From: VBerweiler@kohlpharma.com
Sent: vendredi 16 décembre 2011 16:54
To: SANCO GMP
Cc: TBauroth@kohlpharma.com
Subject: SANCOC8/AM/an D (2010) 380358 Public consultation on the proposed Commission Guidelines on Good Distribution Practice of Medicinal Products for Human Use

Dear Sir or Madam

Public consultation on the proposed
Commission Guidelines on Good Distribution Practice of Medicinal Products for Human Use

COSTEFF is a European association promoting the interests of its members – healthcare companies and organisations – determined to bring cost-efficiency and innovation to the heart of health policies in Europe. Created in July 2009 by a group of private healthcare companies, COSTEFF is a pan-European advocacy group that seeks to create a new alliance around the issue of cost-efficiency and innovation in healthcare, including both public and private actors. COSTEFF wants to promote free movement of goods, fair competition in the healthcare sector and the development of an EU legal framework conductive to greater dialogue across the various branches of healthcare.

After reviewing the proposed commission guidelines we want to point out that from our point of view there is no need to expand the current commission guidelines into such long and too detailed new guidelines. The following items shall be commented:

Computerised Systems, 3.21
In order to prevent unnecessary work, the passage “how the computerised system is used” should be changed as follows (in cursive): “how the computerised system is used (*by a risk assessment approach)*.”

Computerised Systems, 3.23
In order to prevent unnecessary work the second sentence should be changed as follows (in cursive): “Stored data should be […] and accuracy *by a risk assessment approach.*”

Chapter 5 Operations, Principle
Medicinal products show differences regarding their sensitivity to temperature influence. Basically there is no pharmaceutical risk if medicinal products, especially solid forms, that have to be stored at maximum 25°C, will be transported e.g. at 28°C for a short time. It can be shown and it is proven by relevant ICH stability testing data, that exceeding 25°C moderately will not have any relevant effect on the quality of medicinal products transported. Nevertheless it could be important to distribute e.g. semisolid forms such as suppositories at temperatures not above 25°C. [Literature cited: F. Lang C. Höhne, F. Poetsch, Pharm. Ind. 70, Nr. 6, 763-766 (2008)]

Therefore a risk based approach is a useful tool in order to generate safety without creating unnecessary work that will not lower any pharmaceutical risk. Due to this the first sentence of this chapter should be changed and completed as follows:

“All actions […] should ensure […] that wholesale distribution is handled according *a risk based approach It has to be shown that temperature deviations do not inflict damage on product quality.”*

Storage 5.23
As there is not any quality or product risk to be minimized, the second sentence should be deleted.

Qualification of suppliers 5.7
The word “due-diligence” should be changed into “a verification”.

Returned Medicinal Products 6.9 ii)
All medicinal products are distributed to wholesalers and public or clinical pharmacies. These are all members of a circle of experts, where the products are handled and stored in a correct manner. Today's procedure demonstrates that it is useful, safe and practicable how returned medicinal products are handled currently. There is neither any need nor any benefit to accept returned goods only if they are returned within five days of original dispatch. The complete sentence should be deleted.

Returned Medicinal Products 6.9 v)
It is just a theoretical wish and proposal, that "a copy of the original delivery note is attached". However in practice, this is not reasonable, relevant and feasible. The part of the sentence should be deleted.

Returned Medicinal Products 6.10
It is not clear what has to be done from the customer and what has to be fulfilled from the distributor. The points should be formulated more precisely and clearly.

Returned Medicinal Products 6.11
The currently performed procedure as well as the experience and knowledge gained in the past have demonstrated that it is sufficient and appropriate when returned medicinal products are evaluated and documented by experienced, well trained employees according to written procedures. There is no need that returned medicinal products will be "approved by the Responsible Person and recorded", only. Therefore the second part of this sentence should be deleted.

Medicinal Product Recalls 6.16
Why "should the procedure be periodically tested?". Are there experiences and data gained in the past, which demonstrate that "non testing of a medicinal product recall", causes defects, faults and risks? This topic should be considered on a risk based approach. There is no additional benefit in testing medicinal product recalls. So, the second sentence should be deleted or modified with respect to a risk based approach.

Chapter 9 Transportation, Principle
As already explained under Chapter 5 Operations, Principle, the sentence of paragraph 3 should be changed as follows (in cursive):

"*Medicinal products should be transported in accordance with a risk based approach. It has to be shown that temperature deviations do not inflict damage on product quality."*

Transportation, 9.1
As already expressed under "Chapter 5 Operations, Principle" as well as "Chapter 9 Transportation, Principle" this sentence should be changed and completed as follows (in cursive):
Evaluation by a risk assessment approach should show if it is necessary to maintain the required storage conditions for medicinal products during transportation within the defined limits as described on the packaging information. *It has to be shown that temperature deviations during transport do not inflict damage on product quality.*

Transportation, 9.2
As it is neither useful nor practicable or necessary to report a deviation to the recipient, the words "and recipient" should be deleted.

Transportation, 9.12
It is not comprehensible, why hubs should hold a wholesale distribution authorisation. As the responsible wholesaler maintains a comprehensive quality system according to GDP, there is no necessity regarding a wholesale distribution authorisation for each hub. This would not enhance and support the issues required by GDP. Therefore the complete passage "Where medicinal products […] hold a wholesale distribution authorisation" should be deleted.

Temperature Control during Transport, 9.19
The necessity for a regulation like this is not comprehensible. This would require a lot of energy without any additional benefit. Therefore the beginning of the passage should be altered as follows (in cursive):
"*Where necessary, using a risk based approach,* validated temperature- control systems […].

After the expiry of the deadline for public consultation we propose to carry out a meeting with the stakeholders to discuss the Guidelines on Good Distribution Practice of Medicinal Products for Human Use. Costeff would be happy to take part in this discussion.

Kind regards

Thilo Bauroth
Member of the Board

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