



PCPD/12/01 — Public Consultation on paediatric report
Therakind Ltd Comments

**Public Consultation on
European Commission Concept Paper on the Format and Content
of Applications for Paediatric Investigation Plans
(Article 10 Of Regulation (EC) No 1901/2006)**

(Document Reference: Ares(2013)3208979 - 09/10/2013)

Comments from Therakind Limited (a SME)

Date: 19 November 2013

Consultation item No 1: Do you have any comments on the format and content of applications for agreement on or modification of a paediatric investigation plan and requests for waivers or deferrals?

Comment:

We have noted that it is proposed that a paediatric investigation plan for a paediatric use marketing authorisation may be limited to certain paediatric subsets (lines 76 & 77) and agree with that proposal.

Consultation item No 2: Do you have any comments on the operation of the compliance check and/or the compliance statement?

Comment:

We have no comment on this - we have used the compliance check successfully already without problems.

Consultation item No 3: Do you have any comments on the assessment criteria for significant studies?

Comment:

We have no comment on this - the proposal appears to be appropriate.

Consultation item No 4: Do you have any comments on the key elements of a paediatric investigation plan? Is it appropriate to list key elements in this guideline or should key elements only be specified in the individual decision of the Agency agreeing a specific paediatric investigation plan?

Comment:

We think that it would be appropriate to list the key elements in this guideline as an example of potential key elements but indicate that these key elements will be individualized for each Agency decision agreeing a paediatric investigation plan.

Consultation item No 5: Please feel free to raise any other issues or make any comments which have not been addressed in the consultation items above.

Comment:

We have no other comments.