Outsourcing, the medicine for Supply Chain headaches?

A White Paper on logistics outsourcing within the pharmaceutical industry

•GROENEWOUT•
CONSULTANTS & ENGINEERS

Alain Beerens

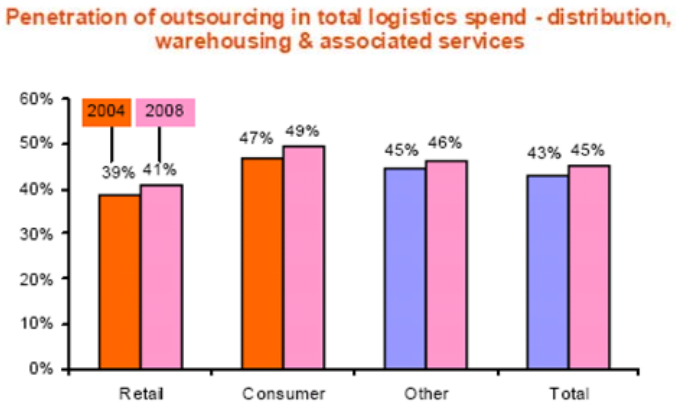
June 2005
Edition 1.3

TABLE OF CONTENTS

1 INTRODUCTION

1.1 Outsourcing and the pharmaceutical industry

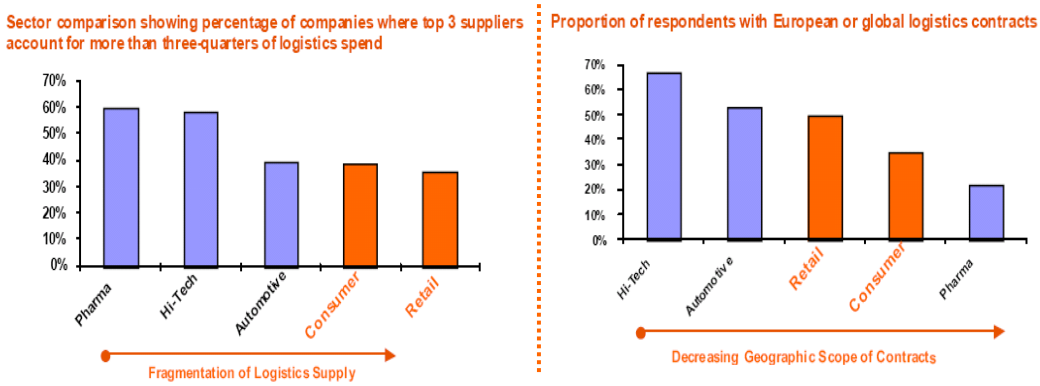
Today many companies in various industry sectors, like the fast moving consumer goods, electronics, automotive and spare parts, focus on core activities to maintain and strengthen their competitive advantage. The non-core logistics activities are often outsourced to Logistics Service Providers. It has been estimated that about 40 percent of the global logistics is outsourced[1].



© Datamonitor

FIG. 1: OUTSOURCING PENETRATION

In several industries outsourcing of logistics activities is not yet common. Especially in the pharmaceutical industry, one of the biggest industries, only a small part of the non-core logistics activities is outsourced. In relation to other industries the outsourcing of logistics activities in the pharmaceutical industry is limited. The graph below shows that outsourcing logistics spends are smaller and more scattered within Pharma compared to other industries, giving an indication that the level of maturity for outsourcing acceptance within Pharma in less.



© Datamonitor

FIG. 2: SECTOR COMPARISON OUTSOURCING

[1] Source: Customer perceptions on logistics outsourcing in the European consumer goods industry

A reduction in supply chain costs provides one of the best means to decrease the costs of goods sold and improve profit margins. This is especially the case in the pharmaceutical sector where Supply Chain costs cover 5% to 15% of total costs of goods sold. In this margin improvement process, the outsourcing of logistics activities within the pharmaceutical supply chain can definitely be a valuable tool to increase supply chain efficiency and to derive a competitive advantage.

Then why are the non-core logistics activities in many cases still operated by the pharmaceutical companies themselves, to a much greater degree compared to other industries? This is caused by the fact that the pharmaceutical industry is a conventional industry with logistics activities and regulations that within the industry are perceived as specifically complex. The transportation, storage, handling and production activities are strictly regulated by national governments. For this reason the pharmaceutical companies have always wanted direct control over their total supply chain.

However the figure below *(the typical rational logistics outsourcing drivers across all industries)* indicates that these considerations (to a more or lesser extent) are applicable to other industries as well.

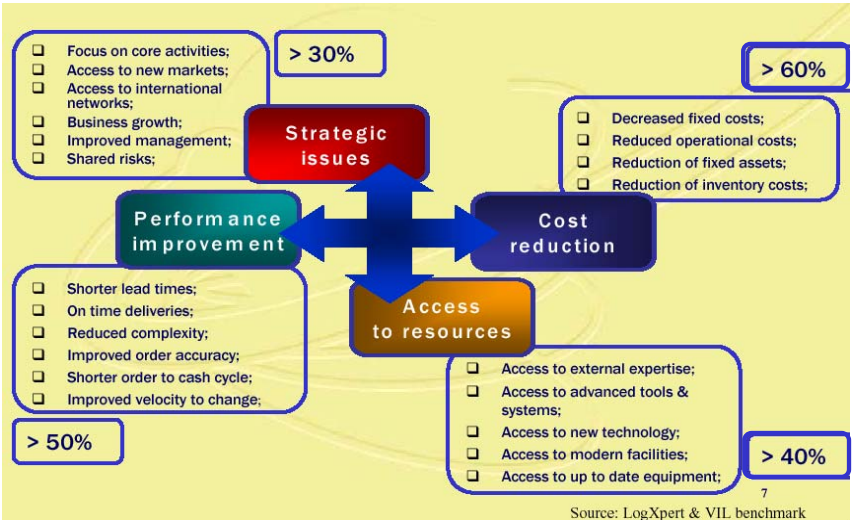


FIG. 3: LOGISTICS OUTSOURCING RATIONAL DRIVERS

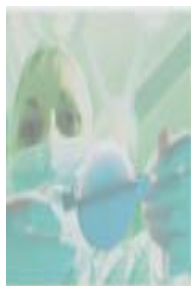
So is the skepticism towards outsourcing in the pharmaceutical justifiable or just a myth?

