

KEY LOGISTICS TRENDS IN LIFE SCIENCES 2020+

A DHL perspective on how to prepare for future growth



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	Preface	3
	Introduction and Executive Summary	4
1.	Megatrends	6
2.	Challenges for the Life Sciences Sector	8
2.1.	Shifting Disease Patterns	8
2.2.	Better-informed Patients	9
2.3.	New Health Markets	10
2.4.	Growing Competition	11
2.5.	Increasing Cost Pressure	12
2.6.	Outsourcing and More Complex Supply Chains	13
2.7.	More Stringent Regulation	15
2.8.	Innovation	16
3.	Logistics Implications and Required Actions	18
3.1.	Differentiating Supply Chains	18
3.2.	Empowering the Consumer	18
3.3.	Building Up Local Capabilities	20
3.4.	Increasing Supply-chain Transparency and Visibility	21
3.5.	Maintaining Supply-chain Adaptability	21
	Sources	23
	For More Information	27

Dear Reader,

We live in a world of 24-hour news coverage with the internet, TV, radio, newspapers and magazines all vying for our attention across multiple devices. For business leaders, there's an intense pressure to be constantly connected to information channels and always keep up-to-date with the latest business headlines, viewpoints and trends.

The abundance of opinion and plethora of 'must-read' stories can be bewildering. It can cloud the 'real' issues and leave the practitioner unaware of and disoriented regarding key opportunities and challenges of the future.

With this white paper, DHL seeks to cut through the extraneous chatter and white noise. Our aim is to extract the key trends for '2020 and beyond' that are relevant to you — logistics decision-makers with pharmaceutical and medical device manufacturers — and thus provide suggestions for your focus, consideration and action.

The structure of the white paper follows a three-stage approach:

- Collection and analysis of the most important megatrends
- Identification of the key challenges for the life sciences sector resulting from these macro changes in society, technology, the economy, the environment and politics
- Deriving the respective logistics implications, pinpointing areas where action is required

We hope to provide a comprehensive repository of knowledge for our customers and partners. Our aim is to stimulate collaborative discussion throughout our networks and alliances, resulting in new ideas, innovative projects and solutions, and creating value for all involved.

This white paper benefited tremendously from cooperation with Z_punkt The Foresight Company, a leading foresight consultancy.

We now invite you to peruse our view of the 'Key Logistics Trends in Life Sciences 2020+'.

Please feel free to share it with your colleagues and peers, and don't hesitate to share your thoughts, observations and insights with us.

Yours faithfully,



Marlus buch lans Dr. Markus Kückelhaus



Dr. Michael Terhoeven

Introduction and Executive Summary



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 2016 (IMS 2012a). Strong growth rates until 2020 are also forecast for the market for medical devices.

Logistics has long been considered a basic supporting function within the life sciences sector. However, the importance of logistics is growing for a number of reasons: (1) the increasing relevance of **emerging markets** and **globalization of supply chains**, in turn (2) driving **increasing regulatory efforts** in particular around **temperature management** and, finally, (3) a **changing product portfolio** that, on the one hand, allows new **direct-to-market approaches** notably for specialties and, on the other hand, requires **differentiated 'value-focused' approaches for value products and generics**, where the cost of logistics drives a larger share of total cost.

This white paper is intended to contribute to the endeavor of managing the resulting challenges. Its aim is to systematically identify the most important required actions for life sciences logisticians for the coming years. Our key findings for life sciences logistics include the following:

- We expect a shift from undifferentiated logistics structures to more differentiated supply chains, with the mode of transportation, warehousing and depth of distribution tailored to different life sciences product categories.
- We believe that manufacturers in the life sciences sector will build up direct-distribution channels to the end consumer. They will either develop their own e-commerce operations or distribute their products via third-party platforms.
- 3. We see pharmaceutical and medical device manufacturers expanding their capabilities to tier-2 and tier-3 cities and sometimes even to rural areas in emerging countries. However, there are likely to be differentiated approaches to depth of distribution and to implementation strategies.
- 4. In future, we expect that better visibility in the supply chain will be required not only for product security and integrity, but also because of the need to control and optimize logistics processes (for example, with outsourcing and emergency logistics complementing slower-mode transportation and demand-driven supply chains). At the same time, visibility will enable differentiation and create value (for example, with direct-distribution models, mentioned in 2. above).
- 5. Finally, we foresee the need for manufacturers in the life sciences sector to keep supply chains flexible to adapt to new regulatory standards and the distribution requirements of innovative products. We expect more temperature-differentiated supply-chain solutions, as well as infrastructures adaptable for product bundles and more personalized medicines and implants.

Our approach follows three steps:

Step 1

As a first step, the most important megatrends in the environment of healthcare are briefly reviewed.

From Megatrends – to Challenges – to Logistics Implications

1. Megatrends								
Demographic Changes and Urbanization	Consumerism	Shifting Centers of Economic Activity	Changing Competitive Landscape	Technological Progress	Climate Change and Environmen- tal Pollution			

Step 2

In the second step, we identify the key challenges for the life sciences sector resulting from these macro changes in society, technology, economy, environment and politics.

