GOING DIRECT: BOLD STRATEGY FOR HEALTHCARE SUPPLY CHAINS

DHL Supply Chain

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Producers of pharmaceutical products and medical devices have long tied their success to the development of innovative products. Now they are under pressure to apply the same bold approach to moving their products to market.

While known for pioneering drug development and advanced technology, the life sciences and healthcare industry remains remarkably traditional when it comes to getting product into the hands of its customers, be they hospitals, pharmacies or consumers. Healthcare manufacturers still rely, in large part, on a distribution model that has not changed in decades – despite the fact that the state of the art in supply chain management has evolved radically.

The traditional go-to-market model for healthcare manufacturers has relied primarily on a wholesaler model in which the manufacturer hands over ownership and control of its product to a tier of intermediaries. This system has enabled companies to concentrate on research and development (R&D), manufacturing and marketing. While it has worked well, it may not be the best model for manufacturers in the future.

Why? Because a host of new market forces is converging to change the business paradigm for manufacturers. The cost of drug development is soaring, causing margins to shrink at an alarming rate. The expiration of patent protection for certain lucrative drugs, with the resulting flood of generics, presents yet another challenge. At the same time, a rise in the number of large-scale mergers is putting pressure on surviving manufacturers, which are also facing the growing market power of wholesalers and pharmacies.

To future-proof their businesses, healthcare manufacturers are beginning to distribute direct to the customer in targeted markets and for certain product types. In specific instances, the manufacturer assumes full, direct control of distribution to the customer in a direct-to-market (D2M) channel, bypassing the traditional hand-off to an intermediate wholesaler.

A D2M strategy represents a bold departure from the status quo healthcare product distribution model. For certain products, it offers potentially powerful benefits, including improved margins, visibility into actual sales, consumption and usage, and direct control of the order-to-cash cycle.

This paper explores the concept of the integrated D2M channel strategy and why it represents a strategic but targeted opportunity for healthcare manufacturers. It also looks at what is driving manufacturers to consider a direct solution, provides advice on evaluating where and when such a strategy makes sense and presents a case study example of D2M at work.

PART 1:
MARKET DYNAMICS AND DRIVING TRENDS

The healthcare manufacturing industry is under siege, buffeted by a set of market dynamics not previously encountered.

COST PRESSURES AND RISING FINANCIAL RISK

Pharmaceutical manufacturers now face a mounting array of cost and financial risk pressures in the new day-to-day of global business. The first – cost pressure – stems from the fact that the universally rising cost of healthcare is prompting payers (governments, insurers and consumers) to play a larger role in the purchasing equation.

"Payers' collective buying clout – and hence their ability to demand cost reductions – is formidable and growing," notes Michael Bebbington, Vice President, Global Product Development, Life Sciences and Healthcare, DHL Supply Chain. "They are all focused on one thing – paying less."

This is particularly true in light of the fact that the cost for many of today's new drugs has skyrocketed as pharma companies shift their product portfolios away from a primary reliance on small molecule/chemical pharmaceuticals towards more structurally complex biotechnology drugs. A single treatment cost of $1,000 per dose is not uncommon; and annual per-patient treatment costs can reach $100,000.

Spending on these new biotechnology drugs is growing dramatically worldwide. In the United States, for example, expenditure on these new specialty drugs is expected to quadruple between 2012 and 2020 (Figure 1).

