COMMENTS TO THE DRAFT COMMISSION GUIDELINE ON GOOD DISTRIBUTION PRACTICE OF MEDICINAL PRODUCTS FOR HUMANE USE

SANCO/C8/AM/an D(2010) 380358

CHAPTER 3

3.4.

„Medicinal products not intended for the Union market should be kept in segregated areas."

Comment

The relevance of this clause is not understandable, because all products need to be stored separated according to their batch number (independently from their target market). There is no reason to distinguish between EU and non EU products because all need to be stored under the same conditions. Storage conditions are dependent from the active ingredient and the pharmaceutical form, but never from the target market.

In addition, there might be products approved in the European Union that are also sold in third countries using the national packaging of the European Union. Taking this point into consideration, distinguishing between the products is to scrutinize even more.

Deletion of this sentence is required.

CHAPTER 5

5.7.

„Due diligence should be carried out by the distributor when entering a new contract with new suppliers in order to assess the suitability, competence and the reliability of the other party to supply medicinal products. A risk based approach should be used for this purpose considering:
i) searches for the new supplier´s reputation or reliability and its authorized activities;
ii) certain medicinal products are more likely to be target of falsification;
iii) large offers of medicinal product which are generally only available in limited quantities;
iv) out of range prices."

Comment

It is not considered meaningful to search for the new supplier´s reputation or reliability. It is not clear how this could be done without possibly getting wrong information. Comments on a website of the new supplier or other social media networks are sometimes not reliable at all and need to be questioned. Clarification is appreciated.

5.9.

„Checks and periodic re-checks may include (but are not limited to): requesting copies of customer´s authorizations according to national law, verifying status on an authority website, requesting evidence of qualifications or entitlement according to national legislation."

Comment

It is not possible to ensure the qualification of each customer *at any time* by periodic re-checks. It must be the responsibility of each customer to inform all other contract partners in case of changes in its status or the authorization. If a re-check is done every six months, no one can assure that the license is not revoked by the national authority the day after the re-check.

The clause needs to be reworded to include the responsibility of the customer to inform all suppliers in case of changes to its authorization.

AOP Orphan Pharmaceuticals AG 29.12.2011
Agnes Kohl

5.18.
„Incoming containers of medicinal products should be cleaned, if necessary, before storage."

Comment
The company is asking for clarification. It can only be possible to clean the secondary packaging of incoming containers in an appropriate way. Further clarification is appreciated.

5.33.-5.35.
„5.33 The export of medicinal products falls within the definition of "wholesale distribution". A person exporting medicinal products must thus hold a wholesale distribution authorization of a manufacturing authorization. This is also the case if the exporting wholesale distributor is operation from a free zone.
5.34 The rules for wholesale distribution apply in their entirety in the case of export of medicinal products, with the following exceptions:
a. The medicinal product does not have to be covered by a marketing authorization of the EU or a Member State;
b. The customer does not have to be holder of a distribution authorization;
c. Moreover, where the medicinal product intended for exportation has been obtained directly from another third country, without the product being prior to that placed on the market (i.e. without prior import), the supplier does not have to bear a wholesale distribution authorization.
5.35 If the medicinal product is supplied to a person in a third country authorized or entitled to supply medicinal products to the public, the rules for document enclosure apply as for supply of the medicinal product established in the EU.""

Comment
Further clarification is urgently required. All clauses mentioned above (5.33 – 5.35) are difficult or impossible to understand. Do these clauses refer to export within the European Union or out of the European Union to third countries?
In addition, there is a typing error in clause 5.33 – last sentence ("operation" vs "operating").

CHAPTER 6

6.9. ii)
„Medicinal products which have left the premises of the distributor should only be returned to saleable stock if:
ii) medicinal products returns from a customer not holding a wholesale distribution authorization should be returned to saleable stock if they were returned within five days of original dispatch;"

Comment
Since Austrian pharmacies (and maybe also pharmacies in other European countries) do not have a wholesale distribution license, pharmacies should be definitely excluded from this clause. It is an obligation for pharmacies to store medicinal products according to the given specific storage conditions, even if they do not have a wholesale distribution authorization. This clause needs hence to be reworded accordingly.
In addition, a return within 5 days will not be possible in many cases. The company requests a change to 5 *business* days at least.

