11th Cold Chain Global Forum
September 30 - October 4, Chicago
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Editor’s Welcome

Each year, the Cold Chain Global Forum features a “Focus Day” devoted to a timely industry topic. It was a no-brainer to make BRIC countries this year’s key focus.

Cold chain infrastructure growth in BRIC countries is far outpacing the rest of the world, as is pharmaceutical consumption and manufacturing.

This Special Report: Cold Chain in BRIC Countries presents an in-depth look at the opportunities and challenges these four countries represent. The individual sections devoted to Brazil, China, India and Russia include articles, graphics and relevant links.

This report only scratches the surface on the type of in-depth discussion that will take place at the Cold Chain Global Forum. 650+ attendees will engage in case studies and interactive learning sessions from September 30th – October 4th in Chicago.

I hope you enjoy this Special Report and I hope to see you in Chicago!

- Shawn Siegel

Contributors

Carlos Castro – Clinical Supply Chain at Gilead Sciences
Andrea Charles - Senior Editor of Pharma IQ and Cold Chain IQ
Karan Chechi - Research Director at TechSci
Bert & Isabelle Lamaire - Owner & CEO at Soncotra
Huo Peiqiong - Head of Supply Chain at Guangdong Zhongjian Medicine
Shawn Siegel – Digital Content Manager - IQPC
RuiQi Wang - Affiliate Quality Officer, Sanofi-Aventis

Articles From: ColdChainIQ.com, Dyzle.com & PharmaIQ.com
Challenges of Entering BRIC Markets*

Top 10 Challenges:

- Initial Cost
- Culture
- Finding a Trusted Partner
- Infrastructure
- Lack of Control
- Lack of Expertise
- Market Knowledge
- Regulations/Customs
- Time
- Transportation Laws

* PharmaIQ.com surveyed its membership about the hottest markets and industry priorities in April 2013.
Why BRIC Countries? Part One:
PharmaIQ.com surveyed its membership about the hottest markets and industry priorities in April 2013.

1. Move into emerging Markets 33%
2. Outsourcing distribution and logistics 25%
3. Temperature controlled Logistics 16%
Why BRIC Countries? Part Two:

Projected Growth of Cold Chain Logistics over the Next Three Years:\(^1\)

- 18% in North America
- 21% in Europe
- 46% in Asia
- 57% in the Rest of the World (Emerging Markets)

Projected growth of the Active Pharmaceutical Ingredient Market:\(^2\)

- 6.5% Worldwide
- 15-20% in BRIC Countries

Projected Growth of Drug Sales:\(^3\)

- Emerging Markets = 5% of Drug Sales in 2007
- Emerging Markets = 25% of Drug Sales Today
- In 2016, Emerging Market Drug Sales Will Equal US
- India’s pharma market is forecast to grow from $12.6 billion to $55 billion by 2020

Projected Economic Growth:\(^4\)

- 3.7% in Brazil
- 3.9% in Russia
- 7.4% India
- 8.5% in China

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1 Andrew J. Mills, CEO – Americas: DGP Intelsius
2 Fierce Pharmaceutical Manufacturing (quoting CPA Report)
3 IMS Health. Emerging markets defined as 16 countries including BRIC
4 IMF Projections from 2012-2017
FOCUS ON BRAZIL
One of the challenges facing cold chain professionals in Brazil is the cold chain capacity and/or infrastructure at the major airports. There is a need to integrate and collaborate with the government authority (INFRAERO) to streamline the import process. Another concern is ensuring the proper storage condition while the cargo is waiting for clearance and expanding the cooler capacity at airports, especially at those cities different then Sao Paulo and Rio. Some improvements can be made by engaging the freight forwarders, carriers and pharma companies to understand better the process at the airport. Another challenge is the limited capacity of reefers for ground transportation. The current trucking companies do not seem to fulfill the requirements of the industry so there is a demand for a better service. One of the participants pointed out that sometimes customs release the cargo but the truck or reefer is not there so the products are moved to inadequate areas for storage (outside the warehouse) to free up warehouse space. It is important to mention that the major airport in Sao Paulo is running at 80-90% capacity.

