ADEX Pharma

Association governed by the 1901 Act

Declared under N°W923000262

European Commission - general health and consumer department (SANCO)

European medicine agency (EMA)

Sèvres, on December 16, 2011

To whom it may concern,

As a non profit association, ADEX Pharma's purpose is to represent its members distributing wholesale health products abroad (DGE), duly agreed by French health authorities (AFSSAPS) according to art. R. 5124-2 of French Public Health Code. The structure includes the main companies in the industry in France, as shown by our membership list appended hereto.

To assert their will to work as health professionals, those companies have passed an ethical charter appended hereto. In line with that, ADEX Pharma puts its expertise at the disposal of the European commission and authorities to exchange - occasionally or regularly - on all subjects relating to the exportation of health products.

As a result, we are hereby sending our analysis regarding the plan to revise the European good practice guide for distribution, which has been submitted to public consultation until 31 December 2011. It is notably a question of reviewing the text regarding manners and practices in force in the professional area of the exportation of health products.

I am obviously at your disposal for any further information that you may need regarding the document. Yours sincerely.

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Good practices for the distribution of health products for human use
EC revision and changes suggested by ADEX Pharma

Date

Dec. 16, 2011.

Purpose

This document reproduces the changes suggested by the dedicated working group within ADEX Pharma, following the public inquiry by the EC regarding a plan to revise the European good practice guide for distribution.

Item 2.5 : person responsible

Original text...

« His responsibilities include, but are not limited to, :

vi) supplier and client qualification and approval. »

Proposed text...

« His responsibilities include, but are not limited to, :

vi) supplier and client approval. »

Comment...

Currently the concept of qualification does not seem appropriate: DGEs are not to substitute to relevant authorities in assessing the ability of players in the pharmaceutical line to comply with professional rules. Therefore the group suggests changing paragraph vi and deleting the notion of qualification.

Conversely, the concept of approval done by a competent person seems relevant and sufficient for ensuring the safety of the pharmaceutical line at DGE level, when it is duly documented.

Item 3.14 : environment temperature and control

Original text...

> « The temperature of storage areas should be mapped in representative conditions and taking into account seasonal-based variations. An initial mapping should be done before using the storage areas. The mapping should be renewed regularly, according to the results of the risk analysis conducted in the area and inn the event of any significant change in the thermal facilities. The temperature control instruments should be located according to the results derived from the mapping. »

Proposed text...

> « The temperature of storage areas should be controlled in representative conditions and taking into account seasonal-based variations and according to the results of the risk analysis conducted in the area. The temperature control instruments should be located according to a scientific and sited approach, derived from the risk analysis. In addition the temperature control instruments should be checked according to an appropriate frequency, derived from the risk analysis. »

Comment...

The completion of a temperature mapping in the warehousing areas seem inescapable, including for refrigeration chambers. The risk analysis should allow to define the frequency of such qualification, in the event of any change in the buildings and facilities.

However, their regular completion is a complex and costly constraint whereas pharmaceutical establishments are the subject of ongoing supervision, reinforced for temperature parameter.

Therefore the group offers to amend the text and delete the concept of mapping, and simply mention the need to control the environment in the warehousing areas. The distributors are free to determine the appropriate terms for their business, after analysing the risks.

In line with that, it is also suggested that the probes used as environment control for the ongoing tracking be located according to a scientific and suited approach, derived from the risk analysis.

It is also suggested that the probes be checked according to an appropriate frequency, derived from the risk analysis. That information should help make a case in favour of a longer frequency, when several successive checks do not show any significant deviation on the measuring device.

Item 5.2 : supplier qualification

Original text...

> « When the pharmaceutical products are supplied through another wholesale distributor, the wholesale distributors should ensure the compliance of the flow with the principles and guidelines set by the good distribution practices. This implies checking the supplier's status and the existence of a distribution permit. »

Proposed text...

> « When the pharmaceutical products are supplied through another wholesale distributor, the wholesale distributors should ensure the compliance of the flow with the principles and guidelines set by the good distribution practices. This implies checking the supplier's status and the existence of a distribution permit. »

Comment...

