Is there a need for SCM standards for transporting dry pharmaceutical products?

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The Indian pharmaceutical sector has witnessed an increase in demand for pharmaceutical products due to the demographic shift. To ensure that the needs are met, the Supply Chain Management (SCM) needs to be strong. In this context, do we need SCM standards while transporting dry pharmaceutical products?

Dr Amita Birla
Associate Director - Clinical Operation, Karmic Lifesciences

Yes, definitely there is a need for better SCM for dry pharmaceutical products as this is one sector that is not paid much attention to. We believe that if it is vaccine it needs to be transferred at a particular temperature; if it is a tablet it can be transported under any circumstances and temperature. However, this is not the case. Temperature is not given the due importance. Today, before any product is released stability data is established, which includes the temperature, humidity and other factors that the product can withhold. When the product is being transferred and the range of temperature is not maintained, it can also have an effect on the end user. Hence, it is of critical importance that the SCM standards be maintained for dry products. We need to force our regulators to see to it that even this comes under the purview and the dry pharmaceutical products are transported appropriately with the required temperature. However, at Karmic, we ensure that all the standards are maintained at all levels.

Hemanth D P
COO – Hub Development, Cargo and Free Trade Zone, GMR Hyderabad International Airport Ltd

Any medicine intended for human use or veterinary product administered to food producing animals, presented in its finished dosage form or as a starting material for use in such a dosage form, should be controlled by pharmaceutical legislation in both the exporting and the importing state. Storage conditions for pharmaceutical products should be in compliance with the labeling, which is based on the results of stability testing. Special transport and/or storage conditions should be stated on the label. If a pharmaceutical product is intended for transfer outside the control of the manufacturer's products management system, the name and address of the manufacturer, special transport conditions and any special legal requirements including safety symbols should also be included on the label. Packaging materials and transportation containers should be suitable to prevent damage of pharmaceutical products during transport.

Parag Risbud
VP - Logistics, Avalon Consulting

The Indian pharma sector is expected to grow rapidly. Today, it is nearly $ 18 billion and is expected to reach $ 60-70 billion by 2020. Also, the global pharma opportunity is approximately $ 75 billion, which is growing at a rate of 15 per cent CAGR. With the growing pharma exports the industry is also facing challenges with respect to the SCM system. With the foreseen potential in the bio-pharmaceuticals segment the cold chain segment will further gain momentum. Today, the most important aspect of pharmaceutical logistics is the integrity to monitor and control the temperature of products during storage and transportation from origin to definition. It is the responsibility of all supply chain participants to maintain the safety and efficacy of pharma products. Considering that cold chain requires significant capital investment and also has incurring operating expenses, the viability of expenses on an ongoing business is always a challenge. However, the logistics service providers are gearing up to meet the demands and the regulated protocol. Hence, in my opinion having standards for dry pharmaceutical products is extremely important and the industry is trying to change its approach to ensure the products are delivered in the right quality and temperature.

Surendra Deodhar
Head – Material Management, Reliance Life Sciences Pvt Ltd

A package during its journey from manufacturer to the consumer may get subjected to various abuses including impact, vibration, pressure, tilt, temperature, humidity, light rays, X-ray and so on. Different formulations react differently to each one of these factors. It is also worth noting that a package gets handled by several people till it is finally consumed. And it is not fair to expect that all these people in the chain to have competence to exercise judgment about handling of packages with due consideration to all the factors. Hence, the need for standards. Packaging solution deployed by a pharma company is not just regulation oriented. But in addition depends on several technical as well as soft cultural aspects such as appetite for risk, strategy to 'just meet' or 'exceed expectations' of the stakeholders, respect for innovation and so on. It also depends on factors such as the customer profile, rural or urban market.

Standards provide a common denominator through all this variety. However, standards per se are not effective, unless backed by measures like training and audits.

V Gopalakrishnan
Counsellor, Confederation of Indian Industry

Temperature sensitivity is not the only concern in pharma logistics. Besides temperature, there are many other factors like environmental contamination (air, moisture, particulate penetration etc) and optical interference (excess light impact), which even the dry pharma products have to be protected from. Else, their microbiological integrity and pH stability would get affected, thereby making drastic changes to the drug. It would be a risky call trying to address these constraints at the transportation stage, as it involves multiple handling and adverse transport conditions, which cannot be monitored economically. Hence, rather than introducing standards and regulations in transportation of dry pharma products, it should be done within the factory itself, through effective packaging solutions. Else, it would still worsen the logistics cost. If the external temperature is crossing the stability level of the drugs, then it would lead to volatility, thereby affecting its physical and chemical properties. To avoid this, preservatives are added to it after thorough analysis, so as to widen this tolerance level of the medicines. Besides this, there are packaging solutions readily available in the market to provide further thermal protection to the drug. Hence, adding more regulations or stringent packaging conditions is not necessary, as it would just complicate the whole supply chain, rather than adding value to it.

Editorial take

For any product to be transported from one place to the other having a strong SCM system is of critical importance. The importance of a proper SCM system increases further while dealing with dry products as the damage may not be visible but the irregularity of the temperature might cause damage to the produce. Hence, it is of critical importance to have SCM standards for dry pharma products.