



# **TRANSFORMING THE EUROPEAN MEDICAL DEVICE SUPPLY CHAIN: ADDING VALUE AND REDUCING COSTS**

**DHL Supply Chain**

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# EXECUTIVE SUMMARY

“The medical technology sector (also known as the medical device sector) is weathering a perfect storm, caused by three concurrent trends: the move toward value-based healthcare, cost/margin pressures and increasing regulatory/compliance requirements.”<sup>1</sup> That is how consulting firm EY (formerly Ernst & Young) recently characterized the current state of the medical device industry worldwide.

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S&OP and Supply Chain Performance for Edwards Lifesciences, at a recent medical device sector conference. “In particular, the industry must become far more efficient, and that requires transformational strategies for managing the supply chain as a whole.”<sup>2</sup>

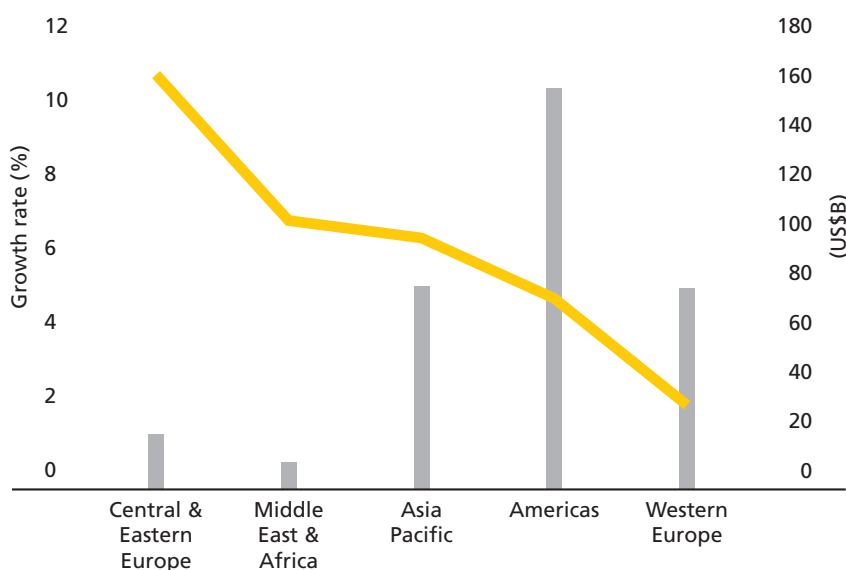
In Europe, achieving such transformation is no easy task for one key reason: the region is not a one-size-

fits-all market. At US\$122 billion (€114 billion) in 2013, Europe’s total medical device market is the second largest in the world, after the United States.

Looking beyond these macro numbers, the European medical devices sector clearly breaks down into two distinct markets: mature (Western Europe) and emerging (Eastern Europe).

Consulting firm PricewaterhouseCoopers (PwC) pegs American and Western

**FIGURE 1: GLOBAL MEDICAL DEVICE MARKET (CAGR AND SIZE)<sup>3</sup>**



2016 E Mkt size 2010 – 2016 CAGR (compound annual growth rate)

Source: PwC, 2013.

<sup>1</sup> Ernst & Young, “Pulse of the Industry: Medical Technology Report 2013,” 2013, p. 2.

<sup>2</sup> Vinay Asgekar, Bob Michaels, “Supply Chain Strategies for a Challenging Med Tech Landscape,” Medical Device and Diagnostic Industry, 2014.

<sup>3</sup> PwC, “Med Tech Supply Chain Management Trends and Leading Practices, MassMEDIC Roundtable,” 2013, p. 7.

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European growth at 4.1 percent versus 7.4 percent for the rest of world (2010 – 2016 CAGR), as the yellow line in Figure 1 depicts. However, Central and Eastern Europe is expected to experience the fastest growth during this same period, forecast at 10.8 percent.

While illness patterns in the emerging Eastern European markets are starting to match those in the mature Western European countries, product preferences, payer mechanisms, regulations and distribution channels differ widely by country. “There are significant differences in how products are being secured and distributed, as well as the nature of stakeholders involved in the sales and distribution process,” notes Luiz Moreira, Vice President, Global Products and Accounts Leader at DHL Supply Chain. “These practices vary country by country, making Europe a very complex market to serve.”

