Whitepaper

IntegriChain®

The Case for a Market Access Platform

The Time Has Come!

All businesses depend on certain core processes to successfully operate. For example, every company needs to buy some type of goods and services, so they have at least a basic procure-to-pay process. Similarly, all companies have a type of order-to-cash or lead-to-cash process for generating revenue and attract-to-retain processes for managing their human capital.

In the Life Sciences industry, drug commercialization is one of those core processes. While there are many variations, they all involve a stepwise flow from hypothesis development to discovery, pre-clinical development through multiple clinical phases, regulatory approval and eventually launch. So, we can think of this as a specialized version (due to the regulatory requirements) of a traditional design-to-deliver manufacturing process. If you research drug commercialization processes, you'll find they all end with "deliver" or launch. Is that really the end? Is that truly the outcome Life Sciences manufacturers are seeking? At IntegriChain, we see launch as an important milestone, but an interim one at that. Instead, we see patient initiation and adherence to therapy as the true end state. So, what does this mean? It means there is a second, less-hyped business process called launch-to-adherence or, in common terms, market access.

Emergence of the Market Access Paradox

Every year, there are between 4 billion and 4.5 billion prescriptions written by healthcare providers (HCPs) in the United States. These can range from basic antibiotics for a sinus infection to complex therapies for rare diseases. Industry

research shows that 30% or more of those scripts are never filled. This is a staggering figure and one of the key points about why "design-to-launch" doesn't tell the whole story of what it takes to succeed in the Life Sciences industry. There needs to be a complementary process that ensures that the newly-launched drug/therapy gets to the right patients in a timely manner and that patients can readily begin and stay on the treatment as long as prescribed. There are many reasons why this doesn't happen which we'll cover later in this paper.

Before we dive in deeper, let's examine three fundamental changes in the way Life Sciences companies go to market and the three operational shifts they cause.

Shift in the Recipe for Success. Historically, the key to brand success was demand generation. Life Sciences manufacturers targeted conditions evident in large populations of hundreds of thousands or even millions. They built large sales forces to cover the market and call on HCP offices and encourage them to write prescriptions for their products. Additionally, they developed relationships with key opinion leaders (KOLs) and from an internal support perspective, built large commercial data warehouses, operations, and processing capabilities. It was all about brand, sales, and scale.

However, today's market dynamics are extremely different. For example, the average Life Sciences brand is targeted at a population of only 20,000 or so, not millions. We've gone from a broad approach to one that is more targeted. As manufacturers target more narrowly-defined diseases and indications, the entire business model changes.

- It's less about calling on every HCP but rather focusing on those providers who focus on the specific conditions.
- The role of payer support becomes even more important as these targeted therapies often carry a hefty price tag.
- Not only are these therapies more expensive, but they can require complex dosing and administration, not to mention significant side effects. All of this puts greater responsibility on the manufacturer to provide patient services to ensure patients actually get their scripts filled, begin therapy and stay with it.

- The specialty nature of these Life Sciences often requires a more specialized distribution channel and reimbursement structures become more complex.

Shift in Commercialization Strategy of Pre-Commercial Companies. In the past, tiny companies with innovative products stood no little chance of achieving market access. Unlike the large Life Sciences manufacturers, these start-ups lacked the scale, capital, and resources necessary to reach populations in hundreds of thousands or millions. So, the standard approach was to invest in R&D, get to clinical phase 2 or 3, and then sell to one of the major manufacturers. However, in today's market where the focus is on targeted therapies for very specific indications, scale isn't as critical. For start-ups, this means it is more attractive to bring their own solutions to market instead of selling-out to a major manufacturer. This means there are more companies than ever looking to build market access capabilities, even if it is only for one specialized brand.

Organizational Shift. Historically, Life Sciences organizations were organized very functionally:

- The sales accounting team that was responsible for calculating and tracking the financial performance of the drug, reported into the Finance organization.
- The trade and channel team that handled all of the distribution relationships reported into the head of market access.
- The payer management team and the contract and pricing teams reported into the head of commercial operations.

All of this makes perfect sense from a functional perspective; however it did create the proverbial siloes with one department not always understanding how their decisions and actions impacted the others. More on this shortly.

