European Supply Chain Overview: Life Sciences & Health

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Introduction

About this document

This “European Supply Chain Overview: “Life Sciences & Health” has been composed by HIDC (Holland International Distribution Council) and its members. It is a background document containing information on the European supply chains for the life science industry including pharma and medical technologies and their respective logistics characteristics and the Dutch Life Sciences and Health logistics proposition. Also, it is a living document, being updated regularly to reflect changes in the market and supply chains.

HIDC welcomes any additions and suggestions to improve this document.

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Life Sciences & Health: Industry definition and market overview
The **life sciences** or **biological sciences** comprise the branches of science that involve the scientific study of **life** and **organisms** – such as **microorganisms**, **plants**, and **animals** including **human beings**.
Life Sciences & Health: Market overview

- While the global health care spending continues to increase at a faster pace, the demand for logistics services facilitating this growth will continue to grow as well.

- While the life expectancy also continues to increase there will be an increased demand for pharmaceuticals and medical technologies.

Source: Deloitte, 2019 Global Life Sciences Outlook
Pharma grows at a pace of 6.5% per year till 2022.

With a growing cost focus and increased competition by generic medicines new players are getting a piece of the marketshare, this brings opportunities for their logistics operations.

Smaller niche companies are the drivers behind innovation as larger players are cutting their R&D budgets.
Life Sciences & Health: Market overview

- Medtech market will reach 595 billion USD by 2024 with in vitro diagnostics being the largest segment.
- The top ten players will make up a significant part of the market, interesting to their developments and supply chain requirements.
- The orphan drug market will double in the next five years. Orphan drugs are drugs that are developed in cooperation between a private company and a government as otherwise the development would be possible. This means there is a need for extra labspace as well as medical devices.
- CAR-T therapy is also a very promising field with associated supply chain requirements.

Source: Deloitte, 2019 Global Life Sciences Outlook
• More demand for cheaper drugs, driven by governments.
• Personalized medicine will increase substantially. The impact to supply chains is considerable and brings opportunities.

Source: Deloitte, 2019 Global Life Sciences Outlook
Life Sciences & Health: Market overview

EU 28 ageing: age as a % of total population in 2008 and 2060

Source: Eurostat, EUROPOP2008 convergence scenario
Over the past decade the global life sciences sector has experienced healthy growth. The world market for pharmaceuticals, for example, has doubled within a decade. It has reached a value of about USD 1 trillion and is expected to grow by another 3 to 6 per cent per annum until 2015 (IMS 2012a). Strong growth rates until 2020 are also forecast for the market for medical devices.

Source: DHL – Key logistics Trends in Life Sciences 2020+

Life expectancy in OECD countries is rising, but so is the burden of chronic diseases

Population ageing increases demand for long-term care and puts pressures on public spending, despite informal care

Source: Health at a Glance 2013 – OECD indicators

The sector invests

OVER € 2 BILLION IN R&D EACH YEAR

It already accounts for 2.5% of GDP

With approximately 350 life sciences companies clustered within a 120-mile radius, The Netherlands is the most geographically concentrated region in the world when it comes to creating economic and social value in Life Sciences & Health.

Source: Infographic – Dutch Life Sciences sector
European healthcare equation

- There is an increasing demand for healthcare products and services while at the same time there is an increasing focus on driving down costs.
- This focus on cost effective solutions brings opportunities for supply chain optimizations as well.
Life Sciences & Health: Trends & Developments
2019 Key 8 Predictions for Global Healthcare Industry

1. **Value-based Care Progresses as Outcomes Focus Globalizes**
2. **AI explodes across the Healthcare & Life Sciences post Flagship Use Cases yield Positive Results**
3. **Digital Health will come of Age with an Increased Focus on Individual Care**
4. **Asia become the New Local Innovation focus for Global Drug and Device OEMs**
5. **Healthcare Data Analytics shifts from Big Data to Meaningful Small Data by Hospital Specialty**
6. **Healthcare will be a Dominant Vertical in Voice Applications**
7. **Blockchain moves from Hype to Reality with further Commercial Implementations**
8. **Innovative Private Insurance Models Shake up Healthcare Payer Industry**
Life Sciences & Health: Trends & Developments

New business models: 'Beyond the pill', outcomes and real world data are providing health data and transforming what is possible.

Supply drivers:
- Medical & patient data: Electronic health records (EHRs), health sensors, social media, and genomics create rich new data sources for analytics.
- Big Data analytics: Cheaper computing power and sophisticated analytics drive insights into patient behaviour, treatment costs and R&D.
- Mobile/MHealth: Pervasive mobile and smart phone adoption creates new engagement models within daily routines.
- Healthcare professional digital workflow: Increasing integration of EHRs and telehealth driving new digitally-enabled coordinated workforce models of care.

Demand drivers:
- Rollout business models tied to patient outcomes that also reduce medical errors and improve quality.
- Discover and deliver targeted and personalized therapies with real world evidence of impact.
- Influence patients’ behaviours ‘beyond the pill’ and sustain engagement outside the traditional care setting.
- Drive population management, protocol driven patient risk pool and stratification management.

Source: Monitor Deloitte
Life Sciences & Health: Supply Chain Characteristics
What is an intelligent supply chain?
Patient-centric and focused on innovation and continuous improvement. It is:

- SMART
- CONNECTED
- LEARNING
- AGILE

The rise of specialty medicines and the shift from a product to a patient outcome orientation create a burning platform for a new, more intelligent supply chain.

Source: Accenture, 2018
Life Sciences & Health: Supply Chain Characteristics

- The global megatrends and challenges for the Life Sciences Sector have several logistics implications.

- These five implications and associated actions are the key to success in implementing a successful LSH supply chain.
There will be a shift towards more differentiating supply chains per LSH product category, meaning transportation, warehousing and distribution models will be specialized for a certain part of the industry.

This development will result into more specialist players in the LSH supply chain.

This development will also result that more generic solutions will become obsolete.

The strong network of specialized logistics service providers in the Netherlands gives ample choice for LSH shippers to differentiate their supply chain.
Manufacturers will develop direct distribution models to end consumers either by building up own e-commerce capabilities or through a platforms.

This development brings opportunities for LSH shippers to make use of the broad network of strong logistics players in the Netherlands that can develop and run this kind of solutions.
Pharma and medtech companies will continue to expand their markets both from a production and selling point of view.

This development asks for logistics providers that have strong global, regional and local networks so they can move with the demands of LSH shippers.

The Netherlands is home to a wide range of LSP’s that can offer that.
The need for ever more transparency and visibility is not only required for product integrity and security but also to be able to optimize supply chains.

Examples of this include demand driven supply chains (direct to consumer) or emergency logistics combined with slower transport modes.

Also managing several partners in the supply chain requires 100% visibility and transparency.

Many LSP’s in the Netherlands offer this full visibility as systems and processes are state of the art.

In addition many LSP’s offer control tower solutions that will oversee and manage shippers’ full supply chain.
• Being able to adapt to changing circumstances in for example rules and regulations, temperature solutions and personalized medicines requires a flexible supply chain
• The Netherlands has a broad range of logistics service providers that offer this kind of flexibility
Life Sciences & Health: Supply Chain Characteristics

Segmentation

Supply chain characteristics

<table>
<thead>
<tr>
<th>Elements</th>
<th>High value pharma / biotech</th>
<th>Large Pharma</th>
<th>Medtech</th>
<th>Medical Disposables</th>
</tr>
</thead>
<tbody>
<tr>
<td>Value density</td>
<td>++ / +++</td>
<td>- / +</td>
<td>++ / +++</td>
<td>-</td>
</tr>
<tr>
<td>Volume</td>
<td>-</td>
<td>++</td>
<td>-</td>
<td>++ / +++</td>
</tr>
<tr>
<td>Order to delivery leadtime (EU)</td>
<td>Next-day</td>
<td>Next-day – 72 hours</td>
<td>Next-day (pre-x)</td>
<td>Next-day – 72 hours</td>
</tr>
<tr>
<td>Temp control importance</td>
<td>+++</td>
<td>++</td>
<td>+</td>
<td>0 / +</td>
</tr>
<tr>
<td>Distribution profile</td>
<td>Parcel</td>
<td>Pallet</td>
<td>Parcel</td>
<td>Pallet</td>
</tr>
<tr>
<td>Level of country-specific SKUs</td>
<td>+++</td>
<td>++</td>
<td>+++</td>
<td>+ / ++</td>
</tr>
<tr>
<td>Main commercial channel</td>
<td>Mix Direct/Indirect</td>
<td>Indirect</td>
<td>Direct</td>
<td>Mix Direct/Indirect</td>
</tr>
</tbody>
</table>

Source: Buck Consultants International
Life Sciences & Health: Supply Chain Characteristics

**Medtech**
- Centralization of Supply Chain Control: Common Practice for many years
- Network Consolidation: Common Practice for many years
- Visibility: Control Tower / Transport Management concepts, Linking inbound, intercompany and secondary distribution, Information is Key
- Outsourcing & Partner Portfolio Reduction: Main DCs still often insourced (at least at the big players), Development towards outsourcing observed

**Pharma**
- Strengthening of SC Organizations
- Investments in SC Talent
- Corporate SC taking ownership of the downstream supply chain
- Consolidation of Distribution Networks
- Mix of full centralization, regionalization and hub-spoke models
- Scope: downstream, still lack of full chain scope
- Control Tower / Transport Management concepts
- Linking inbound, intercompany and secondary distribution
- Information is Key
- 3PL landscape in pharma has improved highly
- Towards LLP/4PL models
- Strong reduction of number of partners used
- Towards harmonized (global) contracts

Source: Buck Consultants International
### Life Sciences & Health: Supply Chain Characteristics

<table>
<thead>
<tr>
<th>Customer Service / Order to Cash process harmonization</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Medtech</strong></td>
</tr>
<tr>
<td>● CS/O2C mainly in-house</td>
</tr>
<tr>
<td>● Increasing interest in outsourcing and centralization of back-offices</td>
</tr>
<tr>
<td><strong>Pharma</strong></td>
</tr>
<tr>
<td>● CS and O2C activities closely linked to physical supply chains</td>
</tr>
<tr>
<td>● Harmonization &amp; centralization of CS and O2C organizations</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Supply Chain Differentiation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Medtech</strong></td>
</tr>
<tr>
<td>● From one size fits all to differentiated supply chains per product/ market combination</td>
</tr>
<tr>
<td>● SC becoming a stronger counterpart for the commercial team, challenging service requirements</td>
</tr>
<tr>
<td><strong>Pharma</strong></td>
</tr>
<tr>
<td>● From one size fits all to differentiated supply chains per product/ market combination</td>
</tr>
<tr>
<td>● SC becoming a stronger counterpart for the commercial team, challenging service requirements</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Supply Chain Collaboration</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Medtech</strong></td>
</tr>
<tr>
<td>● Logistics not a key differentiator, therefore the industry is recognizing the opportunities of collaboration</td>
</tr>
<tr>
<td>● How to break through from pilots to full realization?</td>
</tr>
<tr>
<td><strong>Pharma</strong></td>
</tr>
<tr>
<td>● Logistics not a key differentiator, therefore the industry is recognizing the opportunities of collaboration</td>
</tr>
<tr>
<td>● How to break through from pilots to full realization?</td>
</tr>
</tbody>
</table>

Source: Buck Consultants International
### Life Sciences & Health: Supply Chain Characteristics

