

Heating Up

While a short stop on the tarmac is a necessary evil for pharma transportation, fluctuating temperatures can cause complications. Establishing a strong cold chain is key

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One cannot complain that cold chain for the pharmaceutical and biotechnology industries is lacking challenges – shipping products globally by airplanes or ocean freighters, for instance, is a hot discussion topic. This obstacle is not new for products and vaccines shipped in the 2-8°C range, but for other expanses, like 15-25°C, it has a considerable impact.

Almost 50% of temperature excursions take place on the tarmac of an airport; thus, a compliant shipment is important. The only way to maintain product quality is to keep it in prescribed conditions until the moment of use. No patient can benefit from an expired treatment or an inaccurate blood sugar level measurement because the strips were not kept in the right conditions. Even worse, products could become harmful instead of helpful.

From a cost perspective, as well as a qualitative one, the use of ocean freight is transcending that of air transport. Ocean shipping is not only considered for low-value products, but also for high-value ones, such as vaccines.

The challenges differ in each of the various modes of transportation. A growing number of companies are using sea freight solutions for traditional pharma and even for their cold chain (2-8°C) products. Their view is that, while ocean takes more time, temperature compliance is at a higher level.

Regulation Challenges

In 2013, Europe issued the new Good Distribution Practice (GDP) guidelines, which intended to ensure that today's global supply chains keep the product in the right conditions and safe for



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patient use. Especially in the area of international temperature-controlled shipments, this has consequences. The importance of compliance is increasing in the 15-25°C area because manufacturers are required to ship as labelled, which adds an obstacle where lower-value products are also frequently shipped. The mandated equipment and transit station validation is an area that needs attention and investments.

Pharma in the MENA Region

Notably in the Middle East and North Africa (MENA) region where high temperatures are common, leaving a shipment on the tarmac can result in an excursion, meaning compliance is more difficult for developing facilities and services here. In past years, investments have been made by logistics service providers, brand owners, airlines, airports and others to elevate the provided services to the required level and avoid these issues.

Governments are keen to streamline administrative processes such as

customs, allowing for better product availability in their country. At many airports in the region, special processes and facilities are installed to improve the transfer, such as in Dubai, Abu Dhabi and Sharjah. A growing number of providers expand their services with their own investments or ones done in partnership with local players. This is an encouraging trend, but it will take a couple of years to develop a truly competent and competitive landscape.

Market Strategies

More healthcare companies are looking for the opportunity to centralise operations in this region. Dubai – with its airports and seaport, in combination with the bonded possibilities in the Jebel Ali free zone – provides a home base for many organisations. Instead of bringing products from Asia into Europe and then shipping them back into the 23 MENA countries, an abundance of firms select Dubai as their regional warehouse location. This area can then also serve the broader region.

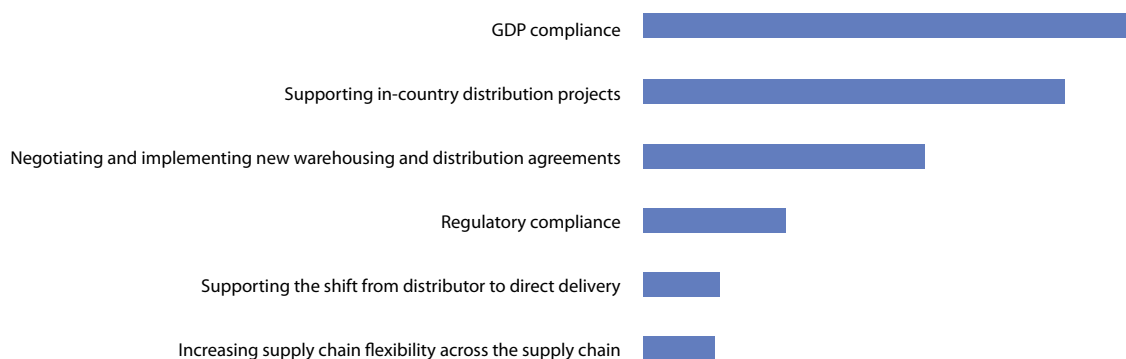


Figure 1: Top priorities of supply chain executives in the next 18 months

Source: MENA Healthcare Survey 2016, BCI Global

This trend was first seen in the technology sector where products are often manufactured in the Asia Pacific (APAC) region. The route to market was initially via Europe, then companies started to use the Middle East as a hub; now, pharma is starting to follow this path. Since the manufacturing bases are shifting from traditional countries into APAC ones – including Singapore, China and India, to name a few – and with the growing number of biotech company centres in locations such as Japan, Korea and Singapore, more products are being produced in the East. This allows for more streamlined and centralised supply chain models, with an inventory position in the Middle East. The priority list, as retrieved from a survey carried out in 2016, clearly indicates the resulting challenges for supply chain executives in the region.

