

National Interest

The Korean bio/pharmaceutical industry is a promising sector with unique opportunities for global companies and investors. Strong government support coupled with high investments and promotional policies are stimulating growth, but in order for Korea to become a major player, several challenges will need to be met with an increase in knowledge of cold chain, global regulations and quality control

Vivian Berni at LifeConEx

In the *2011 Cold Chain Biopharma Logistics Sourcebook* growth rates for pharma, biotech, vaccines, blood products and clinical materials, US and international regulatory bodies, and air, ground and ocean carrier modes were surveyed. The report suggested that seven of the top 10 global pharma products in 2014 will require cold chain handling. According to industry estimates, vaccines will grow on average eight per cent per year through the next five years. While pharmaceutical cold chain shipments to North America and Europe have shown the greatest growth and continue to dominate the market, the greatest shipment growth will most likely come from emerging markets.

Cold Chain as a Competitive Advantage

There are correlations between advancement of bio/pharmaceutical export capacity of a country and its regulatory compliant cold chain capabilities. Consider Europe and the US as examples of regions which have a coherent approach to cold chain regulatory compliance.

The world is getting both smaller and overly complicated, particularly where the transportation of cold chain products is involved.

As the regulatory environment continues to become more stringent globally, this will create a challenge for many Korean bio/pharmaceutical companies. Canada, Saudi Arabia, Singapore, Malaysia and Argentina are among the countries that have made documentation of individual shipments of cold chain pharmaceuticals an entry requirement. The growing trend is for life science organisations to make their internal processes more rigorous, and demand more quality assurance measures from their cold chain logistics providers. Health authority inspectors, such as Brazil ANVISA, UK MHRA and Canada Health are looking for the following during the regulatory process:

- Standard operating procedures (SOPs)
- Temperature monitoring in warehouses
- Validation of freezer and refrigerators
- Product storage conditions
- Temperature control during transport
- Procedure for investigation and actions in case of temperature excursion from the set parameters

Eventually, all health authorities will demand the same for all imported temperature-sensitive products.

According to the 14th Annual Global CEO Survey conducted by PricewaterhouseCoopers, competitive threats, industry dynamics and regulation are the most important factors driving change for the pharma

Figure 1: Global market versus Korean market

Global market

- In 2015, the market will have grown to \$310 billion at a growth rate of 15 per cent
- Further highlighted as developing and underdeveloped countries is expected to grow at a rate of 18 per cent

Korean market

- 18 per cent of growth (0.3 per cent of sales to GDP)
- 2.2 per cent of global market share in 2005
- The future growth engine of the industry
- Major export markets China (35 per cent), the US (25 per cent), the EU (15 per cent) and Japan (10 per cent)