While the pressures facing the European medical device industry are not new, they are gaining intensity and gathering momentum. New layers of complexity and cost are being added to the medical device supply chain at a time when pressure from governments, payers, healthcare providers and patients to cut costs has never been greater.

This white paper explores, in two parts, these market dynamics, what impact they have on medical device companies in general and on their supply chains in particular, and how these businesses are re-thinking their supply chain practices to tackle them.

**Part 1:** The current state of the European healthcare environment and its impact on the supply chain.

**Part 2:** How innovative supply chain strategies can help medical device manufacturers address these sector dynamics.



## PART 1:

# CURRENT STATE – CHANGE DRIVERS AND IMPACTS

While numerous factors affect the state of the European medical devices market, three in particular are high on every manufacturer's list of concerns. These three, discussed in detail below, are:

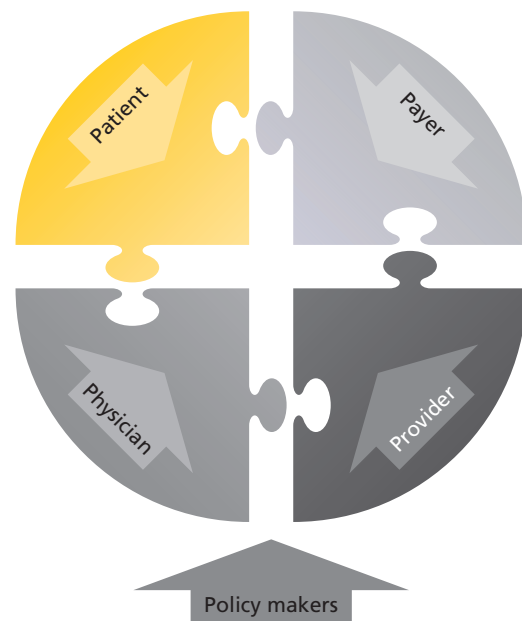
- The move towards value-based healthcare
- Intensifying cost and margin pressure
- Stricter regulations.

### THE MOVE TOWARDS VALUE-BASED HEALTHCARE: A CHANGING SALES PARADIGM

A major shift in how medical devices are purchased is under way in Europe. This shift is driven, in large part, by a transition toward value-based healthcare, i.e. the drive to provide higher return on investment.

Device-buying decisions used to be made by just two people – the patient and the physician (2P) – and delivered on a traditional fee-for-service model, explains Tony Freeman of Manning Advisors.

FIGURE 2:  
**5P DECISION MAKERS**



The need to rein in healthcare costs has changed all that. The world is transitioning to a 5P model, meaning that five different parties are involved in the final purchase decision:<sup>4</sup>

- Patient
- Physician
- Provider (hospital/clinic)
- Payer (insurance company, government or other entity)
- Policy maker (government).

This new process has changed the medical device industry drastically, claims the CEO of Invendo Medical, Berthold Hackl, who observes: "With the old model, you developed a new product and showed it to physicians. They liked it and it went

<sup>4</sup> Tony Freeman, "Trends in Global OEM Strategy," <http://www.slideshare.net/TonyFreeman2/trends-in-global-medical-device-oem-strategies>, February 11, 2013.



from there. Those days are over. With new devices and technologies, you have to look at the environment in which they will be used.”<sup>5</sup>

These changes mean manufacturers must take into account all five decision-makers when designing the supply chain. Manufacturers can no longer just replicate their current structure when introducing a new product, but need to tailor its supply chain attributes, capabilities, service levels and cost structures so that they synchronize better with product profits.

## INTENSIFYING COST AND MARGIN PRESSURES

Historically, the global medical device industry enjoyed enviably healthy profit margins – as high as 20 to 40 percent, according to consulting firm Deloitte.<sup>6</sup>

However, the recent economic woes, especially those in Europe, have changed that – permanently.

“Hospitals do not have money, distributors do not have money and manufacturers have less money,” states Kevin Stout, Executive Director of the Medical Device Supply Chain Council. “This means that organizations have to be more creative and, even though times are incredibly difficult, look for new ways of working.”

These “new ways of working” have led to a greater focus on economic measures in the healthcare sector as a means of reducing costs. The United Kingdom provides an excellent case in point. Deloitte explains: “Over the last three years, the UK government has increased healthcare funding by only 0.1 percent in the face of increasing demand of around

<sup>5</sup> Ernst & Young, “Pulse of the Industry: Medical Technology Report 2013,” 2013, p. 4.