1.2 Readers guideline

The first part of this white paper discusses the different sectors within the pharmaceutical industry along with their respective requirements and the very specific demands that are placed on their respective supply chains (chapter 2 & chapter 3). The second part focuses on the current status and typical trends in the pharmaceutical industry when considering outsourcing logistics (chapter 4 & 5). The third part covers the capabilities of third-party outsourcing providers that are currently available in the market (chapter 6). This leads to the conclusion of the white paper (chapter 7) which addresses the very question as to whether outsourcing brings added-value and also offers insight into the key success factors in this process.





2 PHARMACEUTICAL INDUSTRY

2.1 Four sub-industries

The pharmaceutical industry can be divided into four main sub-industries:
1. Patented drugs
2. Non-patented drugs
3. Biopharmaceuticals
4. Medical devices.

Each of these sub-industries has individual particulars that necessitate a specific characteristics and requirements portfolio for their logistics operations.

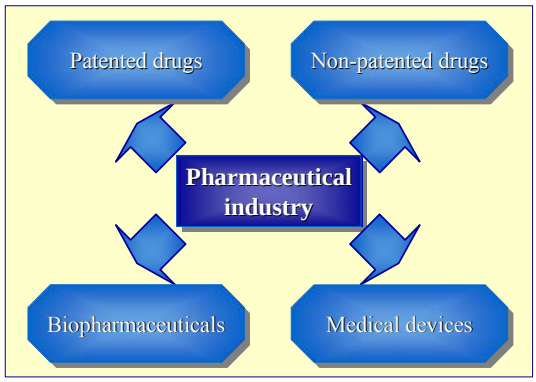


FIG. 4: FOUR PHARMACEUTICAL SUB-INDUSTRIES

Patented drugs
The patented drugs sub-industry is a R&D intensive sub-industry and dominated by multinational companies, which cover about 50% of the European market. Patented drugs can be divided into:
- Patented human description drugs
- Patented veterinary drugs.

Non-patented drugs
The non-patented drugs sub-industry consists of smaller, national companies which are specialized in the sales of non-intensive drugs and operate almost exclusively in their own markets. This sub-industry determines about 50% of the pharmaceutical market. Once a drug becomes generic, the value to the company that developed it drains away. The products within the non-patented drugs sub-industry are:
- Generic pharmaceuticals (patent protection has ended)
- Over the Counter (OTC) products (vitamins and health supplements)
- Incontinent materials.

Biopharmaceuticals

The biopharmaceutical sub-industry is becoming an important sub-industry within the pharmaceutical world; it is delivering significant advances in healthcare. The biopharmaceutical companies are the product innovators within the pharmaceutical industry. Biotechnology refers to any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify processes of specific uses[2]. A large growth in the world market is expected in the biopharmaceutical sub-industry. Products within the biopharmaceutical sub-industry are amongst others: vaccines, hormones and enzymes.

Medical devices

Medical devices are often sold through business to business channels (unlike the other sub-industries). A large growth in the world market is also expected in this sector. The medical devices sub-industry produces a wide range of medium and high technology products, such as: surgical & medical instruments, electro medical equipment, X-ray, CAT and MRI equipment, dental equipment & supplies, diagnostic products and medical disposables.

2.2 Logistics characteristics & requirements per sub-industry

According the SCOR methodology (Supply Chains Operations Reference Model) (www.supply-chain.org) we measure overall Supply Chain performance at 5 key Indicators.

Performance Attribute	Performance Attribute Definition	Typical Key Performance Indicator (KPI's)
Supply Chain Delivery **Reliability**	The performance of the supply chain in delivering: the correct product, to the correct place, at the correct time, in the correct condition and packaging, in the correct quantity, with the correct documentation, to the correct customer.	Delivery Performance
		Fill Rates
		Perfect Order Fulfillment
Supply Chain **Responsiveness**	The velocity at which a at which a supply chain provides products to the customer.	Order Fulfillment Lead Times
Supply Chain **Flexibility**	The agility of a supply chain in responding to marketplace changes to gain or maintain competitive advantage.	Supply Chain Response Time
		Production Flexibility
Supply Chain **Costs**	The costs associated with operating the supply chain.	Cost of Goods Sold
		Total Supply Chain Management Costs
		Value-Added Productivity
		Warranty / Returns Processing Costs
Supply Chain **Asset** Management Efficiency	The effectiveness of an organization in managing assets to support demand satisfaction. This includes the management of all assets: fixed and working capital.	Cash-to-Cash Cycle Time
		Inventory Days of Supply
		Asset Turns

Fig. 5: Key performance attributes Supply Chains

[2] Source: Biotechnology

For each of the four pharmaceutical sub-industries the operational excellence of the Supply Chains should focus on different SC performance attributes.

Patented drugs

The patented drugs sub-industry is an especially knowledge based sub-industry, making R&D, intellectual property and innovation critical success factors. In this arena new product launch is extremely important and the time to market determines the ultimate competitive advantage a company can create. Supply chain flexibility and agility (ability of a supply chain in respond in market changes) therefore is key. Supply chain reliability and responsiveness are important supply chain elements to secure the companies position through ensuring that products are available (OTIF = On-Time-In-Full) at a reasonable lead-time. However many drug patents have or will soon expire which translates into lower drug margins and the necessity for lower operational costs.

	Patented Drugs
Performance Attribute	**SC Performance versus Competition**
Reliability	advantage
Responsiveness	advantage
Flexibility	superior
Operational Costs	parity
Asset Utilization	parity

superior advantage parity

Non- patented drugs

The products within the non-patented drugs sub-industry have significant lower profit margins compared to the patented products and the competition is strong. Therefore supply chain efficiency determines the competitive advantage. Customers have wide product choice. Products must be available to them otherwise products of the competitor will be substituted. An optimal stock policy is a way to reduce working capital and to reduce supply chain costs.

	Non-Patented Drugs
Performance Attribute	**SC Performance versus Competition**
Reliability	advantage
Responsiveness	parity
Flexibility	parity
Operational Costs	superior
Asset Utilization	superior

superior advantage parity

Biopharmaceuticals

Biopharmaceutical products often require special transportation and storage conditions which have to be maintained from the production release up to the final distribution to the customer. Supply chain reliability is of utmost importance in this so called cold chain. Supply chain agility and product availability are two other important elements within this sub-industry.