<table>
<thead>
<tr>
<th>Factors</th>
<th>High value pharma / biotech</th>
<th>Large Pharma</th>
<th>Medtech</th>
<th>Medical Disposables</th>
</tr>
</thead>
<tbody>
<tr>
<td>Closeness to market (COG)</td>
<td>-</td>
<td>++</td>
<td>-</td>
<td>++</td>
</tr>
<tr>
<td>Closeness of main integrator hubs</td>
<td>++</td>
<td>- / +</td>
<td>+++</td>
<td>0</td>
</tr>
<tr>
<td>Availability of healthcare 3PLs</td>
<td>+++</td>
<td>++</td>
<td>0 / +</td>
<td>0 / +</td>
</tr>
<tr>
<td>Political Stability</td>
<td>++</td>
<td>++</td>
<td>++</td>
<td>++</td>
</tr>
<tr>
<td>Labor Market Stability</td>
<td>++</td>
<td>++</td>
<td>++</td>
<td>++</td>
</tr>
<tr>
<td>Tax, Labor, Customs Landscape</td>
<td>++</td>
<td>++</td>
<td>++</td>
<td>++</td>
</tr>
<tr>
<td>Intermodal Solutions</td>
<td>-</td>
<td>(+)</td>
<td>-</td>
<td>(+)</td>
</tr>
<tr>
<td>Peer Presence</td>
<td>++</td>
<td>+</td>
<td>++</td>
<td>+</td>
</tr>
<tr>
<td>Transport-related costs</td>
<td>+</td>
<td>(+)</td>
<td>++</td>
<td>+++</td>
</tr>
<tr>
<td>Facility-related costs</td>
<td>0</td>
<td>(+)</td>
<td>(+)</td>
<td>+++</td>
</tr>
</tbody>
</table>

Source: Buck Consultants International
Medtech: Industry definition and market overview
• Medical technology[^edit]
• Medical technology, or "medtech", encompasses a wide range of healthcare products and is used to treat diseases and medical conditions affecting humans. Such technologies are intended to improve the quality of healthcare delivered through earlier diagnosis, less invasive treatment options and reduction in hospital stays and rehabilitation times.[^4] Recent advances in medical technology have also focused on cost reduction.[^citation needed] Medical technology may broadly include medical devices, information technology, biotech, and healthcare services.

[^edit]:
[^4]:
[^citation needed]:
1 European Commission. The classification of medical devices is a ‘risk based’ system based on the vulnerability of the human body taking account of the potential risks associated with the devices. The classification rules are based on different criteria such as the duration of contact with the patient, the degree of invasiveness and the part of the body affected by the use of the device.

2 European Commission. IVD classification is based on the degree of health risk posed to an individual and public, and is related to the risk of an incorrect result arising from the use of the IVD.

Source: MedTech Europe – The European Medical Technology industry in figures
There are more than 500,000 medical technologies registered. These fall within 16 categories of products, as determined by the Global Medical Devices Nomenclature (GMDN) Agency.

<table>
<thead>
<tr>
<th>Code</th>
<th>Classification</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>01</td>
<td>Active implantable technology</td>
<td>Cardiac pacemakers, neurostimulators</td>
</tr>
<tr>
<td>02</td>
<td>Anesthetic respiratory technology</td>
<td>Oxygen mask, gas delivery unit, anaesthesia breathing circuit</td>
</tr>
<tr>
<td>03</td>
<td>Dental Technology</td>
<td>Dentistry tools, alloys, resins, floss, brushes</td>
</tr>
<tr>
<td>04</td>
<td>Electromechanical medical technology</td>
<td>X-ray machine, laser, scanner</td>
</tr>
<tr>
<td>05</td>
<td>Hospital hardware</td>
<td>Hospital bed</td>
</tr>
<tr>
<td>06</td>
<td>In vitro diagnostic technology</td>
<td>Pregnancy test, genetic test, glucose strip</td>
</tr>
<tr>
<td>07</td>
<td>Non-active implantable technology</td>
<td>Hip or knee joint replacement, cardiac stent</td>
</tr>
<tr>
<td>08</td>
<td>Ophthalmic and optical technology</td>
<td>Spectacles, contact lenses, intraocular lenses, ophthalmoscope</td>
</tr>
<tr>
<td>09</td>
<td>Reusable instruments</td>
<td>Surgical instruments, rigid endoscopes, blood pressure cuffs, stethoscopes, skin electrodes</td>
</tr>
<tr>
<td>10</td>
<td>Single use technology</td>
<td>Syringes, needles, latex gloves, balloon catheters</td>
</tr>
<tr>
<td>11</td>
<td>Technical aids for disabled</td>
<td>Wheelchairs, walking frames, hearing aids</td>
</tr>
<tr>
<td>12</td>
<td>Diagnostic and therapeutic radiation technology</td>
<td>Radiotherapy units</td>
</tr>
<tr>
<td>13</td>
<td>Complementary therapy devices</td>
<td>Acupuncture needles/devices, bio-energy mapping systems/software, magnets, moxibustion devices, suction cups</td>
</tr>
<tr>
<td>14</td>
<td>Biological-derived devices</td>
<td>Biological hearth valves</td>
</tr>
<tr>
<td>15</td>
<td>Healthcare facility products and adaptations</td>
<td>Gas delivery systems</td>
</tr>
<tr>
<td>16</td>
<td>Laboratory equipment</td>
<td>Most IVD which are not reagents</td>
</tr>
</tbody>
</table>

Source: MedTech Europe – The European Medical Technology industry in figures
The European medical technology industry employs directly more than 675,000 people. Germany has the highest absolute number of people employed in the medical technology sector, while the number of medtech employees per capita is highest in Ireland and Switzerland. This high level of employment shows that the medical technology industry is an important player in the European economy.

In comparison, the European pharmaceutical industry employs more than 750,000 people1.

There are almost 27,000 medical technology companies in Europe. Most of them are based in Germany, followed by the UK, Italy, Switzerland, Spain and France. Small and medium-sized companies (SMEs*) make up around 95% of the medical technology industry, the majority of which employ less than 50 people (small and micro-sized companies)2.
Medtech: Industry definition and market overview

The European medical technology market is estimated at roughly €115 billion in 2017. Based upon manufacturer prices, the European medical technology market is estimated to make up 27% of the world market. It is the second largest medical technology market after the US (+43%).

Europe has a positive medical devices trade* balance of €19.7 billion (2017). In comparison, US medical devices trade surplus is at €2 billion. Compared to the previous years, the main European medtech trade partners remain the same: the US, China and Japan.

Source: MedTech Europe – The European Medical Technology industry in figures 2019
Medtech: Industry definition and market overview

Top 7 countries with highest direct employment in the medical technology industry, 2017 (ref. 3)

- United Kingdom: 100,000
- Germany: 200,000
- Ireland: 38,000
- Switzerland: 58,500
- France: 85,000
- Spain: 24,000
- Italy: 76,000

Number of people directly employed in the medical technology industry per 10,000 inhabitants, 2017 (ref. 3)

Source: MedTech Europe – The European Medical Technology industry in figures 2019
In Europe, an average of approximately 10% of gross domestic product (GDP) is spent on healthcare. Out of the total healthcare expenditure, around 7.2% is attributed to medical technologies, i.e., less than 1% of GDP. The spending on medical technology is estimated to vary significantly across European countries, ranging from around 5% to 10% of the total healthcare expenditure. Expenditure on medical technology per capita in Europe is at around €213 (weighted average).

Source: MedTech Europe – The European Medical Technology industry in figures 2019
Medtech: Industry definition and market overview

European medical device market by country, based upon manufacturer prices, 2017 (ref. 6)

- Germany: 27.4%
- France: 15.0%
- UK: 11.0%
- Italy: 10.2%
- Spain: 6.0%
- Netherlands: 4.1%
- Switzerland: 3.9%
- Belgium: 2.7%
- Sweden: 2.5%
- Austria: 2.4%
- Others: 14.7%

European IVD market by country, 2017 (ref. 7)

- Germany: 20.3%
- Italy: 15.0%
- France: 13.4%
- Spain: 9.2%
- UK: 8.7%
- Switzerland: 4.3%
- Poland: 3.5%
- Belgium: 3.4%
- Netherlands: 2.5%
- Austria: 2.4%
- Others: 17.4%

Source: MedTech Europe – The European Medical Technology industry in figures 2019
Medtech: Industry definition and market overview

World medical device market by region based upon manufacturer prices, 2017 (ref. 6)

- USA: 43%
- Europe: 27%
- Japan: 7%
- China: 6%
- Canada: 2%
- Brazil: 1%
- Russia: 1%
- Others: 13%

Source: MedTech Europe – The European Medical Technology industry in figures 2019
Medical technology offers solutions for many disease areas. On a worldwide perspective, in–vitro diagnostics are the largest sector, followed by cardiology and diagnostic imaging.
**Medtech: Industry definition and market overview**

The European medical device market has been growing on average by 4.3% per annum over the past 10 years. Demand fell in 2009 due to the economic crisis, resulting in a growth rate of only 1%. The market recovered in 2010, but growth rates fell back in 2011. In general, there is ever since a 2-5% growth per annum.

The European IVD market growth has been slowing down until 2013, while annual growth rates in the pre-crisis period were at around 2.4%. In 2013 the European market started to recover and the annual growth rate in 2017 was around 1%.

Source: MedTech Europe – The European Medical Technology industry in figures 2019
Medtech: Industry definition and market overview

Top European medical devices export destinations, 2017 (ref. 6)

Top suppliers to European medical devices market (imports), 2017 (ref. 6)

Source: MedTech Europe – The European Medical Technology industry in figures 2019
Medtech: Trends & Developments
Medtech: Supply Chain Characteristics
Life Sciences & Health: Trends & Developments

**CMO Areas of Expansion Within the Next 3 years:**

**PHARMA/BIOPHARMA**

- **API Production**: 79%
- **Packaging**: 71%
- **Formulation**: 67%
- **Development**: 67%

**MEDICAL DEVICE**

- **Diabetes**: 86%
- **Diagnostics**: 71%
- **• Cardiology**
  - **• Orthopedics**
  - **• Radiology**
- **43%**
  - **• Imaging**
  - **• Surgery**
  - **• Nephrology**
- **29%**
  - **• Pediatrics**
  - **• Respiratory**
  - **• Dental**
  - **• Vision**
- **14%**
  - **Neurotechnology**

Figure 2

Figure 3
Life Sciences & Health: Trends & Developments

The medical device industry will continue to grow CMO capacity to build smart devices.

