Warsaw, April 2, 2013

European Commission

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

B-1049 BRUSSELS

Ref. Template for the Qualified Person's declaration concerning GMP compliance of investigational medicinal products manufactured in non-EU countries, Ares(2013)148089

Dear Sir or Madam,

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

It would be valuable to provide an explanatory introduction with regulatory basis and guidance notes (similarly as in the template for the QP's declaration concerning GMP compliance of the active substance used as starting material and verification of its supply chain, EMA/CHMP/CVMP/QWP/696270/2010).

It is indicated in sections B(i) and B(ii) that audits are expected to be carried out within the last 3 years prior to issuing of QP declarations. However neither directive 2001/20/EC nor Commission Communication CT-1 requires GMP audits of the IMP manufacturing sites every 3 years.

Moreover according to GMP annex 13 section 39(c) (mentioned also in article 13.3(b) of directive 2001/20/EC) when a IMP is imported directly from a 3rd country that is not a subject to MRA, the Qualified Person should determine that equivalent GMP standards apply through knowledge of the quality system employed at the manufacturer. This knowledge is normally acquired through audit of the manufacturer's quality systems. However, it is acknowledged that the Qualified Person may also certify a batch on the basis of documentation supplied by the 3rd country manufacturer enumerated in section 40 of the annex. It would be valuable to indicate or reference these provisions in section B(iii) of the template in a more detailed manner.

As for B(ii) section the phrase "including another QP employed by the importer" is not necessary.

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

Yours faithfully,

Pawel Widomski

CMC Department, Expert