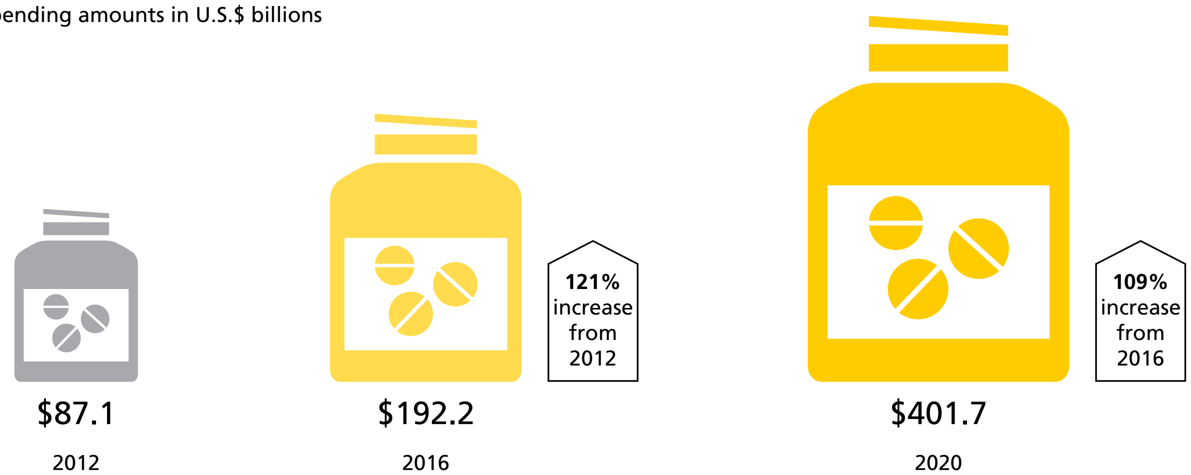
WHOLESALER, MANUFACTURER AND PHARMACY CONSOLIDATION

The past five years have witnessed global and regional consolidation among wholesalers, healthcare manufacturers and pharmacies, with

FIGURE 1:
U.S. SPECIALTY DRUG SPENDING WILL QUADRUPLE BY 2020

Projected speciality drug spending from 2012 to 2020

Spending amounts in U.S.$ billions



Source: PwC Health Research Institute estimates based on data from CVS Caremark, 2014.

companies around the world engaging in large-scale takeovers. On the pharmacy side, for example, the merger of Walgreens and Alliance Boots in 2014 gave the global pharmacy giant a presence in more than 25 countries.

The new company, Walgreens Boots Alliance Inc., also purchased an equity position in U.S. wholesaler AmerisourceBergen. As a result, the company is now the world's largest purchaser of prescription drugs, giving it tremendous buying power and the clout to pressure manufacturers to reduce prices. This runs in parallel with the trend of payer pressure for lower costs.

Manufacturers have also escalated their merger and acquisition (M&A) activity, particularly in the area of large global pharma companies buying up smaller biotech and biologics firms. In 2014, for example, deals worth $200 billion were announced. While some of the M&A activity was driven by tax conversion opportunities, the longer-term strategy behind this activity focused on acquiring – versus organically developing – an up-and-coming product pipeline.

NEW TRACK AND TRACE REGULATIONS

Counterfeiting, particularly in emerging markets, poses another threat to healthcare manufacturers. The World Health Organization estimates that one in every 10 drug products in poorer nations is counterfeit. The problem is rife, due to the number of points in the traditional wholesaler-based supply chain where counterfeits can be introduced.

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To counter this growing concern, many countries are passing new governmental regulations requiring manufacturers and their supply chain partners to track products throughout the supply chain, starting from the manufacturing plant and ending with final consumption. Although these regulations help protect the end consumer and are likely to open up new markets, they are adding costs and complexities to all those involved in the pharma supply chain, where there is currently no global standard.

PART 2:
D2M – A STRATEGY FOR CHANGING TIMES

The market dynamics explored in part one of this paper are having a direct impact on the performance of life sciences manufacturers. In order to combat the mounting pressures, manufacturers are looking at different opportunities to reduce costs and improve margins. These include:

- **Streamlining the supply chain**
  As payer mergers and consolidations continue to place downward pressure on pricing, manufacturers are looking at ways to streamline their supply chain by reducing the number of intermediaries

- **Gaining ownership of the customer relationship**
  With the increasing negative effect of the patent cliff, manufacturers want to increase their connection with end customers to help influence sales, increase product loyalty, and importantly, improve patient compliance to correct product usage

- **Obtaining direct access to sales data and market intelligence**
  Manufacturers are often left in the dark as to actual sales, forcing them to rely on purchased third-party aggregate sales data for their marketing intelligence. This lack of visibility makes it very difficult to make the correct commercial and supply chain decisions

- **Improving security and product protection**
  With the increasing costs of new drugs, the impact of theft and counterfeiting can be severely detrimental to a manufacturer. By reducing the number of handlings and touchpoints, it becomes easier to secure the supply chain and provide greater visibility into the chain of custody

- **Controlling the e-commerce sales channel**
  To prevent the introduction of fraud and counterfeiting, manufacturers are looking to establish a direct relationship with patients. This helps build product loyalty and patient compliance. It also reduces the chance they will turn to unauthorized websites for their drug and healthcare needs.

