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Enpr-EMA newsletter

December 2012

Dear colleagues,

Before the year 2012 draws to an end we want to briefly inform you about Enpr-EMA's activities throughout the year.

1. 42 Enpr-EMA members were asked to complete a survey on young people and family involvement in Enpr-EMA Networks. 17 members completed the survey:

- 9/17 networks indicated that they directly work with young people
- 7/17 networks have dedicated staff for the involvement of young people/family
- Only 3/17 networks have young people/family involvement strategies or guidelines available within their networks
- Only 4/17 networks have a budget to support young people/family Advisory Groups

We would like to thank all the 17 members who completed this survey. The outcome of the survey will be summarised in a short publication next year.

2. Collaboration with small and medium sized enterprises (SME) office at the EMA has been initiated following the report on the SME initiative 2006-2011 where the need for increased collaboration between industry and academic was outlined, particularly in the field of paediatric medicines. Enpr-EMA secretariat and the Agency's SME office are now acting as liaison between SMEs and academic investigators in paediatric-medicine research, to help finding partners that complement their research interests. Please use this opportunity when looking for industry partners. A few queries from SMEs have already been received and interested partners from academia could be identified.

3. Update on emerging networks activities: Following the initiation meeting in November 2011, efforts towards development of additional European-wide paediatric networks in key therapeutic areas throughout 2012:

Gastroenterology: The United European Gastroenterology approved a bid, jointly submitted by the Dutch, British and Irish Society of Gastroenterology, for funding to develop a European paediatric gastroenterology clinical trial network. The next steps include organising job interview and selection of a project manager, as well as organising a meeting at the 2013 annual conference of the European Society of Paediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN) in London in order to

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inform members about this project. In addition, a European clinical trials skills and feasibility survey will be performed to identify potential centres and investigators with the ability and capacity to perform clinical trials in this therapeutic area.

Cardiology: the European Association of Paediatric Cardiologists (EAPC) has agreed to create a working group on clinical trials and to arrange a face-to-face meeting in the next few months as well as a larger meeting at the EAPC annual conference in London in spring 2013. A call for expressions of interest will be sent out to all EAPC members.

Endocrinology/Diabetes: two meetings took place with 27 interested participants from various European countries, including 1 representative from the European Society of Paediatric Endocrinology (ESPE) and industry representatives to create an (Enpr-EMA) European Children and Adolescent Diabetes and Endocrine Trials Network. An initiation meeting is scheduled for 25th Feb 2013 at the Agency during the EMA workshop on type 2 diabetes mellitus, with participants from academia, PDCO, Pharma Industry & patient representatives.

Neurology/Psychology: The European College of Neuropsychopharmacology (ECNP) expressed interest in developing a European-wide paediatric clinical trial network within ECNP.

4. The coordinating group submitted a corporate Enpr-EMA commentary to the European Commission during the public consultation on the impact of the European Regulation on medicinal products for paediatric use.

5. An Enpr-EMA standard set of slides has been prepared and published on the Enpr-EMA webpage for downloading. Please feel free to use (parts of) them when reporting on Enpr-EMA at scientific meetings.

6. An Enpr-EMA brochure, summarising basic information about Enpr-EMA, its mandate and objectives has also been prepared and can be downloaded from the Enpr-EMA webpage.

7. Collaboration with PDCO: Enpr-EMA members were asked

- to provide information on activities/arrangements they have in place to raise awareness in parents/patients on the need for clinical trials and for participating in clinical trials.
- to review the EMA list of class waivers, and comment if they see how the waived "adult" diseases and paediatric diseases could be linked by making reference to innovative disease classifications, by any recent scientific findings on biological similarities or characteristics, or by providing examples of medicines which are used in adults for the currently waived conditions but due to their mode of action could be useful in paediatric conditions.
- to comment on a development strategy for asthma medication in children, which is under discussion by PDCO and will be based on the EMA/CHMP asthma guideline currently under revision and scheduled to be put for public consultation in January 2013. Enpr-EMA members will again be invited to submit comments.

We hope you find the newsletter helpful to keep you all informed about Enpr-EMA's activities. We'd appreciate any feedback and proposals you might have.

We want to take the opportunity to thank you all for your support and activities towards Enpr-EMA. We wish you and your families a merry Christmas, some relaxing holidays and all the best for a successful new year.

Peter Helms
Chair

Irmgard Eichler
Co-Chair