2. Challenges for the Life Sciences Sector								
Shifting Disease Patterns	Better- informed Patients	New Health Markets	Growing Competition	Increasing Cost Pressure				
	Outsourcing and More Complex Supply Chains	More Stringent Regulation	Innovation					

Step 3

For the third step, we extract the respective logistics implications and required actions.

3. Logistics Implications and Required Actions



bold = exemplary impact route from megatrend to life sciences logistics

1. Megatrends





Megatrends are long-term transformation processes with a broad scope and a potentially dramatic impact (Z_punkt 2012). They will shape the life sciences sector as well as many other industries over the next few decades. Demographic Changes and Urbanization can be considered the most influential megatrend. The global population is expected to increase from 6.9 billion people in 2010 to 8.0 billion in 2025, with growth found almost exclusively in developing countries. At the same time, the population in almost all countries is aging. The average age in Germany will rise from 44 in 2010 to 48 in 2025, while the median age in China will increase from 35 to 40 during the same period (UN 2010). This will be accompanied by a growing demand for healthcare and a shift towards age-related disease patterns. Apart from population growth and aging, mankind will witness an unprecedented migration from rural to urban areas. By 2025, the share of people living

in cities, globally, will have increased to 58 per cent from 52 per cent in 2010 (UN 2011). This shift will have direct consequences for healthcare infrastructures and logistics.

Cities are also the place for modern lifestyles, which are at the core of the **Consumerism** megatrend. There is a global trend towards individualization, meaning that in almost all societies worldwide traditional relationships will decrease in importance, whereas individual choice and responsibility will grow. This will lead to rising health awareness and more differentiated demand for products in healthcare and life sciences, as well as in other sectors.

The consumerism trend in emerging economies will go hand in hand with global Shifting Centers of Economic Activity. This megatrend underlines that economic growth in the emerging world is much





faster than in industrialized countries. From 2010 to 2030, GDP (gross domestic product) in Europe is expected to increase by 50 per cent, while GDP in the BRIC countries (Brazil, Russia, India, China) will rise by 190 per cent, almost tripling economic production (PwC 2011a). This megatrend will lead to rising incomes in the emerging world and rising export opportunities for life sciences manufacturers. At the same time, we will see a Changing Competitive Landscape with pharmaceutical and medical device manufacturers, for example, from India and China, entering the global market.

Economic growth is associated with several other megatrends. The first of which is Technological Progress, which, during the next decade, will still be characterized by increasing digitization. Driven by information technology, the progress in neurology (imaging) and biotechnology (genomics,

proteomics, biomics) is expected to be impressive and will have an impact on healthcare treatments and products. On the other hand, economic growth is still associated with an increased burning of fossil fuels. This will lead to Climate Change and Environmental Pollution, primarily in fast-growing megacities facing new healthcare challenges. Experts assume that globally urban air pollution is responsible for 1 million premature deaths and 1 million prenatal deaths each year (UNEP 2013).

2. Challenges for the Life Sciences Sector

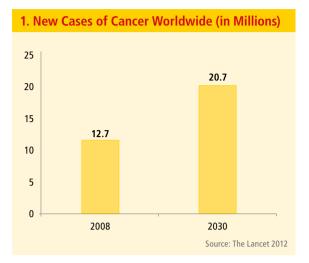
The megatrend-based challenges for the life sciences sector during the next decade are manifold and they will have specific implications for logistics. We have identified eight challenges covering very different aspects of healthcare from shifting disease patterns, growing competition and cost pressure to new and partly disruptive technological innovations that are approaching market readiness.

2.1. Shifting Disease Patterns

As a result of longer life expectancies, changing lifestyles and environmental influences, such as climate change, and air and water pollution, the frequency and relative impact of diseases will shift (IHME 2010). We expect that the healthcare and life sciences sector has to prepare to treat certain diseases more often, in other places than today and even to deal with new diseases.

Firstly, lifestyle diseases, such as type 2 diabetes, cancer, cardiovascular diseases and psychological illnesses, will become more common globally. The main reasons are a high-calorie diet, physical inactivity and higher levels of stress, increasingly also in developing countries. For 2030, the WHO (World Health Organization) estimates that **about 8 per cent of the world's population could suffer from diabetes alone, costing the world about 5 per cent of global GDP.** In 2010, 8 million people died from cancer, over a third more deaths than back in 1990. And for 2030, the incidence of cancer is estimated to grow by another 75 per cent, with cases nearly doubling in some developing countries (The Lancet 2010 and 2012) (see Figure 1).

On the other hand, the proportion of muscular and skeletal diseases as well as mortality and morbidity due to infectious diseases are likely to continue to decline on a global scale with multiple

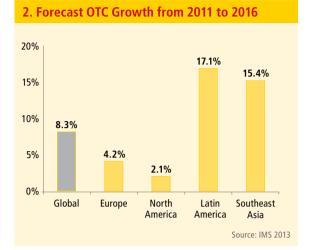


The shift in disease patterns is expressed, among other ways, by the increasing incidence of cancer. 12.7 million new cases of cancer were reported in 2008, globally. This number is expected to rise to 20.7 million by 2030.

advancements being made in healthcare, and in lifting millions of people out of poverty.

At the same time, **tropical and infectious diseases continue to pose threats to public health**. In the future, rapid urbanization and globalization of travel and trade as well as global warming will increase the risk of a partial trend reversal with more outbreaks, new diseases and pandemic threats. In an increasingly globally linked world, the spread of diseases is much more rapid (e.g. SARS, swine flu).