To take advantage of these opportunities, healthcare manufacturers have begun to implement a new supply chain strategy, direct to market distribution, which allows them to capitalize on improving margins, streamlining the supply chain and solidifying relationships with their end customers. More specifically, manufacturers are considering two versions of direct distribution:

- Direct to market (D2M), serving pharmacies, healthcare institutions and other providers

- Direct to patient (D2P), covering both home care and e-commerce channels.

"Revenue from the sale of a pharmaceutical product typically has to be divided between a manufacturer, a distributor, a pharmacy and a jurisdiction (in the form of taxes and discounts)," notes Accenture in a recent healthcare industry report. "Self-evidently, to stay profitable… companies need to retain as much as possible of the sales prices."[1] One way to achieve this objective is to bypass wholesalers and serve customers directly.

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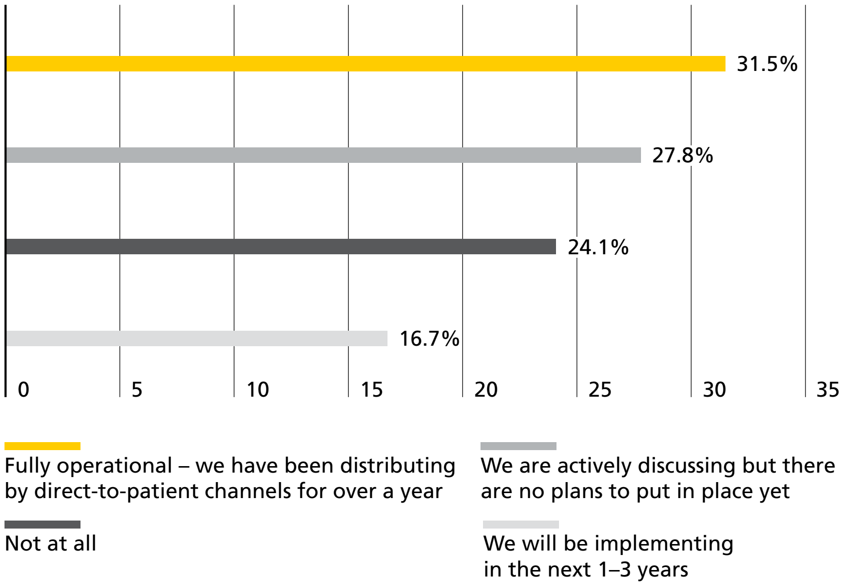
Some of the world's largest drug companies, including AstraZeneca, GlaxoSmithKline, Novartis and Pfizer, have switched some of their drugs to direct channels in certain markets. However, the practice is still in the early stages of adoption according to a 2015 benchmarking study by Worldwide Business Research (WBR).

For instance, nearly 70 percent of respondents in the study do not currently have any direct-to-patient channels in place. However, due to the increasing market pressures, a growing number of manufacturers are actively considering the issue (Figure 2).

[1] "Pharmaceutical Distribution: In a changing world, a decisive opportunity for margin improvement," Accenture, 2011, p. 2.

FIGURE 2:

HOW FAR ALONG IS YOUR COMPANY IN IMPLEMENTING DIRECT-TO-PATIENT DISTRIBUTION CHANNELS?



Source: Worldwide Business Research, 2015.

Advances in information systems and logistics make a D2M business model easier to implement today than even five years ago. As a report from the Organization for Economic Co-operation and Development explains, "Full-line wholesalers have traditionally played a fundamental role in offering retail pharmacies the option of working with a few providers instead of a myriad of manufacturers, thus reducing their administrative burden and operating costs. However, having multiple providers has become less burdensome for pharmacies with advancements in IT and logistics."[2]

There is no doubt that there is room in the supply chain for both direct and distributor channels, but the challenge is knowing which one will provide the optimal solution.

BENEFITS OF A D2M CHANNEL STRATEGY AT A GLANCE

- Own the customer relationship
- Gain direct access to sales and market data
- Reduce costs by eliminating an entire distribution/handling tier
- Improve security and quality assurance via end-to-end control
- Ensure safe e-commerce sales
- Help secure patient loyalty to the brand

[2] "Competition Issues in the Distribution of Pharmaceuticals," Organization for Economic Co-operation and Development, 2014, p. 5.

PART 3:
WHEN AND WHERE TO DEPLOY D2M

"There is no question that going direct is a big strategic decision for a healthcare manufacturer," acknowledges Michael Terhoeven, Vice President Strategy and Development for Life Sciences and Healthcare, DHL Customer Solutions & Innovation. "But the time is right for considering it. 30 percent of the overall cost for an innovative product is incurred after the product leaves the manufacturing plant. As downward pressure on pricing increases worldwide, manufacturers are realizing they could capture greater margins if they take control of what happens to their product after it leaves the production plant."