6.9. v)
„Medicinal products which have left the premises of the distributor should only be returned to saleable stock if:
v) the distributor has reasonable evidence that th the product was upplied to that customer and the batch number of the dispatched product is known, that a copy of the original delivery note is attached and that there is no reason to believe that the product has been falsified."

Comment
Please note that there are typing errors in paragraph v) in the first line:
"…..that **th** the product…." and "(**s**)upplied"

CHAPTER 7

7.2.
„The Contract Giver is responsible for assessing the competence of the Contract Acceptor to carry out successfully the work required and for ensuring by means of the contract and through audits that the principles and guidelines of GDP are followed. An audit of the Contract Acceptor should be performed before the beginning of the outsourced activities and afterwards audits should be done periodically."

Comment
In case goods are delivered to a warehouse that has not been supplied before by the Contract Giver an audit might not be possible before the beginning of the outsourced activity. It is recommended to reword this clause also allowing acceptance of paper based audits before starting any activities in order to avoid "audit tourism". Normally, big warehouses are audited by many other companies and acceptance of audit reports from other companies or current GMP certificates from authorities should also be considered acceptable.

CHAPTER 9

9.5.
„Delivery drivers (including contract drivers) should be trained in the relevant areas of GDP."

Comment
If medicinal products are delivered by common courier services (DHL, UPS) using validated and monitored transport boxes, a training of each driver is not considered relevant. It is considered sufficient that the transport is organized according to GDP Guidelines and the customer controls all documents upon arrival of the products. Rewording of this clause is recommendable and should be limited to actively temperature controlled transports.

9.6.
„There should be procedures in place for the operation and maintenance of all vehicles and equipment involved in the distribution process, including cleaning and safety precautions. Particular attention should be paid to the fact that cleaning agents should not have an adverse effect on product quality."

Comment
Clarification is needed on what is mentioned in the last sentence. Who should decide which cleaning agents are used and how should this be decided? What kind of proof is required to show that cleaning agents are not having an adverse effect on product quality?
It is recommended to delete the last sentence of this clause.

9.12.

„Where transportation hubs are utilized in the supply chain, a maximum time limit of normally 24 hours should be set to await the next stage of the transportation route. Where medicinal products are held on the premises for longer than this defined time limit, the hub will be deemed to be acting as storage site and required to obtain a wholesale distribution authorization. For refrigerated product any storage at a transportation hub for any period of time would required that premises to hold a wholesale distribution authorization."

Comment

Each transport is organized as quickly as possible, but a duration of less than 24 hours to await the next stage of the transportation route cannot be guaranteed (even for deliveries within the EU). Considering also the points mentioned below (9.13.) it cannot be a requirement for all hubs (airports) to obtain a wholesale distribution license.

In addition, obtaining a wholesale distribution license is only necessary for companies that in fact deal with pharmaceutical goods. Hubs and other temporary storage sites are never dealing with pharmaceutical goods and hence, a respective license is not considered necessary.

9.13.

„In the event that the transportation of medicinal products requires unloading and reloading e.g. at terminals and hubs, these premises should be audited and approved prior to deployment. Whenever any changes are made to the approved premises or functions, attention should be paid to the continued suitability of the changed premises or functions for their intended use. Particular attention should be paid to temperature monitoring, cleanliness and the security of unguarded intermediate storage facilities."

Comment

In case of sending products to destinations within or out of the European Union the concrete supply chain is not automatically known on the day of dispatch. For example, a delivery to Australia might be via Frankfurt, Amsterdam, London or similar airports. Therefore the various hubs that might be used are not known before (on the day of dispatching) and hence auditing of all hubs worldwide is not possible. The same is true for deliveries within the European Union (f.e. deliveries to the North of Sweden).

A requirement as described in clause 9.13 would cause huge problems for all companies that intend to supply their products also to countries far away from the manufacturing site. Moreover, we would rather say that such a commitment is impossible to give considering the reasons mentioned above.