I see a great opportunity for immediate collaboration to ensure there is a resilient supply chain before Brazil hosts the World Cup and the Olympic Games, two major events that will stress all logistics capabilities. I would love to see how much advancement will be made by next year in closing these gaps. This task concerns all supply chain links because the weakest link will set the pace of the supply chain.

FYI:

In Brazil, drugs account for 20% of everything that is transported currently, and should reach 25% in 2015.*

*WBR Research
Thoughts on May’s Proposed Anvisa Changes by ColdChainIQ.

Brazil’s National Health Surveillance Agency (Anvisa) opened a consultation on the 4th April to propose the formation of an electronic tracking system for drugs from point of production through to the point of dispensing to the patient.

The proposed tracking system is to be based on the two-dimensional barcode, the Datamatrix, that will be included on sales packaging as well as secondary packaging such as pill packs and hospital packs.

The CEO of Anvisa, Dirceu Barbano said: "Companies holding registration with Anvisa will be responsible for placing on each package a Unique Drug Identifier (IUM) formed by the drug registration number for the product containing thirteen (13) digits, plus the serial number, expiration date and lot number."

The comment period closed on May 9th, 2013. For an outline of the proposal go to: http://s.anvisa.gov.br/wps/s/r/b1oO

More information:
Anvisa Portal
BRAZIL’S CUSTOM STRIKE IMPACTS COLD CHAIN
Andrea Charles

With Brazil customs offices still on strike cargo is being delayed from 2 days to several weeks at major ports, airports and warehouses. Stakeholders in the pharmaceutical cold chain continue to monitor the situation with product integrity at risk due to supply chain delays.

In a recent interview with Angela Mazzeo, Quality Analyst at the Butantan Institute the largest producer in Latin America of immunobiologicals and biopharmaceutical, Mazzeo said: “One of the top 3 risks to the temperature controlled pharmaceutical supply chain is red tape situations at the airport”.

Brazil’s largest port, Santos, is worst affected by the strike, also impacted are Manaus, Santana Itacoatiara, Salvador, Paranagua, and Santarem. Customs officers are demanding better remittance packages and working conditions.

Brazil is already recognized as a region with complex customs regulations, any delay could risk supply chain integrity and the efficacy and safety of medication. For this reason many perishables are being cleared more quickly, and ensuring clinical trials materials and other temperature controlled pharmaceutical products are moving through the supply chain is of paramount concern.

Stakeholders in the cold chain logistics must always be prepared and many cold chain solution providers have contingency plans firmly in place and have publicly assured their customers that their products are not being affected by the strike.

Most are hoping the situation will be resolved through government negotiations by next week, until then the world watches the next host of the Summer Olympics.
LEARN MORE ABOUT COLD CHAIN IN BRAZIL
At the 11th Cold Chain Global Forum

Attend These Sessions at the BRIC Focus Day at the 11th Cold Chain Global Forum:

9:45 AM - GDP Updates in Brazil – Ensuring Compliance through Increasing Regulatory Requirements
Jair Calixto – Manager of Good Practices and Audits – SINDUSFARMA

Noon - Evaluating Your Carrier’s Infrastructure – Visiting and Auditing Facilities
Carlos Castro – Global Transportation and Logistics – Bayer Healthcare

2:25 PM - Developing your Supply Chain Operations in the BRIC Countries
Mick Sutherland – Director of Logistics, Americas – CSL Behring

REGISTER NOW
FOCUS ON CHINA
Overcoming Cold Chain Challenges in the Chinese Market

Huo Peiqiong and RuiQi Wang

Like many industries in China, biopharmaceuticals has recently experienced substantial growth and the country is now close to becoming the world's largest biopharma market.

To take full advantage of the potential, however, China must find an effective way to deal with some of its complex challenges, such as the logistics of temperature-controlled supply chains.