<sup>6</sup> Sanjay Behl, Terry Hisey and Ralph Marcello, “Moving Target: Life Sciences, Healthcare Reform and the New Marketplace,” Deloitte Review, 2011.



four percent per year. This has resulted in stringent austerity measures being applied, including staff pay freezes, pressure on pharmaceutical and medical technology spending, and rationing of some services. The requirement to achieve around four percent annually in productivity and efficiency savings by 2014 – 2015 is likely to continue to 2020 – 2021...<sup>7</sup>

As part of this trend, European healthcare cost control measures have successfully reduced the cost of medical procedures in many cases, as illustrated in Figure 3.

“The downward pricing pressure from all payers – government, insurers, healthcare providers and

FIGURE 3:  
**EUROPEAN HEALTHCARE COST CONTROL**

|                                       | Cost in US | Cost in France, UK, Spain |
|---------------------------------------|------------|---------------------------|
| Hip replacement                       | \$40,000   | \$10,000                  |
|                                       | €37,000    | €9,300                    |
| Magnetic resonance imaging (MRI) scan | \$1,100    | \$300                     |
|                                       | €1,030     | €280                      |

Source: Boston Consulting Group, 2013.<sup>8</sup>



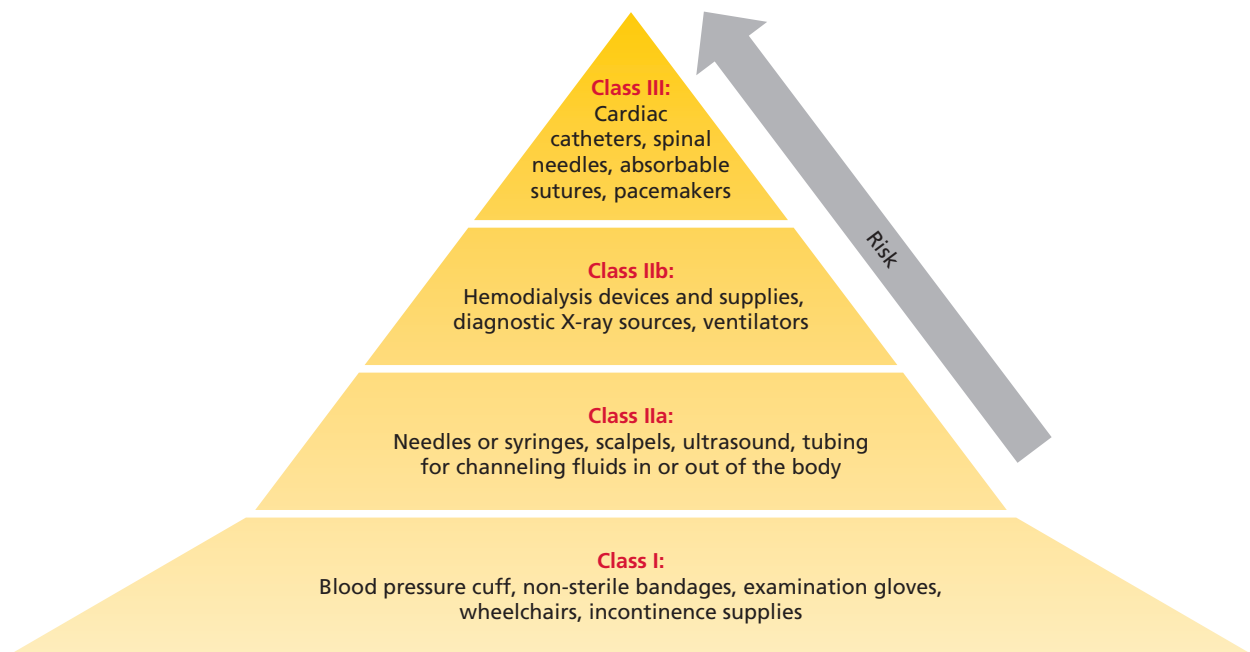
patients – is causing price erosion and commoditization across a broad range of medical products,” Luiz Moreira of DHL observes. “Low-value disposables are most affected by this trend; however, high-value cardiology devices such as stents and pacemakers are also experiencing growing cost pressures.” Moreover, because of the new financial constraints, the institutions that pay for medical devices are not buying device innovations and upgrades unless their marginal value to patient outcomes significantly exceeds their cost.

