EEA Response to the Commission consultation on Guidelines on Good Distribution Practice of Medicinal Products for Human Use

1. Introduction

Express Delivery companies are important providers of transportation services to the healthcare sector. The recently published report on the economic impact of the express delivery sector by Oxford Economics indicates that the healthcare sector represents 8% of the customer based on the express delivery sector.

More and more manufacturers and distributors of pharmaceutical products look for just in time transport solutions, time and day definite transport and delivery, allowing them to save cost on inventory and storage. This ultimately helps to reduce the cost of pharmaceutical products.

The distribution of medicinal products in the European Union is regulated by, inter alia, directive 2001/83/EC, implemented on the basis of the current guidelines on GDP (94 C 63/03). The European Commission (EC) has on 15th July 2011 issued draft guidelines for good distribution practice (GDP or the "guidelines") for a public consultation period open until December 31st 2011, with the objective of replacing the GDP guidelines last issued in 1994 in 2012.

2. Transport is different from Storage

The guidelines seek to tighten the definition of the term "wholesale distribution" (WD) – trading, brokerage and storage of medicinal products – so as to regulate the periphery of this activity that was not previously directly addressed. The draft guidelines use the term storage for medicinal product that was previously considered to be in transit and define any period of refrigerated storage of medicinal products and medicinal products held on a premises for longer than 24 hours as a regulated activity requiring a GDP authorisation on a site by site basis, subject to full oversight and inspection by regulatory bodies. The draft guidelines moreover do not clarify that "refrigerated product" excludes passive temperature controlled packaging such as isothermic boxes. The draft guidelines also suggest that loading, unloading and reloading should be subject to audit and approval procedures resulting from the new proposed GDP.

In practice, it is possible that goods, once handed over to a transportation company, do not continuously move and are temporarily staged in one of the transportation company's sites for more than 24 hrs during the transportation process. However, staging of goods – even if this is done in a controlled environment – is not the objective of the express transportation process. In addition, passive temperature controlled packaging is frequently used. Finally, goods also need to be loaded, unloaded, staged and transported during the process of being moved from origin to destination as defined on the waybill/shipping document.

Therefore, without a clarification, the proposed guidelines seem to require the transportation company involved in these steps to convert all its sites into WD compliant facilities. These requirements would significantly increase the cost of the medicinal product supply chains.

3. Solution

To allow the pharmaceutical sector to benefit from cost effective transportation, additional clarification of the draft guidelines is necessary to indicate that temporary staging – even if this is done in a controlled environment – during a transport service is excluded from warehousing or storage of medicinal products as defined by article 9.12 of the proposed GDP.

Furthermore, it should be clarified in 9.12 that passive temperature controlled packaging is excluded from the term "refrigerated products".

We also propose that the guidelines confirm that activities such as loading, reloading and unloading of shipments to move them from one form of transport to another (example: unload from a vehicle to load on an aircraft) are excluded from the provisions listed in 9.13, in particular when it does not involve opening the shipment and repacking of product.

The guidelines would also benefit from removing article 9.1 as article 9.4 already provides the necessary clarity on the need to ensure the provision of correct storage conditions as part of the responsibility of the distributor. Given that Article 9.4 sets the leading principle, it should in our view be move to the beginning of the elements listed under transportation.

4. Rationale

The rationale for supporting a specific distinction between staging goods during transportation and formal storage and warehousing under WD regulations is consists of the following arguments:

Quality: whereas quality and safety are two of the leading issues that the revised GDP seeks to address it is important to note that shipper (manufacturer or wholesaler) and transporter work with carefully prepared transportation solutions that already seek to prevent quality and safety issues.

The shipper's requirements are cemented in contractual agreements assuring the shipper's obligation to comply with its sector or even product specific regulations (e.g. the need for a temperature controlled environment).

It is in the transportation company's interest to comply with these standards to avoid liability. Further regulation of the transportation company is not required to achieve these goals.

Cost and efficiency: the ability to use express delivery networks for delivery of pharmaceutical products allows the healthcare sector to manage inventory and orders in an efficient way. It provides for predictability of transit and delivery times and efficient response to customer requests and orders.
It is clear that transportation of certain pharmaceutical products requires special procedures related to temperature control and product integrity. Treating all shipments in an identical fashion and having to comply with the highest common denominator would however result in additional cost for

transportation of products where alternatives are available and can be covered in the contractual agreement between shipper and the transportation company.

It would be prohibitive to use high cost transport for products that do not require sophisticated transportation solutions.

Cost-effective compliance with paragraph 9.4 is assured by contract through which the shipper may demand, for example: (a) the use of a validated container or (b) a combination of stability data and lane mappings, making paragraph 9.1 obsolete.

There would be considerable cost increases associated with this stricter requirement if paragraph 9.1 would be maintained. Controlled condition ambient LTL transportation can easily add 30% or more to the current non-conditioned LTL costs. Specific condition ambient small package materials are many times the cost of currently used corrugate packaging for ambient shipments. In a market where billions of Euros are spent on the transportation of goods every year these percentages represent a significant increase for manufacturers and ultimately consumers to bear. (It is estimated that in 2011 greater than 10 billion Euros will have been spent on ground transportation and small package movement – data monitor survey).

Control: the exemption of staging during transport would apply to the transportation segment covered by the waybill/shipping document. The nature of express delivery networks is such that there is a clear contractual relationship between shipper and transportation company, represented by the waybill. Given that goods travel under one waybill from start to finish, implies that they are controlled by the express delivery company and generally travel fast and within a pre-defined timeframe.

EEA website:
www.euroexpress.org

Oxford Economics report, December 2011 - “Economic impact of express carriers on Europe”:
http://www.euroexpress.org/uploads/ELibrary/EEA_RA2011_LR.pdf