



Pharma Market Growth and The Cost of Doing Business

May X, 2010



Agenda

- Pharma Market Overview
- Pharma Market Trends
- Cold Chain Complexities
- Freight Overview
- Pharma Costs and the Cost of Loss and Excursions
- Risks in Cold Chain
- Solutions
- Q&A

Pharma Market

- Substantial growth in the development of high value temperature sensitive products.
 - Pharmaceuticals
 - Clinical Trials
 - Biotechnology Products
 - Hi-Tech Materials
 - Medical Devices
 - Reagents



- 70% of drugs in clinical trials are temperature sensitive (FDA)
- Vaccines and Biologics are causing an explosion in demand

“Between 2004 and 2005 the biopharmaceutical market grew 17.1%, much faster than the traditional pharmaceutical market - which grew about 7% over the same time frame.” Am. Pharmaceutical Outsourcing Apr/May 2008

Cold Chain Market Trends

- Pharmas are seeking partners who can provide superior performance, in transport, product safety and service.
- Pharmas are looking for methods/vehicles that will decrease their risk of loss during transportation without complex servicing procedures and costs.
- Industry is requiring ever greater regulatory compliance.
- Pharmas are asking to expand their transportation options. No longer room for only one or two suppliers and one business model.
- Reputations are made or broken based on performance.

A new source of revenue exists for those who can provide a risk free solution that meets regulatory compliance and offers customers routing options for transport of their sensitive cargo.



Cold Chain Complexities

“...typical international transportation can easily consists of three airports, three ground handlers, two different airlines, two truckers, one freight forwarder and one customs broker with two different country regulations in three different climate zones.”

www.futurepharmaus.com, Q1 2007

Pharma Freight Overview

- 40% of the world's overall freight (by value) is shipped by air.
- Approximately 5% of air cargo volume (kgs) is perishable goods of which healthcare products represent less than 5%. ----- However, when it comes to value, the majority of perishable freight value is attributed by pharmaceuticals and biotech products*
- An RKN Cool Container filled with multiple boxes of a product, such as a recombinant erythropoiesis hormone, priced at approximately 500 USD/package, can have a sales value of 7.3 M USD with an estimated replacement value of approx. 1 M USD. --- However, a typical air transportation cost would amount to only 0.4% of replacement value and 0.06% of sales value.
- Cost is not always the most important driver in supplier decisions.

Pharma Industry Costs

Typical Pharma Costs

- **R&D**

- Development costs for new drugs that will reach more than 1B USD in sales, the R&D costs average >16% of sales*

- **Marketing and Sales**

- The costs for sales forces, as well as advertising campaigns, can exceed 30% of product sales**

Contrast that with...

- **Distribution**

- Distribution Costs are estimated to range from 1% to 3% of sales***
- Transportation costs account for approximately 40-50% of these overall distribution costs***

*Pharmaceutical Research and Manufacturers of America Industry Profile, 2008

**Annual Reports of Pharmaceutical Companies

***Interviews and Transportation Journal Jan 2005



Risk Factors in the Cold Chain

- Numerous factors have the potential to affect global cold chain shipments

- Inadequate Packaging
- Conditioning Issues
- Delays in Pick Ups
- Reefer Truck Availability
- Documentation Errors
- Routing Issues
- Weather Delays
- Airline Equipment Availability
- Lack of Training / Education
- Ground Handling Errors
- Customs Delays
- Exposure on Tarmac
- Inadequate Communication
- Dry Ice Availability
- Mechanical Issues
- Flight Schedules – Availability/Changes
- Pilferage/Damage
- Cold Storage Errors
- Regulations – IATA, TSA

The Cost of Losses

Product Losses:

- The US Vaccines for Children Program states an annual loss of **\$20 mil USD due to bad** refrigeration, expiration, and shipping damages. For a program valued at **1.7 B USD**, this corresponds to a damage rate of **1.1%**
- The interviewed experts from pharmaceutical companies indicated that they budget up to **5% of their sales as scrap, up to 30% of which can be attributed to logistics issues.**
- Also estimate that approximately **0.5% of transported goods are damaged during** transport through non-compliance to temperature guidelines.
- For a pharmaceutical company generating sales of **1 Bn USD**, this amounts to **5 M USD** sales value / **1.2 M USD replacement value (assuming Cost of Goods sold at 24% - industry average)**
- A pharma company with an antibody product portfolio estimated lost sales at 30% of distribution cost. Under the assumption of a \$1 Bn USD company with 2% of distribution cost, loss are > \$6M USD per year.

The Cost of Temperature Excursions

- In a small number of cases, **temperature excursions, leads to the complete loss of the freight.**
- In the **majority of excursions , the products can still be approved for patient use or at least for research.**
- A mid-sized pharmaceutical company, estimates the **overall effort to handle cases with temperature excursions in the logistics process at up to 180 full working days per year over different headcounts, corresponding to personnel cost of up to \$100K USD.** This does not include the time and resources required by other parties in the cold chain.
- Higher insurance premiums.

Results of Cold Chain Risks

- Compromised cold chain and temperature excursions can result in:
 - ***Jeopardized patient safety***
 - Product efficacy issues
 - Product losses
 - Additional expense of investigations
 - Non-compliance to regulations/standards resulting in investigations, fines, sanctions, plant shutdowns, etc.
 - Impact to corporate image and reputation
 - Process and supply chain disruptions
 - Financial consequences

Solutions



- Many solutions on market:
 - Dry Ice RKNs and RAPs
 - Active or battery powered heating and cooling RKNs
 - Thermal blankets
 - Passive Pallet Shippers
- Active or battery powered heating and cooling RKN
 - Best for challenging environments where extreme temperatures are a factor
 - Ideal for lanes where ramp times are difficult to control or handling might be an issue
 - Optimum for long duration shipments where customs or regulatory clearance may be an issue.
 - Does not require temp controlled transport.

AcuTemp[®] RKN

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