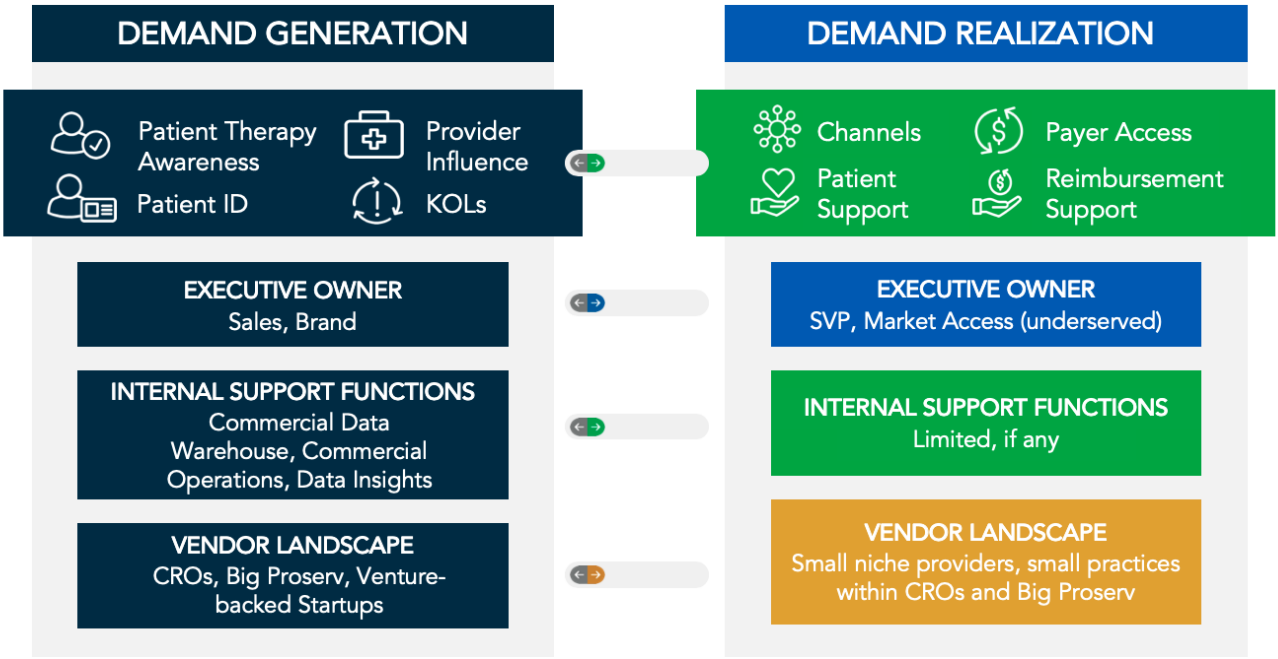


Figure 1 - Change in Pharmaceutical Operating Model

All of this had three profound operational implications.

1. Whereas the traditional model was all about demand *generation*, today's success formula is about demand *realization (Figure 1)*. The data proves that simply getting more and more prescriptions written isn't the key to success. It's getting patients the right therapy, at the right time, with the proper support so that they can get better.
2. Secondly, it is virtually impossible to achieve market access success and efficiency managing all of the access-related functions in a siloed manner. Instead, a more integrated approach would be necessary.
3. This also means there's a new "hero" in the story: the head of market access. This leader is responsible for ensuring all of the proper contracts, pricing, programs, relationships, policies, and metrics are in place to ensure patient success and in turn, a successful product.

This is where the story takes an unfortunate twist. Finance, HR, and R&D executives run their operations by leveraging their enterprise resource planning (ERP), human capital management (HCM), and drug commercialization platform, respectively. What about the head of Market Access? What do they have as their platform? This is the Market Access paradox.

Why the Platform Wins

The age-old story of “best-of-breed versus platform” plays-out every time there are unmet data, applications and analytics needs. While some companies segment their market access challenges and purchase a separate solution to address each need. However, in the case of market access, the needs cut across different functions, making this point-solution approach troublesome.

