European Medicines Agency
Pre-authorisation Evaluation of Medicines for Human Use

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Workshop on FP7 and Off Patent Medicines Developed for Children

REPORT

A workshop jointly organised by the European Commission (DG Research) and the EMEA took place on Wednesday 6 June 2007 at the EMEA.

The objective of the workshop was to provide information and practical guidance on funding of studies into off-patent medicinal products. This follows the provision of the Regulation of the European Parliament and of the Council on medicinal products for paediatric use (Regulation EC (No) 1901/2006, as amended (hereafter the Paediatric Regulation).

The **presentations** are annexed to this report.

Medicinal products which are off-patent[1] are widely used outside the terms of the marketing authorisation to treat children. The Paediatric Regulation aims at encouraging the development of medicinal products for paediatric use, both recent and older products through various incentives and rewards. Studies are needed because medicines do not behave in children's body as they do in adults, and specific age-appropriate formulations are needed to allow safe administration of accurate doses.

Funding will be provided through the Framework Programme(s) of the Community. Funding in the second call of the 7th Framework Programme is available to individuals, academics or research centres and networks, or to both small and large companies. For the development of off-patent medicines studies, the deadline is **18 September 2007**. A maximum of € 6 million per project and a total of € 30 million for the next 2 years are anticipated.

Agnès Saint Raymond from the EMEA presented the Paediatric Regulation and the revised Priority List of Off-patent Medicinal Products, which indicates the products likely to obtain funding. The List can be found in the Annexes.

Fergal Donnelly for DG Research presented the 7th Framework Programme (Health programme) with special emphasis on the call for studies into such off-patent medicines. Very practical information on how to apply, who can apply and when, was provided. The evaluation process was also explained and emphasis was put on the elements considered essential for a successful bid.

Industry trade associations presented the expected benefits and limitations of the Paediatric Regulation. Michael Banks, representing the European Generic medicines Association (EGA) explained why generic companies may be interested in developing partnerships with academics to apply for the new type of marketing authorisation covering the paediatric indication and formulation, called PUMA (Paediatric Use Marketing Authorisation).

Small and Medium Sized companies are also expected to use this opportunity; help can be provided to SME's through the contact points of DG Research and at the EMEA through the EMEA SME Office.

The need for partnership between academics, networks, patients, industry, and regulators was highlighted to cover all aspects of research, development, formulations and regulatory approval.

[1] 'Off-patent' refers to the lack of basic patent in the meaning of Council Regulation (EEC) No 1768/92

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Funding for research into paediatric medicines is not reserved to SME and generic companies and the European Federation of Pharmaceutical Industry Associations (EFPIA), represented by Christine-Lise Julou, also supported the Paediatric Regulation and the need for integrated paediatric development.

Ethical aspects of research in children are essential to protect this vulnerable population. François Hirsch from DG Research presented the ethical review process which takes place when applications to DG Research are evaluated. There is a need for a European approach to ethics of various types of research in children. Currently, principles and practicalities have been developed only for trials using medicinal products: the Draft Ethical Recommendations for clinical trials with children are published on the European Commission and EMEA websites.

The main messages and clarifications brought about in the workshop were:

- The identification of the 2007 June revised version of the EMEA Priority List as the reference one for applications to DG Research;

- The need for later updates of the Priority List, but only after September 2007, and probably at the beginning of 2008;

- It was clarified that there is no need to include or refer to an agreed Paediatric Investigation Plan in this call, as the Paediatric Committee is not established and agreement would not be available for the deadline of September 2007;

- Applicants are reminded that strict criteria are applied by DG Research in terms of acceptability, in particular with respect to timelines of applications, ensuring that no part of the application is insufficiently developed, and ethical principles. From past experience, areas that were insufficiently developed were 'Management structures & procedures' and 'Resources' in part B2 (i, iv);

- Information on potential industrial or academic partners can be found both on DG Research website (within the 6th Framework Programme webpage), and through EGA who has identified interested companies. This allows meeting the call's requirement to include partners from at least 3 Member States or associated countries;

- Help can be provided to SME's through contact points of the European Commission and the EMEA SME office;

- Help to answer the call can be provided through national contact points for DG Research;

- DG Research is inviting more individuals with appropriate expertise to register to evaluate calls;

- In the future, a collaboration to develop an European ethical framework for paediatric research beyond that for clinical trials falling under the Clinical Trials Directive (Directive 2001/20/EC, as amended) will be set up.

A next workshop will be held jointly by DG Research and the EMEA beginning of 2008 to prepare for the next 2008 call.

List of Annexes:

Annex 1 - Agenda
Annex 2 - List of Participants
Annex 3a and Annex 3b - Presentations by Dr Agnès Saint Raymond
Annex 4 - Presentation by Dr Fergal Donnelly
Annex 5 - Presentation by Dr Christine-Lise Julou
Annex 6 - Presentation by Dr Michael Banks
Annex 7 - Presentation by Dr Francois Hirsch

Hyperlinks to the above mentioned websites:

Information on Priority List of Off-patent Medicinal Products: can be found here.

Information on SME Office can be found here.

Information on ethical aspects to be considered for FP7 application can be found here.