Warsaw, January 3, 2014

European Commission
Directorate-General for Health and Consumers
Unit SANCO/D/5
BE-1049 Brussels, Belgium

Ref. Commission guideline on the format and content of applications for paediatric investigation plans, concept paper submitted for public consultation.

Dear Sir/Madam,

SciencePharma welcomes the Commission's initiative to consult the concept paper of the *Commission guideline on the format and content of applications for paediatric investigation plans*, and appreciates the opportunity to comment on this important document.

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.

We would like to submit the following comments for Comission's consideration.

General comment:

FDA and EMA Harmonization - we recommend that EMA and FDA work to harmonize the elements of paediatric programs in order to optimize the process of paediatric drug development.

Specific comment on text:

Line 703: We recommend that only crucial inclusion and exclusion criteria should be described. *Proposed change*: Crucial inclusion and exclusion criteria.

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

Yours faithfully,

Joanna Pawlak

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