Huo Peiqiong, head of supply chain and quality at Guangdong Zhongjian Medicine Company, recently discussed this issue in an interview with Cold Chain IQ. She noted that cold chain logistics are particularly important for her company, as about 70 per cent of the drugs in its business lines require temperature-controlled environments.

According to Huo, one of the most significant current trends in this area relates to packaging.

Some types of cold chain packaging can store products effectively for up to 70 hours, while others are only usable for two or three hours.

"Packaging is a top priority for me because China is so big and there are such extremes in temperature from north to south," said Huo. "How to use packaging correctly and training staff is important too."

Weather, transport and workforce training are the three biggest concerns for the temperature-controlled pharmaceutical supply chain in China, according to the company executive.

RuiQi Wang, affiliate quality officer at Sanofi-Aventis, told Cold Chain IQ that the quality of subcontractors and extreme winter weather conditions are among the biggest risks for this aspect of the industry.

He highlighted periodic quality reviews and adherence to internal directives and published guidelines as good approaches to ensuring quality in the supply chain.
China's importance within the global pharmaceutical industry is growing. However, this growth requires more robust infrastructure and regulations.

Henning Voss, director for World Courier, North Asia, described the challenges and situation in China as complex.

"Domestic transport companies do not yet fully understand the many international standards at play in handling these types of shipments," Voss said.

To remain competitive in the global pharmaceutical industry, the country is taking steps to improve the quality of its pharmaceutical supply chain. In January this year the Chinese State Food and Drug Administration (SFDA) published a newly revised Good Supply Practice for Pharmaceutical Products (GSP), which will go into effect as of June 1, 2013. The revised guidance sets higher qualification requirements, increases standards for drug distribution and also has higher requirements for quality management.

The revised GSP is made of four chapters, including the General Provisions, Quality Management for Wholesale of Pharmaceutical Products, Quality Management for Retail of Pharmaceutical Products and Supplementary Provisions.

The revised GSP means that many local pharmaceutical companies will need to lift their game when storing and handling drug products or they risk getting left behind their competitors.

Charlie Xu, Vice President for Clinical Operations at Frontage Lab China said that compared to multinational companies, many local players don’t have stringent compliance records and the regulations are intended to raise the standards of GSP in the country.

“Good supply practices amongst local pharmaceutical companies are not great compared to international players. Unlike large companies, many smaller players don’t have in-built QAQC [Quality Assurance and Quality Control] systems,” said Mr Xu.
Based on container shopping volumes

15 of the Top 20 Are in Asia >>

View the [Complete Top 20 List](#)
LEARN MORE ABOUT COLD CHAIN IN CHINA
At the 11th Cold Chain Global Forum

Attend These Sessions at the BRIC Focus Day at the 11th Cold Chain Global Forum:

11:00 AM - Designing a Quality Strategy for your Supply Chain in China
An interactive discussion session

2:25 PM - Developing your Supply Chain Operations in the BRIC Countries
Mick Sutherland – Director of Logistics, Americas – CSL Behring

3:20 PM - Developing a Global Excursion Temperature Management Process
Jamie Pope – Quality Manager, Controlled Temperature Distribution - Genzyme

REGISTER NOW
FOCUS ON INDIA
With 3500+ players, the Indian cold chain market is highly fragmented. While the current life science supply chain in India is extremely complex, it presents great market opportunities for those working in the temperature controlled supply chain.

According to the TechSci Research report “India Cold Chain Market Forecast & Opportunities, 2017” the cold chain market in India is anticipated to grow at a CAGR (Constant Annual Growth Rate) of 28.7% during 2012-2017, which will make the market reach US$ 11.6 Billion by 2017.

"The demand for cold chain logistics from organized retail, pharmaceutical industry has been growing day-by-day," said the report.

In an interview with Cold Chain IQ, Bhusan Mohapatra, Head-Commercial Indian Immunologicals, noted that the predicted growth in the Indian vaccine market indicates a lot of opportunities for those involved in the cold chain, from the manufacturer to logistics service provider, the technology provider to trace & track and related software provider.