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The key question for companies, though, is in which markets and for which customers they should consider a direct channel strategy. Also, should they adopt a full direct model or a blended one, in which wholesalers continue to play a modified but still important role?

Answering these questions requires the consideration of many variables, and is situation-specific, Terhoeven notes. However, there are four key areas to consider when evaluating the options:

Will greater connectivity with the end customer or pharmacist help influence sales?

- For example, when a drug migrates from patent to generic the risk of lost sales increases as markets and customers have lower cost alternatives. By going direct, the original manufacturer can help to preserve and manage

its brand equity through a direct relationship with pharmacists and customers. This helps build brand loyalty and mitigate the inevitable loss of sales revenues.

What is the value and margin of product?

- Distributors trade on the value of the product, taking a percentage of the value as their fee for services. Thus, with the significantly higher value of specialty products, like oncology or orphan drugs, distributors gain a significant share of the products' bottom line contribution. By going direct, manufacturers are able to recapture these margin points. In addition, since these products are typically administered at a smaller number of select hospitals, manufacturers can more easily manage the relationships and ensure product is used in adherence to protocol to produce the optimal patient outcome
- A manufacturer may capture increased value by going direct to tier 1 hospital customers that provide the largest revenue streams to the manufacturer. "As a manufacturer," explains Terhoeven, "I'd want to eliminate the intermediary in these customer relationships, so I capture a greater percentage of total revenues. For tier 2 and 3 hospitals, I may still leave that business with the wholesalers."

Is there an already established supply chain, or is this a new product or a new market with no established supply chain?

- When new products are brought to market, either through the over-the-counter (OTC) or prescription channels, manufacturers have the opportunity to choose the best distribution channel for maximizing profit and serving customers – to create the optimal channel from scratch rather than be tied to an existing channel strategy designed for existing products
- In many emerging markets, there is no strong, established distribution network. Going direct may be the best way to market in these growing economies.

How important is security to product distribution?

- With the cost of new drugs skyrocketing, and as new track-and-trace regulations take effect around the world, it becomes essential for manufacturers and their supply chain partners to be able to trace product from point of manufacturing to point of consumption. A direct channel helps streamline the distribution path, thereby reducing the number of hand-offs in the channel and providing the level of visibility required by the new regulations
- With the increase of e-commerce sales, taking greater control of this distribution channel helps in fighting against the introduction of counterfeit product into the supply chain by ensuring a secure, verified and tracked product flow from manufacturer to consumer.

PART 4:
IN-HOUSE OR OUTSOURCED SOLUTION

The next step in the direct model is deciding whether to execute using an in-house solution or look to an outside partner – a third party logistics provider (3PL) that specializes in the life sciences sector. A direct-to-market distribution model requires facilities, systems, processes and resources all geared to providing complex customer fulfillment that meets very stringent handling and regulatory requirements.

It also requires the commercial systems to process individual orders from customers, be they hospitals, pharmacies or patients. This represents a very different type of commercial and supply chain infrastructure than that required for primary distribution to a handful of large wholesalers. Figure 3 provides a checklist of what is required to establish a D2M distribution channel.

One of the benefits inherent in an outsourced logistics solution derives from tapping the third party's established logistics infrastructure and expertise to enter and develop new markets quickly and cost-effectively. An outsourced D2M solution also delivers cost savings through process and systems standardization. "Whereas bespoke solutions can typically require high customer

FIGURE 3:
D2M REQUIREMENT CHECKLIST

- Front and back office commercial systems and infrastructure to fulfill orders and manage order-to-cash flows
- Call center/response center staffed by knowledgeable customer service representatives – to handle customer interactions and queries
- Pharma grade fulfillment centers – to provide turnkey pick/pack/ship capabilities with high service levels
- Validated warehouse management systems (WMS) – to optimize warehouse processes and reduce costs
- Delivery/transportation services – to provide short lead time transportation solutions for delivery to customer
- Temperature-controlled packaging and distribution – to preserve product integrity to end delivery point
- End-to-end tracking, including delivery verification – to ensure compliance with customer key performance indicators and regulations
- Supply chain tracking systems – to provide complete chain-of-custody control of product
- Regulatory expertise and compliance management – to ensure patient safety, product quality and data accuracy are maintained
- Standardized, replicable logistics platform and processes – to reduce costs and accelerate rollout into new markets
- Shared services and multi-user facilities – to spread costs across multiple manufacturers

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demand to justify initial implementation costs, a standardized third party logistics (3PL) solution spreads the cost across multiple customers, thereby lowering the individual customer's supply chain costs," explains Bebbington.