	Bio-Pharmaceuticals
Performance Attribute	**SC Performance versus Competition**
Reliability	superior
Responsiveness	advantage
Flexibility	advantage
Operational Costs	parity
Asset Utilization	parity

superior advantage parity

Performance Attribute	Medical Devices SC Performance versus Competition
Reliability	●
Responsiveness	●
Flexibility	●
Operational Costs	●
Asset Utilization	●

● superior ● advantage ● parity

Medical devices

The medical devices sub-industry has a lot of similarities with the electronics industry and in both industries; customer service is one of the most important elements. Innovation and new product technologies make production flexibility also an important element to determine competitive advantage. The medical devices products are characterized by their high value density and stock policy an important factor to prevent extreme high working capital in inventory.

3 PHARMACEUTICAL LOGISTICS

3.1 GMP & GDP requirements

Today's world knows many regulations and guidelines to increase the quality and safety of medicinal products for human and veterinary use. These regulations and guidelines often vary from country to country; therefore, making it difficult for pharmaceutical companies to interpret all regulations correctly. In the US, the US Food and Drug Administration (FDA) and in Europe, the European community and the European Agency for the Evaluation of Medicinal Products (EMEA) deal with rules, regulations and guidelines.

The most common European quality guidelines for logistics are described in the Good Manufacturing Practice (GMP: Manufacturing guidelines for development, manufacturing and control of medicinal products.) and in the Good Distribution Practice (GDP: Guidelines for distribution of medicinal products)[3].

The choice of individual companies to be compliant with FDA (North America) and/or GDP/GMP (Europe) is fully dependent of the sales markets where they operate.

3.2 Outsourcing: operational & tactical activities

If we look at the range of supply chain activities we see day-to-day operational activities as transportation, warehousing, VAL (Value Added Logistics) and assembly (postponed manufacturing). This is a typical subset of activities that is generally outsourced and operated by Logistics Service Providers (LSP's) in sectors as the automotive, FMCG and electronics.

FIG. 6: PORTFOLIO OF LOGISTICS ACTIVITES VIABLE FOR OUTSOURCING

[3] For specific details on the GMP and GDP regulations we refer to the addendum.

The planning and administrative activities on a tactical level (order entry, account management, after sales up to Vendor Managed Inventory and Supply Chain Integration) are lagging behind. Although numerous Logistics Service Providers (LSP) position themselves to take over these activities (4PL's = 4th party logistics providers), many companies are reluctant to outsource these activities. The increasing dependency of the LSP and the selling-out of the internal supply chain expertise are the main decision drivers for this strategy.

For the scope of this white paper we will focus on the operational aspects of supply chain outsourcing: "transportation", "storage & handling", "Value Added Logistics (VAL)" and "production".

3.3 Operational supply chain activities

Operational logistics activities can be divided into transportation, storage, handling, Value Added Logistics (VAL) activities and production. The operational complexity differs per activity (see Fig. 7).

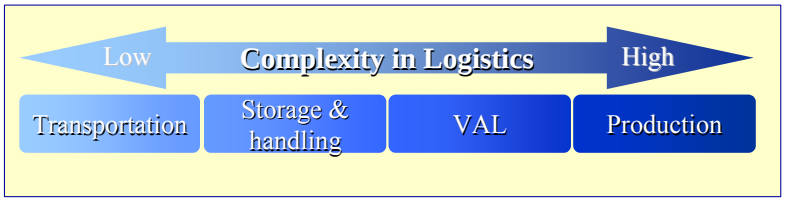


FIG. 7: COMPLEXITY IN LOGISTICS

The complexity in logistics determines if operating according the GDP or GMP requirements is required. For transportation and storage and handling, operating according the GDP requirements is in general sufficient. The requirements for the VAL activities is a grey area where both GMP and GDP could possibly be applicable (depends fully on the complexity of the VAL activity). Production, the most complex logistics activity, is to be operated according the GMP requirements.

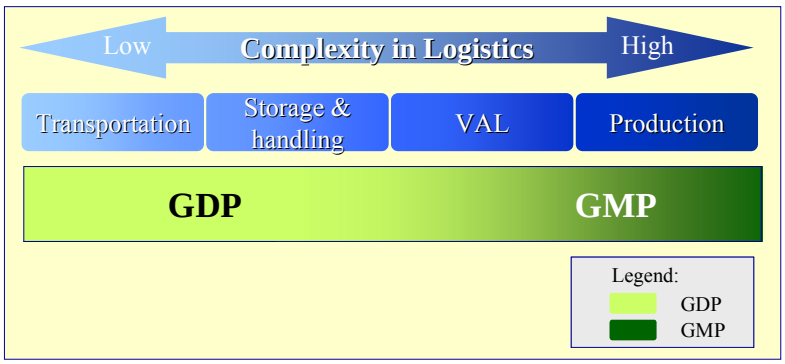


FIG. 8: GDP & GMP

For each of the four main operational logistics activities the main requirements on GMP and GDP are mentioned below.

3.3.1 Transportation

Transportation of pharmaceutical products is one of the most important elements in the execution of the supply chain. Transportation can be divided into inter-company, inbound and outbound transportation. The choice for a transportation modality (air, sea, road, rail) is mainly determined on product value density in relation to the working capital in (pipe-line) stock. The inbound and inter-company transportation for patented drugs and the high valuable medical devices are therefore mostly shipped by air. The low valuable pharmaceutical products are mostly shipped in full containers or in full truck loads. The outbound transportation from the pharmaceutical companies to their customers (final distribution) is mostly carried out using parcel services or less than full truck loads. High flexibility, on time and safe delivery are important transportation elements during new product launches.

To comply with the GDP requirements, storage conditions (e.g. temperature and humidity control) should be observed during transportation. A track & trace system and an effective recall procedure should be in place. To support this concept customized pharmaceutical Key Performance Indicators (KPI's) are required. Target values should be set and periodically performance measurement and appropriate actions should take place if the KPI's are not met. According to the GDP requirements it should be ensured that the right products are delivered to the right address within a satisfactory time period. To measure this delivery performance a typical KPI like "On-Time-In-Full" (OTIF) is effective.

