

Logistics demand attention as outsourcing picks up

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The European Medical Agency (EMA) recently raised concerns that since many sources of active substances for life-saving medicines are now wholly located outside Europe, it is of high importance that an efficient and standardized supply chain is maintained in all the countries through which the shipment is routed.

The agency pointed out that globalization of manufacture has continued to increase in importance and many medicinal products have extended manufacture and supply chains, which increases the risk of supply disruption, including new vulnerabilities.

Multiple manufacturing sites are not the only factor that raises concern over safety of the drugs circulated in market. The focus of the industry is gearing towards biopharmaceutical products that include blood plasma, insulin, vaccine or other biological pharmaceuticals that need tailor-made shipping services at all places and time.

The EMA notes that disruption in supply of medicines can lead to failure to treat; the use of less desirable and often expensive, unfamiliar alternative medicinal products; an increased potential for errors and poorer patient outcomes caused by absent or delayed treatment or incidence of preventable adverse events associated with alternative medicinal products or dosage forms.

Taking note of such instances, implementation of an effective supply chain system enables pharmaceutical companies to manage inventory levels to match current and future demand of products and support complex replenishment and logistics processes.

Mr Fred Bauman, vice president, Industry Strategy, JDA Software, supply chain management and software company, shared in an interview with BioSpectrum that because of lower production of new drugs and drop in demand, the R&D expenses are rising. By 2013, the industry will experience patent drop off. To cut down the cost, pharmaceutical companies are looking at outsourcing the supply chain strategies.

Supply chain solutions for biologic products need specific infrastructure and careful handling during shipping. Swiss company Envirotainer provides active temperature control for air transportation of temperature-sensitive healthcare products. The

company provides containers for air cargo on a rent-it-when-you-need-it basis through its global network and related services that ensure correct temperature throughout the transportation, from loading to delivery.

In an interview, Mr Gustaf Ljunggren, CEO and group president, Envirotainer, mentioned that more than half of the total flight time of drugs is spent on the ground. "That's where the most common risks occur, due to wide variations in ambient temperature. Envirotainer's solutions are designed to handle these uncertainties. Active sensors monitor the temperature in order to maintain the required conditions inside the container. And data monitoring and documentation ensure to follow up the exact status of shipment."

India manufactures majority of the world's total vaccines. Also, domestic biotech companies are aggressively looking to tap the biosimilars space with the help of a strong logistics set-up that is based on collaborations and partnerships. DHL, along with the Organization of Pharmaceutical Producers of India, drew the attention of industry in 2012 about the need of strong connection between biotech companies and their need for logistical support.

Mr Christoph Remund, CEO, DHL global forwarding, India, spoke to BioSpectrum about a white paper, 'Transforming Life Sciences Logistics in India', that talks about the competitive landscape of the life sciences industry and analyzes how logistics can be a crucial enabler of the growing life sciences sector in India. The study highlights 12 assets and enablers that need to be implemented in order to achieve world-class life sciences logistics in India. It includes setting up a dedicated pharmaceutical zones at airports, goods and services tax implementation, faster co-ordination amongst all ground handling agencies, multi-user warehouses and shared reefer vans and ocean freight containers, maintaining the supply chain integrity by using latest technology, such as RFID, GPS and anti-counterfeit equipment.

Talking about the challenges while managing the shipment of crucial drugs, Mr Ljunggren mentions that besides airport, the key challenge for is dealing with airport officials, authorities, customs, freight holders and ground holders that together can create impact on time and temperature of the product. The entire management of airport handling team needs to know what the special service is all about.

Handling the challenges

As a strategy to safeguard biologics from any exposure or mishandling, Envirotainer has developed its own quality assurance system that ensures quality standard of each airport for delivering the service. If certain airport does not comply with the quality measures, they are not qualified.

"Moreover, one cannot see the product getting damaged or spoiled like in perishables. Therefore, the difficult part that we face is to get everyone understand the crucial requirement of quality standards, the knowledge and believe in our requirement," says Mr Ljunggren.

Mr Brian Kohr, president and CEO of US-based AcuTemp, mentions in his website that process of effectively transporting temperature-sensitive items, such as pharmaceuticals and biologics, is a multifaceted endeavor, necessitating stable, reliable packaging capable of maintaining required temperatures for the duration of a journey, as well as coordinated communications between all parties along the cold chain transportation route. AcuTemp specializes in temperature-controlled shipping services.

"With the emergence of massive pharmaceutical and life sciences markets in China and India, adjustments in cold chain strategies and regulatory guidelines have been necessary in order to assimilate these markets on both infrastructural and logistical levels. Largely due to expansion of vaccination programs and increased demand for the latest life sciences products in China and India, the growth rate of Asia's cold chain market is projected to be almost double of the rest of the world over the next few years. Booming cold chain demand in Asian markets adds urgency to ongoing efforts to streamline the cold chain distribution process throughout Asia and to increase the efficiency of its cold-chain-related infrastructure," he mentions on his company's website.