To ensure the quality of their suppliers, the distributors can only rely refer to the permits secured by them and issued by the relevant authorities. The working group therefore suggests amending the text and restricting the check of the supplier quality to that sole Item.

Item 5.5 : supplier qualification

Original text...

> « An appropriate qualification should be completed prior to any procurement. The selection, including supplier qualification and approval, is a key operation. It should be checked via an operational procedure and its results should be duly documented and controlled. »

Proposed text...

> « A supplier should be approved by a competent person prior to any procurement. That significant operation should be controlled via an operational procedure and its results should be duly documented and controlled. »

Comment...

In line with the comments made on Items 2.5 et 5.2, the concept of qualification does not seem appropriate. Therefore the group suggests amending the text and removing that concept and replacing it

with the notion of approval, which is better suited.

Item 6.17 : pharmaceutical product recall/withdrawal

Original text...

> « Recall operations can be initiated promptly and at any time. »

Proposed text...

> « Recall operations can be initiated promptly and at any time during the establishment's business hours. »

Comment...

Recall/withdrawal operations should promptly trigger the identification of the respective products and information to the clients.

However, the identification of the products seems necessary only during the establishment's business hours, not at any time : during non business hours, the risk of marketing the products is non existent.

In addition, for exportation, any notice received by the AFSSAPS has to be confirmed by the laboratory partner. This cannot be done at any time, since there is no permanent service established by the industry.

Therefore the group suggests amending the text and deleting the implementation at all times : the provisions should be triggered at all times during the business hours of the establishments.

Item 9.12 : transport

Original text...

> « When the products go through logistics centres, a maximum time of 24.0 should elapse before the transfer to the next rung in the road carriage line. If not, the logistics centre will be considered as storage site and should secure a wholesale distribution permit. For products in the refrigeration chain, any storage at a logistics centre will require locals to secure a wholesale distribution permit, whatever the warehousing time. »

Proposed text...

> Pure et simple deletion.

Item 9.12 : transport

Comment...

In addition to the fact that the times selected are not compatible with exportation constraints.

The concept of time does not seem appropriate : deterioration and loss risks exist whenever the products enter a logistics centre.

In addition, a carriage intermediary cannot suddenly access the status of pharmaceutical establishment, merely because warehousing times are exceeded.

Lastly regarding thermo-sensitive products, these should be carried in controlled conditions, in accordance with required temperature requirements.

Therefore the group suggests purely and simply deleting this Item from the standard.

Item 9.19 : transport of products requiring specific conditions

Original text...

> « Approved temperature maintaining systems (refrigerated packaging, controlled temperature containers, refrigeration vehicles) should be used to ensure that adequate transport conditions are maintained between the distributor and the client. [...] ».

Proposed text...

> « Approved temperature maintaining systems (refrigerated packaging, controlled temperature containers, refrigeration vehicles) should be used depending on the outcome of the risk analysis conducted in the area to ensure that adequate transport conditions are maintained between the distributor and the client. [...] ».

Comment...

Systematically using temperatures tracking by environment controls placed throughout the transport of health products does not seem realistic, considering the current equipment of the fleet and the cost to comply, that would have to be incurred later.

However that control measure is crucial to ensure the quality of some flows. Therefore the group suggests amending the text by introducing the concept of risk analysis throughout the transport chain.

Item 9.24 : exportation

Proposed text...

> « The responsibility for implement the principles and guidelines set by the good distribution practices goes no further than the ownership limits of the pharmaceutical products such as set by applicable incoterms. »

Comment...

In order to take into account specificities related to health product exportation, the group suggests adding an item setting the pharmaceutical liability limits of DGEs : alignment on goods transfer of title, such as defined by the incoterms.

Indeed, the export flows are set by established commercial provisions.

For instance when the DGEs deliver health products according to the « FCA » incoterm, the end client appoints the agent at its option and sets the transport terms relating thereto. In that system, the DGE has no influence on that option.

However, pharmaceutical risks remain controlled since that part of the transport is done under the control of a pharmaceutical establishment, as the GE only distribute to authorized providers.

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List of members (Déc. 16, 2011)
CONTINENTAL Pharmaceutique
E.P.DIS
EURIMEX PHARMA
MEDEX
PHARMA CDI
TRIDEM DISTRI