Brand Owner Usage of CMOs:

<table>
<thead>
<tr>
<th>Category</th>
<th>Currently Leveraging</th>
<th>Planning to Leverage in the next 3 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital Care/ Patient Monitoring</td>
<td>80%</td>
<td>20%</td>
</tr>
<tr>
<td>Diagnostics</td>
<td>80%</td>
<td>20%</td>
</tr>
<tr>
<td>Respiratory</td>
<td>64%</td>
<td>36%</td>
</tr>
<tr>
<td>Orthopedics</td>
<td>64%</td>
<td>36%</td>
</tr>
<tr>
<td>Cardiology</td>
<td>60%</td>
<td>40%</td>
</tr>
<tr>
<td>Surgery</td>
<td>80%</td>
<td>20%</td>
</tr>
<tr>
<td>Pediatrics</td>
<td>56%</td>
<td>24%</td>
</tr>
<tr>
<td>Imaging</td>
<td>86%</td>
<td>14%</td>
</tr>
<tr>
<td>Vision</td>
<td>52%</td>
<td>48%</td>
</tr>
<tr>
<td>Dental</td>
<td>52%</td>
<td>48%</td>
</tr>
<tr>
<td>Radiology</td>
<td>48%</td>
<td>52%</td>
</tr>
<tr>
<td>Neurotechnology</td>
<td>40%</td>
<td>60%</td>
</tr>
<tr>
<td>Diabetes</td>
<td>40%</td>
<td>60%</td>
</tr>
<tr>
<td>Nephrology</td>
<td>28%</td>
<td>72%</td>
</tr>
</tbody>
</table>

CMO areas of expansion within the next 3 years:

- 86% Diabetes
- 71% Diagnostics
- 57% Cardiology, Orthopedics, Radiology
- 43% Imaging, Surgery, Nephrology
- 29% Pediatrics, Respiratory, Dental, Vision
- 14% Neurotechnology
Figure 10. Connected medical devices helping medtech companies move from innovative product suppliers to insightful partners in healthcare.

Medtech is transforming from an innovative product supplier...

- 31% are implementing new funding models for data as a service to a large extent
- 39% are adopting a value-based approach to pricing to a large extent
- 43% are using real-world evidence to drive business decisions to a large extent

...to an insightful partner for patients and healthcare, rewarded for improving healthcare performance.

Source: Medtech and the Internet of Medical Things, Deloitte Centre for Health Solutions, 2018
Medtech: Supply Chain Characteristics
The Netherlands is the second largest ex- and importer of medical devices in Europe.

Although the Netherlands does not have the largest health market nor production market, these figures indicate that many shippers use the Netherlands as gateway to and from Europe.

The wide range of services as well as the high number of well-classified LSP’s in combination with the attractive fiscal climate and logistics infrastructure through the Dutch mainports makes the Netherlands a strong entry or exit point to and from Europe.

Source: MedTech Europe – The European Medical Technology industry in figures 2019
Medtech: Industry definition and market overview

- The Netherlands has a positive trade balance of more than 2.8 million euros
Most common European supply chain solutions

1. **Direct delivery** – Often for unique custom made products

2. **Combination centers** – Hospitals and patients serviced from same facility

3. **Dedicated centers** – Hospitals and patients serviced from separate locations

4. **Store distributed** – Patients are serviced from hospitals

5. **Hybrid model** – Combination of the above strategies based on geography, SKU segment (type or velocity)

Source: Buck Consultants International, 2012
Combination center model

Characteristics

- Hospitals and patients are serviced from same facility
- This can be a single facility or multiple facilities (as shown on the map)
- Service areas (store and direct to consumer can overlap)

Source: Buck Consultants International / DHL 2012
Supply chain trends & developments

Decentralization of warehouse set-up. Get closer to customers.

Cost pressure

In Hospital solutions: Local consigned stock at the hospital. Ability to react quickly.

Regulatory pressure increases by new MDR (2017) regulations

Late stage customization increases

Stock management 24/7 service agreements

More info on MDR: https://www.lr.org/en/mdd/mdr/
Medtech: Supply Chain Characteristics

Segmentation

Supply chain characteristics

<table>
<thead>
<tr>
<th>Elements</th>
<th>High value pharma / biotech</th>
<th>Large Pharma</th>
<th>Medtech</th>
<th>Medical Disposables</th>
</tr>
</thead>
<tbody>
<tr>
<td>Value density</td>
<td>++ / +++</td>
<td>- / +</td>
<td>++ / +++</td>
<td>-</td>
</tr>
<tr>
<td>Volume</td>
<td>-</td>
<td>++</td>
<td>-</td>
<td>++ / +++</td>
</tr>
<tr>
<td>Order to delivery leadtime (EU)</td>
<td>Next-day</td>
<td>Next-day – 72 hours</td>
<td>Next-day (pre-x)</td>
<td>Next-day – 72 hours</td>
</tr>
<tr>
<td>Temp control importance</td>
<td>+++</td>
<td>++</td>
<td>+</td>
<td>0 / +</td>
</tr>
<tr>
<td>Distribution profile</td>
<td>Parcel</td>
<td>Pallet</td>
<td>Parcel</td>
<td>Pallet</td>
</tr>
<tr>
<td>Level of country-specific SKUs</td>
<td>+++</td>
<td>++</td>
<td>+++</td>
<td>+ / ++</td>
</tr>
<tr>
<td>Main commercial channel</td>
<td>Mix Direct/Indirect</td>
<td>Indirect</td>
<td>Direct</td>
<td>Mix Direct/Indirect</td>
</tr>
</tbody>
</table>

Source: Buck Consultants International
Medtech: supply chain

- Centralization of Supply Chain Control
  - Common Practice for many years

- Network Consolidation
  - Common Practice for many years

- Visibility
  - Control Tower / Transport Management concepts
  - Linking inbound, intercompany and secondary distribution
  - Information is Key

- Outsourcing & Partner Portfolio Reduction
  - Main DCs still often insourced (at least at the big players)
  - Development towards outsourcing observed

- Customer Service / Order to Cash process harmonization
  - CS/O2C mainly in-house
  - Increasing interest in outsourcing and centralization of back- offices

- Supply Chain Differentiation
  - From one size fits all to differentiated supply chains per product/market combination
  - SC becoming a stronger counterpart for the commercial team; challenging service requirements

- Supply Chain Collaboration
  - Logistics not a key differentiator, therefore the industry is recognizing the opportunities of collaboration
  - How to break through from pilots to full realization?

Source: Buck Consultants International
Medtech: Setting up your operations in the Netherlands
Logistics, fulfilment, distribution, value added, financial and customer services include:

- 4PL
- analyses and testing
- assembly/configuration
- build surgical kits
- build, pack to order
- carrier management
- clean room storage
- cleaning & refurbishment
- client inquiries including order taking
- consignment stock
- customs clearance
- dust free shelf storage
- expiry dates control
- fiscal representation
- import/export handling
- Intrastat reporting
- inventory management
- KPI & business indicator reporting
- labeling & relabeling
- medical device testing
- online inventory & status visibility
- online order visibility
- order-to-cash packaging & repackaging of medical devices
- pick, pack, ship processes based on lot, serial, batch number or expiry date
- quality control recall management
- receiving
- recovery planning
- repair services
- returns management (quality check)
- reverse logistics
- sourcing & consolidation
- storage of ambient, cool & frozen
- surgical kits usage reporting
- tracking & tracing
ISO 13485 certified logistic service providers in HIDC network
ISO 13485:2003 specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer requirements and regulatory requirements applicable to medical devices and related services. The primary objective of ISO 13485:2003 is to facilitate harmonized medical device regulatory requirements for quality management systems. As a result, it includes some particular requirements for medical devices and excludes some of the requirements of ISO 9001 that are not appropriate as regulatory requirements. Because of these exclusions, organizations whose quality management systems conform to this International Standard cannot claim conformity to ISO 9001 unless their quality management systems conform to all the requirements of ISO 9001.

All requirements of ISO 13485:2003 are specific to organizations providing medical devices, regardless of the type or size of the organization. If regulatory requirements permit exclusions of design and development controls, this can be used as a justification for their exclusion from the quality management system. These regulations can provide alternative arrangements that are to be addressed in the quality management system. It is the responsibility of the organization to ensure that claims of conformity with ISO 13485:2003 reflect exclusion of design and development controls.

If any requirement(s) in Clause 7 of ISO 13485:2003 is(are) not applicable due to the nature of the medical device(s) for which the quality management system is applied, the organization does not need to include such a requirement(s) in its quality management system.

The processes required by ISO 13485:2003, which are applicable to the medical device(s), but which are not performed by the organization, are the responsibility of the organization and are accounted for in the organization's quality management system.
Medtech – Setting up your operations in NL – Indirect Taxes

Import duties
- EU import duties on medtech are frequently 0%
- Actual percentages depend on tariff code and origin

VAT
- Import VAT on medtech in The Netherlands can be 6% or 21% depending on the classification of the product
- Other EU countries can have different import VAT percentages than The Netherlands
- It is possible to have a neutral cash flow in relation to import VAT administration in The Netherlands
- VAT on intra-community (EU) transactions differs per type of transaction (business-to-business, business-to-hospital, business-to-patient/consumer) and Inco-term

HIDC highly recommends to make use of specialized advisors in order to structure a tax effective supply chain.
European supply chain solution

Although the industry as such is not homogeneous, there appear to be some very distinct ‘value drivers’ or critical supply chain attributes for the industry as a whole

The European supply chain solution should be:

A. Very proximate to market
B. Highly cost effective
C. Flexible, agile and responsive
D. Fully visible and transparent
E. Fully compliant
F. Able to perform a wide range of VAS
Lead-times to either hospitals or patients become ever more important. With direct to patient deliveries as well as in hospital logistics solutions lead-times continue to become shorter. To make this happen close proximity to market is key. A decentralization of our company’s warehousing set-up might be a good solution.

A. Very proximate to market

Shipping from a local or regional DC
There is a constant cost pressure on the Medtech supply chain. In order to be as cost effective as possible a broad range of choices between LSP’s will make sure that there is a competitive offer available. We will be able to benefit from the economies of scale achieved by the LSP.

The possibility to outsource an extensive range of activities will make sure I choose the most cost effective solution each time.
C. Flexible, agile and responsive

To tap into a **mature and sophisticated logistics** industry with LSP’s specialized in medtech supply chains is a real added value. The LSP is up to date with the latest developments and will drive innovation in our company’s supply chain.

To be right in the middle of EU's main markets for an **European hub** in combination with state of the art infrastructure like the main ports and connections to integrator hubs will **really benefit my customers**. Also **direct to hospital deliveries** are of great added value.
European supply chain solution

D. Fully visible and transparent

LSP’s offer **end-to-end supply chain visibility**, mainports, customs etc. are connected. This will always allow me to make well informed decisions. The possibility to have advanced KPI dashboards monitoring our company’s performance as well as allowing us to react quickly to a changing business environment will **set us apart from competition**.
It becomes ever more important that we are compliant in a **high regulatory environment**. To make use of the knowledge and services of LSP’s specialized in this area gives me confidence for growing our company’s markets in a correct way. We also benefit from the up to date **knowledge, skills and advise** from the LSP in this ever more important area of our business.