When asked specifically about the pharmaceutical cold chain market in India, TechSci Research’s Research Director, Karan Chechi, said to Cold Chain IQ: “Currently the market value of temperature controlled vehicles which are deployed for the transportation of pharmaceutical products is more than USD 3.8 Million, which is likely to reach at around USD 17.1 Million in next five years.”

Continued...
Chechi continued: “Under the 12th Five Year Plan (2012-2017), The Department of Pharmaceutical has asked for the assistance of around INR 50 Crore (USD 9.2 Million) for setting up the cold chain facilities across India.

The market value of vaccine market in India is around USD 180.5 Million, which is growing at a healthy pace of around 25%-30% annually.

Vaccines require the support of temperature controlled environment right from the point of their initial stage of production to their final distribution. This indicates the unexplored potential for both the domestic as well as the international players which are present in the cold chain management system.”

The report noted that over the past few years, the Indian cold chain industry has witnessed some positive changes: "Private sector participation has increased in the cold chain industry to cater to the increasing demand for cold chain logistics."

“It is anticipated that many large domestic and foreign companies will join the league in coming years to cater the growing demand of cold chain logistics. This will inject required investment and latest technology in the Indian cold chain industry in near future. Cold chain industry of India is also expected to witness some major mergers and acquisitions by the big companies to establish their base and to expand their reach,” said Chechi.

The pharmaceutical distribution system in India is undergoing a paradigm shift and we will continue to see improvements, through compliance with the latest standards and the implementation of the latest technologies for supply chain management.

**FYI:**

The Indian pharmaceutical market is expected to grow from US$ 12.6 billion to a staggering US$ 74 billion by 2020.

*PWC Report*
Economic growth and increased international trade means India’s freight forwarding market is expected to enjoy considerable expansion over the next few years. With the economic outlook generally healthy, foreign direct investment (FDI) on the rise and the transport infrastructure of India due to witness major improvements, freight forwarders and logistics companies look set to reap the benefits.

The pharmaceuticals industry will be one of the main drivers of demand for freight forwarding services. The value of the India pharma market is forecast to grow from $12.6 billion to $74 billion (£8.2 billion to £36 billion) by 2020, by which point it will account for eight per cent of global pharmaceutical production.

India’s pharma industry is already the third largest in the world in terms of production volume, with branded generics continuing to dominate the business models of many companies.

Focusing on the production of cheaper versions of branded drugs once their patent protection runs out has proved an effective strategy for Indian pharma companies. Last year, Gurgaon-based Ranbaxy achieved revenues of $600 million over a six-month period from sales of a generic version of Pfizer’s blockbuster cholesterol treatment Lipitor.

Another wave of big-name drugs will see their patents expire over the next three years, which makes Indian manufacturers well-placed to capitalize on the huge demand for generic alternatives in the US and Europe. The market for medicines losing patent protection by 2015 is worth an estimated $250 billion.

Continued...
In October last year, the Indian government announced its intention to capture a share of this market worth between $30 and $40 billion with the launch of its Brand India Pharma campaign.

"We want to send out a message to the world that we have the capacity to fill in this space with high-quality yet cheap medicines," said additional commerce secretary Rajeev Kher in comments reported by the Economic Times.

With the international export of generic drugs from Indian manufacturers therefore set to increase significantly, freight forwarding providers look set to benefit from buoyant demand.

Recent reports, such as Freight Forwarding Market in India 2012 by Research and Markets and this month's Logistics Services Market in India 2013 by Netscribes, have noted how the growth in international trade is driving an increased need for logistics services in India, including freight forwarding.

However, certain challenges remain for pharmaceutical manufacturers and the freight forwarders they partner with. Chief among these is the complex regulatory environment surrounding the temperature controlled supply of life sciences in India.

Restrictions on FDI in retail prevent overseas firms from investing in the necessary cold chain infrastructure, while the majority of cold storage facilities are located in a handful of states, making them inaccessible to some users.