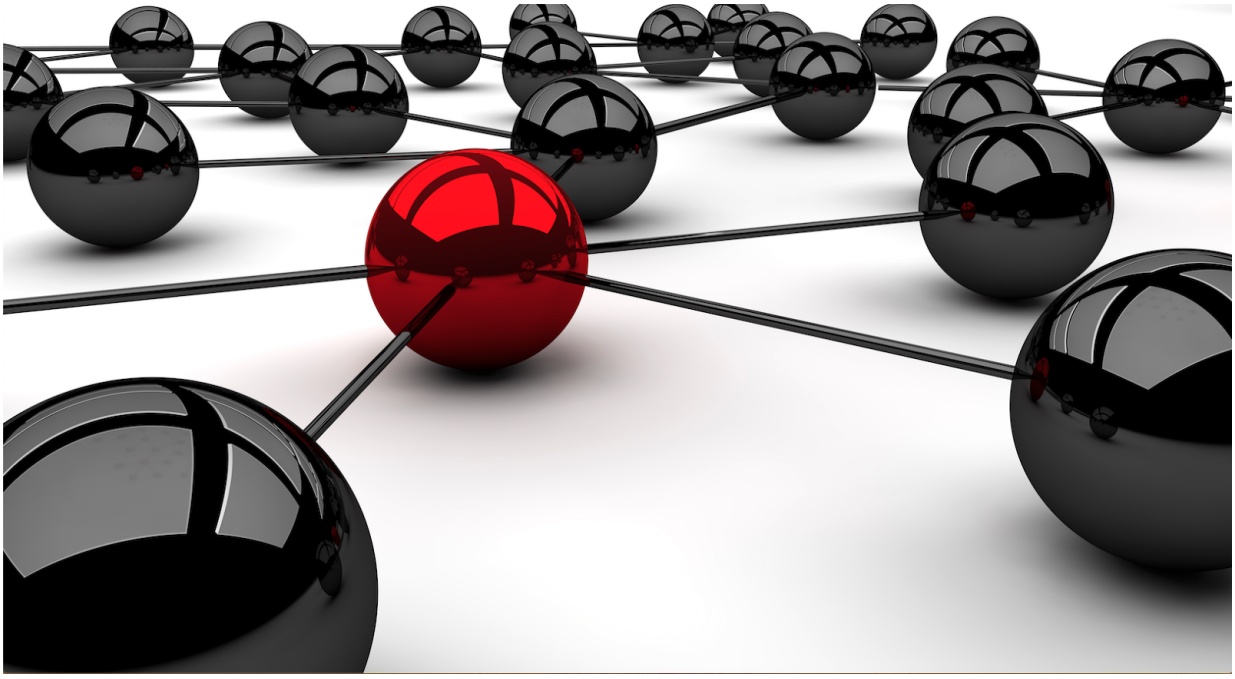
To look at the market access implications, let us consider a Life Sciences manufacturer with five brands. Two of the brands require specialty pharmacies, two rely on retail distribution, and one needs a hybrid model. There are a variety of commercial and government payer contracts needed and three of the brands are expensive, are complex to administer and two of those have potentially significant negative side effects. Now, let’s explore some of the market access management challenges:

- **Patient Services.** Patient services have become increasingly important as drugs have become more expensive and require greater patient out-of-pocket payments. Additionally, therapies that have significant side effects or require intravenous (IV) or other complex routes of administration also create a need for greater patient education. However, all of the cost of all of these services need

to be taken into account by the finance and accounting teams in terms of managing their accruals process and accurately calculating net-price or gross-to-net
Implication: We have clear dependencies between Patient Services and Gross-to-Net functions.

- **Channel Management.** For the retail drugs, ensuring all of the distribution centers (DC), pharmacies, and other points of care (POC) have the right amount of inventory of the proper drugs is critical. Omits (or stock-outs) can result in delays in patients getting the medications they need and also have a negative impact on the brand's financial performance. Furthermore, channel performance needs to be compared to the contractual commitments that have been agreed upon by both the manufacturer and their trading partners. Finally, excess inventory and/or product returns must be accurately planned and accrued to ensure the gross-to-net calculations are accurate.
Implication: We have clear dependencies between Channel performance both Contract and Pricing and Gross-to-Net functions.

- **Data Quality.** In the Life Sciences industry, as with virtually every other industry, data is gold. Whether it is information about the inventory and sales of the product in the retail channel or data from your specialty pharmacy partners about patient initiation and adherence statuses, all of this data is vital to the manufacturer and is a critical part of every manufacturer-trading partner contract. In fact, it is not uncommon for the data to represent a significant portion of the overall contract value. However, this data needs to contain specific information, delivered in a specific format, on a regular basis. Every manufacturer struggles with missing, inaccurate, or blinded data that limits their ability to manage their product and ensure a successful patient journey.
Implication: We have clear dependencies between Channel and Patient data and contractual obligations and commitments.