The majority of logistic service providers specialized in medtech are **ISO13485 certified**.
To have the flexibility to react to market and customers’ demands quickly is of extreme added value to have partners that can do more than just the standard warehousing and distribution activities. The LSP is able to perform a wide range of services. The LSP should really be an extension of our own operation allowing us to grow and adapt quickly to changing markets.
### Your challenge | Competences in The Netherlands
--- | ---
We want to focus on core processes | • Mature and sophisticated logistics industry with logistic service providers specialized in medtech supply chains

We want to reduce cost and increase profitability | • Logistic service providers offer economy of scale, best practices and in-depth knowledge of medtech supply chains
• Logistic service providers work on activity based costing principle providing you with a variable and flexible cost structure

We want to develop a flexible, responsive and agile supply chain | • Mature and sophisticated logistics industry with logistic service providers specialized in medtech supply chains
• Strategic location, right in the middle of EU’s main markets, European hub function
• State of the art infrastructure: mainports and multimodal hinterland connections, connections to integrator hubs

We need full supply chain visibility | • Logistic service providers offer end-to-end supply chain visibility, mainports, customs etc. are connected

We have an increased need for value added services | • Logistic service offer a wide range of value added services related to the medtech supply chain
• Fiscal system and customs facilitate tax effective value added services
## Your challenge | Competences in The Netherlands
--- | ---
We want to improve order-to-cash | • Order-to-cash is part of the services provided by logistic service providers specialized in medtech
We face challenges with direct deliveries to hospitals | • Logistic service providers offer tailored medtech/hospital delivery solutions
We want to optimize information management | • The logistic sector is highly automated and connected
We want to optimize supply chain related cash flow | • Favorable indirect tax administration
We want to have a supply chain that is compliant with EU regulation | • Logistic service providers offer compliant European supply chain solutions
| • Logistic service providers offer compliance as a service
We need an ISO13485 certified logistic service provider | • The majority of logistic service providers specialized in medtech are ISO13485 certified
We need to get a better understanding of indirect taxes in the EU | • Logistic service providers offer tax effective European supply chain solution with focus on indirect taxes
| • Many service providers offer indirect tax related advice and services (consultancy, fiscal representation, etc.)
We need to get a better understanding of what processes we can outsource | • Logistic service providers in offer a wide range of services
### Medtech: Setting up your operations in NL - Competences

<table>
<thead>
<tr>
<th>Your challenge</th>
<th>Competences in The Netherlands</th>
</tr>
</thead>
<tbody>
<tr>
<td>We need to understand the optimal supply chain model for our company to cater</td>
<td>• Logistic service providers offer a broad range of optimized solutions to cater to the European</td>
</tr>
<tr>
<td>to the European market</td>
<td>market</td>
</tr>
<tr>
<td>We need to understand how we can use our supply chain as a differentiator</td>
<td>• There are many case studies of European supply chain operations in The Netherlands that are</td>
</tr>
<tr>
<td></td>
<td>used as a differentiator available</td>
</tr>
<tr>
<td>How do we find the right partners</td>
<td>• HIDC provides advice on European supply chain structuring and offers matchmaking services</td>
</tr>
</tbody>
</table>
Pharma: Industry definition and market overview
• Definition of the pharmaceutical industry:

The **pharmaceutical industry** discovers, develops, produces, and markets **drugs** or pharmaceutical drugs for use as **medications** to be administered (or self-administered) to **patients**, with the aim to **cure** them, **vaccinate** them, or alleviate the **symptoms**.\(^1\)\(^2\) Pharmaceutical companies may deal in **generic** or **brand** medications and medical devices. They are subject to a **variety of laws** and regulations that govern the **patenting**, testing, safety, efficacy and **marketing of drugs**.
Pharma: Industry definition and market overview

The global drug sales continue to grow at a 6.4% CAGR from 2018-2024.

Orphan drugs are the fastest growing sector.

- The global drug sales continue to grow at a 6.4% CAGR from 2018-2024.
- Orphan drugs are the fastest growing sector.
The global pharmaceutical market could be worth nearly $1.6 trillion by 2020.
## Pharma: Industry definition and market overview

### Figure 3. Top 15 prescription drug & OTC therapy categories by worldwide sales, 2016-2022

<table>
<thead>
<tr>
<th>Therapy Areas</th>
<th>WW Sales 2017 (US$B)</th>
<th>Projected WW Sales 2024 (US$B)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Oncology</td>
<td>104.0</td>
<td>233.0</td>
</tr>
<tr>
<td>2. Anti-diabetics</td>
<td>46.0</td>
<td>59.5</td>
</tr>
<tr>
<td>3. Anti-rheumatics</td>
<td>55.7</td>
<td>56.7</td>
</tr>
<tr>
<td>4. Vaccines</td>
<td>22.7</td>
<td>44.6</td>
</tr>
<tr>
<td>5. Anti-virals</td>
<td>42.4</td>
<td>39.9</td>
</tr>
<tr>
<td>6. Immunosuppressants</td>
<td>3.7</td>
<td>38.1</td>
</tr>
<tr>
<td>7. Bronchodilators</td>
<td>27.2</td>
<td>32.3</td>
</tr>
<tr>
<td>8. Dermatologicals</td>
<td>12.9</td>
<td>30.3</td>
</tr>
<tr>
<td>9. Sensory organs</td>
<td>21.6</td>
<td>26.9</td>
</tr>
<tr>
<td>10. Anti-hypertensives</td>
<td>23.0</td>
<td>24.4</td>
</tr>
<tr>
<td>11. Anti-coagulants</td>
<td>16.8</td>
<td>22.9</td>
</tr>
<tr>
<td>12. MS Therapies</td>
<td>22.7</td>
<td>21.5</td>
</tr>
<tr>
<td>13. Anti-anticoagulants</td>
<td>12.7</td>
<td>20.4</td>
</tr>
<tr>
<td>14. Anti-hyperlipidemics</td>
<td>11.3</td>
<td>16.4</td>
</tr>
<tr>
<td>15. Anti-anemics</td>
<td>7.6</td>
<td>15.7</td>
</tr>
<tr>
<td><strong>Top 15</strong></td>
<td><strong>445.0</strong></td>
<td><strong>683.0</strong></td>
</tr>
<tr>
<td>Other</td>
<td>379.0</td>
<td>567.0</td>
</tr>
<tr>
<td><strong>Total WW Prescription &amp; OTC</strong></td>
<td><strong>825.0</strong></td>
<td><strong>1247.0</strong></td>
</tr>
</tbody>
</table>

Source: EvaluatePharma, 2018
Pharma: Industry definition and market overview

Europe is the second largest global market

Note:
New medicines cover all new active ingredients marketed for the first time on the world market during the period 2012-2017. Europe (Top 5) comprises Germany, France, Italy, Spain, and United Kingdom. Pharmeder comprises 21 countries ranked by IQVIA as high-growth pharmaceutical markets. (Argentina, Bangladesh, Brazil, Colombia, Chile, China, Egypt, India, Indonesia, Kazakhstan, Mexico, Nigeria, Pakistan, Philippines, Poland, Russia, Saudi Arabia, South Africa, Turkey and Vietnam.)

Source: IQVIA (MIDAS May 2018)

Source: The pharmaceutical industry in figures – key data 2018 - EFPIA
### PHARMACEUTICAL MARKET VALUE
(at ex-factory prices)

<table>
<thead>
<tr>
<th>Country</th>
<th>€ million</th>
<th>€ million</th>
</tr>
</thead>
<tbody>
<tr>
<td>Austria</td>
<td>3,657</td>
<td>Lithuania</td>
</tr>
<tr>
<td>Belgium</td>
<td>4,771</td>
<td>Malta</td>
</tr>
<tr>
<td>Bulgaria</td>
<td>1,026</td>
<td>Netherlands</td>
</tr>
<tr>
<td>Croatia</td>
<td>710</td>
<td>Norway</td>
</tr>
<tr>
<td>Cyprus</td>
<td>180</td>
<td>Poland</td>
</tr>
<tr>
<td>Czech Republic</td>
<td>1,639</td>
<td>Portugal</td>
</tr>
<tr>
<td>Denmark</td>
<td>2,446</td>
<td>Romania</td>
</tr>
<tr>
<td>Estonia</td>
<td>230</td>
<td>Russia</td>
</tr>
<tr>
<td>Finland</td>
<td>2,333</td>
<td>Serbia</td>
</tr>
<tr>
<td>France</td>
<td>28,362</td>
<td>Slovakia</td>
</tr>
<tr>
<td>Germany</td>
<td>30,815</td>
<td>Slovenia</td>
</tr>
<tr>
<td>Greece</td>
<td>4,880</td>
<td>Spain</td>
</tr>
<tr>
<td>Hungary</td>
<td>2,225</td>
<td>Sweden</td>
</tr>
<tr>
<td>Iceland</td>
<td>147</td>
<td>Switzerland</td>
</tr>
<tr>
<td>Ireland</td>
<td>1,977</td>
<td>Turkey</td>
</tr>
<tr>
<td>Italy</td>
<td>25,958</td>
<td>U.K.</td>
</tr>
<tr>
<td>Latvia</td>
<td>225</td>
<td></td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>199,234</strong></td>
<td></td>
</tr>
</tbody>
</table>

- Overview of the European pharma market in EUR per country
The Netherlands has a relatively high share of imports in relation to the size of the country. This clearly indicates that the Netherlands is used as a European hub for importing pharmaceuticals.
### PHARMACEUTICAL EXPORTS

<table>
<thead>
<tr>
<th>Country</th>
<th>€ million</th>
<th>Country</th>
<th>€ million</th>
</tr>
</thead>
<tbody>
<tr>
<td>Austria</td>
<td>8,405</td>
<td>Lithuania</td>
<td>724</td>
</tr>
<tr>
<td>Belgium</td>
<td>40,723</td>
<td>Luxembourg</td>
<td>324</td>
</tr>
<tr>
<td>Bulgaria</td>
<td>804</td>
<td>Malta</td>
<td>647</td>
</tr>
<tr>
<td>Croatia</td>
<td>891</td>
<td>Netherlands</td>
<td>28,495</td>
</tr>
<tr>
<td>Cyprus</td>
<td>281</td>
<td>Norway</td>
<td>705</td>
</tr>
<tr>
<td>Czech Republic</td>
<td>2,226</td>
<td>Poland</td>
<td>2,701</td>
</tr>
<tr>
<td>Denmark</td>
<td>12,301</td>
<td>Portugal</td>
<td>1,131</td>
</tr>
<tr>
<td>Estonia</td>
<td>76</td>
<td>Romania</td>
<td>706</td>
</tr>
<tr>
<td>Finland</td>
<td>840</td>
<td>Russia</td>
<td>338</td>
</tr>
<tr>
<td>France</td>
<td>28,271</td>
<td>Slovakia</td>
<td>516</td>
</tr>
<tr>
<td>Germany</td>
<td>69,513</td>
<td>Slovenia</td>
<td>2,503</td>
</tr>
<tr>
<td>Greece</td>
<td>1,059</td>
<td>Spain</td>
<td>10,497</td>
</tr>
<tr>
<td>Hungary</td>
<td>4,452</td>
<td>Sweden</td>
<td>7,308</td>
</tr>
<tr>
<td>Ireland</td>
<td>30,189</td>
<td>Switzerland</td>
<td>64,508</td>
</tr>
<tr>
<td>Italy</td>
<td>20,524</td>
<td>Turkey</td>
<td>788</td>
</tr>
<tr>
<td>Latvia</td>
<td>409</td>
<td>United Kingdom</td>
<td>30,318</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>373,333</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Note:**
All data based on SITC 34
Norway: veterinary products excluded, 2014 data
Source: Eurostat (COMEXT database – February 2018)
Norway: Statistics Norway; Switzerland: Swiss Federal Customs Administration

- The Netherlands has a relatively high share of exports in relation to the size of the country. This clearly indicates that the Netherlands is used as a European hub for exporting pharmaceuticals.
Pharma: Industry definition and market overview