3.3.2 Storage & handling

The storage and handling activities are in most cases relatively complex compared to transportation. These activities within the pharmaceutical industry are from a supply chain perspective comparable with the food industry. Both industries are focused on reducing a health risk and have comparable driving factors for the storage and handling of their products. In theory, the storage and handling activities within the pharmaceutical industry need to comply according to the GDP regulations. Authorities often have no binding restriction to comply with GMP regulations. In practice however, the pharmaceutical companies are acting according to GMP regulations (or FDA) for storage and handling on their own initiative.

The influence of GMP and GDP requirements are not limited to the physical warehouse alone, but on:

- Logistics design and operation
- Warehouse design and material handling
- Logistics information systems (tracking & tracing, FEFO, lot-numbering)
- Stock level management
- Handling of products.

Logistics design and operation
Operating in the GMP environment requires incorporating the GMP requirements in all aspects of logistics design and operation. All warehouse processes should be defined and validated and all instructions and procedures should be written in an instructional form.

Warehouse design and material handling
The storage areas and material handling systems should be designed in a way that safety is secured, anti theft securities are implemented and contamination of products is avoided. The quality status of products should be guaranteed. Certain products should be stored in conditioned areas (temperature, humidity, sterilized) and these storage conditions should be observed on a continuous basis.

Logistics information systems
The logistics information systems require additional functionalities compared to other industries. The information systems should be able to track and trace on lot level in case of problems and products which do not meet quality standards must be blocked. The monitoring of FEFO (expiration dates) through all phases of the warehouse processes (receipt, storage, picking, consolidation & shipping) should be guaranteed.

Stock level management
Stock level management within the pharmaceutical industry is of utmost importance due to the specific product characteristics:
- Limited shelf life
- Health risks
- Relatively high product value
- Product range increased due to country / label specifics
- High cost for space due to conditioning requirements
- Extra space required for separated storage of lots
- An adequate turnover of the stored medicinal products should take place.

Stock level management requires an excellent forecasting method to estimate future demands and an outstanding production planning method. The production planning should be flexible in quantities to be produced and the timing of the production. Regular cycle counting is required to check the actual stored quantities and compared to other industries, cycle counting is an essential element in the pharmaceutical industry.

Handling of products
Due to the extreme quality requirements a high picking accuracy and a minimization of human errors is a prerequisite when handling pharmaceutical products. To guarantee an excellent picking accuracy and to avoid any human errors the following trends can be seen within the pharmaceutical warehouses:

- High level WMS support
- Automation and mechanization of processes
- Online information through Radio Frequency (RF)
- Increase of RF control quality by introducing standardized bar coding
- KPI's to measure picking accuracy.

3.3.3 Value Added Logistics

Value Added Logistics (VAL) is a common practice in the pharmaceutical industry. VAL is a combination of logistics and light industrial activities that are implemented to customize products for the clients or country in question[4]. VAL can be divided into two categories[4]:

- *High-end-value-added logistics*
  High-end value added logistics activities generally add considerable value to the product, such as: sterilization of medical devices, testing, repairs and assembly of kits (assembly can also be a low-end-value-added service, depending on the degree of difficulty).

- *Low-end-value-added logistics*
  Activities which generally add little value to the product, such as printing and labeling, packaging and repacking, adding manuals, bundling of promotion material, sealing, quality checking (quality checking can also be a high-end-value-added service, depending on the degree of difficulty).

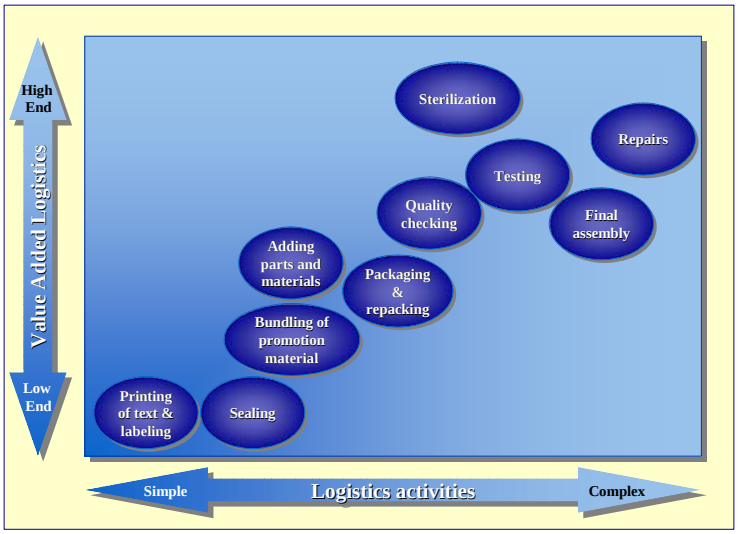


FIG. 9: VALUE ADDED LOGISTICS

[4] Source: Medtech Logistics: A study on European Logistics in the medical technology industry

Simple VAL activities like printing of text and labeling need to be operated according the GDP requirements, the complex VAL activities, like repairs and assembly, need to comply the GMP regulations. In practice however it shows that the pharmaceutical industry wants to comply according to GMP regulations for both the simple as well as the complex value added activities.

3.3.4 Production

Production of pharmaceutical products is considered the most complex logistics activity. The production activities need to comply the GMP regulations. Within the sector there is a trend to centralized production as a direct result of the recent business consolidations. Contrary to other industries there is no significant trend to move the production to low-labor costs countries due to the strict safety standards and the high level of automation in modern plants.

GMP requirements focus upon manufacturing processes and the training of people.

- *Manufacturing processes*
  All production processes have to be defined and reviewed. Validation of all critical steps within the production processes is required and necessary to mitigate any risks.

- *Training of people*
  Instructions and procedures have to be written and personnel should be trained and qualified to carry out the procedures.

Contract manufacturers should incorporate the same GMP procedures as the pharmaceutical company. This however is still regarded as one of the main showstoppers for the pharmaceutical sector with regards to outsourcing.



4 PHARMACEUTICAL TRENDS

4.1 Important developments and trends

Within the pharmaceutical industry there are several trends that will have a (in)direct impact on pharmaceutical logistics.

1. Increased quality requirements
2. Government's role and rules
3. Global medication issues
4. Patents ending
5. Consolidation.

4.1.1 Increased quality requirements

The pharmaceutical industry is an important industry for public health and safety. Technology has improved the last decades with all its benefits to product development. The quality and safety requirements are getting more stringent. Condition and safety requirements are becoming more and more important (e.g. narcotics) resulting in higher investments and operational costs.