Better-informed patients are more open to self-medication in many cases. The trend towards self-medication is expressed by an estimated growth in over-the-counter medicines (OTC) over the coming years. Globally, an 8.3 per cent increase until 2016 is expected.

Climate change will also lead to a shift in disease risks (The Lancet 2009). Rising temperatures will affect the geographical range and seasonality of mosquitos and related vector-borne diseases like malaria. Generally, pathogens that cause diarrheal disease reproduce more quickly in warmer conditions (EPA 2012).

The first signs of such a trend reversal can already be seen. In China, for instance, mortality and morbidity of notifiable infectious diseases have started growing again since 2002 (Zhang/Wilson 2012). Also, worldwide cholera incidents have increased steadily since 2004, especially in sub-Saharan Africa, Asia and more recently in the Caribbean (WHO 2013b).



2.2. Better-informed Patients

Primarily thanks to the Internet, we see today's population being better informed about health issues. People are questioning more carefully the value of medicines, medical procedures and claims of medical superiority. Information asymmetries between physicians and patients are narrowing, and there are more opportunities for patients to influence treatment decisions. With growing health awareness, the perception of health is changing generally. The focus on the absence of disease is shifting to a concept of health as a state of comprehensive well-being. Many people want to exercise more and gain control of their own health.

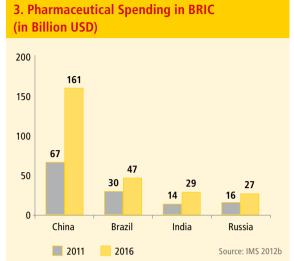
At the same time, self-medication is booming. The market for OTC (over-the-counter) medicines is forecast to grow by 8.3 per cent annually until 2016 (IMS 2013), thereby continuing to outgrow the total pharmaceutical market. World revenue for OTC medicines could reach USD 81 billion by 2014 (Visiongain 2012), supported by a trend for drugs to move from prescription-only to OTC use (Rx-to-OTC switching) (see Figure 2).

The self-medication trend is accompanied by more and more people tracking their health, bodily functions and even behavior (the most extreme expression of which is the Quantified Self movement). The concept is making its way into the mainstream in industrialized countries, as ever smaller and cheaper devices enable convenient digital health tracking. In the US, 69 per cent of adults already track their own health records, 34 per cent of which share their data online (Fox/Duggan 2013). With further progress in the fields of sensing and miniaturization, the idea of having a portable, multifunctional health diagnostic device could increase the quality of diagnostics but also alter the role of physicians in the future. Analyzing data and giving recommendations, and even coaching for behavioral changes will become more important.



2.3. New Health Markets

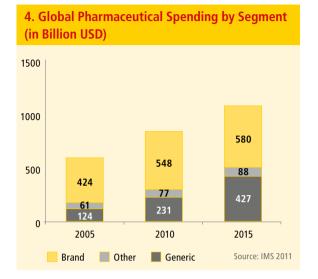
As the global economy shifts its center of gravity from the US, Europe and Japan towards China and other emerging countries, global pharmaceutical markets will also shift their center of gravity to these regions (Quah 2011) (see Figure 3). Markets like Brazil, Russia, India, China (BRIC), Mexico and Turkey will play an ever-more important role. Already today, they represent one of the fastest-growing segments of the global pharmaceutical and medical device industries, promising to grow at double-digit rates over the next decade. In 2020, these countries could account for nearly a third (USD 500 billion) of the expected global pharmaceutical sales of USD 1.6 trillion (PwC 2012a). In 2011, their share was approximately 19 per cent.



The BRIC countries do not only have high economic growth rates, they also form some of the most important new health markets in the coming years. Pharmaceutical spending in China, for example, is expected to grow from USD 67 billion in 2011 to USD 161 billion in 2016.

By 2020, China alone could well have become a bigger force in this market than Europe. According to PwC projections, China and India will have the highest health spending increase globally in absolute figures until 2020, as their economies grow and they extend their currently underdeveloped health systems (PwC 2011b). In China, health spending, including spending on a new health infrastructure, is expected to increase by 166 per cent between 2010 and 2020. A 140 per cent increase is expected in India within the same period.

On the other hand, global health markets are characterized by rising health disparities within most countries. People's health conditions will diverge especially in those countries with fast urbanization, such as **India**, which will **increase its urban population from 380 million in 2010 to about 540 million in 2025** (UN 2011). Urban populations tend to have a better health status than rural populations; however intra-urban health disparities will also increase, particularly in



The segment of generic drugs is expected to grow from USD 124 billion in 2005 to USD 427 billion in 2015. This growth will also mean increased competition between manufacturers as entry barriers in the generics segment are relatively low.

fast-growing centers and megacities. Some experts argue that the health status of the urban poor is on a par with that of rural populations (Ivins 2012).

2.4. Growing Competition

We expect that the competitive environment for pharmaceutical companies will become increasingly challenging, and this stems from a small number of developments.

