EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Paediatric Committee (PDCO)

Concept paper on the involvement of children and young people at the Paediatric Committee (PDCO)

Agreed by PDCO	August 2012
Adopted by PDCO for release for consultation	5-7 September 2012
Start of public consultation	17 September 2012
End of consultation (deadline for comments)	19 November 2012

Comments should be provided using this template. The completed comments form should be sent to paediatrics@ema.europa.eu

Keywords	Children, young people, involvement, participation, consultation

1. Introduction

The main institutional task of the European Medicines Agency as set by the current legislative framework is to provide “*the best possible scientific advice on any question relating to the evaluation and safety of medicinal products for human […]*”. (Art. 57(1) of Regulation 726/2004-the “Regulation”). As part of this *The committees […] shall* ***in general matters*** *establish contacts, on an advisory basis, with parties concerned with the use of medicinal products, in particular patient organisations and health-care professionals’ associations”. (*Art. 78(2). As such, all external direct consultations of the public is aimed at providing committees with information related to scientific matters and not related to socio-economic issues.

Following the Paediatric Regulation (EC) No 1902/2006 as amended, which came into force in 2007 the Agency now has a responsibility to consult the views and opinions of children and young people.

According to Art. 25(2) of the Universal Declaration of Human Rights, children are "*entitled to special care and assistance*"*.* At international level, the Convention on the Rights of the Child (CRC)[1], ratified by all the Member States of the Union puts the duty of protection into specific terms by stating that in all actions concerning children undertaken by public institutions, "***the best interests of the child shall be a primary consideration***"*.* Art. 12 of the CRC declares the right of the child to be listened to and taken seriously, in any judicial or administrative proceedings affecting the child "*in a manner consistent with the procedural rules of national law*"[2].

Art. 24(1) of the Charter of Fundamental Rights of the European Union of 7 December 2000 stipulates that "*Children shall have* ***the right to such protection and care as it is necessary for their well-being****. They may express their views freely.* ***Such views shall be taken into consideration on matters which concern them in accordance with their age and maturity***".

2. Problem statement

There are several challenges and obstacles in accessing the views of children and young people. Such as:

- Access;
- Language / ability to express oneself;
- Ethnic and cultural differences;
- Chronological age and maturity;
- Ill-informed or preconceived notions about a child's level of understanding and maturity.

The objective of this concept paper is to develop a framework of interaction for the involvement of children and young people in the work of the PDCO, particularly: i) when and to what extent and ii) how their views can be sought, and iii) the manner in which their views can be applied.

Prior to the engagement and involvement of children and young people it is important to determine the scope of involvement, and to define the expectations from such a dialogue. The main objectives should be defined, with endorsement from all PDCO members, and organisations representing children and young people for their input, to ensure the maximum benefit from such interaction.

Issues to be defined include, but are not limited to:

- The main objectives of such engagement;
- When to obtain feedback during such engagement;
- How to identify and approach children and young people [access];
- How best to capture the views and opinions of children and young people;
- How to incorporate the views and opinions of children and young people into the work and outcomes of the PDCO;

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[1] UN Treaty Series Vol. 1577, p.43.

[2] The full text of art. 12 of the CRC reads as follows:

"1. States Parties shall assure to the child who is capable of forming his or her own views the right to express those views freely in all matters affecting the child, the views of the child being given due weight in accordance with the age and maturity of the child.

2. For this purpose, the child shall in particular be provided the opportunity to be heard in any judicial and administrative proceedings affecting the child, either directly, or through a representative or an appropriate body, in a manner consistent with the procedural rules of national law."

- What is the added value that children and young people can bring to the scientific evaluation.

3. Discussion (on the problem statement)

A mapping exercise is considered necessary to identify organisations that are already experienced in consulting the views and opinions of children and young people on issues related to health. This is to reflect level of expertise within and beyond the PDCO and to maximise resources.

Consultation with children and young people across a wide age range, disease groups and across many Member States and cultural groups is considered essential.

Format of contact and dialogue for consultation needs to be agreed upon: for example, in person vs. virtual through social media / web based forums;

The frequency of contacts needs to be agreed upon (ad-hoc vs, regular, e.g. quarterly/annually;

The type of issues to be covered by the interaction needs to be agreed upon: e.g. general issues and overview vs, procedure-specific consultations.

Some of the proposed areas for consultation are as follows:

- In the evaluation of individual Paediatric Investigation Plans;
- To define significant therapeutic needs according to therapeutic areas: not product specific / in the development of guidelines /specific to therapeutic areas/disease;
- Clinical assessments used as endpoints: invasiveness of tests / frequency of tests, duration of tests;
- Preferences on clinical trial design features: randomisation / placebo/frequency of visits / duration of study / number of tests;
- Medicines of choice: Acceptability of route of administrations / Acceptability of formulations / Preferred formulation type / Palatability / Frequency of dosing / container closure systems and other packaging issue.