"A comprehensive suite of IT applications, configured specifically for the needs of the life sciences market and capable of deployment in a modular fashion, allows faster and easier system replication, enabling quicker results," he continues. "Companies can also take advantage of benchmarking across the 3PL's customer network, and reap the advantages of best practices transferred between markets."

Whether deciding to keep the solution in-house or outsource to a 3PL, manufacturers need to ensure that all the new trading relationships, systems and processes are fully understood and established before embarking on this bold new strategy.

HIGH-VALUE DRUG DISTRIBUTION IN AUSTRALIA: A D2M CASE IN POINT

One major global biopharmaceutical manufacturer decided to try something new in its Australia operation: an outsourced direct-to-market (D2M) distribution solution for two of its high-value drugs. The end-to-end solution included commercial processes, as well as prescription fulfillment to patients via hospitals and pharmacies. The company selected DHL, the leading global third party logistics service provider (3PL) with extensive expertise in the healthcare sector as its partner in this endeavor.

The 3PL had been managing the pharma company's pre-wholesale business for years – providing traditional deliveries to wholesalers across Australia. The company's growth strategy meant an elevated focus on its pipeline of new, specialized medications. The company sought a supply chain option that provided the product integrity, speed to market and compliance required for specialized, high-value products.

Chief among these reasons was the desire to gain absolute control of product as it moved across the supply chain. "Once product goes into the wholesaler's network, the manufacturer loses sight of it," explains Australia's Director of Direct to Market. "When products are this complex, they require very exact cold chain handling, are heavily regulated, are high value and need to be monitored for compliance and condition integrity across the entire supply chain.

Furthermore, the wholesaler model trades on the value of the product, taking a percentage as compensation for services. With such high-value drugs, this percentage can amount to a sizable sum – which naturally eats into the manufacturer's margins.

The outsourced D2M solution, in contrast, is based on a cost-to-serve fee structure, rather than a percentage-of-value model. That cost-to-serve model includes everything from storing and distributing the product, to providing customer service via a call center and accounts receivable collection. The 3PL does not take ownership of the product, instead acting solely as the distribution agent. The 3PL's call center takes orders and inquiries from pharmacists and hospitals directly, and flows them into its enterprise resource planning (ERP) order management system for fulfillment and

HIGH-VALUE DRUG DISTRIBUTION IN AUSTRALIA: A D2M CASE IN POINT
(CONTINUED)

accounting reconciliation – while maintaining rigorous cold chain compliance.

One facet that made the solution attractive to the pharma company was the 3PL's existing commercial relationships with Australia's 5,200 pharmacies. "We have established accounts with signed business terms and conditions with nearly every pharmacy and hospital" reports the DTM Director for Australia. "Manufacturers don't have to worry about setting up their own trading relationships with each and every pharmacy or hospital. This makes the transition to D2M like flipping a light switch for the manufacturers."

Visibility into actual orders and usage was another selling point for the healthcare manufacturer in considering D2M. "Through D2M manufacturers are afforded real time data all the way down to a batch level for their products, at no cost."

Finally, control over the products' condition – and regulatory compliance – all the way to the end customer was critical to the manufacturer. With the D2M solution, the drug company gained a single-provider and expert control over its temperature-controlled supply chain.

CONCLUSION

Clearly the direct model is not appropriate for every market or every customer. Wholesalers and distributors continue to play a key role in many established markets, and that is unlikely to change in the near term.

That said, one thing seems certain: the direct model of distribution, by which a producer can control and strengthen ties with all categories of customers, while executing orders with maximum quality, security and efficiency, is here to stay. It is likely to grow as market pressures to manage risk, reduce costs and improve margins intensify. And because of the complexities inherent in implementing this model successfully, it cannot succeed without a healthcare-specific supply chain designed expressly to execute this strategy. In an industry steeped in tradition, the time is right for considering this new approach.

ABOUT THE AUTHOR

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Lisa's articles have appeared in Fortune, Industry Week, The Economist, Inbound Logistics, The European Business Review and many other publications.

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