

Warsaw, April 30, 2013

European Commission

Directorate General for Health and Consumers, Unit SANCO/D/6

B-1049 BRUSSELS

Ref. Guidelines on the principles of good distribution practices for active substances for medicinal products for human use, Ares(2013)148102 - 05/02/2013

Dear Sir or Madam,

SciencePharma welcomes the Commission's initiative to consult with stakeholders the above mentioned draft and appreciates the possibility to provide its comments.

SciencePharma is a Polish consultancy company offering comprehensive regulatory services to the pharmaceutical industry. SciencePharma falls within the EU definition of a small and medium-sized enterprise.

- 1) It would be advisable to unify the period of retaining records specified in point 12 with the period provided in GMP part II section 6.13.
- 2) Point 23 is recommended to be clarified. SciencePharma considers that it should be changed into a more clear version.
- 3) Point 24 does not seem to be necessary as active substances may be supplied not only to registered distributors of active substances or to authorised manufacturers, but also to research entities or for any further synthesis. Moreover provision relating to sourcing of active substances by manufacturers of medicinal products are already given in point 10.
- 4) Point 27 is recommended to be precised. SciencePharma considers that it would be advisable to precise requirements concerning temperature monitoring during transportation.
- 5) Point 34 is recommended to be revised. SciencePharma considers that in some cases it is not necessary to destroy the active substance after finding of inappropriate storage or shipping. Deviations under storage conditions such as

short temperature excursions often do not lead to deterioration of active substance quality. In our opinion, the distributor should also have possibility to return the active substance to manufacturer for further testing or reprocessing, if feasible.

- 6) SciencePharma considers that the commented guideline could be supplemented with more details concerning requirements for transportation activities, especially for substances requiring special storage/shipping conditions.

We hope that you will find our comments constructive. We remain at your disposal, should you need further clarification.

Yours faithfully,

Pawel Widomski  
CMC Expert