

AESGP comments on the Commission Guidelines on the principles of good distribution practices for active substances for medicinal product for human use

AESGP represents the manufacturers of non-prescription medicines of either chemical or herbal origin at European level. Through its wide national and associate membership, it represents many small and medium-sized as well as multinational companies.

We have considered the draft guideline on the principles of good distribution practices for active substances for medicinal products for human use and we have the following detailed comments:

- Point 6: A management representative should be appointed in each distribution point, or, in distribution networks requiring many distribution points at least one management representative per country.
If a distributor of active substances holds a distribution authorisation for medicinal products (according to Article 77 of Directive 2001/83/EC) as well, the management representative can be the same person as the person named according to Article 79(b) of Directive 2001/83/EC.
- Point 9: Computerised systems are used for various processes carried out by distributors of active substances. Often ERP (Enterprise Resource Planning) systems are used as integrated software packages containing modules for various processes including modules/functions not related to quality and traceability of actives substance. To make clear that only the GDP related modules/functions in the computerised system should be validated, preferably on the basis of a risk assessment, we propose the following changes:
*"All documentation should be made available on request of competent authorities.
Electronic documentation **of GDP related processes critical to quality and traceability of active substances** should comply with Chapter 5.4 of Part II of Eudralex, the Rules Governing Medicinal Products in the European Union, Volume 4 (EU Guidelines to Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use – hereafter 'EU-GMP'), or its Annex 11 (Guidelines on Computerised Systems)."*
- In case controlled temperature storage is required for an active substance, it is evident that appropriate transportation conditions have to be ensured but controlled temperature transportation may not always be required. The best knowledge for that should be with the original manufacturer. Therefore, the transportation conditions to be maintained should be in accordance with the manufacturer's recommendations. This is also in line with the wording in the related paragraph of the EU GDP Guide for medicinal products, section 9.2.
We therefore suggest the following wording:
*"Active substances requiring controlled temperature storage should also be **transported under appropriate conditions as described by the manufacturer.**"*
- Point 15: We propose the following amendment:
*"Areas for receiving active substances should protect deliveries from bad weather during unloading. **This applies of course only if this requirement applies for transport as well.**"*

- Other comments: Distributors of atypical actives may not be aiming at meeting pharmaceutical-like standards for distribution as these substances are primarily used in other sectors (e.g. cosmetic or food industries). Other standards may be in use. Hence it would be extremely helpful to have the existing EMA [Q&A #6](#) amended to reflect the distribution aspect.

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