Firstly, the mix of spending between innovative (and patented) products and generics is shifting towards the latter, reducing barriers to entry and increasing competition. The share of generic drugs as a proportion of spending on medicines could increase to as high as 39 per cent in 2015, up from 20 per cent in 2005 (IMS 2011) (see Figure 4). Over USD 220 billion of sales are at risk from patent expirations between 2013 and 2018 (EvaluatePharma 2012). Even in

industrialized countries, generics account for the majority of prescriptions, and governments and payers continue to encourage their use as they try to manage overall costs. In the US, about 80 per cent of all prescriptions written today are for generics – up from only 19 per cent in 1984 (Department of Health and Human Services 2013). It is forecast that this number could climb to 85 per cent in 2015 (Looney 2012).

Secondly, a growing share of these generics in the industrialized world comes from manufacturers in emerging countries, notably India. The value of Indian exports of drugs, pharmaceuticals and fine chemicals grew by 270 per cent between 2002 and 2011 (Government of India 2012). It is likely that in the next decade pharmaceutical manufacturers from the emerging world will also develop innovative medicines in their own labs. Global manufacturers will react by integrating successful manufacturers in the emerging markets and slowly shifting their research and development (R&D) resources into these countries.

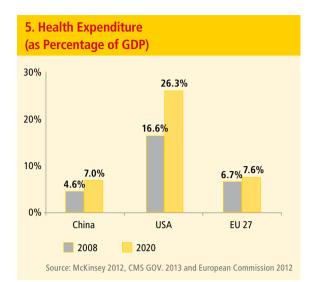
Similarly, inexpensive technology for emerging markets, but also from emerging markets, is about to transform the sector for medical devices. Companies are increasingly realizing that the current innovation paradigm, in which healthcare innovation must achieve a device more high-tech, more sophisticated, more complex and hence more expensive, will no longer guarantee success. This is especially true for resource-poor settings in developing countries. 'Frugal innovations' which focus on very basic user requirements are not only expected to spread in these regions. They could also spread to Western markets and cost-effectively replace more expensive solutions. For example, Bangalore-based Forus Health has developed a portable and rather inexpensive prescreening device that allows patients to check their eye conditions and defects (The Times of India 2012). It costs about a quarter of comparable, established

devices. Big Western companies like General Electric and Siemens are starting to develop cheaper medical devices as they are feeling growing pressure from competitors in new markets.

Thirdly, producers of both innovative products and generics are being confronted with a growing number of counterfeits which are deliberately and fraudulently mislabeled with respect to identity and/or source. The WHO estimates that 10 per cent of the medicines in circulation are counterfeit, with the majority of cases reported from developing countries (Bale 2000). The number of reported cases has increased steadily over the past decade, also in the big Western markets. The 170 cases that were investigated in the US in 2012 represent a new all-time high, up from about 10 to 30 cases at the beginning of the 21st century and 50 to 70 in the late 2000s (FBI 2012). According to some estimates only about 5 per cent of cases are reported in the US, thus real numbers could be far higher. A main driver for the rise in counterfeiting is seen in the stretching of pharmaceutical supply chains across continents, which makes comprehensive controls more difficult.

2.5. Increasing Cost Pressure

We expect that the pressure to contain or drive down health system cost will continue. In the US, healthcare expenditure per person has risen by almost 78 per cent since 2000 to USD 8,700 in 2011 (Centers for Medicare & Medicaid Services 2012). In Europe, the proportion of healthcare costs as a share of GDP is predicted to rise from 6.7 in 2008 to 7.6 per cent by 2020 (see Figure 5). And in China healthcare spending might almost triple between 2010 and 2020 to USD 1 trillion per year by 2020 (Bloomberg 2012). Aging populations count as a key factor for growing cost pressures within many of the world's most advanced health systems.



Health spending as a percentage of US GDP is expected to increase from 16.6% in 2008 to 26.3% in 2020. However, the pressure to contain health system cost is rising in almost every country.

Managing access to healthcare providers, pharmaceuticals, medical devices and procedures will thus become an increasingly crucial factor for managing the cost of healthcare in industrialized countries. Increasing constraints and limits on reimbursement will support the shift towards self-medication and OTCs. According to a US study, every dollar spent on OTC medicines saves between USD 6 and 7 for the US healthcare system as a whole (Booz & Company 2012).





The fact that outsourcing plays a more important role in life sciences is expressed by the growing market for pharmaceutical contract manufacturing organizations. Their revenues are expected to increase from USD 32 billion in 2012 to USD 60 billion in 2018.

Moreover, pressure on cost of healthcare is likely to show regional spikes, as the financial crisis, the economic downturn and slow recovery have further tightened the budgetary situation in many countries. According to OECD figures, member states had to borrow USD 16 trillion in 2010 alone (OECD 2010). Public health programs are a prime target of cost-cutting efforts, not to mention 'legacy' issues. For example in markets with the highest debt problems in Europe, like Spain, Italy, Portugal and Greece, payers owe more than EUR 12.5 billion in unpaid bills to the pharmaceutical industry.

2.6. Outsourcing and More Complex Supply Chains

Rising cost pressure in healthcare systems will also have an impact on the operating models of manufacturers of pharmaceuticals and medical devices. **Overall, we expect more differentiated and thus more** **complex set-ups with value add and supply chains differentiated by product and region.** This particularly applies to R&D, manufacturing and distribution.