4. Recommendation

There is a need to define a framework of interaction between EMA, PDCO and children and young people, including the organisations that they may be part of. This framework should:

- Define the expectations from children and young people by the PDCO;
- Define the role of children and young people to support PDCO activities;
- Identify organisations that have the skills and experience of such interaction with children and young people, and the means of contacting suitable children and young people;
- Develop clear criteria on which situations need the consultation of and/or dialogue with children and young people;
- Propose a work plan and guidance on how the interaction would take place in practice, including any necessary measures to ensure the safety of the minors (psychologically and physically), any necessary training prior to involvement, from initial formulation of question, to identification of

children and young people, the format of consultation, and the introduction of children's views into the PDCO decision making process.

5. Proposed timetable

Release concept paper for external consultation by 17 September 2012.

Identify a working party within PDCO to collate comments received and define the following, for agreement:

- The aims, objective and priorities for involving children and young people;
- The best format for involving children and young people;
- Identification of organisations that are willing to be consulted;
- The areas to be covered in consultation with involving children and young people.

Deadline for comments: 19 November 2012.

Re-discussion by PDCO in December 2012.

Expected date for adoption of outcome by Committee by January 2013.

6. Impact assessment (anticipated)

This work intends to provide a basis for the involvement of children and young people in the development of medicines for children. It should also result in a transparent account to industry and other stakeholders of how the views of children and young people are incorporated in decision making. Reasoned involvement can lead to better targeting of needs as identified by the target populations.

7. Resource requirements for the following areas

This document will require active participation from all members of the PDCO and EMA Public Information and Stakeholder Networking (P-MI-PIN).

Consultation with all Members States and across many therapeutic areas is considered essential for this exercise to be effective.

Current establishments/ resources in place which may be able to facilitate and collaborate in this project are EnprEMA, GRiP and all EMA eligible patient/consumer organisations.

Language – there will be a need to identity and agree on the number of languages that can be worked in according to level of interest identified in Member States and interested organisations.

Technical – there will be a need to identity and agree on the format of consultation, be it through meetings/ workshops, social media, web based forums etc.

Expected impact needs to be defined.

Issues impacting on the resources required are: number of consultations, number of children and young people to be consulted, number of therapeutic areas to be discussed, number of PIP procedures influenced by consultation.

8. Interested parties

PDCO, [CHMP, SAWP, COMP] Patients' and Consumers' Working Party, EnprEMA networks according to therapeutic areas, GRiP.

Other **European Organisations**:

It would appear that the only organisations working exclusively on the involvement of children in healthcare decisions are 'national' organisations; A 'European-wide' organisation with this focus has not been identified.

When consulting with the EMA eligible patient/consumer organisations, it seems that many of these organisations (and/or those within their umbrella), especially those which are disease-specific, have some experience working with children/young people, wherever appropriate.

In order to locate and make contact with suitable children, the EMA may consult, on a case-by-case basis, individual organisations as follows (depending on therapeutic area and the subject matter):

- National organisations who are devoted solely to working on the involvement of children in healthcare, and/or;
- European / national patient/consumer organisations specialised in a particular therapeutic area;
- and/or;
- European / national general patient/consumer organisations.

The EMA has a list of 34 different patient and consumer organisations who regularly work with the Agency and who comply with the EMA eligibility criteria, which ensures they are appropriate organisations focusing on the interests of patients. Wherever possible these organisations should be involved to help the EMA contact children and their parents (as they currently do for other EMA committees, meetings, consultations, etc.).

In addition, PDCO members (especially patient representatives) would investigate within their networks for potential participants.

Some initial suggestions of organisations who could help locate children for involvement in PDCO:

- BOKS - Belgian patient organisation for metabolic diseases - members are 80% children/young adults (www.boks.be).
- The International confederation of childhood cancer parent organisation (www.icccpo.org), has member organisations from all over Europe and each national organisation has local member groups.
- The European Institute of Women's health is committed to child/family health as many members are parent organisations for sick children. European Institute of Women's Health.
- Belgium organisations for children: http://www.kinderrechten.be/ kinderrechten@vlaamsparlement.be.
- The European Patient Forum Youth Group involves young patients aged 15-25 European Patients' Forum.
- There are many organizations which deal with children's medical conditions – one of these is Matthew's Friends which supports ketogenic diet for children with refractory epilepsy (http://www.matthewsfriends.org).

- German cancer organization for children (www.kinderkrebsstiftung.de).
- UK Medicine for Children Network (http://www.mcrn.org.uk/children) has a Young Persons Advisory Group.
- European Youth MS organisation EMSP www.emsp.org

9. References to literature, guidelines, etc.

UN Committee on the Rights of the Child, General Comment No 12 (2009): The right of children to be heard.

Committee of Ministers of the Council of Europe, Guidelines on Child-Friendly Healthcare (2011).

Kilkelly, U (2011) Child-friendly Healthcare: The views and Experiences of Children and Young People in Council of Europe Member States *(offers and example of an approach taken at a European level to consult with children and learning arising from it).*