From: Piergiorgio Galletti [mailto:p.galletti@pierrel-research.com]
Sent: Monday, December 16, 2013 2:44 PM
To: SANCO PHARMACEUTICALS D5
Cc: Dehlinger-Kremer, Martine
Subject: PCPIP/13/01 — Public consultation on PIP guideline (A4003915)

To the Directorate-General for Health and Consumers, Unit SANCO/D/5, BE-1049 Brussels (sent to: sanco-pharmaceuticals-D5@ec.europa.eu).
From: Piergiorgio Galletti, on behalf of the **Paediatric Working Group (PWG) of the EUCROF, the European CRO Federation (Contract Research Organizations)**

The Paediatric Working Group of EUCROF, the European CRO Federation, has reviewed the Concept Paper referring to the format and content of applications for paediatric investigation plans (PIPs). Herewith the comments for your consideration.

- Lines 81-82: "one comprehensive paediatric investigation plan should be included in the application".
  Comment: "**unclear if/when to use more than one PIP**"

- Lines 128-129: "Information on all different pharmaceutical forms and formulations under development …should be provided**".**
  Comment: "**why not also "strength" and "route of administration" ?"**

- Lines 159-160: "The planned submission date for the marketing authorisation … should be provided".
  Comment: "**would it be possible to specify in the paper whether a PIP modification will be required if the planned marketing authorization submission date changes ?**"

- Lines 163-164: "For medicinal products not yet authorised ... the date of completion of adult pharmacokinetic studies should be provided".
  Comment: "**does the date of completion of adult pharmacokinetic studies refer to the anticipated date of presumptive completion (if the PIP is submitted before the start of the phase I), or the date of actual completion (if the PIP is submitted at the end of the phase I) ?**"

- Lines 165-166: "When an application is submitted later than upon completion of the human pharmacokinetic studies in adults, a justification should be provided in this section"
  Comment: "**would it be possible to specify in the paper what will be the consequence if the justification for a late PIP submission is not accepted by the EMA ?**"

- Line 362: "potential issues in relation to excipients to be used in the paediatric population"
  Comment: "**only potential issues, or discussion of each excipient ?**"

- Line 413 : "General aspects"
  Comment: "**Do previously approved PIPs have an impact on the number - extension - methods of new pediatric clinical development plans for substantially similar products ?** "

- Line 480: "justification of type of study, study design and methodology"
  Comment: "**what is the position with regard to the adoption of special, adaptive, designs (e.g. Bayesian) ?**"

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- Lines 532-533: "modifications (to an agreed PIP) are required where key elements of the paediatric investigation plan are unworkable or no longer appropriate"
  Comment: "**will the terms "unworkable" and "no longer appropriate" be defined more specifically in the final paper ?** "

Thank you very much in advance.
Best regards
Privacy Statement: I give permission to the collection and further processing of my personal data in the context of this consultation, as reported in the specific Privacy Statement

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