

31st August 2016

Consultation on consultation on ethical considerations for clinical trials on medicinal products conducted with minors

Response from the European Association of Hospital Pharmacists

european association of
hospital pharmacists

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In general, EAHP supports the consultation document and its content as providing helpful guidance on the ethical expectations surrounding clinical trials involving minors. As stated in the document (line 152-156) *“any recommendations on ethical aspects of clinical trials in minors will also facilitate a harmonized approach to the application of the clinical trials regulation across the EU, thereby facilitating the conduct of clinical trials across the EU, in whichever country the clinical trial in minors occurs.”* EAHP supports this contention.

7.7. Participation of minors in the informed consent process and agreement

EAHP suggest amendment to line 581 “and **strongly** recommends that the investigator obtains agreement from the child in addition to informed consent of the parents/legally designated representative”.

If a child does not give consent this must be treated with the very utmost seriousness.

Clinical trials in minors in emergency situations

The document might describe and advise further in respect to “pre-approval” procedures for consent in emergency situations. An understood example is the processes for organ donation for adults. A similar procedure for children might also be replicated.

9.1 Design and analysis

EAHP suggest amendment to line 829 to: “Adequate dose rationale ~~should~~ **must** be included in the protocol”

17 Paediatric forms and formulations to be used in paediatric trials

EAHP suggest addition to the end of paragraph line 1361-1362: “**The most appropriate paediatric formulation should be discussed with a hospital pharmacist.**”

Annex 1: List of issues to be considered in a clinical trial involving minors

EAHP suggest addition to bullet point 10: “Age appropriate forms and formulations of medicinal products, **in discussion with the hospital pharmacist**”.

Annex 2: List of items recommended to be covered in the information sheets

EAHP suggest “what is a clinical trial” and “where can I find information about the results of the trial” be added to the start and end of this list respectively.