THE EUROPEAN UNION'S TOP 5 PHARMACEUTICAL TRADING PARTNERS - 2017

<table>
<thead>
<tr>
<th></th>
<th>USA</th>
<th>Others</th>
<th>Switzerland</th>
<th>Israel</th>
<th>Russia</th>
<th>Singapore</th>
<th>Japan</th>
<th>China</th>
</tr>
</thead>
<tbody>
<tr>
<td>EU imports</td>
<td>40.0%</td>
<td>11.9%</td>
<td>34.3%</td>
<td>5.2%</td>
<td>-</td>
<td>4.5%</td>
<td>-</td>
<td>4.1%</td>
</tr>
<tr>
<td>EU exports</td>
<td>31.1%</td>
<td>39.6%</td>
<td>13.4%</td>
<td>-</td>
<td>4.6%</td>
<td>-</td>
<td>5.2%</td>
<td>6.1%</td>
</tr>
</tbody>
</table>

Source: Eurostat, COMEXT database, June 2018
Pharma: Trends & Developments
Pharma: supply chain characteristics

Figure 2: Numerous forces are dictating the need for a different sort of supply chain

<table>
<thead>
<tr>
<th>1 New product types</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>• More complex manufacturing and distribution processes</td>
<td></td>
</tr>
<tr>
<td>• Different supply chains for different product types</td>
<td></td>
</tr>
<tr>
<td>• Shorter product lifecycles</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2 Live licensing</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Incremental launch of new medicines</td>
<td></td>
</tr>
<tr>
<td>• Ability to scale up and down very rapidly</td>
<td></td>
</tr>
<tr>
<td>• Step changes in the revenue curve</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>3 Increasing emphasis on outcomes</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Expansion into health management service</td>
<td></td>
</tr>
<tr>
<td>• Lesser and more adaptable cost structure that preserves gross margins at every stage of the product lifecycle</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>4 New modes of healthcare delivery</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Blurring of the boundaries between primary and acute care</td>
<td></td>
</tr>
<tr>
<td>• Much wider distribution network</td>
<td></td>
</tr>
<tr>
<td>• Demand-driven manufacturing and distribution processes</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>5 Growing importance of emerging markets</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Offerings designed for patients in emerging markets</td>
<td></td>
</tr>
<tr>
<td>• More widely dispersed and more robust supply chain</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>6 Greater public scrutiny</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Heavier regulation</td>
<td></td>
</tr>
<tr>
<td>• Robust risk assessment and risk-management capabilities across the extended supply chain</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>7 Environmental pressures</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Sustainable eco-friendly processes</td>
<td></td>
</tr>
<tr>
<td>• Relocation of plant to less vulnerable regions</td>
<td></td>
</tr>
</tbody>
</table>

Even more importantly, few, if any, pharma companies have supply chains capable of meeting tomorrow’s needs. Numerous forces - both internal and external - are reshaping the environment in which the industry operates, with profound consequences for the way in which it manufactures and distributes its products (see Figure 2).

The collective impact of these trends

To sum up, the current model for manufacturing and distributing medicines isn’t fit for Pharma’s future needs, as many industry executives recognise. The high margins that made it feasible to tie up capital in large stocks of raw materials and finished goods are ending. Most companies also have asset bases that are ill-suited to produce the sort of therapies that are now in the pipeline or to cope with new environmental regulations, so they’ll have to sell or re-engineer much of their existing plant.

The change in the industry’s remit has even more fundamental implications. Pharma companies will have to manage a vast network of service providers, as well as manufacturing and distributing their own products. They will also have to acquire a much deeper understanding of patients. In a world where outcomes count for everything, it’s not molecules that create value but, rather, the ability to integrate data, products and services in a coherent business offering. Understanding this shift of emphasis from products to patient outcomes is critical; those firms that can develop and supply integrated product-service packages will be able to deliver significant benefits to every stakeholder in the healthcare value chain.
Pharma: Trends & Developments

- **Societal Expectations**
  - Europeans live with a two-class medicine
  - Detailed patient data is available
  - Trust is insufficient to avoid detailed governmental regulations
  - A slight majority is sceptical about lifestyle drugs
- **Governmental Policies**
  - Pricing and reimbursement decisions reward the added value of new medicines
  - The industry is the main source of product information for healthcare professionals
  - Development costs and time reach unprecedented highs
- **Healthcare Powerplay**
  - New retail channels have made their mark
  - Greater buyer concentration drives down industry profitability
  - Generics and biosimilars are first-line treatments
  - Payers are in control
- **Industry Moves and**
  - The industry is dominated by a few giants
  - Large pharmaceutical companies are unattractive for private equity
  - Integrated care models prevail
- **Innovation Potential**
  - Biotechnology investments have paid off
  - R&D success is more predictable
  - Preventive medicine is highly profitable
  - Personalized medicine is highly profitable and well accepted

Source: Fit for future? The pharmaceutical industry in Europe: trends and strategic options – Management Engineers - INSEAD
Pharma: Trends & Developments

Figure 2. Rapid growth of cell therapies being investigated

Approximately an 80% increase within the last 12 months

USA and China are the leaders in the development of cell therapies

CAR-T therapies represent the largest share of the global cellular therapy market

China has the largest number of CAR-T therapies under investigation (280+) followed by the USA (170+)

Note: The percentages indicate the proportion of studies for certain intervention/therapy and the number inside the donut hole indicates the grand total of studies conducted.

Date as of September 24, 2018
Externalized manufacturing will keep expanding

**NEXT 3 YEARS:**
- 91% of manufacturers plan to expand use of CMOs
- 78% of CMOs plans to increase capacity

One in five brand owners now work with over 100 external partners

Companies are lacking visibility, control, and standardization

**BIOPHARMA’S COMPRESSIVE DISRUPTION**

- Pipeline replacement ratios are declining.
- 50% decline expected from 2012 thru 2022.
- More specialized treatments coming to market that treat smaller patient populations generating lower revenues.

The life sciences industry is transitioning as it shifts toward complex biopharmaceuticals and highly personalized medical therapies and devices.

**AS A RESULT,**
this shift is driving more complexity in supply chain operations.
CMO Areas of Expansion Within the Next 3 years:

**PHARMA/BIOPHARMA**

- API Production: 79%
- Packaging: 71%
- Formulation: 67%
- Development: 67%

**MEDICAL DEVICE**

- Diabetes: 86%
- Diagnostics: 71%
- Cardiology, Orthopedics, Radiology: 57%

- Imaging, Surgery, Nephrology: 43%
- Pediatrics, Respiratory, Dental, Vision: 29%
- Neurotechnology: 14%

Figure 2

Figure 3

Life Sciences & Health: Trends & Developments
Biopharma companies plan to take advantage of CMO capacity expansion across multiple new science therapeutic areas.

CMO areas of expansion within the next 3 years:
- 79% API Production
- 71% Packaging
- 67% Formulation
- 67% Development

Brand Owner Usage of CMOs:
- Lungs/Respiratory: 77%, 13%
- Cardiology: 70%, 30%
- Oncology: 70%, 30%
- Migraine: 67%, 33%
- Brain: 63%, 37%
- Neurodegenerative conditions: 60%, 40%
- Immunotherapy: 60%, 40%
- Rheumatology: 50%, 50%
- Genetics: 50%, 50%
- Dermatology: 47%, 53%
Pharma: Trends & Developments
Pharma: Supply Chain Characteristics
Pharma: supply chain characteristics

Figure 1: The supply chain is the backbone of a pharma company

Source: PwC
## Pharma: Trends & Developments

<table>
<thead>
<tr>
<th>Key Challenges</th>
<th>Step change</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Cost Pressures on the industry</td>
<td>From margin driven to cost driven</td>
</tr>
<tr>
<td>2 Changing Commercial Business Model</td>
<td>From indirect to direct marketing and sales</td>
</tr>
<tr>
<td>3 More Responsive Supply Chains</td>
<td>From “push” to “pull” driven</td>
</tr>
<tr>
<td>4 Information and Visibility</td>
<td>From black box to information highway</td>
</tr>
<tr>
<td>5 Final Mile Delivery Component</td>
<td>From one fits all to product/ market/ customer choice</td>
</tr>
<tr>
<td>6 Collaboration and Partnership</td>
<td>From single to collaborative supply chains</td>
</tr>
<tr>
<td>7 Leadership and Change Management</td>
<td>From fragmented to single chain of command</td>
</tr>
<tr>
<td>8 The role of e-commerce</td>
<td>From manual and indirect order2cash to online, automated and direct</td>
</tr>
</tbody>
</table>

Source: Buck Consultants International
Pharma: Trends & Developments

- Large impact to supply chains and a lot of opportunities for LSP’s with a dense network

**Healthcare Future**
- Transition of care in hospitals to homecare
- Only complex, specialist and major operations in hospital
- After operations transition to homecare ASAP

**Homecare Future**
- Expansion of medical homecare product- and service portfolio
- Increase of volumes and movements towards home patients
- Segmentation of homecare distribution
- Overnight to same day delivery

Source: Jan de Rijk Logistics 2017
Pharma: Trends & Developments

- More direct distribution models will change the scope of work for parties in the chain

- Direct to patient makes certain parties in the chain obsolete for a specific process
Supply chain trends & developments

- Centralization of warehouse set-up. Regional hubs.
- Cost pressure
- Direct to patient models increase. Get medication at home
- Regulatory pressure. New rules for serialization
- Temperature control is key for the new (B2C) models
- Biotech companies continue to grow, often outsource entire supply chain
Pharma: supply chain characteristics

Segmentation

Supply chain characteristics

<table>
<thead>
<tr>
<th>Elements</th>
<th>High value pharma / biotech</th>
<th>Large Pharma</th>
<th>Medtech</th>
<th>Medical Disposables</th>
</tr>
</thead>
<tbody>
<tr>
<td>Value density</td>
<td>++ / +++</td>
<td>- / +</td>
<td>++ / +++</td>
<td>-</td>
</tr>
<tr>
<td>Volume</td>
<td>-</td>
<td>++</td>
<td>-</td>
<td>++ / +++</td>
</tr>
<tr>
<td>Order to delivery leadtime (EU)</td>
<td>Next-day</td>
<td>Next-day – 72 hours</td>
<td>Next-day (pre-x)</td>
<td>Next-day – 72 hours</td>
</tr>
<tr>
<td>Temp control importance</td>
<td>+++</td>
<td>++</td>
<td>+</td>
<td>0 / +</td>
</tr>
<tr>
<td>Distribution profile</td>
<td>Parcel</td>
<td>Pallet</td>
<td>Parcel</td>
<td>Pallet</td>
</tr>
<tr>
<td>Level of country-specific SKUs</td>
<td>+++</td>
<td>++</td>
<td>+++</td>
<td>+ / +</td>
</tr>
<tr>
<td>Main commercial channel</td>
<td>Mix Direct/Indirect</td>
<td>Indirect</td>
<td>Direct</td>
<td>Mix Direct/Indirect</td>
</tr>
</tbody>
</table>

Source: Buck Consultants International
Pharma: supply chain characteristics

- **Centralization of Supply Chain Control**
  - Strengthening of SC Organizations
  - Investments in SC Talent
  - Corporate SC taking ownership of the downstream supply chain

- **Network Consolidation**
  - Consolidation of Distribution Networks
  - Mix of full centralization, regionalization and hub-spoke models
  - Scope: downstream, still lack of full chain scope

- **Visibility**
  - Control Tower / Transport Management concepts
  - Linking inbound, intercompany and secondary distribution
  - Information is Key

- **Outsourcing & Partner Portfolio Reduction**
  - 3PL landscape in pharma has improved highly
  - Towards LLP/4PL models
  - Strong reduction of number of partners used
  - Towards harmonized (global) contracts

- **Customer Service / Order to Cash process harmonization**
  - CS and O2C activities closely linked to physical supply chains
  - Harmonization & centralization of CS and O2C organizations

- **Supply Chain Differentiation**
  - From one size fits all to differentiated supply chains per product/market combination
  - SC becoming a stronger counterpart for the commercial team, challenging service requirements

- **Supply Chain Collaboration**
  - Logistics not a key differentiator, therefore the industry is recognizing the opportunities of collaboration
  - How to break through from pilots to full realization?