In line with the increased requirements the reviewing and approving of new products is more time consuming than a decade ago. A slower approval of products acceptance results in shorter patent protection and an increased research, marketing and legal expenses. In addition competition is increasing and product launches are delayed resulting in a longer time-to-market. As a result profit margins are under pressure.

4.1.2 Government's role and rules

The government regulations will slow the launch of the so-called 'blockbuster' drugs, the expensively researched medical breakthroughs where the major pharmaceutical firms traditionally made much of their money[5]. Pharmaceutical companies as well as pharmaceutical logistics service providers have to interpret these regulations for their own business and use it as a good business tool to reduce compliance and increase performance. In many markets, the government is also the largest purchaser of pharmaceuticals. This purchasing power of the government is used to negotiate prices.

4.1.3 Global medication trends

The life science market is strongly increasing because of aging population which is of course in favor of the pharmaceutical companies. Also, a large growth in the world market for medical devices and biotechnology is expected.

[5] Source: Prescription for change

In the third world countries AIDS medication is increasing but the pharmaceutical companies are under pressure to provide products to these countries at a much lower costs compared to other countries.

4.1.4 Patents ending

The pharmaceutical industry faces a record number of patent endings. Once a patent no longer protects a product, other companies will start producing it at lower prices. The original patent holder may expect a decrease in revenues, leading to a costs reduction focus to maintain minimal profit margins.

4.1.5 Consolidation

The endings of patents, high profit expectations and economies of scale in R&D have led to many mergers and acquisitions. Consolidation is still the major trend, especially in the medical devices, biopharmaceuticals and patented drugs sub-industries.

4.2 Profit margins under pressure

The pictured developments and trends have a huge impact on the profit margins within the pharmaceutical sector. In Europe the profit margins for drug are already lower compared to the USA. The USA drug prices are now about twice the level of European prices[6]. As a direct result the European pharmaceuticals companies are redirecting their strategy from growth & reliability to cost reductions. Inasmuch as supply chain costs can make up from 5% to 15% of costs of goods sold, the supply chain is one of the main focus areas for efficiency improvements.

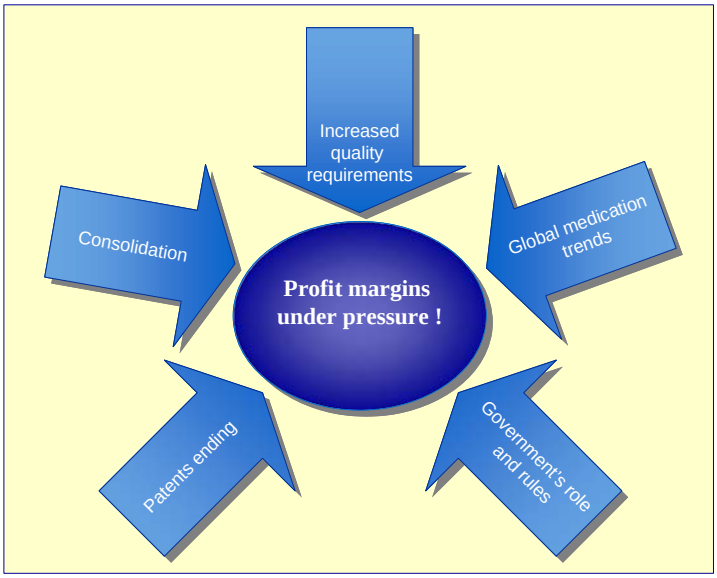


FIG. 10: PROFIT MARGINS UNDER PRESSURE

[6] Source: Europe suffers from its low drug prices

5 LOGISTICS OUTSOURCING FOCUS

5.1 The outsourcing status

Public warehousing and transportation may be the oldest forms of outsourcing of logistics[7]. The second step for logistics service providers was to provide VAL activities. The outsourcing of the production to Logistics Service Providers (or contract manufacturers) has been recently growing. In general, the most common reasons for outsourcing are: cost reduction, improvement of service levels, increase in operational flexibility, focusing on core competences and improvement of assets utilization. Logistics Service Providers have the ability to provide their clients with expertise and experience.

It has been estimated that about 40 per cent of the global logistics is outsourced to Logistics Service Providers[8]. In comparison, initial estimations are that 5 to 10 percent is outsourced to Logistics Service Providers in the European pharmaceutical industry. Pharmaceutical companies still tend to keep direct control over the many supply chain activities such as production, storage and handling and in some cases, transportation[9]. However, the pharmaceutical industry is developing a positive view on outsourcing, especially on transportation. Especially within the biopharmaceutical, medical devices and the non-patented drugs sub-industry, the outsourcing of warehousing and handling is growing. On the other hand we still see some reservations towards outsourcing as outsourcing the non-core production activities to service providers is still considered unconventional.

For each of the four pharmaceutical sub-industries (patented drugs, non-patented drugs, biopharmaceuticals and medical devices) the complexity in logistics will determine the outsourcing focus for the next coming years (see Fig. 11).

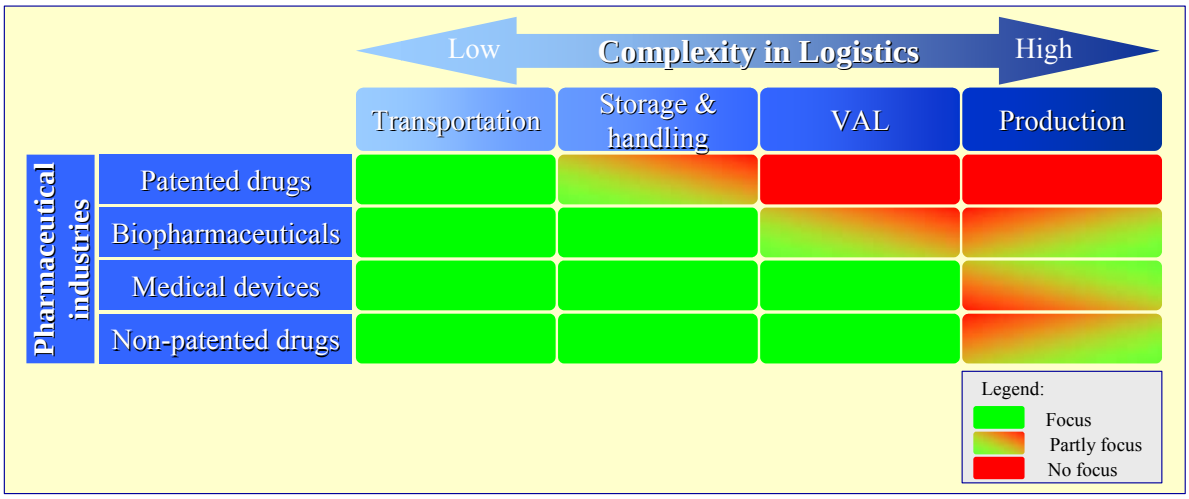


FIG. 11: PHARMACEUTICAL OUTSOURCING FOCUS IN NEXT COMING YEARS

[7] Source: Outsourcing of logistics functions: a literature survey
[8] Source: Customer perceptions on logistics outsourcing in the European consumer goods industry
[9] Source: Prescription for change