David Cameron made an official visit to India this week in a bid to strengthen economic ties with the UK. The prime minister encouraged a more open and flexible business relationship between the two countries, calling for India to give British organizations an incentive to invest by cutting regulation and red tape. Implementing such changes in the area of temperature controlled logistics could certainly create new opportunities for multinational pharma firms, Indian manufacturers and freight forwarding providers.

**FYI:**
The Indian cold chain market is expected to jump more than two-fold to $8 Billion by 2015 on the back of increased investment.*

*Yes Bank Report*
In January 2013, The Central Drugs Standard Control Organization (CDSCO) of India, the country’s Authority for Medicinal Product, published a draft Guidelines on Good Distribution Practices for Pharmaceutical Products for public opinion.

The objective of these guidelines is to ensure the quality and identity of pharmaceutical products during all aspects of the distribution process. These aspects include, but are not limited to procurement, purchasing, storage, distribution, transportation, documentation and record-keeping practices.

The draft guidance does not yet have a date by which it will become effective.

The Indian pharmaceutical market remains attractive and is expected to grow to US$ 55 billion by 2020 according to the McKinsey & Company report titled “India Pharma 2020: Propelling access and acceptance realizing true potential”.

Although India is one of the most significant emerging markets, there are challenges around product quality and regulatory complexity. The new guidelines will have a positive impact on the SME industry in India.

The pharmaceutical distribution system in India is undergoing a paradigm shift and we will continue to see improvements, through compliance with the latest standards and the implementation of the latest technologies for supply chain management.

In an interview with Cold Chain IQ, Bhusan Mohapatra, Head-Commercial Indian Immunologicals, noted that the predicted growth in the Indian vaccine market indicates a lot of opportunities for those involved in the cold chain, from the manufacturer to logistics service provider, the technology provider to trace & track and related software provider.
The government of India has taken various initiatives for better food management which are also encouraging factors for the Indian cold chain industry.

The government of India has decided to open various mega food parks which will require both; temperature controlled vehicles as well as temperature controlled warehouses. By allowing the 100% FDI in the cold chain industry, government has shown its support towards the development of cold chain infrastructure. Till now these initiatives have not been able to make remarkable changes but in medium term these initiatives are expected to make positive changes.

These initiatives are likely to make the market value of India cold chain market to grow at a healthy CAGR of around 28.7% during the period 2012-2017. This will make the value of cold chain market in India to touch the whooping figure of around INR 640 Billion (USD 11 Billion) by 2017. There are large numbers of small players present in the Indian cold chain industry but have failed to meet the increasing demand from various sectors due obsolete technology; some of the well-known organized companies operating in the Indian cold chain market are Snowman, FHEL, RK Foodland Pvt. Ltd., MJ Logistic Services Ltd. etc.
The current pharmaceutical supply chain scenario in India is extremely complex. One of the main reasons for this complex supply chain environment is the presence of more than 55,000 retail pharmacies which are spread across India. In India, large number of medicines and other such facilities are required to be transported to the distant areas through poorly connected routes. Due to the poor transport facilities in India the cost of drugs is much higher than the USA or Europe. About 1/3rd of the revenues generated by the drugs companies have been spent on the transportation only.

The problem of poor supply chain management becomes even more severe when the temperature sensitive drugs such as Polio vaccines, life saving drugs, etc. are required to be transported to the far flung areas. Hence the presence of proper supply chain management which also includes the temperature controlled vehicles and store houses have become important for the pharmaceutical industry of India. Now companies as well as the government have started taking initiatives to transport the medicines in such a manner that the drug or vaccines reaches the target area without losing its efficiency. Currently the market value of temperature controlled vehicles which are deployed for the transportation of pharmaceutical products is more than USD 3.8 Million, which is likely to reach at around USD 17.1 Million in next five years. Under the 12th Five Year Plan (2012-2017), The Department of Pharmaceutical has asked for the assistance of around INR 50 Crore (USD 9.2 Million) for setting up the cold chain facilities across India. The market value of vaccine market in India is around USD 180.5 Million, which is growing at a healthy pace of around 25%-30% annually. Vaccines require the support of temperature controlled environment right from the point of their initial stage of production to their final distribution. This indicates the unexplored potential for both the domestic as well as the international players which are present in the cold chain management system.
In India, the cold chain logistics sector is getting ready for the growing number of large multinational corporations providing their global brand products in India. Several new state-of-the-art cold storage warehouses and logistics operations are emerging, to help these international food and pharmaceutical companies to maintain product quality, and ultimately, their global reputation.