The message here is that with reduced payer support, decreasing product values and increasing economic cutbacks, the pressure is immense to improve supply chains in ways that reduce cost and improve efficiency without sacrificing product integrity.

<sup>7</sup> “2014 Global Health Care Outlook: Shared Challenges, Shared Opportunities,” Deloitte, 2014, p. 17.

<sup>8</sup> “The Need to Transform the Medtech Model in Europe,” Boston Consulting Group, [https://www.bcgperspectives.com/content/articles/medical\\_devices\\_technology\\_transformation\\_need\\_transform\\_medtech\\_model\\_europe/?chapter=2](https://www.bcgperspectives.com/content/articles/medical_devices_technology_transformation_need_transform_medtech_model_europe/?chapter=2), December 2013.

FIGURE 4:

**EU'S RISK-BASED MEDICAL DEVICE REGULATORY SYSTEM**

Source: DHL, based on European Commission regulations.

**STRICTER REGULATIONS**

Within the European Union, the European Commission (EC) allows manufacturers to classify their products according to a risk-based system as shown in Figure 4. Essentially, the greater the risk is to the patient, the greater is the EC oversight of product distribution.

However, this risk-based system is undergoing review and is likely to change. Debate is under way about whether to create a centralized regulatory system, similar to the US Food and Drug Administration (FDA) style, which would make the device approvals process in Europe substantially more stringent.<sup>9</sup>

The proposed new rules – the European Medical Device Regulations (EDMR) – are controversial. “Industry experts are concerned that the new regulations will increase costs and eliminate the early access to device innovations that patients in Europe currently experience when compared with the rest of the world,” Robert Packard, President of the Medical Device Academy indicates.<sup>10</sup> Critics of the proposed regulations, including the medical device industry and its investors, worry that if approved, the new directive will make the European medical device approval system as difficult as that of the FDA.

Global concerns for patient safety have pushed regulatory agencies around the world, including

<sup>9</sup> Ernst & Young, “Pulse of the Industry: Medical Technology Report 2013,” 2013.

<sup>10</sup> Robert Packard, “What to Expect from New EU Medical Device Regulations,” MDDI, 2014.



those in Europe, to begin to develop regimes for tracking medical devices throughout the supply chain – all the way to the patient. The FDA, one of the staunchest proponents of such tracking, issued regulations requiring that manufacturers assign a Unique Device Identifier (UDI) for all medical devices, which would be used to track them through the supply chain. Phased implementation is under way in the US, with first-level deadlines beginning this year.<sup>11</sup>

As part of the UDI regulations, manufacturers must not only adhere to standards of labeling, but must also provide device attributes for inclusion in a global Unique Device Identification database. Similar labeling, tracking and reporting rules are being promoted throughout Europe.

The idea behind the UDI is to create a globally harmonized medical device identification method that would simplify product recalls and improve risk control in areas such as counterfeit prevention and diversion. As they emerge, the new tracking/reporting requirements present significant challenges for the industry, particularly for the supply chain, states Susanne Amholt, DHL's Vice President for Business Development, Life Sciences & Healthcare, Europe.

"Many companies don't have the systems or processes in place to manage this kind of tracking," Amholt says. "The difficulty lies in setting up a system that can track a product all the way to the patient. Product is easy to track as it moves through the supply chain, but once it gets to the hospital, tracking the product's final use is problematic. Hospitals are not set up to do this level of tracking. But the rules cover the supply chain from end to end, so hospitals must become part of the solution."

<sup>11</sup> "Protecting products to save lives: securing the pharma supply chain," DHL Supply Chain, 2015.



## PART 2:

# INNOVATIVE SUPPLY CHAIN SOLUTIONS

Studies show that medical device manufacturers carry more than 150 days of inventory, compared to about 70 days for fast-moving consumer goods and two or three weeks for the automotive industry.<sup>12</sup> This level of waste in the supply chain can no longer be accepted as the status quo. In view of the mounting pressures on margins, combined with the shift towards value-based pricing and new governmental regulations, European medical device manufacturers must find new approaches to reduce costs while still guaranteeing the expected high service levels. These key strategic supply chain decisions include:

- Segmenting supply chains by product value
- Creating a direct-to-customer channel
- Leveraging shared-use distribution centers
- Outsourcing logistics to a third party.