- **Payer Contracting.** Sometimes, pharma manufacturers don't contract with certain payers and just accept whatever coverage and restrictions (e.g., prior authorizations) are given. However, in many cases, manufacturers contract with payers (and provide discounts) for more favorable coverage and terms, all in an effort to make it easier (and often, more affordable) for the patient to initiate and adhere to therapy.
  Implication: We have clear dependencies between payer contracting strategies and Gross-to-Net functions.

- **Patient Journey Insight.** As noted earlier, many patients never get their prescriptions filled and of those that do, many never begin or stay on their course of treatment. The reasons for this vary:
  - Patient was sent to a pharmacy that didn't accept their insurance
  - Patient's insurance wouldn't cover the therapy
  - Patient lost the prescription

- Patient started taking the medications but stopped because of negative side effects
- Patient was too scared about administering the medication and never started
- Patient had questions about the prescription and couldn't find someone to answer it, so they postponed starting the treatment
- Patient went to get the prescription filled and they didn't have it in stock

It is critical for the manufacturer's market access team to have accurate, timely insight into all of these situations in order to know how to eliminate the access obstacle. Finance-related obstacles could require detailed discussions and case reviews with payers. Administration or side effect issues could involve working more closely with HCPs and specialty pharmacy partners. Product availability could involve conversations with channel partners.

Implication: We have clear dependencies between Patient and Channel data and Patient Services, Contracting, and Gross-to-Net functions.

These are just examples of some of the relationships between contracts, discounts, patient services, channel relationships and gross-to-net that need to be managed on a daily basis. The increasing need for greater efficiency, deeper, and faster insight and the ability to ensure accountability and performance across the entire market access ecosystem demands an integrated approach to market access management. There is simply no way to accomplish this using a siloed or point-solution approach.

Essential Platform Capabilities

For the purposes of this paper, we're going to look at the key capabilities in terms of being able to manage market access in an integrated manner. For that, the platform needs to offer:

- **Data Management.** This includes being able to aggregate channel data as well as patient status update data, apply data science techniques to enrich and refine the data and eliminate duplicates.
- **Operational.** This includes the ability to establish and monitor payer and channel contracts, process chargebacks and process and adjudicate all types of Medicaid and managed care rebates. This also must include meeting compliance with all filings relating to government programs and contracts.

- **Analytics.** Many companies struggle with data overload. The market access platform must have robust analytics capabilities to be able to proactively identify potential access-related issues, regardless of whether they are payer, channel, provider, or product-related. These analytics need to support trending, enable root cause analysis and identify key patterns that could be opportunities for operational improvement.
- **Integration.** Integration here is two-fold. First, there needs to be a common data schema to allow all of the different functions (e.g., contracting, pricing, gross-to-net) to leverage the same data so there is "one version of the truth." Secondly, the platform needs to be designed with APIs and connectors to allow integration with external systems such as Model N's revenue management system.

- **Scalability.** Finally, the platform needs to be able to support growth in terms of users, trading partners, contracts, transactions (e.g., rebates processed) and governance of massive amounts of data.

With these capabilities, a manufacturer will realize:

- More accurate accruals and more timely gross-to-net forecasts
- More efficient compliance with government programs
- Strong relationships with channel and specialty pharmacy partners
- Faster and more proactive identification of potential obstacles to patient initiation
- Deeper insights into product performance and the overall patient journey

Conclusion

The Life Sciences industry has silently undergone a huge shift which has caused market access or "launch-to-adhere" to become a major area of focus for manufacturers of all size and complexity. Furthermore, this has necessitated the creation of a true platform for managing market access. By managing market access in an integrated manner, manufacturers will realize operational improvements across all of the functional areas, leading to strong trading partner relationships, better patient outcomes, and stronger financial performance.

Authors:
Michael Kerman, VP Marketing, mkerman@integrichain.com
Mia Scioscia, Product Marketing Manager, mscioscia@integrichain.com

About IntegriChain

IntegriChain delivers Life Sciences' only comprehensive data and business process platform for market access. More than 230 life science manufacturers of all size and complexity rely on IntegriChain's analytics, applications, managed services and expert advisors to power their operations and harness the value of their channel, patient and payer data. IntegriChain has played a vital role in more than 70% of product launches over the past two years including 35 first launches. For more information, please visit www.integrichain.com or ic@integrichain.com.