5.2 Transportation

At this moment a large part of the transportation of pharmaceutical products is already outsourced to Logistics Service Providers. This will not change dramatically in the future. Pharmaceutical companies are putting a great effort in the carrier selection, a reliable partner is required. Temperature control, tracking and tracing, anti theft securities are of utmost importance for the transportation of pharmaceutical products. These requirements often mean dedicated transportation which is more expensive compared to regular transportation.

5.3 Storage & handling

Storage and handling activities are at this moment often operated by the pharmaceutical companies their selves. From a functional Supply Chain perspective the storage and handling within the pharmaceutical industry has much parallels with the electronic and food industries. The latter two industries are typically known for their high percentage of outsourcing.

The main differentiator is the obligation to work under GDP/GMP regulations. As a result of the strong competition within the warehousing and transportation sector , Logistics Service Providers are continuously looking for new markets. Logistics Service Providers consider the pharmaceutical industry as a commercial interesting playing field on the rise. For this reason Logistics Service Providers are investing in an effort to become GMP/GDP compliant for storage and handling. So there is not only demand for outsourcing, but also supply. Therefore the overall expectation is that outsourcing of the storage and handling activities will certainly increase within the biopharmaceutical, medical devices and the non-patented drugs sub-industry the next coming years.

5.4 Value Added Logistics

The forefront of the Logistics Service Providers are at this moment equipped to sterilize, repair and assemble medical devices. The outsourcing of VAL activities within the non-patented drugs sub-industry is definitely a rising star. It is not expected that the VAL activities of the patented drugs will follow. The pharmaceutical manufacturers of patented drugs still elect to maintain their direct control over their VAL activities. An additional factor playing a role in their course of action is the need to ensure the confidentiality of ingredients.

5.5 Production

Pharmaceutical companies still tend to keep control over the production activities to a much greater degree than in other industries. Partly because of the GMP regulations but also caused by the fact that the pharmaceutical industry is a conventional market.

For example, in the electronics industry, which can be compared with the medical devices sub-industry, outsourcing to subcontractors is common, while in the medical devices sub-industry this is not yet a common standard. Both in the electronics and computer industry[10], no real manufacturing is done by the industry itself, the actual production is handled by the subcontractors. In the pharmaceutical industry, the use of subcontractors is currently only considered on a larger scale in the medical device and non-patented drug production.

There is no operational or legal reason that Logistics Service Providers (or subcontractors) can not be compliant the GMP and GDP regulations. Outsourcing of production in the medical devices sub-industry, the non-patented drugs sub-industry and the biopharmaceutical sub-industry will definitely take place more often in the near future. The pressure on productivity improvements will speed up this production outsourcing growth.

[10] Source: Prescription for change

6 PHARMA LOGISTICS SERVICE PROVIDERS ?

6.1 The LSP market – two options

When considering outsourcing for the pharmaceutical industry there are two options:

1. team up with a traditional Logistics Service Providers like DHL, TNT, with an extensive logistics expertise but limited pharmaceutical background
2. team up with pharmaceutical wholesalers who offer their logistics activities to 3rd parties, concerning companies as Celesio and Red Swan.

6.2 The traditional LSP

Logistics companies serving the pharmaceutical sector have usually been small, local specialists[11]. The traditional and large Logistics Service Providers like DHL, Exel, Fiege, Geodis, Kuehne & Nagel, Panalpina and TNT have lot of experience in complex electronics industries. They have the supply chain knowledge and the right infrastructure in place. Most of these Logistics Service Providers have significant global coverage. Supply chain efficiency and transparency on a global scale is what they aim for. To extend their markets, these logistics service providers are getting more experienced in the logistics activities within the pharmaceutical industry.

6.3 The pharmaceutical specialist

Recently, several pharmaceutical wholesaling and retail pharmacies like Celesio, Phoenix and Alliance Unichem have been professionalizing and externally marketing the distribution and warehousing of pharmaceutical products. These companies are already specialized in handling pharmaceutical products through their mother company. They have an respectable European coverage, but their competitive advantage is more on pharmaceutical expertise than on a distribution network efficiency.

6.4 What can we expect?

The availability of logistics service providers specialized in pharmaceuticals with a global coverage will grow rapidly in the near future. On the one hand, the traditional Logistics Service Providers will gain more experience in the handling of pharmaceutical products, complying with the company and government standards. Moreover, they can assure validation. On the other hand, it is expected that the former pharmaceutical wholesaling and retail pharmacies will achieve more global coverage.