Different product and payer profiles require that supply chain cost structures are aligned to the margin characteristics of these different product and customer/payer categories.

### THE SEGMENTED SUPPLY CHAIN

As discussed earlier in the paper, not all products or markets in the European medical device sector are created equal. Different product and payer profiles (e.g. premium product with high value/margin; private payer model versus national health payer) require that supply chain cost structures are aligned to the margin characteristics of these different product and customer/payer categories.



<sup>12</sup> Thomas Ebel, Erik Larsen, and Ketan Shah, "Strengthening Health Care's Supply Chain: A Five-step Plan," McKinsey, 2013, p. 2.

Leading device manufacturers are, therefore, restructuring their supply chain networks and processes to embrace segmentation. This includes tailoring transportation and warehousing with the depth of distribution in each country to the type and category of medical device. Low-value, high-volume consumer medical devices may be transported by ocean and long-haul road freight (with selected higher-cost modes for 'emergency' situations, when a standard, slow-mode shipment misses a checkpoint or encounters a hold-up). From a network perspective, these same products may be distributed

By 2025, many analysts believe medical device companies will have completed the segmentation process, which includes tailoring transportation and warehousing with the depth of distribution in each country to the type and category of medical device.

via regional distribution centers or cross-dock facilities located in closer proximity to the end market.

