



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14/11/2012

Submission of comments on 'Concept paper on the involvement of children and young people at the Paediatric Committee (PDCO)' (EMA/PDCO/388684/2012)

Comments from:

Name of organisation or individual

European Federation of Allergy and Airways Diseases Patients' Associations (EFA)

[EFA](#) is a non-profit network of allergy, asthma and COPD patients' organisations, representing 35 national associations in 22 countries and over 400,000 patients. EFA is dedicated to making Europe a place where people with allergies, asthma and COPD have the right to best quality of care and safe environment, live uncompromised lives and are actively involved in all decisions influencing their health.

Roberta Savli, EFA EU Policy and Project Officer

Please note that these comments and the identity of the sender will be published unless a specific justified objection is received.



1. General comments

| Stakeholder number <i>(To be completed by the Agency)</i> | General comment (if any) | Outcome (if applicable) <i>(To be completed by the Agency)</i> |
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| | <p>EFA very much welcomes this consultation and the first paper from PDCO to take the involvement of children and youth forward.</p> <p>The need for children and youth involvement</p> <p>The involvement of children and youth in decisions influencing their health is a priority for our federation. Indeed, asthma and allergies are the most common chronic diseases in children and the leading cause of school absences, emergency department visits and hospitalisations. Worldwide, up to 40% of children are affected by some form of allergy. In Europe, 10% to 20% of adolescents aged 13 and 14 suffer from severe allergic rhinitis. Children with one form of allergy are more likely to develop other forms of allergy. Furthermore, a large body of evidence points to a link between allergic rhinitis and asthma. [reference: Erkkä Valovirta, <i>EFA Book on Respiratory Allergies – Raise Awareness, Relieve the Burden</i>, 2011, available at: http://www.efanet.org/documents/EFABookonRespiratoryAllergiesFINAL.pdf]</p> <p>It is well recognised that even small children should be involved in their own care. Same rationale says that children have the right to be listened to in the same way as adults and elderly. It is evident that some specific</p> | |

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| | <p>problems should be taken into account, such as ethics, accessibility, format, maturity and language barriers. However, their participation is needed because they are the best to explain their symptoms and expectations, complemented by the participation of their parents/carers. Listening to children/youth opinions before making decisions could lead to a win-win situation: help increase their adherence, well-being and therefore improve their health even for the future.</p> <p>Indeed, in the case of our disease areas, asthma control in childhood will help to prevent exacerbations and severe damage of the lungs later in life. Poor control (increased daytime cough, daytime wheeze, etc.) is a strong predictor of exacerbation in children with asthma under the age of 5. [reference: Swern A.S., Tozzi C.A., Knorr B., Bisgaard H., Predicting an asthma exacerbation in children 2 to 5 years of age, Ann Allergy Asthma Immunol, 2008, 101] Appropriate control in children may also reduce the need of medication, thus preventing possible side effects and a “future risk” of harm due to excessive medications.</p> <p>Some issues related to the involvement</p> <p>Asking parents/carers is good, but it is not the same. They may give a completely different advice/perspective on the issue. Thus, involving children and young people may be difficult, but is necessary. EFA’s members have</p> | |

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| | <p>already experience in this field. EFA is ready to help and put its expertise and its members' knowledge at the service of EMA. Children/young people experts should be identified in each disease area using current network of patients' organisations. Their participation could then be encouraged through motivation tools, such as awards, as it was proposed by our Lithuanian member Lietuvos astmos klubu taryba.</p> <p>Children and youth under age cannot travel alone, a web-based system that takes into consideration their school hours could be one option. Another issue to consider is their involvement in person, whether that could take place in their own country or whether its necessary to travel to EMA.</p> <p>To make their involvement meaningful, children and youth should use a language they are comfortable with and be trained in beforehand on the content of the discussion. Those who are going to have a dialogue with them will need to be trained as well so that they can have a meaningful dialogue with children. In case of children, interactions always need to be in their own language. For young people, English can be considered in case by case basis.</p> <p>The use of social media and other forms of communication should be explored as it would make their participation easier. Children are eager Internet users and finding new ways to offer and spread</p> | |

