manufacturers, with 96% of the top 25 pharmaceutical companies, who rely on Model N to maximize their revenue by minimizing revenue leakage and compliance risk.



ABOUT THE AUTHOR

Model N is the leader in revenue management solutions. Driving mission-critical business processes such as configure, price and quote (CPQ), contract and rebate management, business intelligence, and regulatory compliance. Model N solutions transform the revenue lifecycle from a series of disjointed operations into a strategic end-to-end process. With deep industry expertise, Model N supports the complex business needs of the world's leading brands in pharmaceutical, medical device, high tech, manufacturing and semiconductors across more than 120 countries, including Pfizer, AstraZeneca, Sanofi, Gilead, Abbott, Stryker, AMD, Micron, Seagate, STMicroelectronics, NXP, Sesotech, and Southern States. For more information, visit www.modeln.com. Model N® is the registered trademark of Model N, Inc. Any other company names mentioned are the property of their respective owners and are mentioned for identification purposes only.



Model **N**