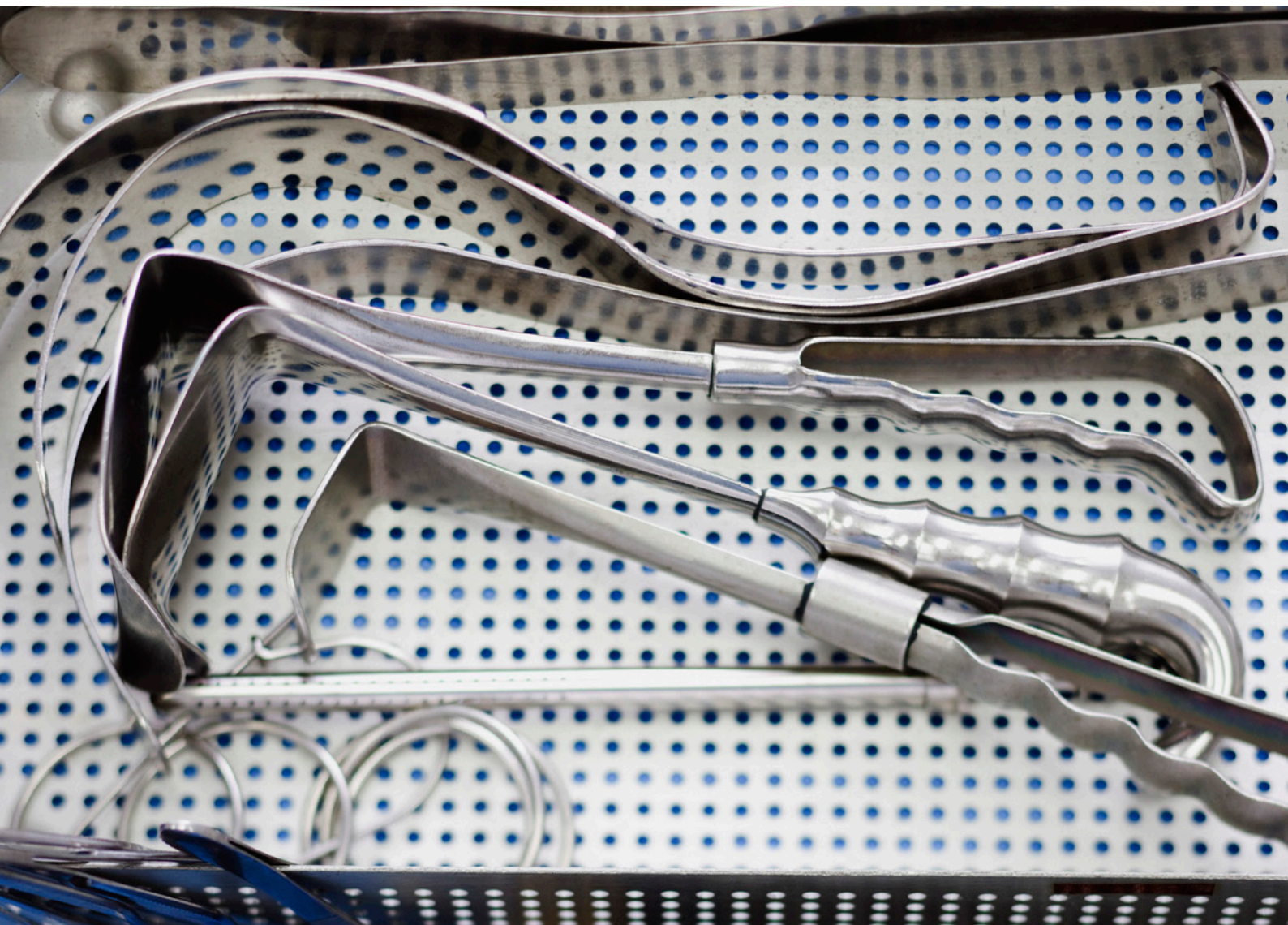






FIGURE 5:  
**SUPPLY CHAIN SEGMENTATION STRATEGIES**

Logistics requirements vary greatly, depending on the geographic location and segment of the medical device. The marketing program needs to be tailor-made to optimize communication capabilities.

|        | Consumables/<br>disposables       | Implantable devices<br>and surgical<br>equipment  | Diagnostic agents<br>& combination<br>products  | Imaging, diagnostics<br>and surgery capital<br>equipment  |
|--------|--|--|--|--|
| Europe | Solution based on large, dedicated regional distribution centre, with easy access to bulky air and road transport. | Medium-sized dedicated or multi-user local facility or regional distribution centre, close to express air hub.                     | Local multi-user facility with short lead time to final delivery.  | Medium-sized dedicated or multi-user local facility or regional distribution centre, close to express air hub.                               |

Source: DHL, 2014.

Speciality and high-value devices would be shipped using premium, faster transportation modes, such as air or express services, and might be distributed from a single global or regional distribution hub directly to the hospital or ward. This could include an end-of-runway approach, where critical parts or products are located at a central air hub at a major European airport, ready to move on the next flight out to meet urgent needs. An alternative distribution method would be to utilize forward stock locations, which are small shared-user warehouses located close to the usage point, to ensure rapid response to hospitals. Both of these methods would significantly reduce the amount of inventory in the system.

By 2025, many analysts believe medical device companies will have completed this segmentation process, tailoring their supply chains along four basic categories:

- High-value products – includes implants
- Innovative standard devices

- Generic or frugal/low-tech devices
- Lower-value consumer medical devices.

Figure 5 depicts these different product-based supply chain segmentation strategies.

### THE DIRECT DISTRIBUTION MODEL

To reduce costs and increase profits, manufacturers are beginning to look at serving certain customers direct; an approach that provides an alternative to the traditional distributor-intermediary model (figure 6). However, the decision between going direct versus through a distributor is highly reliant on several factors, including attributes such as cost of product, security needs and number of final distribution points.<sup>13</sup>

Moreira observes, “An increasing number of manufacturers are looking at serving more of their customers directly, rather than through distributors or agents, especially in developing Eastern European

<sup>13</sup> “Going direct: bold strategy for healthcare supply chains,” DHL Supply Chain, 2015.

countries. There is a mutual interest between manufacturers and their customers (healthcare providers) to create these direct bonds. Hospitals can benefit from product knowledge transfer coming directly from the people who make the products. Manufacturers can collect more accurate sales and customer usage information, and get direct customer feedback about product performance and service satisfaction.”