[11] Source: Prescription for change

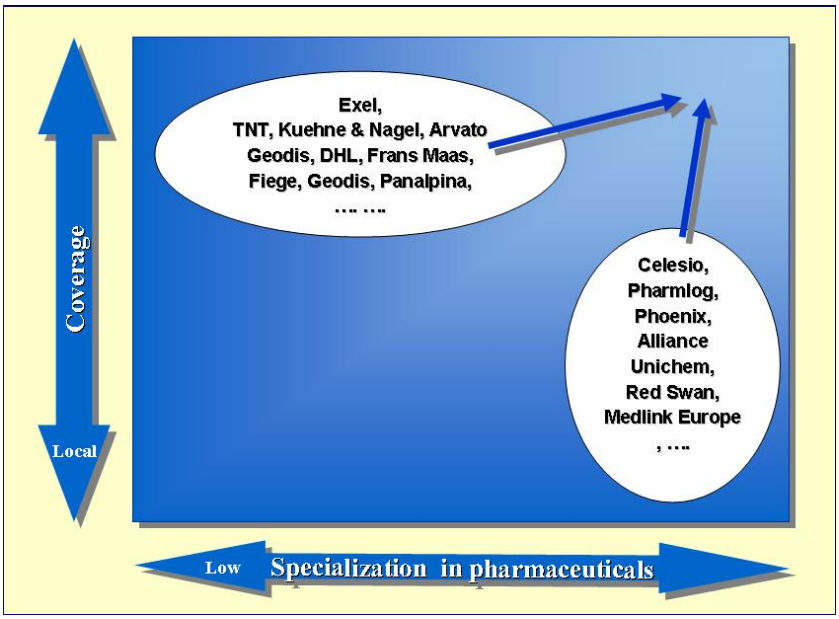


FIG. 12: LOGISTICS SERVICE PROVIDERS WITHIN THE PHARMA

As the above figure shows, there is a supply of Logistics Service Providers who are able to provide (global) logistics services complying with the quality and safety regulations according to GMP/GDP (and FDA) in an efficient manner. If the pharmaceutical industry becomes more aware of the strengths and the opportunities of outsourcing, the availability of pharmaceutical Logistics Service Providers serving the global market will certainly get a boost.

7 CAN OUTSOURCING SOLVE MY HEADACHE

7.1 So is outsourcing a medicine worthwhile considering?

There is suitable momentum to provide for a trend shift in the outsourcing strategy for storage, handling and distribution activities within the pharmaceutical industry. Other sectors like high-tech, automotive and food -each with intense requirements on agility, flexibility and reliability- are working with an outsourced logistics operation. The success of outsourcing within these demanding environments is explained by the fact there is still strong, dedicated management attention on logistics although the actual physical logistics operation is operated by a 3rd-party. Too often companies believe that together with the outsourcing the operation all coordination and management activities can be made redundant as well.

It is to be comparable with child daycare. Our children are our most valuable possessions. However we feel perfectly comfortable with bringing them to daycare because we have full trust in the expertise and responsibility of the daycare staff. Supported through a careful daycare selection process, we made a choice on quality and costs rather than price alone. And we do this with the full understanding that bringing our kids to daycare does not relief us from our parental responsibilities.

Exactly the same reasoning applies to your most valuable professional possessions. Outsourcing can definitely bring added value to the pharmaceutical supply chain as long as there is internal awareness and focus on managing the 3rd-party logistics provider. Outsourcing should be a partnership where reliability, service and expertise are as much as important drivers as costs. Outsourcing can solve your supply chain headache, but it does not dismiss you from the responsibility to treat your body carefully.

7.2 The key success factors

So in principal outsourcing of warehousing and distribution can provide competitive and financial benefits, as long as the main key success factors are considered.

1. As a pharmaceutical company you outsource the logistics day-to-day operation, leaving you a certain dependency with the Logistics Service Providers. Therefore it is vital to:
   - sustain specific supply chain expertise within your company
   - have a clear and dedicated management structure towards the Logistics Service Provider on both the a strategic and tactical level
   - the quality of (electronic) information exchange is essential for a successful partnership.

2. To guarantee a high quality operation the focus should be on creating partnerships with the LSP rather than a "commodity" cost reduction. A valuable tool for creating this mutual understanding and partnership is the contract i.e. Service Level Agreement (SLA). An SLA consists of a main (legal) document and several schedules concerning performance levels, logistics services, transition management, relationship management, etc. It is not just a legal document but should serve as a directive for day-to-day business processes as well.

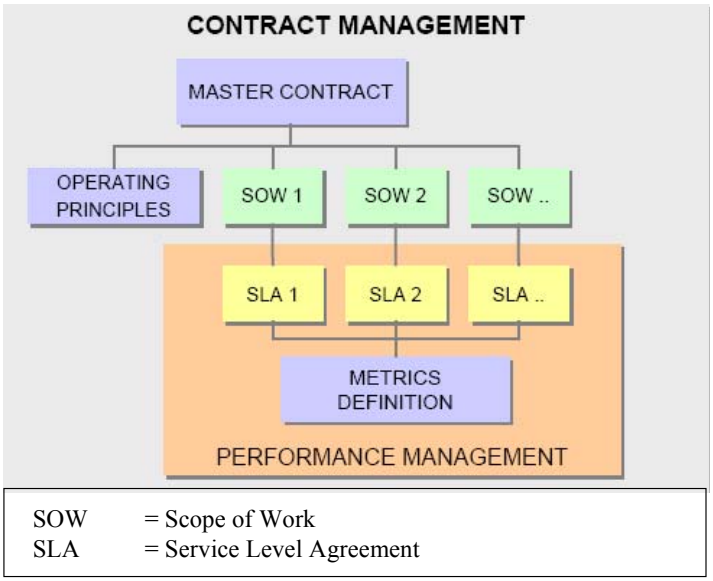


FIG. 13: CONTRACTUAL SETUP LOGISTICS OUTSOURCING

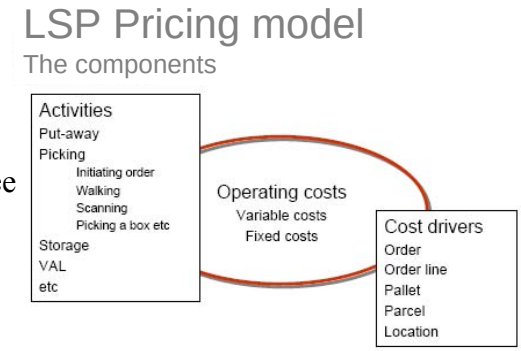
3. Be aware warehouse outsourcing does not automatically bring savings.
   - Yes the average wages in the transportation sector are lower on average, but additional efficiency savings have to be actively looked for. This relates to opportunities as "public warehousing", leveraging seasonality's, workload management with other businesses, etceteras.
   - Many companies do not assign all their logistics costs one-to-one on a supply chain budget (e.g. not all IT costs are fully assigned to supply chain, the incidental help from production employees to get rid of the warehouse backlog). Outsourcing provides full transparency on your total supply chain costs, which could be higher than the current perception in the company

4. Do not outsource to solve your operational logistics disorder. A Logistics Service Provider will not solve them (as the root of the problem is often of a non-supply chain nature) and will charge you for his additional costs as a result of the disruption in his warehouse and distribution process