In R&D, firstly, we assume continued outsourcing to contract research organizations (CROs), the biggest of which have already developed into truly global corporations (MedCity 2012). Innovators will need to decide and manage own, in-house clinical development and integrated CRO offerings, as well as unbundled set-ups, e.g., splitting specialist laboratory and logistics tasks. Furthermore, early research and development as such will increasingly be outsourced to universities and start-ups.



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Secondly, outsourcing is playing an ever more important role with regard to the manufacturing of medical devices and pharmaceuticals. This is illustrated, for example, by the market for pharmaceutical contract manufacturing organizations (CMOs), which is expected to grow from USD 32 billion in 2011 to USD 60 billion by 2018 (Scrip Insights 2012 and Morrison 2012) (see Figure 6). Outsourcing is no longer limited to precursor chemicals of active pharmaceutical ingredients (APIs). As cost and competitive pressure have increased, the tendency to outsource has moved even closer to the core of supply chains (Bottomley/Houlton 2013). More and more, API manufacturing is being outsourced, either in a contract manufacturing set-up or in ad-hoc short-term agreements.

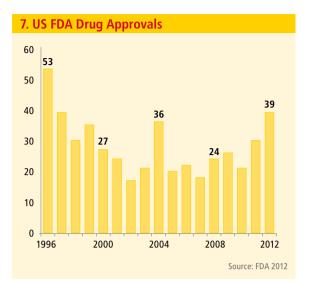
As a consequence, about 80 per cent of the APIs used in US drug manufacturing are already coming from outside the country (Deborah 2011).

Also subsequent manufacturing stages are in scope of outsourcing. Primarily, for mature products, filling and finishing is increasingly being shifted to contract manufacturers.



For more innovative specialties and niche products, late production stages can be outsourced or postponed with late-stage customization depending on local demand. A similar set-up might also be the result of specific regulatory requirements: some governments enforce local partnerships to support the local pharmaceutical industry. In other countries, special serialization requirements have to be implemented locally.

Thirdly, **outsourcing is playing an increasingly important role in the distribution of medical devices and pharmaceuticals**. On the one hand, there is legacy infrastructure that is no longer considered 'core', for example, owned warehouses for finished product. On the other hand, 3PL, 4PL and control tower concepts (3PL and 4PL refer to third- and fourth-party logistics) cover tactical and administrative logistical activities as well as specialist services, for example, temperature management, emergency or courier shipments, recall management and patient assistance programs. Supply-chain



Stricter drug approval requirements are one example of a more stringent regulation in the life sciences sector. The number of new drugs approved by the FDA decreased from 53 in 1996 to 24 in 2008. Since then, the number has increased again.

visibility is an important if not essential enabler for the more advanced outsourcing approaches; therefore, IT investments and outsourcing often go hand in hand.

In general, we expect more differentiated operating models with a broader and more differentiated spectrum of service providers, depending on product characteristics. For specialties, for example, there will be an increasing build up of ownership down to the point of application (direct-to-hospital/ pharmacy).

2.7. More Stringent Regulation

Due to more complex supply chains, among other things, policy makers worldwide are enforcing stricter regulations for manufacturing and logistics.

Selected manufacturing problems and growing public pressure have caused the US Food and Drug Administration (FDA) to strengthen GMP standards (Good Manufacturing Practices) and control them more strictly. Within a decade, the number of FDA warning letters sent to medical device manufacturers has increased threefold, from 61 letters in 2002 to 181 in 2012 (ECA 2012). Also, the number of FDA inspections of drug and biologics manufacturers has grown continuously. In the years to come, the FDA expects domestic GMP inspections to decrease and more inspections in the foreign arena (FDA 2013) reflecting the trend towards more globalized supply chains. At the same time, most emerging countries themselves are increasing their regulatory requirements. China published new GMP guidelines in 2012 and is calling on pharmaceutical companies to pursue GMP certification by the end of 2013.



Hand in hand with GMP standards, governments and international organizations such as the WHO, have established and increased their requirements for Good Distribution Practices (GDP). These standards define how life sciences products, particularly pharmaceuticals, have to be stored, transported and

handled. Higher GDP standards are looming in a number of countries. New guidelines will come into force during 2013 in Brazil, the European Union and China; Singapore is currently drafting new GDP standards (ColdChainIQ 2013). Key new requirements in the European Union, for example, include risk assessment of delivery routes, temperature monitoring and reporting of temperature excursions and the use of dedicated vehicles where possible.

Authorities have not only raised the GMP and GDP standards for pharmaceuticals already on the market, they have also tightened their requirements for the approval of new drugs. This is perceived as a key driver for increasing risk and cost, as well as adding time for the development of new drugs. While the FDA approved 176 new medicines between 1996 and 1999, that number fell to 88 for the four years between 2007 and 2010 (Miller 2011). At least the FDA's drug approvals reached a 15-year high in 2012 with 39, after trending in the lower 20s for most of the last decade (**see Figure 7**).

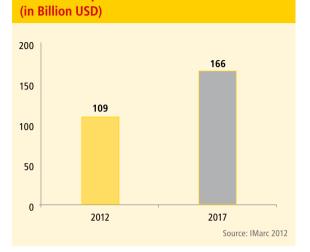
Meanwhile, according to a study from the UK, **the average cost of developing a new drug has increased tenfold since the 1970s** (OHE 2012). One of the most cited studies on pharmaceutical innovation processes estimated the costs for a new drug at USD 802 million on average (DiMasi 2003). Another more recent study sees average costs ranging between USD 1.3 billion and USD 1.7 billion per new drug (Collier 2009).

