Revision of European Commission Guidelines on Good Manufacturing Practice for Medicinal Products

Public consultation on the revision of Annex 15: Qualification and Validation

23 May 2014

The European Express Association (EEA) welcomes the opportunity to contribute to the revision of European Commission Guidelines on Good Manufacturing Practice for Medicinal Products via public consultation**.** The express industry is a fast-growing business sector, and being a multi-modal operator, members of the EEA are impacted by policies which cut across a broad range of sectors, including healthcare policy.

Due to the sensitive nature and health impact of medicinal products, the safe storage and timely transportation of medicinal products is a high priority, and in this consultation response the EEA seeks to ensure a cautious and pragmatic approach towards the storage and transportation of medicinal products, which does not impose unwarranted administrative burden, or compromise our ability to meet the demands of the hospitals, pharmacies, and individual patients we serve.

The EEA wishes to focus on Section 5: of Annex 15, on Verification of Transportation, specifically paragraph 5.4.

Current Text (as featured in consultation document):

> *"Due to the variable conditions expected during transport e.g. delays at airports, continuous monitoring of any critical environmental conditions to which the product may be subjected should be performed."*

EEA Concern with Current Text:

The EEA believes that the current text may be interpreted as a requirement for *all* shipments of medicinal products to be fitted with a device to measure temperature, and result in an unnecessarily rigid and costly implementation of the GMP guidelines.

Devices which monitor temperature, such as data loggers, are currently used for the shipment of temperature-sensitive medicinal products and medical devices. Certain medicinal products however, are unaffected by positive or negative fluctuations in temperature ("stable to heat and cold"), and are therefore transported without such devices. Furthermore, the temperature conditions at certain times of year and throughout certain transportation routes can sometimes provide a safe temperature range for medicinal products which are able to withstand such fluctuations. This flexibility is an efficient and effective means of catering to the variations in the properties of medicinal products.

Alternative Text Proposed:

> *"Due to the variable conditions expected during transport e.g. delays at airports, a risk assessment that takes into account any possible critical environmental conditions to which the product may be subjected may be performed."*

The European Express Association – Square de Meeûs 35 - B-1000 Brussels - Belgium
Tel: +32 2 230 05 45 - Fax: +32 2 230 57 06 - www.euroexpress.org

Rationale:

The EEA proposes two key changes to paragraph 5.4:

In the aim of ensuring consistency between the EU's Guidelines for Good Manufacturing Practice and Good Distribution Practice (November 2013), the EEA recommends the replacement of "*continuous monitoring*" by "*risk assessment*". This more clearly reflects the important process of quality risk management which is detailed in the EU Guidelines for Good Distribution Practice.

Secondly, the EEA recommends the replacement of "*should be performed*" to "*may be performed*", in order to avoid interpretations that *all* shipments of medicinal products must be fitted with a device to measure temperature, even those which do not require such control for safety purposes.

Such a risk based approach will ensure medicinal product safety and effectiveness is protected, and that the transportation of medicinal products is not subjected to unnecessary financial and administrative burden.

EEA Commitment to Safety:

The EEA wishes to highlight that safety remains our unequivocal priority when transporting medicinal products. The implications of alterations to certain medicinal products as a result of external temperature conditions can have serious consequences for both human and animal health, and the EEA remains committed to providing state of the art temperature control solutions where and when required. That said, it is important to recognize that a number of medicinal products which are currently on the market do not require such handling, and are certified as unchanged and safe to use regardless of changing external temperature, posing no risk to the end user.

The European Express Association (EEA) *is the representative organisation for the express industry in Europe. The industry specialises in time-definite, reliable transportation services for documents, parcels, and freight. It allows European business to rely on predictable, expeditious delivery of supplies, thereby enabling them to attain and maintain global competitiveness. The express industry employs over 250,000 people across the EU and supports a further 175,000 indirect jobs in Europe through the supply-chain. The express industry's employees are widely spread across the EU.*