AESGP Comments on the draft Commission Guidelines on Good Distribution Practice of Medicinal products for Human Use

GENERAL COMMENTS

We in principle welcome the revision of this guideline although we note the increasing complexity and level of details of the guideline (from 4 to 32 pages) which does not seem to be in line with the principle of better regulation. We wonder whether this is really necessary to achieve the essential goal of guaranteeing that medicinal products are stored, transported and handled in suitable conditions and can defective medicinal products can be easily recalled.

In addition, we suggest that the scope of the GDP draft is explicitly stated to ensure uniform application and interpretation. We recommend that the document should incorporate a respective statement, for instance: "This document does not cover the distribution of materials such as pharmaceutical starting materials (active pharmaceutical ingredients (API) and excipients), reagents, solvents, process aids, intermediate products, packaging materials and labelling materials."

SPECIFIC COMMENTS

Introduction

The correct reference is *article 85b(3)* instead of 85a(3).

Chapter 3, section "Premises", No. 3.4

According to that request medicinal products not intended for the Union market should be kept in "*segregated areas*".

We fail to understand the reason for such requirement. In addition, it may be extremely difficult in reality to apply it in practice.

We hence suggest deleting it.

Chapter 3, section "Premises", No. 3.10

The first sentence reads: "*Premises and storage facilities should be […] free from litter and dust*".

In fully automated high bay warehouses this requirement cannot be guaranteed. Usually, such facilities are not accessible for employees. Dust cannot be totally prevented.

We propose the following change to the sentence: *"Storage areas should be clean, and free from accumulated waste and vermin."*

Chapter 6, section "Returned Medicinal Products", No. 6.10

The first sentence reads: "*Medicinal products requiring low temperature conditions …"*

This is not precise and what is really important here is the guaranty of the cold chain for medicines which need refrigeration.

We hence propose to rephrase as: “Medicinal products requiring **cold chain** conditions …”

Chapter 9 Transportation, Section “Principle“

Storage conditions refer to a long-term storage process. Transport conditions refer in contrast to a very small time frame, may differ where reasonably justified. Also No. 5.32 of this guideline differentiates between transport and storage conditions.

We propose the following changes: “Medicinal products should be transported in accordance with the storage conditions indicated on the packaging information. **With the exception of medicines that need to be refrigerated, these transport conditions may be different from the storage conditions, if justified**.”

Chapter 9 Transportation, Section Transportation, No. 9.12

The first sentence reads: “*Where transportation hubs are utilised in the supply chain […] for more than 24 hours […]*”

When trucks are unloaded on Friday and reloaded on Monday morning for further distribution, these ‘less than 24 hours’ cannot be guaranteed in all cases. As hubs are normally not run like pharmaceutical warehouses concerning documentation, pallet turn over handling, temperature mapping and calibration of temperature sensors, etc., hubs cannot be compared with a pharmaceutical warehouse – and the GxP level(s) differ from each other.

This cannot be fulfilled for all bonded storages passing the border. There is not commitment from the customs offices to work accordingly!

We propose the following change instead “**Storage of medicinal products in the hub for more than 24 hours should be avoided”.**

Last sentence reads: “*For refrigerated products any storage at a transportation hub for any period of time […]*”

Proposed change: In case **refrigerated products cannot be distributed without transshipping in hubs,** these hubs require premises comparable to pharmaceutical storage areas and have to be authorised like a wholesaler.

In addition, temporary storing for 24 hours or more should be acceptable in the supply chain. This kind of delays and waiting times are rather normal in a global distribution chain due to e.g. ferry schedules and should not be associated in such case with the obligation to have a wholesaler distribution authorisation.

Chapter 9 Transportation, Section Transportation, No. 9.13

If each manufacturer, who acts as a distributor, needs to audit every terminal and hub, it will cause an enormous and unfeasible amount of work.

Chapter 9 Transportation, Section “temperature control during transport”, No. 9.20

The first sentence reads: “ *If refrigerated vehicles are used, the temperature monitoring equipment used during transport should be maintained and calibrated at regular intervals or at a minimum of once a year. This includes temperature mapping […] and take into account seasonal variations”*

This requirement should be managed like any qualification process. The complete data should be generated once and re-qualification process would apply in case of significant changes. A risk based approach (ICH9) should be allowed. The adequacy of the (re-)qualification program can be assessed during audits.

We propose the following change: “If refrigerated vehicules are used, **adequate qualification and maintenance of the used refrigerated vehicles should be regularly evaluated by the contract giver**. This should include temperature mapping under representative conditions and take seasonal variations into account.”

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