The reputational risk is what renowned Indian entrepreneur Kiran Mazumdar Shaw, chairman and managing director of Biocon, referred to in an article in the Indian daily business newspaper, the Economic Times recently. She referred to the damage to the reputation of a major Indian drugs manufacturer due to questions about the product quality.

Speaking in the newspaper, she said, “Companies shouldn’t compromise on quality, compliance and IP.” She also added, “We also need to see better harmonization of the Indian regulatory system with those in the US and Europe”.

This indeed was a debate at the recent Cold Chain India conference in Mumbai. Attendees were conscious of the fact that companies needed better guarantees of product compliance, and that good distribution practice (GDP) needed to be considered more widely in India.

It was also clear that only the large companies that could control their own cold chain were able to guarantee the temperature of a product through the entire product lifecycle. Several instances were cited of companies that relied on multiple transport companies or third party logistics providers, and were unable to assure that product temperature was maintained within required temperature ranges.

Continued...
According to Indian farmers quoted in an article in The Hindu newspaper, in the food sector, 30 percent of food wastage is due to issues related to transportation, and this includes issues related to cold storage.

At the conference, several speakers spoke about the need for technology to support companies with ensuring compliance. By ensuring compliance, they could ensure product quality and safety.

In a country like India, where social media and mobile connectivity is widespread, it only takes one incident where a product doesn’t meet consumer expectations, for the news to spread rapidly and damage the reputation of a company, product or brand. This is what Kiram Mazumdar Shaw was referring to in her article – the reputational risk for a company is high if product quality is compromised.

**Evidence and confidence needed**

In order to enable this assurance of product quality and safety, there was a healthy debate about the need for both evidence of product integrity and confidence in product integrity/quality (a summary of some of this debate can be found in this article in FnBnews).

This requires technology solutions that could provide real-time end-to-end visibility in the entire cold chain. Several speakers referred to the need for such solutions, and there were references to Dyzle’s real-time monitoring and analytics solution, that both provided the evidence of temperature (or other parameter) integrity, as well as providing real-time alerts for corrective action if a digression occurred.

In summary, India’s product and brand owners recognize the need to enhance all aspects of their cold chain so that product safety and compliance can be assured. The major multinationals and major retailers are already aware of this (major local brand Amul was quoted as a good example of having a sophisticated cold chain).

While cultural attitudes of the labor workforce in the industry need to be addressed (eg. with truck drivers understanding of the importance of maintaining power for the trucks they are driving), there is work being done by third party logistics companies and warehouses to install state-of-the-art cold chain storage and logistics. Once this infrastructure is available and cultural issues are addressed, India does have the chance of addressing a significant portion of the wastage that happens in the cold chain, but more importantly, to ensure that company and brand reputations are maintained more consistently.
LEARN MORE ABOUT COLD CHAIN IN INDIA
At the 11th Cold Chain Global Forum

Attend These Sessions at the BRIC Focus Day at the 11th Cold Chain Global Forum:

11:00 AM - Complying with India’s GDP Guidance
Interactive Discussion Session

1:45 PM - Good Distribution Practices in India – From Regulation to Practice
Surendra Deodhar – Head of Materials Management – Reliant Life Sciences

4:00 PM - Case Study: Successfully Navigating Indian Regulations
Steven Moses – VP Technical Operations – NovaRx

REGISTER NOW
FOCUS ON RUSSIA
An in-depth discussion of the long overlooked Russian market.

