

# Developments in Specialty Pharmaceuticals



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Today, specialty pharmaceuticals are special indeed: they are dominating pipelines and their sales are forecasted to grow in Canada at twice the rate of traditional products for the next five years. By 2013, global revenue from specialty products will exceed \$160 billion. Manufacturers are facing some interesting and unique challenges:

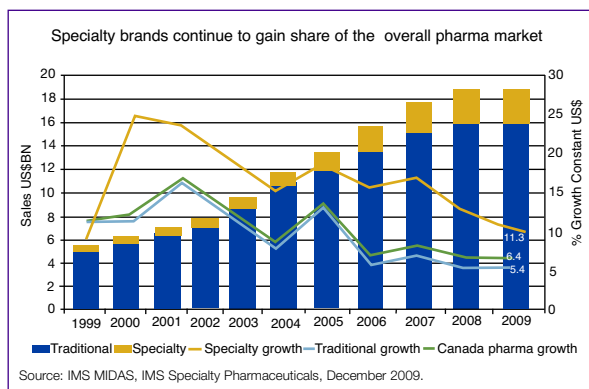
**By 2013, global revenue from specialty products will exceed \$160 billion.**

- The technological evolution behind this extraordinary surge and commanding market presence is driving the need for additional sites of administration and new distribution models. What should manufacturers consider as they navigate the complexities and nuances of their relationships with specialty pharmacies?
  - Intensified cost pressures will challenge the degree of access to specialty products. What strategies can help companies sustain their commercial success?
  - Economic challenges will chip away at patient adherence to these expensive therapeutic regimens. How can manufacturers counteract this trend and support strong patient outcomes?
  - Which key performance indicators are relevant in these highly complex markets?
- This glimpse into the emerging reality is intended to help manufacturers as they bring

new products to market and partner with specialty pharmacies throughout the lifecycle of specialty products.

## Specialty product distribution (SPD)

The direct-to-patient distribution model is evolving rapidly, as patient-centric full-service organizations combine distribution, pharmacy and therapy administration. Accounting for 10.9% of total market and growing by 16.1% in 2009, specialty products are driving more volume through the direct-to-patient distribution model. Two examples of SPDs are Innomar Specialty Logistics and Bayshore Specialty Rx. These organizations prepare, store, distribute and administer to patients treatment therapies of IV and injectable drugs used in anti-infection therapy, chemotherapy, palliative care, enzyme replacement therapy and total parenteral nutrition. The boundary between distributor, retailer and patient care was blurred with Shoppers Drug Mart's July 2008 purchase of Calea's HomeCare division and this merging of roles in the supply chain compounded further in 2009 with AmerisourceBergen's acquisition of Innomar Strategies Inc. The impact of specialty distributors' business model changes suggests longer linkages from product to patient, thereby altering distributors' future capital investment, organization structures and the services that pharmaceutical companies can now partner with to ensure more optimal distribution for their specialty products.



## Applying a “specialty lens” to commercial decisions

In order to make effective commercial decisions, companies operating in the specialty pharmaceutical market need a broad base of evidence on prescribing practices, sales and prescription activity, treatment pathways and patient outcomes. They need access to:

- Sales and prescription volume and share in each relevant channel
- Drug use by indication
- Dosing metrics
- Anonymized, patient-level data tracked over time to reveal penetration patterns by patient characteristic, treatment pathways, utilization history and health outcomes
- Source-of-business metrics, uncovering market dynamics
- Health Care Relational Spheres (HCRS) to understand the affiliations between entities

When advanced analytic techniques are applied to this foundational understanding of how specialty products are being prescribed, distributed and used, it is possible to:

- Direct pipeline investments based on an accurate assessment of market opportunity by indication
- Develop sound distribution strategies early in the product lifecycle so that positioning within the channel becomes a competitive advantage
- Achieve optimal market access, relying on proof of health outcomes to support value demonstration
- Ensure that launches follow the most

## Keys to commercial success

- Understanding fully the market opportunity value
- Implementing the right strategy based on the opportunity
- Seeking out secondary data sources which will support evidence-based decisions
- Constantly refining strategy by utilizing these insights to benchmark performance against key performance indicators

advantageous pricing and reimbursement strategies

- Segment prescribers based on a true understanding of their treatment patterns and visibility into their patient populations
- Allocate promotional resources effectively, by indication
- Manage brands for optimal performance, mindful of competitive moves and market dynamics

## A focus on key performance indicators (KPI)

KPIs are defined as: “a set of quantifiable measures used to gauge or compare performance.” A term used many times in pharmaceutical marketing, but one with a strong need in specialty marketing.

Building out strategy, resourcing brands and driving tactics often rely heavily on qualitative insights, from primary market research and feedback from the sales team. What would be tracked if it could? What we know can make us win, what we don’t know can make us lose. Undertaking a market opportunity assessment, performing treatment tracking and trending, or figuring out how best to target the sales force, remain as critical for specialty brands as they always did for non-specialty brands.

The key to success in specialty brands is to understand the KPIs that will drive the business, then get the insights needed for your metrics and undertake meta-analysis of the data sources. The

key is in asking the right question. The answer will come from various different data sources and the way in which these insights inform each other will provide a comprehensive answer.

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For example in HIV, guidelines are in place, varying from province to province and from unit to unit on how to treat most effectively. Differences occur in the treatment pathway, based on disease progression and viral load. A typical KPI could be to ensure that treatment is used correctly in treatment pathway guidelines, perhaps from a consensus in the CMAJ or issued by the establishment treating the patients. If the brand is being used as per guidelines, the targets are met. The data may be different in each setting, but by asking the right question of the

data, the patient pathways can be built for that unit and tracking of success can begin.

Once the KPI is established then the process of informing data sets can begin. Lab test results such as viral load can be cross-referenced to treatment, demographics and certain prescriber indicators can be ascertained.

Secondary data first is the strategy now of many pharmaceutical companies in their drive to get rigour into the marketing process with specialty brands. So what are the benefits of this approach vs. the traditional primary market research approach? Have prescribing and treatment patterns fully analyzed first. Nothing can beat taking anonymized patient records, prescribing records and building longitudinal analysis for accuracy, statistical significance and most importantly, the data is observational. Once the approach to establishing and tracking KPIs is embedded into the Marketing process, the qualitative research can be added to find out more about the “why.”

For companies already in—or planning to enter—the specialty pharmaceutical market, the shifting landscape presents key business challenges: understanding the dynamics of the market, demonstrating product value in terms that all stakeholders appreciate and developing the best distribution strategy for each product in the portfolio. By implementing a key performance indicator approach, underpinned with the best secondary data, figuring out the right insights required becomes a whole lot more straightforward, enabling optimal return with the resources available. **CPM**