2.8. Innovation

Although, the annual output of new drugs has been rather flat over the past decade, we are optimistic about the innovative outlook of the industry – one of the main commercial success stories of the past decade has been biopharmaceuticals (see Figure 8). We believe that innovation will continue to shape the sector driven by a number of advances in related fields.



Sequencing the human genome is becoming ever cheaper and faster: costs to read an entire human genome are down from USD 95 million in 2001 to USD 1,000. By 2020, genetic testing could become a part of mainstream medical practice and could pave the way for stratified or even personalized medicine, in which treatments are tailored to groups of patients ('strata') or even individuals. Many new biomarkers have already been identified and many more are currently under development, enabled by the decreasing cost of testing and computing. Researchers hope to achieve similar breakthroughs in the field of gene expression in the next few decades and be able, for example, to develop so-called epigenetic drugs which can block or unblock genes involved in certain diseases. A truly personalized medicine, however, might also depend on refining our understanding of the human microbiome - the totality of all microorganisms inhabiting the human body and their interaction -



8. Global Biopharmaceutical Market Sales

Biopharmaceuticals form a rather innovative segment in the life sciences sector. The global market for biopharmaceuticals is expected to grow from USD 109 billion in 2012 to USD 166 billion in 2017.

the analysis of which is becoming an increasingly important research subject (NIH 2013).

Slightly less speculative, more effective vaccines for a much wider range of diseases are expected. New vaccination-delivery technologies are also expanding the ways in which it is possible to prime immune systems towards specific antigens. Some experts predict that vaccines will increase in their commercial relevance as they drive down public health costs in a very effective way.

Regenerative medicine, which includes the replacement or repairing of human cells, tissues or organs, is also regarded as a future growth field. Just recently, 3D printing was used for the first time to replace 75 per cent of a patient's skull (OPM 2013). With further advances the engineering of even more complex structures (e.g. artificial muscles and organs) will become possible.



Technical advances in robotics (e.g. autonomous navigation) are opening the field for new applications. Semi-autonomous care and cleaning robots will enter hospital environments. Robot-assisted surgeries are becoming more and more commonplace. Thanks to advances in mobile technology, augmented reality solutions are beginning to spread into more practical applications, enabling more accuracy in various medical practices. For example, an augmented overlay helps healthcare professionals to perform highly accurate joint arthrography injections (Hall 2012). IT and telecommunications progress is also enabling tele-medical applications. Remote medical consultation and advice (within countries or across borders) can be implemented based on teleconference technology. In a more advanced version, sensors in the patient's clothing or home can support remote diagnosis and treatment. Also remote tele-surgeries will become more common in the future. One of the earliest remote surgeries was conducted in 2001 with a surgeon in New York City performing a cholecystectomy on a patient in France (IRCAD 2001).

There are many more visions about the future of healthcare. One thing for sure is that the life sciences sector will change its face during the next decade. And life sciences logistics will be part of this change.

3. Logistics Implications and Required Actions

Challenges for the life sciences industry will have many consequences for logistics within the sector. Shifting disease patterns and innovative products will have an impact on what is stored and transported. Regulation, competition and cost pressure will affect logistics procedures. Market changes and more decentralized supply chains will lead to new transportation routes. The fastest growth is expected in markets where adequate logistics infrastructures are not yet fully developed. However, in the more established markets we also see logistics demand being subject to change.

3.1. Differentiating Supply Chains

Worldwide, the globalization and digitalization of the economy are impacting supply chains. The changing nature and growing number of distribution channels is most evident in the consumer and retail sectors, which are undergoing rapid changes, and can serve as an example of the changes awaiting the life sciences industry. Thus far, supply chains in the life sciences sector have had a rather specific and undifferentiated logistics structure. In future, it will be increasingly necessary to implement a more differentiated approach to supply-chain structure and organization.

Going forward, companies will tailor the mode of transportation, warehousing and depth of distribution in each country to different pharmaceuticals and medical devices. For example, generic drugs and consumer medical devices may be transported via ocean and long-haul road freight (and selected higher value modes for 'emergency' situations, when a standard, slow-mode shipment misses a checkpoint or encounters a hold up) while specialty drugs will be shipped using air freight, express or even courier services. Generic drugs may be distributed over several logistical steps involving several distributors and transport providers while high-value specialty drugs and medical devices might be distributed from a single global or regional distribution center directly to the hospital (pharmacy or ward) or even the physician specialist at point of care. The move towards differentiated supply chains is driven by several things: by increasing pressure to optimize cost or maximize value for products that differ by volume and value; by the requirement for lead-time service levels (acute versus chronic treatment); by new requirements for temperature management or documentation; and by specific regulatory regimes.

We believe that by 2025 most companies providing medical devices and pharmaceuticals will have tailored their supply chain along these product categories:

- a. High-value/specialty drugs and implants
- b. Innovative standard drugs and devices
- c. Generic drugs and frugal/low-tech devices
- d. OTCs, nutraceuticals and consumer medical devices

In addition, supply chains will also be differentiated within each product category, for example into coldchain and non-cold-chain specialty drugs.