Cold Chain logistics and distribution is one of the most significant and complex challenges for the biopharmaceutical industry, owing to the importance of keeping products such as vaccines, serums and test drugs at a stable temperature.

This is a concern for biopharmaceutical supply chain stakeholders all over the world, but can be particularly demanding for those operating between Europe and Russia, where there are many factors to consider and potential obstacles to overcome.

Customs Clearance

Customs clearance procedures in Russia can be complicated and exhaustive, particularly for unusual and potentially sensitive items such as pharmaceutical drugs.

There are several stages of the clearance process, such as the checking of licenses, permits and other required documents, and the implementation of customs fees and duties or confirmation of exemptions. Officials also have the power to conduct physical inspections to check any risks that may have been identified.

Among the potential causes of delays that pharmaceutical companies should be aware of are discrepancies between documents and the items being transported, incorrect documents and special control categories.

Particular regulations are in place for the transportation of medicines. Registered products must be accompanied by a registration certificate, while unregistered drugs require permission from the Ministry of Health.

Continued...
Clearances can only be completed by a consignee - a company registered in Russia.

**Good Distribution Practice**

Another potential concern for organizations transporting temperature-controlled pharmaceuticals between Europe and Russia is good distribution practice (GDP). This area of regulation follows on from good manufacturing practice and aims to ensure that the level of quality assurance delivered in the production phase is maintained throughout the distribution network.

GDP requirements state that storage conditions are observed at all times, including during transportation, and that contamination from other products must be avoided.

Companies are also obliged to arrange adequate turnover of medicinal goods and to store their shipment in a safe and secure manner.

Furthermore, a tracing system should be implemented to guarantee that any defective products can be tracked and recalled.

**Courier Selection**

According to World Pharmaceutical Frontiers, the selection of an experienced and competent courier is one of the key aspects of executing successful cold chain transportation of pharmaceuticals in Russia and the Commonwealth of Independent States (CIS).

One of the first considerations for the company sending the shipment is whether the delivery provider has past experience in moving sensitive items to relevant locations in the region.

Can the courier guarantee timely delivery of the products? Is it aware of the crucial nature of avoiding deviations in temperature? Will the shipment be quickly and responsibly delivered directly to the appropriate recipient? These are all questions that must receive satisfactory answers before selecting a delivery company.

**Storage**

Ensuring that temperature-sensitive pharmaceutical products reach their intended destination safely is a primary concern, but it is equally important to consider how they will be stored at the other end of the chain.

Continued...
Conducting preparatory quality assurance checks can help to guarantee that warehouses and other storage facilities have the appropriate amenities and operating procedures to protect sensitive drugs or clinical supplies.

Key Performance Indicators

Examining key performance indicators (KPIs) for local warehousing and logistics providers is the most important step to achieving success in temperature controlled deliveries, according to World Pharmaceutical Frontiers.

Companies can request KPIs spanning a period of two years to learn more about the likelihood that a local firm can handle incoming and outgoing shipments in a timely fashion and avoid product losses. This approach can also offer an insight into the key task of temperature control and how successfully it is likely to be executed.

For More On This Topic:

Listen to a podcast with Jan Slezak, Logistics & Supply Chain Manager at NEOMED discussing the biggest challenges to distribution in the Central & Eastern Europe (CEE) region.

FYI:
The Russian pharma market is expected to be worth $31.15 billion by 2016.*

*Frost & Sullivan
CUSTOMS CLEARANCE IS THE BIGGEST CHALLENGE IN RUSSIA & CIS
PharmaIQ.com

Results from a Cool Chain Logistics survey conducted by Pharma IQ revealed that although authorities are making progress in boosting the appeal of their pharmaceutical market, not all are yet convinced about the cool chain infrastructure it has in place.

Some 58% of those polled said they currently have an office located in Russia or ship temperate-controlled shipments to the country, with a further 11% planning on doing so within the next 12 months. However, almost a third (31%) currently had no plans to start shipments to Russia in the future.