The increasing demand for additional and larger facilities in the MENA region also attracts investors both locally and internationally. Having a hub in Dubai, for example, also allows brand owners to better support their sales organisation in surrounding countries. Mode changes become possible by means of using road instead of air movement from the central

MENA warehouses to the affiliated locations. Direct models from passing distributors will become more prominent in the near future.

MENA Facilitators

Several enablers will support the development of the MENA supply chain into a more mature state:

Governmental Efforts

Many governments in the region are well aware of the importance of product availability at the right quality level for the people in their territory. In a number of countries, they are stimulating the developments needed, such as the effort to support knowledge exchange and the streamlining of certain administrative processes.

Regional Hubs

The trend towards using more regional solutions to serve a cluster of markets is supporting the development of facilities and service providers in the MENA region. Due to the heat, all facilities should be able to support products in all temperature ranges. Many companies have already established such a hub in the

Middle East, either with third-party logistics (3PL) or by setting up their own facility. To operate these hubs, the support of inbound and outbound transportation is also changing. The growing focus on this area and the increased scale of the business leads to investment in new services and the availability of facilities and equipment.

Air/Ocean Freight

Temperature-controlled shipments are challenging worldwide, especially in MENA. Most of the weather-related excursions are experienced at hand-over points such as airports. Airlines and ground handlers are asked to provide GDP-compliant facilities to support the goods flow. The first hurdle is the provision of packaging and equipment, including reefers or airfreight containers. Repositioning of this equipment is, and will always be, a challenge and a cost-increasing factor.

GDP facilities in airports need to be compliant. Based on the proper procedures and fast processes, products can be handled and cleared by customs, adhering to the maximum lead-time and temperature levels that the packaging can support.

“ Both warehouses in the Middle East and GDP hubs at airports are faced with the tough task of keeping the inside temperature within range ”



Image © Buck Consultants International

An example of a container based on phase change technology

Temperature-Controlled Packaging

Many packaging solutions still require a person to handle the containers and the power connections at the tarmac. Human interface is, by default, the main cause for excursions. To overcome the temperature maintenance challenges – not only at 2-8°C, but also for 15-25°C shipments – the packaging industry is very active in developing new technologies such as phase change solutions, which are less dependent on human intervention and can be used on different transport modes without any interference with the cargo. This development will bring improvements in reaching a controlled and compliant cold chain without excursions. Especially in a region like MENA and countries where cold chain infrastructure is less developed, these kinds of innovations are essential in finding a solution.

Infrastructure

Both warehouses in the Middle East and GDP hubs at airports are faced with the tough task of keeping the inside temperature within range. The outside heat in summer causes a significant cost increase for operating such a facility. An upgraded building structure and modern construction techniques can be considered to keep the running expenses of the air conditioning within reasonable limits. The focus is too often on avoiding high investments. Existing buildings can be converted into temperature-controlled environments, but leave operations with high annual utility costs.

Another important point is the temperature distribution within the walls; validation and measurements at various levels and positions in the warehouse need to be tested and investigated to determine this. However, substantial differences between high- and low-placed pallets occur as well as between positions far away from a door or closer to a door. Averages here are not enough to prove compliance in a range. A thorough validation procedure should assure the right environment for the product in all corners of the warehouse.

Distribution

Particularly for road and final mile distribution, some development is required. Temperature-controlled trucking and the availability of equipment is still a big issue today. Furthermore, crossing borders by road is not always reliable, as the waiting times at the border between UAE and the Kingdom of Saudi Arabia, for example, do not support smooth and seamless pharma distribution.

The Future

The MENA region is a complex area. This is due to the specific situation regarding the safe delivery of temperature-controlled healthcare products to the end customer, as well as the focus on governments in the region allowing for a rapid and steep development.

Both brand owners and service providers are making significant

investments. Airlines and airports are planning for improvements to support the healthcare supply chain. Strong temperature-controlled management means maintaining the entire chain from beginning to end, which is only possible when all partners involved work together. If one believes the MENA area is an important asset to a long-term strategy, now is the time to act and set up such a system in the region. With the appropriate partners, ensuring a sustainable growth in the future is achievable.

About the author



Martin Gouda is a Partner of Supply Chain Strategies at Buck Consultants International and has over 30 years of experience

in international supply chain optimisation. He has worked in various roles at the strategic and tactical level in management and consultancy. Martin worked for a global 3PL for almost 10 years in various business development positions. In this period, he was responsible for breakthrough and step change projects with pharma companies. In the last three years, he was leading the healthcare sector on a global level. Martin is co-founder and board member of the Healthcare Logistics Forum.

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