Source: Buck Consultants International
Pharma: supply chain characteristics - Serialisation

https://emvo-medicines.eu/
Pharma: supply chain characteristics - Serialisation

Responsibilities of the Supply Chain Partners

- Serialization by MAH
- Risk based verification by Wholesalers
- Verification and check-out at point of dispense

SAFETY FEATURES:
- Code (unique identifier) + Tamper evidence

System set up and governance by MAH together with other stakeholders
- Oversight by competent authorities

NMVS

Product #: 09876543210982
S/N: 12345AZRQF1234567890
Batch: A1C2E3G4I5
Expiry: 135032
Pharma: supply chain characteristics

Besides continuous growth, 3 main priorities characterize the fast-changing pharmaceutical industry landscape:

- **Quality**
  - Increased regulations (GMP & GDP)
  - Efficient and reliable lead times
  - Stricter temperature requirements

- **Innovation**
  - New products and new markets (patent expiration)
  - New and cost-conscious packing
  - Need for real-time monitoring through usage of GPRS

- **Cost savings**
  - Growing competition (mergers & acquisitions)
  - Continuing pricing pressure
  - Rising R&D costs

Source: KLM Cargo 2017
Pharma: supply chain characteristics

Centralized
- Fully centralized
- High value / low volume products
- Often parcel type of distribution

Central + Sats
- Main inventory in central warehouse
- Local sats replenished by EDC
- Sometimes combined with postponement
- Strategic stocks in country DCs
- Medium - High value products

Regionalized
- Regional DCs (4-6) supplying a fixed region
- Logical clusters of countries
- “Big Pharma” portfolios

Hub spoke per region
- Regional DCs (4-6) supplying a fixed region
- Logical clusters of countries
- Differentiated portfolios

Source: Buck Consultants International
We audit and validate all network stations (Origin, Transit, Destination) before they can be added as pharma network station to our Pharmaceutical Logistics network.
Pharma: supply chain characteristics - services

Logistics, fulfilment, distribution, value added, financial and customer services include:

- 4PL
- assembling of kits
- country specific labeling and packaging
- customer service
- delivery to sales reps or GP
- designing of label layouts
- direct-to-patient distribution
- direct-to-pharmacy distribution
- financial services/order-to-cash
- import/export handling
- inventory management
- kitting of displays
- labeling
- legal & regulatory restrictions: manufacturer licence
- order processing
- postponement
- printing
- product release
- quality control
- quantity monitoring
- recall management
- relabeling and repackaging
- reporting
- returns management
- secured storage
- separated from goods for sale
- storage (ambient, controlled, cold)
- temperature controlled transportation
Pharma: supply chain characteristics

Figure 6: By 2020, the pharmaceuticals, medical devices and healthcare services supply chains will be fully integrated

Current Situation

- Pharmaceutical Supply Chain
  - Pharma
  - Intermediate warehouse
  - Hospitals & Pharmacies
  - Patient

- Medical Devices Supply Chain
  - Manufacturers
  - Intermediate warehouse or wholesaler
  - Hospitals & Pharmacies
  - Patient

- Healthcare Services Supply Chain
  - Primary care (Doctor or hospital)
  - Secondary care (Hospital or community care)

Situation in 2020

- Integrated Supply Chain
  - Pharmaceuticals + Medical Devices + Healthcare Services

  - Pharma
  - Intermediate warehouse
  - Hospitals & Pharmacies

  - Manufacturers
  - Intermediate warehouses or wholesalers
  - Hospitals & Pharmacies

  - Primary care (Doctor or Hospital)
  - Secondary care (Hospital or community care)

Areas of full supply chain visibility

Source: PwC
Pharma: supply chain characteristics

Figure 7: The development of care pathways will provide greater supply chain predictability
Pharma: supply chain characteristics

Figure 8: Four options exist for restructuring the pharmaceutical supply chain

<table>
<thead>
<tr>
<th>Operations Strategy</th>
<th>Specialist Therapies</th>
<th>Mass-Market Medicines</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Virtual Manufacturer</td>
<td>Service Innovator</td>
</tr>
<tr>
<td>Create a virtual</td>
<td>Build a service-</td>
<td>Build a reliable,</td>
</tr>
<tr>
<td>network of integrated</td>
<td>oriented supply</td>
<td>‘no-frills’ supply</td>
</tr>
<tr>
<td>supply partners</td>
<td>chain to enhance</td>
<td>chain to deliver</td>
</tr>
<tr>
<td></td>
<td>brands and differentiate</td>
<td>products as</td>
</tr>
<tr>
<td></td>
<td>company from its</td>
<td>economically as</td>
</tr>
<tr>
<td></td>
<td>competitors</td>
<td>possible</td>
</tr>
</tbody>
</table>

Source: PwC
Pharma: supply chain characteristics

Figure 10: By 2020, the management of information will be as important as the management of products

Source: PwC
Increasing supply chain complexity

**Pharma Trends**
- Direct to pharmacy distribution
- Improved life cycle management
- Profit margins are under pressure
- More stringent requirements enforced by GMP/GDP
- Increase investments in R&D

**Logistics Impact**
- Differentiation to distribution channels
- Increase in product portfolio - # SKU’s - late stage customization
- Globalization & standardization of logistics processes
- Temperature controlled logistics / RFID / Track & Trace
- Control net working capital / inventory value

Source: Groenewout Consultants
Pharma:
Setting up your operations in the Netherlands
Pharma: Setting up your operations in NL – Indirect Taxes

**Import duties**
- EU import duties on pharma are frequently 0%
- Actual percentages depend on tariff code and origin

**VAT**
- Import VAT on pharma in The Netherlands can be 6% or 21% depending on the classification of the product
- Other EU countries can have different import VAT percentages than The Netherlands
- It is possible to have a neutral cash flow in relation to import VAT administration in The Netherlands
- VAT on intra-community (EU) transactions differs per type of transaction (business-to-business, business-to-hospital, business-to-patient/consumer) and Incoterm

HIDC highly recommends to make use of specialized advisors in order to structure a tax effective supply chain.
• VAT Rates applied to medicines vary per country. The Netherlands applies the lowest rate.
The European Medicines Agency's (EMA) main responsibility is the protection and promotion of public and animal health, through the evaluation and supervision of medicines for human and veterinary use.

The Agency is responsible for the scientific evaluation of applications for European Union (EU) marketing authorisations for human and veterinary medicines in the centralised procedure.

The EMA is responsible for coordinating the EU's safety-monitoring or 'pharmacovigilance' system for medicines.

The EMA's committees are involved in referral procedures to resolve issues such as concerns over the safety or benefit-risk balance of a medicine or a class of medicines.

The Agency is responsible for coordinating inspections requested by its committees in connection with the assessment of marketing-authorisation applications or referrals.

The EMA is the hub of a European medicines network comprising:
- over 40 national regulatory authorities;
- the European Commission;
- the European Parliament;
- other decentralised EU agencies.

Due to the Brexit and the necessity to be in the European Union, the EMA has been relocated to Amsterdam, the Netherlands as per March 2019.
The Agency is involved in the scientific evaluation of medicines that fall within the scope of the **centralised authorisation procedure**. However, thousands of other medicines that do not fall within this scope are marketed in the EU in individual EU Member States in accordance with **national authorisation procedures** not involving the EMA, or in several Member States through the decentralised or **mutual recognition procedures**.

The mutual recognition and decentralised procedures are overseen by two coordination groups representing the EU Member States: the Coordination Group for Mutual Recognition and Decentralised Procedures - Human (CMDh) and the Coordination Group for Mutual Recognition and Decentralised Procedures - Veterinary (CMDv).

The Agency can become involved in assessing nationally authorised medicines if they are referred to the EMA through a referral procedure. This may be due to a safety concern or an issue that requires resolution in the interest of protecting public health. Significant emerging safety issues concerning a medicine marketed in the EU can be referred to the Agency under the urgent Union procedure regardless of the medicine's initial authorisation route.
The Dutch **Health Care Inspectorate (IGZ)** promotes public health through effective enforcement of the quality of health services, prevention measures and medical products. It advises the responsible ministers and applies various measures, including advice, encouragement, pressure and coercion, to ensure that health care providers offer only 'responsible' care. The Inspectorate investigates and assesses in a conscientious, expert and impartial manner, independent of party politics and unaffected by the current care system.

Good Manufacturing Practice (GMP) is part and parcel of quality management. It ensures that products are always produced and inspected in accordance with the established quality norms for the intended application, as well as the terms and conditions of the marketing authorization. The principles of GMP have their basis in European legislation, namely Commission Directive 2003/94/EC (‘Laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use’). Proper storage and distribution is also part of quality management and ensures that quality is maintained at the level prescribed by the marketing authorization or product specifications throughout the distribution chain (Commission Directive 94/C 63/03).
Good distribution practice (GDP) deals with the guidelines for the proper distribution of medicinal products for human use. GDP is a quality warranty system, which includes requirements for purchase, receiving, storage and export of drugs intended for human consumption. GDP regulates the division and movement of pharmaceutical products from the premises of the manufacturer of medicinal products, or another central point, to the end user thereof, or to an intermediate point by means of various transport methods, via various storage and/or health establishments.

Good manufacturing practices (GMP) are the practices required in order to conform to guidelines recommended by agencies that control authorization and licensing for manufacture and sale of food, drug products, and active pharmaceutical products. These guidelines provide minimum requirements that a pharmaceutical or a food product manufacturer must meet to assure that the products are of high quality and do not pose any risk to the consumer or public. GMP, along with good laboratory practices and good clinical practices, are overseen by regulatory agencies in the United States, Canada, Europe, China, and other countries.

GxP is a general term for Good (…) Practice quality guidelines and regulations. These guidelines are used in many fields, including the pharmaceutical and food industries. The titles of these good practice guidelines usually begin with "Good" and end in "Practice", with the specific practice descriptor in between. GxP represents the abbreviations of these titles, where x (a common symbol for a variable) represents the specific descriptor.


Pharma: Setting up your operations in NL
Maintaining product safety and quality during distribution is of utmost importance in the pharmaceutical industry. Good Distribution Practices (GDP) certification for pharmaceuticals demonstrates your dedication to GDP and quality in every aspect of your service.

GDP is a quality system for warehouse and distribution centers dedicated for medicines. Internationally accepted pharmaceutical GDP regulations stipulate that distributors of pharmaceutical products must align their operations with the standards. The scheme ensures that consistent quality management systems are in place throughout your entire supply chain, from the early delivery of raw materials to the manufacturing plants, to the final shipment of finished drugs to the end user. An independent assessment of compliance against international GDP requirements is the most effective way to establish that your quality management system aligns with GDP guidance.