Looking deeper into the issue, problems start to emerge with the current cool chain provision in the country – the main one in an area where the government does have the power to improve the situation.

For those participants already shipping temperature sensitive products to Russia, customs clearance and border crossing were named as the biggest challenge in cool chain delivery by 58% of those surveyed.

The issue could be connected with the decision by Russia to favor domestically produced pharmaceuticals over international imports, which has led to the signing of some lucrative deals.

Other issues raised in the Pharma IQ survey included the lack of availability of specialized transport, as mentioned by 23% of those polled, which is a particularly big issue is given Russia's large size. Some 11% cited issues with the availability of warehousing, while 8% expressed concerns about security.
Bert and Isabelle Lamaire, the owners and chief executive officers of Soncotra, a specialist in international road transport to and from eastern Europe, the CIS and the Balkans, recently explored the complexities of the Eastern European market in a free webinar with Pharma IQ. They covered topics including the benefits of track-and-trace transport technology with correct temperature conditions and security on the road.

An Increasingly Complex Market

Announcing its March 2013 revisions to rules regarding the transportation of medicinal products, the EU stressed that the modern distribution network is becoming ever more complex, with many different players involved.

The body said it is of "key importance" that the quality and integrity of pharmaceuticals and medicinal products are maintained throughout the supply chain, from manufacturer to patient. By updating its guidelines, the EU intends to provide the necessary tools to help wholesale distributors improve their operations and to prevent falsified medicines from entering the delivery network.

Among the changes is a new requirement for companies to maintain a system clarifying responsibilities, processes and risk management principles with regards to wholesale activities.

Operators are also required to keep suitable documentation to prevent errors from spoken communication and to maintain adequate premises, installations and equipment to ensure proper storage and distribution of products.

Continued...
One update of the EU regulations specifically refers to the need for temperature conditions to be kept within acceptable limits during transport and for medicines to be protected against breakage, adulteration and theft.

**A Market of Great Potential**

There can be no denying the challenges that face companies operating in the pharmaceutical cold chain logistics market, but equally irrefutable is the potential for growth and success in the industry, particularly in CIS and CEE countries.

Professional services firm PricewaterhouseCoopers (PwC) has published a series of studies entitled Transportation & Logistics 2030, the fifth volume of which focuses on emerging nations, asking if the sector is set to see “new hubs, new spokes and new industry leaders”.

The report focused on seven developing markets, including Russia, which boasts a significant geographical advantage in its location between east Asia and Europe.

This factor has not traditionally had a big influence as Europe and Asia have traded over the seas, but Russia is expected to strengthen its position in the industry in future by developing its road and railway networks.

According to PwC, the Russian government sees transportation and logistics as one of its key priorities for the economy and is making investments worth billions of dollars in projects such as the development of Krasnoyarsk and Ulyanovsk airports.

In April 2013, the Lithuanian city of Klaipeda hosted the ninth international Belarusian-Lithuanian economic forum, where topics of discussion included bilateral relations in transportation and logistics, the Belarusian Telegraph Agency reported.

The government of Belarus is also thought to have held talks with Azerbaijan regarding potential joint transport projects, underlining the potential for infrastructure development in the region.
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At the 11th Cold Chain Global Forum

Attend These Sessions at the BRIC Focus Day at the 11th Cold Chain Global Forum:

9:00 AM - Hard Distribution: How to Successfully Ship Products to Siberia
Andrey Kukarenko – Co-founder and Principal Participant in the National Non-Commercial Association - Cold Chain and Biotechnologies Partnership

11:00 AM - Partnerships Matter: Cool Chain Management at Each Level
Elena Adusei – Distribution Director, Russia & CIS Cluster – Johnson & Johnson

3:20 PM - Developing a Global Excursion Temperature Management Process
Jamie Pope – Quality Manager, Controlled Temperature Distribution - Genzyme

REGISTER NOW
11th Cold Chain Global Forum
September 30 – October 4, Chicago

Download the Brochure