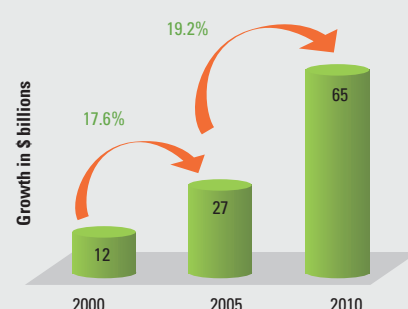
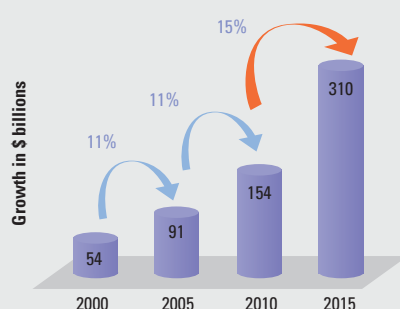
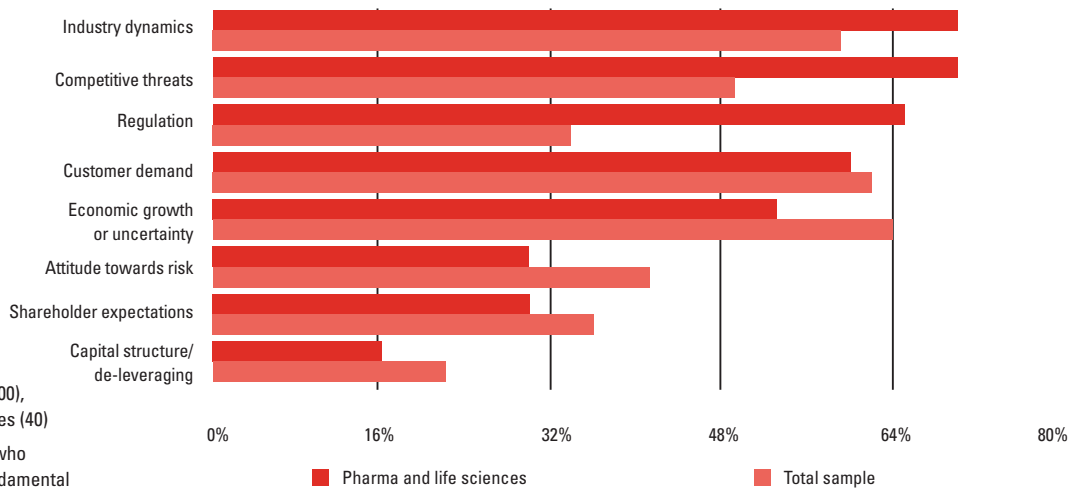


Figure 2: Factors influencing strategy change

Q: Of the following eight factors that may be changing your business, which have significantly influenced your need to change your strategy?

Base: Total sample (1,000), pharma and life sciences (40)

Note: All respondents who stated “changed in fundamental ways” or “somewhat changed”



Source: PwC 14th annual global CEO survey

and life sciences industries. The effect of these factors contributes to the way temperature-sensitive products are transported and to the way cold chain regulations are enforced. By knowing the global standards for regulatory compliance, Korea can efficiently import and export bio/pharmaceutical products.

With every challenge, there is an opportunity for success, and Korea has the potential to achieve great success. Having cold chain as a competitive advantage for Korea will not only inherently make the transportation of medicinal products a smoother process, but will also result in the capacity to release products into a global market quicker.

The Requirements for Success

It is critical to evaluate and understand the cold chain process. Temperature control is important, as it is a key requirement to keep products within a specific temperature range throughout the supply chain. This can be particularly challenging in emerging markets. One

solution is to invest in packaging that can protect products against temperature variations and improve product quality at the final destination. Korean life science organisations also need to have a clear understanding of the product flow and routing dynamics, including the transportation modes and refrigeration capability for exports and imports. Delays in delivery and processing can have severe effects on the quality and integrity of the product, the brand image, and the costs associated with hold-ups in customs/product damages. As a result, organisations without strong cold chain partnerships should seek a contingency plan as transportation usually takes longer than expected in emerging markets.

Partnerships

In today’s biotechnology and pharmaceutical environment, companies must be quick to adapt in order to survive the constantly changing landscape. Recent trends have seen pharmaceutical companies reducing the cost of research and development by merging with or

outsourcing new drug developments from biotech companies. Partnerships are also emerging as an alternative to reducing risk and costs associated with the creation of new medicinal products. Collaboration during drug development is only one portion of the equation though; collaboration and strong partnership during the transportation of these temperature-sensitive products is also a key factor. A cold chain network built upon collaboration and strong partnerships to serve emerging Korean pharmaceutical and biotech companies, who require regulatory compliant cold chain transportation with the highest security and quality standards, is essential.