By contrast, in a distributor or agent distribution model, the manufacturer has no direct connection with the end customer. As a result, it loses visibility and control over the product once it leaves the

manufacturing plant. Often operations are left in the hands of providers who may not have strategic, robust capabilities, resulting in loss of control and exposing the manufacturer to various potential risks – ranging from improper instructions on usage to lack of compliance with local regulations. Furthermore, a direct model not only improves the security of the supply chain, by reducing the number

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FIGURE 6:  
**OLD INSOURCED DISTRIBUTION MODEL**

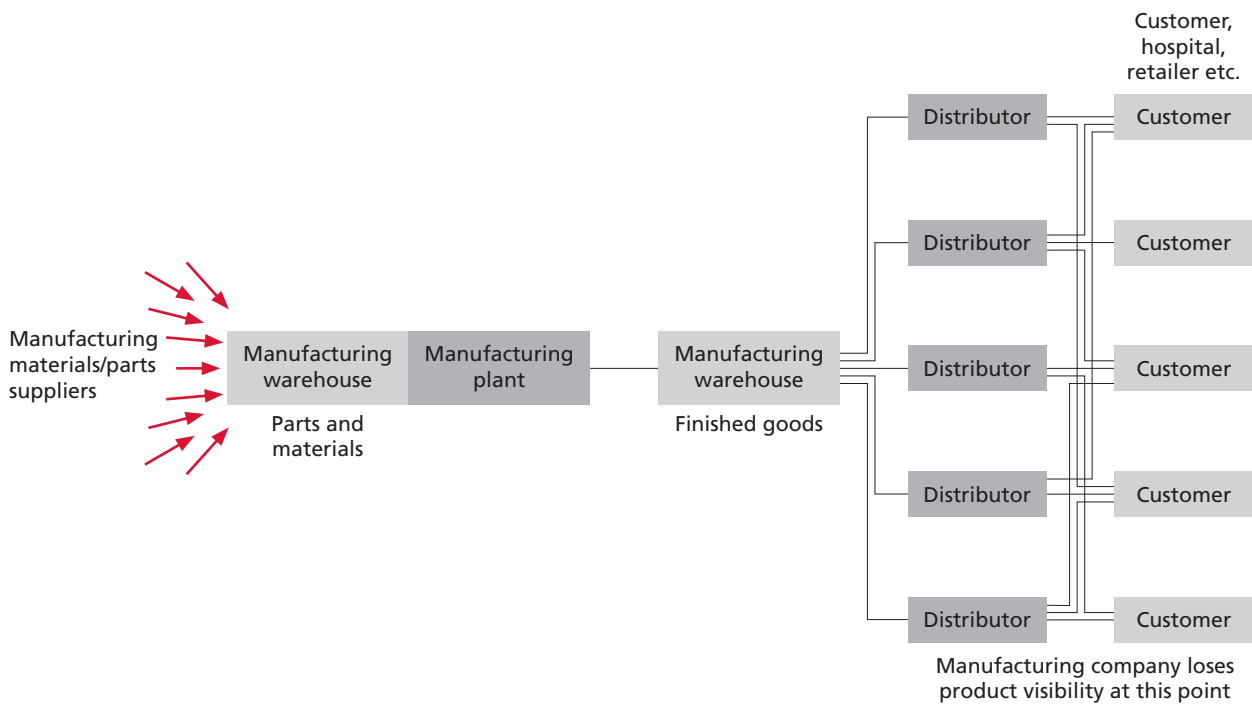
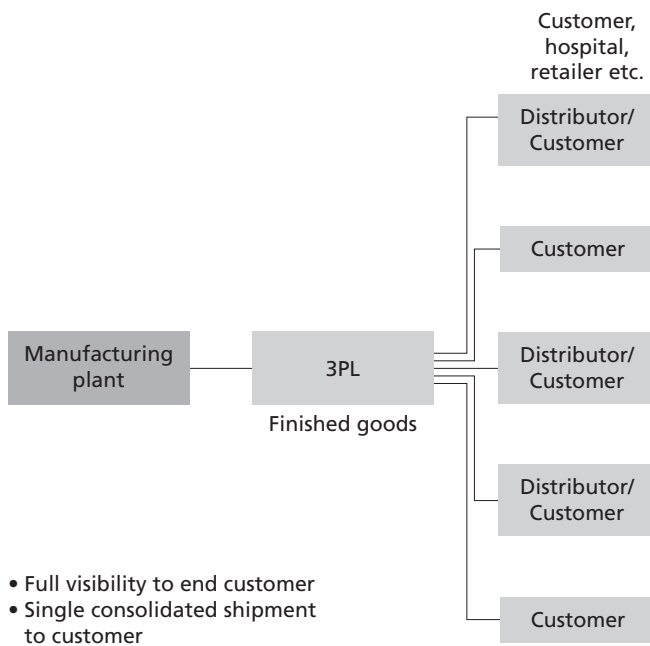


FIGURE 7:  
**NEW OUTSOURCED DISTRIBUTION MODEL**



Source: DHL Supply Chain, 2015.

