Warsaw, April 30, 2013

European Commission

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

B-1049 BRUSSELS

Ref. Guidelines on the formalised risk assessment for ascertaining the appropriate good manufacturing practice for excipients of medicinal products for human use, draft submitted for public consultation, Ares(2013) 148094-05/02/2013

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.

Description of sections 2-4 provided in point 3 is recommended to be precised:

- Section 2: "Determination of appropriate GMP based on type of excipient" provides guidance on how to assess and rank the risk presented by the excipient as well as identify appropriate GMP.
- Section 3: "Determination of Excipient Manufacturer´s Risk Profile" covers ~~identification of appropriate GMP and~~ assessment, ranking and control of the risk profile of the excipient manufacturer.
- Section 4: "On-going risk review ~~Confirmation of Application of Appropriate GMP~~" presents guidance on how to manage the risks of use of the excipient on an on-going basis.

SciencePharma considers that risk assessments described in section 2 should take into account outputs from other activities relating to excipients, in particular supplier evaluation / approval activities as well as risk assessment relating to drug product carried out under ICH Q9.

According to point 7 excipients are expected to be classified as “low risk”, “medium risk” or “high risk”. This classification however is not further discussed in the guideline (in particular no detailed requirements are provided for these risk groups). It should also be noted that according to ICH Q9 (section 4.3) the output of a risk assessment may be estimated both quantitatively and qualitatively; as for the last manner “low”, “medium” and “high” descriptors are given as an example only. Hence, it is recommended to clearly mark the classification given in point 7 as an example. Moreover, it would be advisable to provide an annex to the guideline with examples of different excipients discussed in respect to both risk resulting from source, manufacturing process and function, and recommended good manufacturing practices standards.

In the current version the only examples given are “EU-GMP, Part I, Annex 1 and Annex 2, Part II” (point 10). It is understood that for various excipients with no particular risks identified lower level of GMP would be sufficient. Point 11 enumerates minimum GMP principles to be considered. However for majority of low risk excipients it is not likely that dedicated good manufacturing practices are established. Hence, as mentioned above, it would be recommended to extend range of provided examples, in particular in respect to published guidelines relating to GMP for excipients (e.g. The Joint IPEC-PQG Good Manufacturing Practices Guide for Pharmaceutical Excipients, 2006). Moreover, it would be helpful to provide more detailed description and/or illustrative examples how specifically essential GMP principles listed in point 11 should be considered for excipients of different risk.

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

Yours faithfully,

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