5. Outsourcing has an irreversible component, it a strategic decision which can not be changed every two years.

6. The pricing model in the outsourcing contract deserves specific attention as it directly influences the day-to-day relationship between the shipper and the Logistics Service Provider. It should support an optimal fit between the specific operational characteristics and the ability to manage & control the LSP while maximizing the uniformity of the contract components Therefore the choice for the right cost drivers is crucial.
   - It must be a motivation to decrease overall costs
   - It must be able to manage the performance
   - It must positively influence the ordering profile (e.g. a separate price for normal orders and rush orders can limit unnecessary rush orders)

   Main contractual pricing methods that are commonly used are.
   - *Set pricing*
     - Firm Fixed Price
     - Fixed Price Incentive Fee
   - *Variable pricing*
     - Price per activity / unit
     - Price per activity / unit-Incentive Fee
   - *Cost-plus pricing*
     - Cost Plus Fixed Fee
     - Cost Plus Incentive Fee



7.3 The outsourcing momentum

So in today's pharmaceutical world there is the ultimate momentum to move to outsourcing of warehousing and distribution. Sales margins are under pressure and the reduction of operational costs is not a luxury but a necessity. The rapid growth of capable external service providers with pharmaceutical expertise and a global coverage will encourage the pharmaceutical sector in this direction.

For the pharmaceutical industry, outsourcing is not just a cure for their Supply Chain headaches but equally critical for their financial health.

Literature

- Bijman, Jos, *Life Science Companies: Can they combine seeds, agrochemicals and pharmaceuticals?*, Biotechnology and development monitor, no. 40, 1999
- Commission of the European communities, *Life sciences and biotechnology – A Strategy for Europe*, 2002
- Environmental and Development Service for NGOs, *Biotechnology*, Both ENDS' Information Pack no. 14, 2000
- European Commission, *Good Manufacturing practices, Medicinal products for human and veterinary use*, 1998 edition
- European Commission, *Guidelines on Good Distribution Practice of medicinal products for human use*, 1992 edition
- European Federation of pharmaceutical industries and associations (EFPIA), *The Pharmaceutical Industry in Figures, 2004 Edition,* 2004
- Gapper, John, *Europe suffers from its low drug prices*, 2004
- Holland International Distribution Council, *Medtech Logistics – A study on European logistics in the medical technology industry*, 1998
- Lewis, Chris, *Prescription for change*, Logistics Europe, April 2003
- Lewis, Chris, *Supply chain cure-all*, Logistics Europe, April 2004
- Mitchell, Anthony, *Keeping supply chains healthy*, Pharmaceutical Technology Europe, 2005
- Razzaque, M.A., Chen Sheng, C., *Outsourcing of logistics functions: a literature survey*, International journal of Physical distribution & Logistics Management, vol. 28, no. 2, 1998
- Schulze, F., Geimer H., Dresbach E, PRTM, *Pharmadistribution im Wandel*, Supply Chain Management, number 11, 2004
- Strategic Direction, *Innovations: Becoming wise to biotechnology*, volume 19, number 11 2003
- Wilding, R., Juriado R., *Customer perceptions on logistics outsourcing in the European consumer goods industry*, International journal of Physical distribution & Logistics Management, vol. 34, no. 8, 2004

APPENDIX

I. General trends & developments

II. About Groenewout Consultants & Engineers

III. About the author

I. GENERAL TRENDS & DEVELOPMENTS

GMP requirements

GMP is that part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the Marketing authorization or product specification. The GMP guidelines are published by the U.S. Food and Drug Administration (FDA) and taken over by the European community. GMP is concerned with both production and quality control. The basic requirements of GMP are that[12]:

- All manufacturing processes are clearly defined and systematically reviewed
- Critical steps of the manufacturing processes and significant of all changes are validated
- All necessary facilities for GMP are provided (qualified and trained personnel, adequate premises and space, suitable equipment and services, correct materials, approved procedures and instructions, suitable storage and transport)
- Instructions and procedures are written in an instructional form
- Operators are trained to carry out procedures correctly
- Records are made during manufacturing
- Batches are able to be traced
- The distribution (wholesaling) of products minimizes any risk to their quality
- A system should be available to recall any batch of products
- Complaints about marketed products are examined and appropriate measures are taken to prevent reoccurrence.

GDP requirements

The pharmaceutical industry operates at a high level of quality assurance as described in the GMP guidelines. Operating according to the guidelines described in the GDP ensures that products released for distribution are of the appropriate quality. This level of quality should be maintained throughout the whole distribution network. GDP is the distribution part within GMP.

The quality system operated by distributors and pharmaceutical logistics service providers should ensure that[13]:

- Medicinal products that they distribute are authorized in accordance with Community Legislation
- Storage conditions are observed at all times, also during transportation
- Contamination during from or of other products is avoided
- An adequate turnover of the stored medicinal products takes place
- Products are stored in appropriately safe and secure areas.
- The right products are delivered to the right address within a satisfactory time period
- A tracing system should enable any faulty product to be found
- An effective recall procedure is in place.

[12] Source: Good manufacturing practices, Medicinal products for human and veterinary use
[13] Source: Guidelines on Good Distribution Practice of medicinal products for human use

II ABOUT GROENEWOUT

Contactdetails
Groenewout Consultants & Engineers
Thea van Dooren
P.O. Box 3290
4800 DG Breda
The Netherlands
Telephone: +31 (0)76 5330440
Fax: +31 (0)76 5310191
E-mail: news@groenewout.com

Groenewout is an international consulting company specializing in supply chain and logistics. Our core competency has been honed in supply chain optimization and detailed designs of manufacturing, distribution and fulfillment centers. We therefore place a great deal of emphasis on both the identification and realization of feasible opportunities. We pride ourselves on innovative and creative thinking to arrive the business improvements to our clients' process needs. We desire a strong client participation to address a comprehensive solution.

Our services provided include the focus areas supply chain management, sourcing, manufacturing, warehousing & distribution, transportation and assets & facilities. Although our work performance and technical expertise are recognized as the best in Europe Groenewout has also provided its services to clients in North and South America and Asia.

Since its establishment in 1966, Groenewout has been privileged to count leading international companies from Europe, United States and Japan among its many clients.

For more information about our company we invite you to visit us on our website: www.groenewout.com