Source: SGS
Pharma: Setting up your operations in NL

GDP compliant logistic service providers that provide cold chain services in HIDC network
To enhance air cargo security, the EU requires the "air cargo or mail carrier operating into the Union from a third country airport" to gain an ACC3 designation. As of 1st July 2014, an air carrier's designation only continues to be valid upon successful completion of an EU Aviation Security Validation performed by an Independent Validator accredited by an EU member state. Only validated carriers are authorized to fly cargo or mail into Europe.

IATA has been encouraged by its member airlines and European Regulators to support air carriers in complying with ACC3 EU Security Validation process. To respond to this demand, IATA Training and Development Institute created a pioneer Center of Excellence for Independent Validators (CEIV) to train, advise and support industry stakeholders.

IATA created a CEIV in pharmaceutical logistics with the aim of helping the industry to improve the transport and handling of pharmaceutical products to meet the requirements of shippers and manufacturers.
Pharma: Setting up your operations in NL - CEIV

CEIV Pharma = Highest Global Common Standard

USA
Food, Drug & Cosmetic Act
- CFR chapters on stability, storage temperatures;
- USP1079 ‘Good Storage and Shipping Practices’

EUROPE
Driven by EU Requirements
- EU directive 12/35/EC;
- Guidelines of 5 November 2013 on Good Distribution Practice of medicinal products for human use (EU OPP) (2013/C 341/01)

REST OF THE WORLD
Driven by WMO Guidelines
- ‘Guide to good distribution practices for pharmaceutical products’ (Annex 5);
- ‘Guide to good storage practices for pharmaceuticals’ (Annex 9);
- National Requirements

Share Operational knowledge of Pharma Handling

Temperature Controlled Cargo Handling
Temperature Controlled Container Operations
Risk Management of Temperature Controlled Cargo
Audit and Quality of Temperature Controlled Cargo
Pharma: Setting up your operations in NL - PGA
Pharma: Setting up your operations in NL - PGA

- **Quality**: "IATA CEIV Pharma certified logistics community with best-in-class facilities and capabilities"
- **Innovation**: "Direct link with (academic) centres of innovation focused on pharma supply chain improvements"
- **Transparency**: "Real-time access to temperature data at any time"
- **Efficiency**: "Fast customs clearance and shared processes"
- **Connectivity**: "Direct air connections to 322 destinations, and excellent transport connections by sea, rail and road"
A **cold chain** is a temperature-controlled supply chain. An unbroken cold chain is an uninterrupted series of storage and distribution activities which maintain a given temperature range. It is used to help extend and ensure the shelf life of products such as fresh agricultural produce, seafood, frozen food, photographic film, chemicals and pharmaceuticals. Such products, during transport and when in transient storage, are called cool cargo. Unlike other goods or merchandise, cold chain goods are perishable and always en route towards end use or destination, even when held temporarily in cold stores and hence commonly referred to as cargo during its entire logistics cycle.

There are two major ways to move temperature controlled products or payloads, passive provision or active provision of temperature control.

Active systems are what you typically think of as temperature control; freezers, fridges and cold rooms. When it comes to shipments, these active systems are typically just mounted on trailers, vans or pallets. They provide thermal control which actively responds to the adverse temperatures outside.

Passive systems are less obvious and most people would know them from coolers or chilly bins, combining ice or cool-packs with insulation to provide a fixed amount of thermal protection. Its ability to protect a payload depends upon the design and preparation of the passive system.

The choice between actives and passives involves a large number of factors including:
• Cost
• Level of protection required
• Need for power supply
• Availability for use
• Flexibility of your supply chain
• Extremities of external environment

When powered and handled correctly, active systems can provide a high level of thermal protection, advanced units being capable of both heating and cooling in response to low or high external temperatures. They typically consume fuel, use battery power, or require constant external power to operate. This imposes tight restrictions on handling and shipping. The scale of these systems is typically from single pallet to whole vehicles. For high utilization of space on fixed shipping routes and with good handling agreements, active solutions provide a good level of protection. There are inefficiencies however when only small payloads need to be moved. The high initial costs for the units also pose a barrier to use. To ameliorate the inefficiency, suppliers often lease units to reduce the costs to the single customers while increasing the utilization of the units.

The passive systems in contrast can be scaled from single vials to multi-pallet and once assembled for shipping can be sealed and sent without the need for power supply and typically without temperature aware handling. They can travel through a wide range of carriers and integrators. The thermal performance occurs irrespective of the handling or external environment so re-routing and flexible supply chains can be accommodated. The performance is determined by initial design and preparation, in contrast to active solutions, the duration of the thermal protection is finite. They are comparatively low unit cost and so can be held in stock to allow flexibility of supply. Not requiring special handling and being size versatile, if there are a large number of destinations for payloads, in differing quantities, the passive solutions can provide a very economic solution.

The choice between the active and passive solution, given an acceptable quality level, is best approached on a total cost of ownership model where the flexibility of provision, the security of supply to the market, the replacement and quality costs along with the shipping costs and thermal solution costs are all evaluated.

Source: Intelsius

Pharma: Setting up your operations in NL – Cold Chain
Challenges in the cold chain:

- preserve the adequate storage & handling conditions (temperature) throughout the cold chain
- document the storage conditions (temperature) throughout the cold chain
- maintain the product safety throughout the supply chain (temperature, counterfeiting)
Pharma: Setting up your operations in NL – Cold Chain
Panalpina
- Global logistics company in air and ocean freight
- Approximately 16,000 employees in 500 offices in over 70 countries with global coverage
- 11+ Healthcare Centers of Excellence compliant with Good Distribution Practice (GDP) standards and 43 certified Envirotainer (QEP) stations for cool chain handling
- Net forwarding revenue 6,758 CHF

REQUIREMENTS
- Quality control of cold chain conditions for temperature-sensitive pharma shipments
- Real-time monitoring
- Possibility for real-time supply chain control and interference
- Transparency and visibility
- Modality independent

SOLUTION
- Smartview, developed by Dutch software company Antaris Solutions
- Web platform for cold chain optimization
- Wireless sensors for different shipments and transport modalities

BENEFITS
- End-to-end visibility
- Pro-active temperature monitoring & control
- Real-time shipment management
- Remote facility monitoring
- Real-time vehicle tracking
- Alerting by email and text messages
- Advanced reporting & analytics
- New business development

Pharma: Setting up your operations in NL – Cold Chain
Location: Breda
Activities: European distribution
Industry: pharma
Employees: 2,500 (total in NL)
Country of origin: USA

Abbott Warehousing & Distribution in Breda is the logistical heart of a global pharmaceutical company that is famed for its life-saving and life-extending drugs. The US company certainly lives by its motto, ‘A Promise for Life’, and in Breda Abbott is making that promise come true by demanding the highest quality of both its drugs and its logistical operations.

Abbott, which was founded in 1888 and is headquartered in Chicago, has branches in over 100 nations and more than 80,000 employees around the world.

The company has had a presence in the Netherlands for over half a century and, thanks in part to a number of acquisitions, it has today a workforce of around 2,500 around the country. Since 2006, Breda has served as its logistical center, working closely together with the corporation’s Zwolle branch where finance, planning, customer services and other support services are located. “Abbott Warehousing & Distribution in Breda takes on a pivotal role in distributing our drugs, medical nutrition products and veterinary drugs to over 160 nations,” says Jolanda Cortlever, general manager for both the Zwolle and Breda branches of Abbott. “We move our products through distribution centers and Abbott branches in Brazil, Russia, India, China, South Africa and numerous others. Furthermore, we are also increasingly supplying end-users in Western and Eastern Europe from Breda.”

Transport as another specialty
The Abbott logistical center in Breda is the most high-tech center of its kind and was constructed to resemble a silo where robotic forklifts shift some 30,000 pallets on 30-meter high scaffolding. “We have almost fully automated our logistics process,” explains Cortlever. “This allows us to guarantee that our service is of a consistently high quality.”

Aside from storage and distribution, Abbott’s Breda activities also include value added logistics such as finishing, labeling and postponement. “And our logistical stake in Abbott’s worldwide activities does not stop once the drugs are en route,” the general manager says. We monitor the transport until the products have safely reached their final destination. The activities in our branch are undertaken with the greatest care, a fact that all our staff are well aware of. And we impose the same requirements on transportation, selecting the modality that suits the product, objective and destination the best. The transportation environment must be the absolute best possible, as many drugs are temperature-sensitive – a factor which is always the case when it comes to biological medicines. It is clear that transport has become an additional specialty for Abbott in Breda.”

Abbott’s ambitions find a home in Breda
When it comes to establishing satellites, Breda fits in perfectly with Abbott’s ambition of providing maximum performance for all its customers. “Breda is close to the international Ports of Rotterdam and Antwerp as well as the airports in Amsterdam, Frankfurt and Paris,” says Cortlever. “We also have access to well-trained, multilingual staff who can work very well in English. Moreover, the Netherlands is a country where people with many different cultural backgrounds work well together. Out of the workforce here at Abbott in Breda, I’ve counted over 20 different nationalities. The country is politically stable, while the financial climate and the tax regime and customs facilities are all to our benefit. And finally, we have an excellent level of contact with organizations such as the municipality and BOM Foreign Investments.”

Source: BOM Foreign Investments/NFIA

Pharma: Setting up your operations in NL - Testimonial

NDL/HIDC

Abbott
Pharma: Setting up your operations in NL - PGA
European supply chain solution

Although the industry as such is not homogeneous, there appear to be some very distinct ‘value drivers’ or critical supply chain attributes for the industry as a whole

The European supply chain solution should be:

A. Very proximate to market
B. Highly cost effective
C. Flexible, agile and responsive
D. Fully visible and transparent
E. Fully compliant
F. Able to perform a wide range of VAS
Lead-times to either hospitals or patients become ever more important. With direct to patient deliveries as well as in hospital logistics solutions lead-times continue to become shorter. To make this happen close proximity to market is key. A decentralization of our company’s warehousing set-up might be a good solution.
There is a constant cost pressure on the Medtech supply chain. In order to be as cost effective as possible a broad range of choices between LSP’s will make sure that there is a competitive offer available. We will be able to benefit from the economies of scale achieved by the LSP.

The possibility to outsource an extensive range of activities will make sure I choose the most cost effective solution each time.
C. Flexible, agile and responsive

To tap into a mature and sophisticated logistics industry with LSP’s specialized in medtech supply chains is a real added value. The LSP is up to date with the latest developments and will drive innovation in our company’s supply chain.

To be right in the middle of EU’s main markets for an European hub in combination with state of the art infrastructure like the main ports and connections to integrator hubs will really benefit my customers. Also direct to hospital deliveries are of great added value.
European supply chain solution

D. Fully visible and transparent  Make use of state of the art systems and processes

LSP’s offer **end-to-end supply chain visibility**, mainports, customs etc. are connected. This will always allow me to make well informed decisions. The possibility to have advanced KPI dashboards monitoring our company’s performance as well as allowing us to react quickly to a changing business environment will **set us apart from competition**.
It becomes ever more important that we are compliant in a high regulatory environment. To make use of the knowledge and services of LSP’s specialized in this area gives me confidence for growing our company’s markets in a correct way. We also benefit from the up to date knowledge, skills and advise from the LSP in this ever more important area of our business.

There are many logistic service providers that are GDP certified.
To have the flexibility to react to market and customers demands quickly it is of extreme added value to have partners that can do more than just the standard warehousing and distribution activities. The LSP is able to perform a wide range of services.