**BENEFITS OF USING A 3PL**

What are the potential benefits of transitioning to a 3PL outsourced supply chain management model for the European medical device sector?

1. Improved cost efficiency
2. Consistent, reliable, cost-effective transportation and delivery
3. Greater service and network flexibility
4. Increased end-to-end supply chain visibility
5. Sophisticated track and trace, and condition management
6. Demonstrated supply chain best practices
7. Established continuous improvement processes.

of intermediaries handling the product, but also reduces cost by switching from a service fee based on the cost of the product to one based on the true cost of distributing the medical device (figure 7).

**ADDING SHARED SERVICES**

Another opportunity for manufacturers to reduce costs and streamline their supply comes through leveraging a shared services operating model. Medical device manufacturers typically sell to the same community of customers – e.g. hospitals, clinics and physicians’ offices, resulting in individual manufacturers running parallel supply chains to service these customers. This duplication and redundancy carries a high and unnecessary cost for

manufacturers and their receiving customers – one that the environment of fiscal austerity increasingly will not support.

Under a shared services solution, multiple manufacturers house their product with a single 3PL in a shared network of facilities and transportation capacity. The sharing of these transportation, distribution and warehousing systems streamlines the supply chain for manufacturers and their customers.

**THE OUTSOURCING MODEL**

Outsourcing the logistics activities and operations to a 3PL with expertise in managing medical device supply chains frees up the manufacturer to focus on

its core business – developing and producing medical devices. It enhances flexibility by tapping into the capabilities portfolio, infrastructure and knowledge of a global 3PL – rather than trying to build and maintain those assets and processes in-house.

This type of partnership provides a great benefit: it gives the manufacturer the capabilities and flexibility needed to deal with the complexities of the European market – i.e. different products, regulations, customer requirements and infrastructure. A 3PL that is already established in both the medical devices sector and the European market can provide:

- Tailored solutions that meet the needs of each market or country – the opposite of a one-size-fits-all distribution solution
- Expertise in each country's government regulations, helping to ensure proper packaging, labeling and tracking of medical devices
- Best practice warehousing and transportation management solutions, including state-of-the-art information systems
- Rapid implementation capability to support expansion into new markets and business change.

By partnering with a 3PL a manufacturer can capture significant cost savings generated by a streamlined, optimized supply chain – which is critical in meeting the rising cost pressure under which the sector operates. “The different areas of saving potential can range as high as 20 percent, depending on the solution,” reports DHL's Susanne Amholt. By becoming the supply chain orchestrator, and managing the country-specific distribution operation end-to-end, the 3PL provides visibility into, and control of, product flow; coordinating deliveries, tracking those deliveries, and managing other logistics service providers and distributors – all to ensure timely, accurate and cost-effective delivery to the end customer.

The time has come to re-think the European medical device operating model.

## NEW SOLUTIONS FOR A NEW ERA

Economic challenges, expansion in demand, growth of chronic disease conditions, development of emerging markets, burgeoning healthcare regulations and aggressive government cost-reduction requirements are just some of the challenges facing the European medical device market today. Rather than easing over the coming years, these pressures will only intensify.

The time has come to re-think the European medical device operating model in general and the supply chain in particular. Leading manufacturers are doing just that. They are working with their logistics service providers to reengineer their supply chains to embrace outsourcing solutions, shared services and other supply chain solutions. Meeting the twin challenges of reducing costs and delivering on service commitments is not an easy task. However, with the right partnerships, it can be done in a manner where everyone wins, including the ultimate customer – the patient.

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## ABOUT THE AUTHOR

Strategic consultant, academic and co-author of three books, **Lisa Harrington** offers a global supply chain perspective.

At the Robert H. Smith School of Business, University of Maryland, Lisa is Senior Research Fellow of the Supply Chain Management Center and Faculty Lecturer on Supply Chain Management. She is also President of the Iharrington group LLC, a firm providing strategic consulting services across global supply chain strategy, operations and best practice.

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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