Particularly because of the strong growth in demand for generic drugs and specialty drugs, more specific supply chains for these two segments are initially expected to emerge.

3.2. Empowering the Consumer

Many companies in the life sciences sector are facing a challenge: they must decide if, when, and to what extent they should develop a direct-distribution channel to the end consumer. Direct-to-consumer (DTC) distribution is increasing in relevance.



Sales of products in the OTC category have been growing faster than other pharmaceutical products in the past few years. New kinds of products catering to the consumer desire for private health monitoring are emerging, for example, smartphone apps and add-on devices allow testing and digital recording of blood sugar values for diabetic patients. And for the enthusiast of the Quantified Self movement, they provide the basis for evaluating a broad range of health indicators at home or on the go.

Also, the internet is an increasingly important channel for consumer health information. An impressive 42 per cent of the adult population, according to a US study, rely on social media for health-related consumer reviews on medications, treatments, physicians, hospitals and insurers (PwC 2012b). This is especially true for patients suffering from rare diseases who are often organized in online support groups. Supporting such communities will increase in relevance in the future.

With a more long-term perspective, one can also expect changes in the prescription drug segment

towards a more consumer- or patient-oriented supply chain. In the US, direct-to-home delivery schemes of prescription drugs for patients with chronic diseases are a cost-effective reality. The increase of tele-medicine and home care will drive the need for home delivery of drugs. However, technical and regulatory hurdles remain, and with regulations differing in each country, the international implementation of such schemes may remain a long-term challenge.

Against the backdrop of growing direct-to-consumer segments, online information and tele-medicine, manufacturers in the life sciences sector have to determine whether they want to develop their own e-commerce operation and, if so, whether it should be organized by establishing their own fulfillment capability or by distributing their products via a third-party platform. Building on a wide range of experience in supporting e-commerce retailers in their logistics processes, logistics service providers are well equipped for advising and supporting companies in the life sciences sector in their quest for a more direct channel to the end customer.



3.3. Building Up Local Capabilities

The remarkable growth in many emerging economies provides opportunities for increasing sales of medical devices and pharmaceuticals. Rapid growth is projected not only for the aforementioned OTC products, but also for pharmaceutical products in general. Take the BRIC markets, for example: pharmaceutical spending is projected to more than double in China and India and to grow by over 50 per cent in Russia and Brazil between 2011 and 2016 (IMS 2012b). Almost all companies have established capabilities to export into China. However, their capabilities do not necessarily reach far into fragmented markets. Some manufacturers operate the complete distribution via a single 'national' lead wholesaler and some cater directly for key hospitals in tier-1 cities. With economic growth reaching more remote areas, pharmaceutical and medical device manufacturers are facing the challenge of expanding their marketing and sales capabilities, as well as their distribution capabilities to tier-2 and tier-3 cities in the most effective way. Beyond that, economic opportunities are not restricted to urban areas.

Those 3.3 billion people living in rural areas (UN 2011) – this number will remain constant until 2025 – are in need of medical devices and pharmaceuticals. More and more, companies perceive these markets "at the bottom of the pyramid" as a growth opportunity (Prahalad 2005). Solutions for these markets often entail innovative product and logistics concepts, sometimes as simple as a singly blistered Aspirin (ASA) pill sold at an affordable price by part-time mobile traders. Many pharmaceutical companies have already established training programs for rural physicians or nurses in China, India and Northern Africa (examples in Staton 2013) and some of these ventures are already accompanied by the build-up of local logistics infrastructures.

However, when deciding on how to (further) develop local capabilities, each growth region needs a specifically tailored solution. **Companies must decide** whether to build-up their own logistics infrastructures, and how broad they want their in-country presence to be. Life sciences companies have to decide if they want to organize their distribution only via one leading wholesaler or if they want to organize distribution, for example, to the 100 most important wholesalers and the 20 largest hospitals as well as the top 3 pharmacy chains. Besides the depth of distribution, decisions have to be made on whether the distribution should be implemented inhouse or with the support of logistics service providers, possibly in a 3PL or 4PL set-up.

3.4. Increasing Supply-chain Transparency and Visibility

Supply-chain security (primarily regarding the prevention of product theft) and supply-chain integrity (to ensure the quality, functionality and authenticity of products) are becoming even more important in the life sciences sector. As mentioned above, it is estimated that, already today, 10 per cent of all pharmaceuticals are counterfeit (Bale 2000). Furthermore, about 50 per cent of medicines sold through websites are fake drugs (Carrington 2011). The increase in counterfeit drugs is adding to requirements for proof of origin and product traceability along the supply chain.

At the same time, better visibility in the supply chain is essential to control and optimize logistics process-

es. Traditionally, companies in the pharmaceutical and medical devices sector have used a push logistics approach to distribution, which is characterized by well-filled warehouses throughout the supply chain, season and product lifecycle. Given increasing cost pressures, it can be expected that overall inventories will have to become leaner and supply chains more efficient by changing to a pull or demand-driven approach. However, it is only possible to control and manage inventories if they are sufficiently visible. The need for increased supply-chain visibility will be highest in the generics and OTC segments, where cost pressures are especially strong, as well as in the specialty drugs segment, where inventories tie up large amounts of capital due to the high product values involved. For specialties, we perceive an option to transform the respective supply chain to a direct-distribution model with a single regional or global distribution center generating visibility to multiple points of sale at one stroke.

