SUMMARY OF THE RESPONES TO THE PUBLIC CONSULTATION ON "ETHICAL CONSIDERATIONS FOR CLINICAL TRIALS ON MEDICINAL PRODUCTS CONDUCTED WITH MINORS" RECOMMENDATIONS OF THE EXPERT GROUP ON CLINICAL TRIALS FOR THE IMPLEMENTATION OF REGULATION (EU) NO 536/2014

1. GENERAL REMARKS

With this public consultation the Directorate General for Health and Food Safety, DG SANTE, intended to seek the views of stakeholders - and other interested parties - on the document *"Ethical Considerations for Clinical Trials on Medicinal products conducted with Minors"* revised by the expert group on clinical trials in preparation for the implementation for the Clinical Trials Regulation (EU) No 536/2014.

This document presents a factual summary of the responses to the public consultation. It does not present the views of the European Commission.

2. CONTRIBUTORS TO THE PUBLIC CONSULTATION

The number of contributions received was 30. Five contributors claimed confidentiality or anonymity over their submissions. Their contributions will therefore not be published or published only in anonymous form.

3. OUTCOME OF THE PUBLIC CONSULTATION

3.1 Topics of the responses

The main comments and remarks of the responses were made on the following topics:

- Shortening of the text
- Readability and accessibility for various stakeholders
- Requests for overviews of Member State characteristics
- Requests for describing exceptions to the provided guidance
- Requests for detailed practical instructions beyond ethical considerations
- Requests for clarification and suggestions for rewording
- Definitions of assent, agreement and dissent
- Staggered approach
- The situation when the minor becomes legally competent to give consent
- Trials with adolescents
- Lay summary, understandable for the trial participants

3.2 Responses to questions and requested feedback

As part of the consultation questions were asked and feedback was requested.

Question 1: the table of annex 3 (previously annex 4) has not been changed. Is the proposed categorization of these procedures still adequate?

Question 2: which insights may lead to changes in categorizations (in particular those indicated in yellow)?

Seven contributors responded to the first question. Six contributors responded to the second question, of which five overlap with the contributors to the first question. One contributor was critical of a simple categorisation of procedures, without knowing the circumstances and characteristics of the trial population. Another contributor also expressed doubts, but recognised that a categorisation is necessary and supported the proposal. For many procedures changes for categorisation were proposed, however there was not always consensus between contributors.

Feedback 1: general feedback on clinical trials in minors in emergency situations (within the meaning of article 35 of the clinical trials regulation) is welcome.

Six contributors put forward their feedback on emergency situations. Overall they supported the ethical guidance provided in this paragraph. A request for clarification and some suggestions were made.

Feedback 2: if you are aware of any other relevant references you are invited to put them forward.

Three contributors put forward references.