The LSP should really be an extension of our own operation allowing us grow and adapt quickly to changing markets.
## Your challenge vs. Competences in The Netherlands

<table>
<thead>
<tr>
<th>Your challenge</th>
<th>Competences in The Netherlands</th>
</tr>
</thead>
<tbody>
<tr>
<td>We want to focus on core processes</td>
<td>• Mature and sophisticated logistics industry with logistic service providers specialized in pharma supply chains</td>
</tr>
</tbody>
</table>
| We want to reduce cost and increase profitability | • Logistic service providers offer economy of scale, best practices and in-depth knowledge of pharma supply chains  
• Logistic service providers work on activity based costing principle providing you with a variable and flexible cost structure |
| We want to develop a flexible, responsive and agile supply chain | • Mature and sophisticated logistics industry with logistic service providers specialized in pharma supply chains  
• Strategic location, right in the middle of EU's main markets, European hub function  
• State of the art infrastructure: mainports and multimodal hinterland connections, connections to integrator hubs |
| We need full supply chain visibility | • Logistic service providers offer end-to-end supply chain visibility, mainports, customs etc. are connected |
| We have an increased need for value added services | • Logistic service offer a wide range of value added services related to the pharma supply chain  
• Fiscal system and customs facilitate tax effective value added services |
### Competences in The Netherlands

<table>
<thead>
<tr>
<th>Your challenge</th>
<th>Competences in The Netherlands</th>
</tr>
</thead>
<tbody>
<tr>
<td>We want to improve order-to-cash</td>
<td>• Order-to-cash is part of the services provided by logistic service providers specialized in pharma</td>
</tr>
<tr>
<td>We face challenges with direct-to-patient, -hospital and -pharmacy distribution</td>
<td>• Logistic service providers offer tailored direct-to-patient, -hospital and -pharmacy distribution solutions</td>
</tr>
<tr>
<td>We want to optimize information management</td>
<td>• The logistic sector is highly automated and connected</td>
</tr>
<tr>
<td>We want to optimize supply chain related cash flow</td>
<td>• Favorable indirect tax administration</td>
</tr>
<tr>
<td>We want to have a supply chain that is compliant with EU regulation</td>
<td>• Logistic service providers offer compliant European supply chain solutions</td>
</tr>
<tr>
<td></td>
<td>• Logistic service providers offer compliance as a service</td>
</tr>
<tr>
<td>We need a GxP compliant logistic service provider</td>
<td>• The majority of logistic service providers specialized in pharma are GxP compliant</td>
</tr>
<tr>
<td>We need to get a better understanding of indirect taxes in the EU</td>
<td>• Logistic service providers offer tax effective European supply chain solution with focus on indirect taxes</td>
</tr>
<tr>
<td></td>
<td>• Many service providers offer indirect tax related advice and services (consultancy, fiscal representation, etc.)</td>
</tr>
<tr>
<td>We need to get a better understanding of what processes we can outsource</td>
<td>• Logistic service providers in offer a wide range of services</td>
</tr>
</tbody>
</table>
### Pharma: Setting up your operations in NL - Competences

<table>
<thead>
<tr>
<th>Your challenge</th>
<th>Competences in The Netherlands</th>
</tr>
</thead>
<tbody>
<tr>
<td>We need to understand the optimal supply chain model for our company to cater to the European market</td>
<td>• Logistic service providers offer a broad range of optimized solutions to cater to the European market</td>
</tr>
<tr>
<td>We need to understand how we can use our supply chain as a differentiator</td>
<td>• There are many case studies of European supply chain operations in The Netherlands that are used as a differentiator available</td>
</tr>
<tr>
<td>How do we find the right partners</td>
<td>• HIDC provides advice on European supply chain structuring and offers matchmaking services</td>
</tr>
</tbody>
</table>
Logistics Proposition
Life Sciences & Health
The Netherlands
Logistics hub for LS&H – key reasons

1. **Central location** within the European consumer market
2. **Excellent connectivity** to Europe and all continents
3. High share in **global import** and **export flows**
4. World class **fiscal** and **business environment**
5. **Strong logistics base** for LS&H distribution
6. **Highest quality** and **competitive costs**
European hub for Life Sciences & Health – number 1

1. on the EU Transport Scoreboard (European Commission, 2018)
2. as most connected country (DHL Global Connectedness Index, 2016)
3. on quality of port infrastructure (WEF, Global Competitiveness Report, 2018)
4. on quality of air transportation (IMD World Competitiveness Online, 2018)
Easy access to largest European markets

- Located between Europe’s three major medtech and pharma markets: Germany, France and the U.K.
- To be reached by road within a few hours
- The Dutch trading mentality and cross border business environment made many multinational companies establishing their European logistics base in the Netherlands
- The Netherlands is economically and politically stable

Excellent in- and outbound **infrastructure**

- Within a **300 kilometer** (180 mile) radius:
  - **Rotterdam and Antwerp**, the two largest container ports in Europe
  - **Amsterdam Airport Schiphol**, the #2 best connected airport in the world and #2 cargo airport in Europe
  - **UPS** and **FedEx/TNT**, the two main European integrator air hubs
  - In between is the European **sweet spot for life sciences fulfillment**
Short lead times to European markets

- Most European countries can be reached within **one to three days** with regular road transport
- This is often used for or **replenishment** of forward stock locations or regional DC’s
- **Express networks** provide opportunities for late cut-off times and next or same day delivery in Europe
- Extreme flexible **last mile**; therefore a greater choice in delivery and collection
- Multiple **return** options

Source: Royal Rotra, 2017
The Netherlands has the second largest import and export figures in Europe for **medical devices** from overseas (including European intra-community trade).

Most of these products are imported by sea, **Rotterdam** and air, **Schiphol** and distributed across the EU.

Air connectivity

322 destinations worldwide
31 freighter lines
1.7 million tonnes of cargo

North America: 23 locations
Europe: 194 locations
Middle East: 14 locations
South America: 28 locations
Africa: 32 locations
Asia: 31 locations

Source: Amsterdam Airport Schiphol, 2017
- Fast customs clearance and shared processes
- Direct link with (academic) centres of innovation focused on pharma supply chain improvements
- Real-time access to temperature data at any time
- IATA CEIV pharma certified logistics community with best-in-class facilities and capabilities
- Direct air connections to 322 destinations, excellent connections by sea, rail and road
Fiscal climate – customs

- **The Netherlands**: best overall performer in trade facilitation (119 countries)

- **This is due to the pro-business attitude of customs**

- **Meaning a speedy transshipment of goods** and a low risk of product being delayed at ports or DC’s

- **Netherlands scores 94%; EU average is 62%**

Source: UNESCAP, 2017
Fiscal climate – VAT attractiveness

Source: Deloitte VAT Index, 2016
Fiscal climate – VAT deferment

The advantages of the Dutch VAT system:

- **VAT deferment at import** leads to a considerable cash flow advantage
- Cross-border sales with **0% VAT rate** to other businesses within EU
- Be completely VAT compliant without an entity in Europe by using a **fiscal representative**
Fiscal climate – bonded warehousing

The **advantages** of a customs-bonded warehouse:

- Avoidance of double duty payment and postponement of duty payment
- Possibility of storage for an unlimited period of time
- Less customs interference
- Value added logistics in a customs-bonded warehouse and bonded transport (T1)

Note: Bonded warehousing is possible anywhere in the country and is not limited to, for example, Free Trade Zones.
Business climate - Ease of doing business

- Doing business in the Netherlands is **supported** by regulations: best score in mainland Europe
- The regulatory environment in the Netherlands is **most conducive** to the start-up and operation of a European Distribution Center for medtech and pharma products

<table>
<thead>
<tr>
<th>Country</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Netherlands</td>
<td>7.0</td>
</tr>
<tr>
<td>Ireland</td>
<td>6.0</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>5.5</td>
</tr>
<tr>
<td>Portugal</td>
<td>5.0</td>
</tr>
<tr>
<td>Germany</td>
<td>4.5</td>
</tr>
<tr>
<td>Poland</td>
<td>4.0</td>
</tr>
<tr>
<td>Belgium</td>
<td>3.5</td>
</tr>
<tr>
<td>France</td>
<td>3.0</td>
</tr>
<tr>
<td>Spain</td>
<td>2.5</td>
</tr>
<tr>
<td>Czech Republic</td>
<td>2.0</td>
</tr>
<tr>
<td>Italy</td>
<td>1.5</td>
</tr>
</tbody>
</table>

Executive Opinion Survey based on an index from 0 to 10

Source: IMD World Competitiveness Online, 2018 (Selection of European countries)
Labour force – language skills

- The Netherlands ranks first in terms of adult English proficiency
- Additionally, the Dutch speak a variety of foreign languages (such as German and French)

Source: EF EPI English Proficiency Index, 2018
Value added logistics (VAL) – medtech

Value added logistics include:

- Assembly, reverse logistics and repair
- Testing, sampling and quality control
- Building of surgical kits
- Packing, re-packing and sealing, labelling
- Storage and de-consolidation
- Clean room storage
- Temperature controlled supply chains
- Many Dutch 3PL’s qualify for ISO 13485*

* Facilitates harmonized medical device regulatory requirements for quality management systems
Value added logistics (VAL) – pharma

Value added logistics include:

- Testing, sampling and quality control
- Direct to pharmacy/patient distribution
- Packing, re-packing and sealing
- Reverse logistics
- Secured storage and de-consolidation
- Labelling and coding
- Temperature controlled transportation
- Many Dutch 3PL's qualify for CEIV Pharma certification*, GMP** and GDP certification***

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* Standard for transport and handling of pharmaceutical products
** Ensures that products are produced and inspected in accordance with the established quality norms
*** Ensures that consistent quality management systems are in place throughout the entire supply chain
Value added services (VAS) – medtech

Value added services include:

- Inventory management
- Order processing/invoicing
- Fiscal representation
- Customs (import/export)
- Bonded warehousing
- Track and trace
- Control towers
- Customer service
- Surgical kits usage reporting
Value added services (VAS) – pharma

Value added services include:

- Inventory management
- Order processing/invoicing
- Fiscal representation
- Customs (import/export)
- Quality control
- Quantity monitoring
- Relabeling/repackaging
- Customer service
High quality and competitive costs – medtech

- The Netherlands ranks as a **competitive** country in terms of **operations costs**, with seven specific locations.

- These locations are also able to meet MedTech EDC requirements from a **quality perspective**.

Source: Buck Consultants International, logistics benchmark 2017
High quality and competitive costs – pharma

- The Netherlands ranks as a competitive country in terms of operations costs, with seven specific locations.
- These locations are also able to meet Pharma RDC requirements from a quality perspective.

Source: Buck Consultants International, logistics benchmark 2017
LS&H – who’s there?
Holland International Distribution Council (HIDC/NDL)

HIDC/NDL is:
- A public/private, non-profit organization
- Founded by Dutch logistics industry
- Representing more than 300 members
- Promoting the Netherlands abroad as ‘Gateway to Europe’
- Working closely with the Netherlands Foreign Investment Agency (NFIA)

Services include:
- Advice on cost-effective and agile set-up of European supply chain
- Entry into European market by exporters from North-America and Asia
- Matchmaking and fact finding trips
- Connect to logistics partners
- Free of charge and confidential

Holland International Distribution Council | The Netherlands | www.hidc.nl | info@hidc.nl