The optimization of supply chains will also lead to an increased incidence of stock-out situations, ranging from local, short-term shortages to regional drug shortages, due to manufacturing issues that require dedicated shortage-management efforts. Again, increased visibility of inventories will be essential. Potential excess supplies of product in one place can be moved in time to prevent supply shortages in other places. The same would be true in a local epidemic or even pandemic scenario, when demand for a specific product suddenly shoots up.

Greater supply-chain visibility is also a necessary condition to maximize value creation from outsourcing of logistics services, both in temporary and permanent set-ups. Therefore, when investing in infrastructure and software solutions for supply-chain visibility, most companies also redesign their supply chains and implement 3PL or 4PL concepts and vice versa.

3.5. Maintaining Supply-chain Adaptability

For well over a century, the life sciences sector has been a source of innovative products that have helped to increase the welfare of societies around the world. From today's point of view, innovative solutions can be expected from this sector in the decades ahead. Some innovations might disrupt the status quo and bring massive changes within a relatively short timeframe, but most innovations will unfold their potential over time. Life sciences logistics, in any case, must be ready to react and adapt to the new requirements resulting from these innovations.



Below, we have collected a few first signals and examples reflecting the need to keep supply chains adaptable.

Firstly, we can see increased relevance and differentiation in temperature management: in most regulatory regimes medicinal products are stored under controlled room temperature (CRT - mostly interpreted as 2 to 30 degrees Celsius). Controlled temperature conditions are increasingly demanded - and are entering the regulatory dialogue - in transport, transit and 'ship-to-label' (requiring the same narrow and specific conditions for transport as for long-term storage). At the same time, the number of drugs requiring cold-chain storage and transportation (2 to 8 degrees Celsius) will increase further with the rising share of biopharmaceuticals (IMarc 2012). Additional temperature regimes are emerging - 15 to 25 degrees Celsius, frozen (-20 degrees Celsius), deep frozen, 'ultra-low' or even cryogenic - and this illustrates the need to develop temperature-differentiated supply-chain solutions.

Secondly – supply chains have to remain adaptable for **product bundles**. Very different logistics requirements have to be combined effectively when heterogeneous products are bundled in the supply chain and shipped jointly to the point of application. These bundles might consist of a pharmaceutical drug together with nutritional and care products or of several implants bundled with the respective surgery equipment (requiring return logistics on top of the bundling). Product bundles are getting more relevant not only to serve rare-disease patients but also to treat more common but complex diseases.

Thirdly, there are life sciences growth fields, in which supply-chain adaptations can be considered rather strategic and **logistics becomes a differentiator** and key success factor. These include the abovementioned shortage-management and pandemic logistics as well as e-commerce solutions for B2C segments or the rare-disease pharmaceutical and care bundles described above.



Erank Wojciechowski

Finally, life sciences logistics will play an important role with the emergence of truly personalized medicine, for example, 3D-printed implants, organs or genetically enhanced autologous stem cells where the donor and the recipient are the same person. This potential new healthcare paradigm will require a different type of logistics to realize a 'logistics of one', closer to clinical-trial logistics than today's standard life sciences fulfillment logistics.

By developing and maintaining the ability to adapt supply chains, companies in the life sciences sector will be well prepared to seize the opportunities ahead.

It is DHL's vision to be the leading logistics provider to the life sciences sector.

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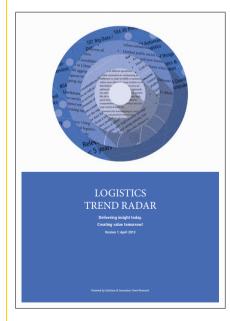
about the 'Key Logistics Trends in Life Sciences 2020+', contact:

Dr. Markus Kückelhaus **DHL Customer Solutions & Innovation** Junkersring 57 53844 Troisdorf, Germany Phone: +49 2241 1203 230 Mobile: +49 152 5797 0580 e-mail: markus.kueckelhaus@dhl.com

Dr. Michael Terhoeven **DHL Customer Solutions & Innovation** Heinrich-Brüning-Str. 5 53113 Bonn, Germany Phone: +49 228 182 30282 Mobile: +49 170 227 3726 e-mail: michael.terhoeven@dhl.com

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PUBLISHER

DHL Customer Solutions & Innovation Represented by Martin Wegner Vice President Solutions & Innovation

DP DHL Research und Innovation GmbH **Tulpenfeld 1** 53113 Bonn, Germany

PROJECT DIRECTOR

Dr. Markus Kückelhaus Solutions & Innovation, DHL

Dr. Michael Terhoeven Strategy and Development Life Sciences & Healthcare Sector Customer Solutions & Innovation (CSI), DHL

Monika Nordmann Marketing Director Life Sciences & Healthcare Customer Solutions & Innovation (CSI), DHL

PROJECT MANAGEMENT AND EDITORIAL OFFICE

Katrin Zeiler Solutions & Innovation, DHL

Global Media Relations Silje Skogstad **SVP** Global Media Relations

Dr. Diane Rinas

IN COOPERATION WITH



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Holger Glockner Kai Jannek Johannes Mahn **Cornelius Patscha**

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