EUROPEAN ASSOCIATION OF CHEMICAL DISTRIBUTORS

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Fecc response to draft guidelines on GDP for active substances for medical products for human

Via email

To,

European Commission - DG SANCO (Unit SANCO/D/6)

sanco-pharmaceuticalsd6@ec.europa.eu

Brussels, 26 April 2013

Subject: Fecc response to draft consultation document on guidelines on the principles of good distribution practices (GDP) for active substances for medical products for human use.

The European Association of Chemical Distributors (Fecc) welcomes the opportunity to comment on the draft consultation document on guidelines on the principles of good distribution practices (GDP) for active substances for medical products for human use.

Fecc represents the chemical distribution industry in Europe and supports any initiative that strengthens the supply chain and increases the safety of active pharmaceutical ingredients (APIs). It is essential that appropriate good practices and guidelines cover the entire supply chain including manufacturing as well as distribution. As a representative for chemical distribution companies engaged in the supply chain of APIs we have reviewed the document and have the following comments.

PARAGRAPH	TEXT AS PROPOSED	PROPOSED REWORDING BY FECC	COMMENTS
DOCUMENTATION			
9.	All documentation should be made available on request of competent authorities. Electronic documentation 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*	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	Computerized 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

	Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use – hereafter 'EU-GMP'), or its Annex 11 (Guidelines on Computerised Systems).	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).	not related to quality and traceability of actives substance. For clarity only the GDP related modules/functions in the computerised system should be validated, preferably on the basis of a risk assessment.
PROCEDURES			
11.	Written procedures should describe the different operations which may affect the quality of the active substances or of the distribution activity: receipt and checking of deliveries, storage, cleaning and maintenance of the premises (including pest control), recording of the storage conditions *, security of stocks on site and of consignments in transit, withdrawal from saleable stock, records, including records of clients orders, returned products, recall plans, etc. These procedures should be approved, signed and dated by the person responsible for the quality system.	Written procedures should describe the different operations which may affect the quality of the active substances or of the distribution activity: receipt and checking of deliveries, storage, cleaning and maintenance of the premises (including pest control), recording of the storage conditions ***if special storage conditions are required by the manufacturer,*** security of stocks on site and of consignments in transit ***if stocked by the distributor or under distributor responsibility,*** withdrawal from saleable stock, records, including records of clients orders, returned products, recall plans, etc. These procedures should be approved, signed and dated by the person responsible	Storage conditions are defined / described by manufacturer in the product SDS (section 7) or/and on the Technical data sheet. The Fecc recommends that only special storage conditions requested by manufacturer are recorded (i.e Cold storage) by distributor. *Security of Consignments in transit*: the distributor can only be responsible for processes under his control.

		for the quality system	
RECEIPT			
15.	Areas for receiving active substances should protect deliveries from bad weather during unloading. The reception area should be separate from the storage area. Deliveries should be examined at receipt in order to check that containers are not damaged, all security seals are present and that the active substance and the consignment correspond to the order.	Areas for receiving active substances should protect deliveries from bad weather during unloading The reception area should be *clearly defined and a process should be in place to avoid mix-up.* Deliveries should be examined at receipt in order to check that containers are not damaged, all security seals are present and that the active substance and the consignment correspond to the order.	Fecc is of the opinion that reception area should be clearly defined from storage area to avoid any product mix up. It is suggested to add "clearly defined" as 'separate' may/ could suggest walls and doors
STORAGE			
18.	Active substances should normally be stored apart from other goods and under the conditions specified by the manufacturer (e.g. controlled temperature and humidity when necessary). These conditions should be monitored periodically and records maintained. The records should be reviewed regularly by the person responsible for the quality system.	Active substances should be stored apart from other goods *if there is a risk of contamination or mix-up* and under the conditions specified by the manufacturer (e.g. controlled temperature and humidity when necessary). These conditions should be monitored periodically and records maintained. The records should be reviewed regularly by the person responsible for the quality system.	Fecc agrees that active substances should be stored apart from substances especially if there is a risk of contamination or mix-up.
23.	Shortages that requires registered importers to notify relevant customers of any		Fecc requests that this should be explained further for more clarity.

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	interruption to supply that the importer or distributor becomes aware of.		
DELIVERIES TO CUSTOMERS			
25.	Active substances should be transported in such a way that: a) their identification is not lost; b) they do not contaminate, and are not contaminated by other products or materials; c) adequate precautions are taken against spillage, breakage or theft; d) they are secure and not subjected to unacceptable degrees of heat, cold, light, moisture or other adverse influence, nor to attack by microorganisms or pests.	d) they are secure and not subjected to unacceptable degrees of heat, cold, light, moisture or other adverse influence *as required by the manufacturer* nor to attack by microorganisms or pests.	Refer to comment on Article 11 - Fecc recommends that only special transport conditions if required by the manufacturer must be followed by the distributor.
26.	Where transportation of the active substance is contracted out the distributor should ensure that the contract acceptor knows and follows the appropriate transport and storage conditions.	Where transportation of the active substance is contracted out the distributor should ensure that the contract acceptor knows and follows the appropriate transport and storage conditions *as indicated by the manufacturer.*	Refer to comment on Article 11
27.	Active substances requiring controlled temperature storage should also be transported by appropriately specialized means.	Active substances requiring controlled temperature storage should also be transported *under appropriate conditions as described by the manufacturer.*	In case controlled temperature storage is required for an active substance it is not necessarily also required to maintain the same conditions for the period of transportation. Nevertheless, appropriate transportation conditions have to be ensured.

			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
TRANSFER OF INFORMATION			
29.	Distributors should transfer all quality or regulatory information received from an active substance manufacturer to the customer and from the customer to the active substance manufacturer.	Distributors should transfer all *required* quality or regulatory information received from an active substance manufacturer to the customer and from the customer to the active substance manufacturer.	Fecc proposes to add 'required' for clarity.
RETURNS			
34.	If the conditions under which returned active substances have been stored or shipped before or during their return or the condition of their containers casts doubt on their quality, they should be destroyed by appropriate means.	If the conditions under which returned active substances have been stored or shipped before or during their return or the condition of their containers casts doubt on their quality, they should be destroyed by appropriate means *or should be shipped back to the manufacturer for further investigation.*	Fecc recommends adding the possibility of sending the substance back to the manufacturer the returned active substances.
COMPLAINTS AND RECALLS			

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41.	Records of complaints should be retained in order to evaluate trends, product related frequencies, and severity with a view to taking additional, and if appropriate, immediate corrective action. These should be made available to competent authorities of the Member States on whose territory the products were distributed.	Records of complaints should be retained in order to evaluate trends, product related frequencies, and severity with a view to taking additional, and if appropriate, immediate corrective action. These should be made available to competent authorities of the Member States on whose territory the products were distributed *upon request.*	Not all complaints are related to patient safety and non safety related information need not be forwarded to the authorities. The addition of 'upon request' also aims to clarity that auto responses need not be provided.
SELF INSPECTIONS			
45.	The distributor should conduct and record self-inspections in order to monitor the implementation of and compliance with this guideline.		This should be Article 47 and not 45

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About Fecc

The European Association of Chemical Distributors (Fecc) is the voice of the chemical distribution industry in Europe. With a growing membership of companies and national associations, Fecc represents around 1,700 companies of which many are small and medium sized enterprises (SMEs). Members service a very wide range of industries and meet the manufacturing requirements of sectors as diverse as paints and textiles to cosmetics and pharmaceuticals each with their own diverse demands and purchase volumes.

The chemical distribution industry in Europe employs around 30,000 people and has an annual sales leverage of approximately €26 billion.

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