Infrastructure

Korea’s Incheon International Airport is the world’s second largest airport in terms of international cargo traffic – but cold chain infrastructure requirements are far more extensive. The key to any cold chain is driving end-to-end processes and efficiency, with successful cold chain management requiring direct delivery with temperature cold trucks, warehousing and advance technology tracking and traceability for drug safety and for adherence to regulatory compliance. Life science companies need to account for geographical aspects as they transport products from one end of a country to the other. In addition, distribution centres (DCs) can play a key role in a country’s cold chain strategy. DCs have the ability to service several layers of the distribution system. This

Table 1: Competitiveness of Biotechnology Industry

	2005	2010	2015	2020
Infrastructure and human resources	75	80	90	95
Core technology	60	65	70	80
Product technology	75	80	90	95
Marketing	55	65	80	85

Note: Competitiveness of the most advanced countries = 100

Source: Survey by Korea Institute for Industrial Economics and Trade, 2006

can further improve distribution and supply efficiencies.

Technology

Technology is a vital investment when seeking to maintain the integrity of a cold chain. Bio/pharmaceutical companies need to consider a long-term perspective in relation to technology. In many instances cold chain technology and equipment are available, but organisations usually tend to avoid the substantial investment. In emerging markets, companies seek simple and cost-effective solutions to problems. For instance, data loggers and packaging may be implemented for one-time use. Having experts with advanced knowledge of technology and its application in the cold chain can allow for appropriate guidance for exporting/importing temperature-sensitive products.

Education

Knowledge is power. The cold chain process is intricate, specific and technical. It is vital for all parties involved in the cold supply chain to know what role they play in the transport. Ultimately, the goal is greater awareness – by all stakeholders – of the importance of cold chain processes from a global regulatory compliance point of view (such as cold chain conference and educational seminar availability in Korea versus Europe, the US, Singapore, and so on). Investment in more cold chain-competent professionals in Korea, including logistics, packaging, data, quality control, warehousing, and trucking, will raise the level of expertise throughout the cold chain.

Vision

The factors mentioned so far are critical for the success of the bio/pharmaceutical cold chain industry in Korea. But ultimately, it's important to have a vision for cold chain in the long term. This is supported and promoted by not only the government, but also by domestic and international organisations, regulatory bodies and patient safety. Being an advocate for cold chain implies having a vision for a healthier society in which product integrity and regulatory compliance counts.

A Changing Landscape

No doubt the industry is evolving, so what awaits for Korea? The answer is biosimilars. The Korean Ministry of Knowledge and Economy projects that the biosimilars market will grow to \$14.3 billion (€10.4 billion) by 2015, especially after 2013 when many patents for major biopharmaceuticals expire. Korea is ready to change the landscape in this arena. Biosimilars cover almost all the diseases under communicable and non-communicable category. On account of this, the major biotech companies in Korea are doing their part in developing the generic versions of blockbuster biologics ready to be launched as soon as the patent of a product expires.

Biosimilars are expected to hit the market by 2015. New technologies that turn refrigerated biotech products into room-temperature-storage products will also kick in, affecting some product temperature and storage requirements. The challenges for biopharma manufacturers will not be in terms of developing new technologies to handle shipments, but in process changes to manage the regulatory and reporting demands cost-effectively.

Furthermore, cold chain has typically referred to temperature ranges of 2 to 8°C or frozen (-20°C). However, the requirements have evolved to include ambient (15 to 25°C) temperatures; these temperatures are more challenging to maintain. This change means that emerging markets will need to catch up on the learning curve and begin to implement proper handling facilities for ambient temperature ranges.

The Future of Cold Chain in Korea

Korea has broad experience of generic medicine development, sufficient human resources, experience of new drug development,



many export cases of drug candidates, and world class stem cell technologies. But what are the opportunities for Korea itself? National interest and support for biotechnology, high quality human resources, powerful research-based bioventures, and intensive support from the government encourage and facilitate the development of cold chain operations within the country.

But that's not all: according to the Korea Food and Drug Administration (KFDA), Seoul ranks fourth in local clinical trials and third in global trials, which indicates that most global clinical trials within Korea are conducted in Seoul. The clinical trials industry is set to increase further during the coming decade. With the projected growth in this key emerging market, there are great opportunities for local and foreign investors.

About the author



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