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| | <p>knowledge (through games, apps, question-and-answer service/consultation services, etc.) are important. All means of communication would be important, e.g.: visual, auditory, hands on, listening, drawing, electronics, etc.</p> <p>Some examples from our member associations on involving the youth and targeted communication</p> <p>In the case of food allergy, one of our Belgian members, Prévention des Allergies, launched a new comic on food allergy for teenagers. The comic book is the idea of Nicole Abécassis, a philosopher and mother of a child with severe food allergy. The illustrations are done by Laurent Poisson, a young student of hers. The objective of the comic is to help teenagers understand that living with food allergy does not mean being excluded from their peers or passing up on social events. Keeping food allergy under control and ensuring that risks are minimised, for example by always carrying an adrenaline auto-injector, may allow teenagers and their families to live uncompromised lives.</p> <p>Allergia- ja astmaliitto, our Finnish member, organises rehabilitation for young persons and children with families who suffer from asthma, allergy and atopic eczema. With allergy, asthma and atopic eczema, the basis of good caring is at home, school and in the environment the child is living in. However, at a certain</p> | |

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| | <p>point, a more comprehensive care/training for the whole family, for example in rehabilitation centers, is needed. Indeed, atopic eczema (atopic dermatitis) in children is one of the worst and common things that can happen for children. They cry and scratch themselves until blood and the whole family is therefore not able to sleep. Their quality of life should be taken into account, and they can have things to say about their care.</p> <p>Astma- og Allergiforbundet (NAAF), our Norwegian member, sets up a special organisation for youth between 15 and 36 years, the Norwegian Asthma and Allergy Association Youth (NAAFU). It is run by youth, has a board of youth members and organises activities and meetings for youth (e.g.: camps, trips). In addition to that, many other activities operated by NAAF's regional or local offices involve youth/children. For example, youth exercise groups and family weekends (a mix between education and fun activities for the whole family) have been constantly organised. In Norway, children currently get education in asthma and eczema in hospitals and clinics through play, drawings and by talking about their experience – in groups and individually.</p> <p>Sometimes, specific projects launched by NAAF's headquarters also target at youth/children. Materials developed under the project National plan for asthma schools include a film, book and audio book about <i>Ane</i></p> | |

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| | <p><i>and Bronky</i>. This material is suitable in order to teach children about asthma management. This project was presented during the EFA Annual General Meeting in Rome in 2009. Link to the movie: http://www.naaf.no/no/astma/trikset/, more details can be provided upon request.</p> <p>NAAF is launching an app in November called "my asthma app." It gives young people the opportunity to obtain information on asthma, add information about their own disease, which can be stored in a format that can be presented to their doctors on their next medical appointment.</p> <p>NAAF is also involved with a project called "Children as competent medicinal users." The aim of this project is to improve the knowledge of children as drug users and facilitate the administration of medicines. The end result of the project will be a prototype of an electronic device (an app) that helps motivate children from 1 to 6 years to take their respiratory medication. A child-friendly product design of such medication might also be developed. The products have been tested on groups of children of different ages.</p> | |

2. Specific comments on text

| Line number(s) of the relevant text <i>(e.g. Lines 20-23)</i> | Stakeholder number <i>(To be completed by the Agency)</i> | Comment and rationale; proposed changes <i>(If changes to the wording are suggested, they should be highlighted using 'track changes')</i> | Outcome <i>(To be completed by the Agency)</i> |
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| Paragraph 2 Problem statement | | <p>Comment: Not only children and youth should be able to speak their own mother tongue, but they should even be allowed to use the level and form of expression they consider more suitable and comfortable.</p> <p>Proposed change (if any): - Language/ability to express oneself/<u>ability to adapt their level and form of expression</u></p> | |
| Paragraph 3 Discussion | | <p>Comment: Bearing in mind organisations that represent parents may be appropriate and sometimes essential when the issue at hand concerns babies and very young children who cannot be consulted.</p> <p>Proposed change (if any): 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, <u>as well as organisations representing their parents</u>.</p> | |
| Paragraph 8 Interested parties | | <p>Comment: It is good to underline the fact that organisations may help EMA not only directly but even through their networks of members.</p> | |

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| | | <p>Proposed change (if any): 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.) <u>through their members or directly</u>.</p> | |
| <p>Proposal 8 Some initial suggestions of organisations who could help locate children for involvement in PDCO</p> | | <p>Comment: EFA is focused on disease areas particularly prevalent in children. Many of our members involve children and some of them have young people's sections (Sweden, Norway).</p> <p>Proposed change (if any): <u>- The European Youth Forum</u> <u>- The European Federation of Allergy and Airways Diseases Patients' Associations (EFA)</u></p> | |