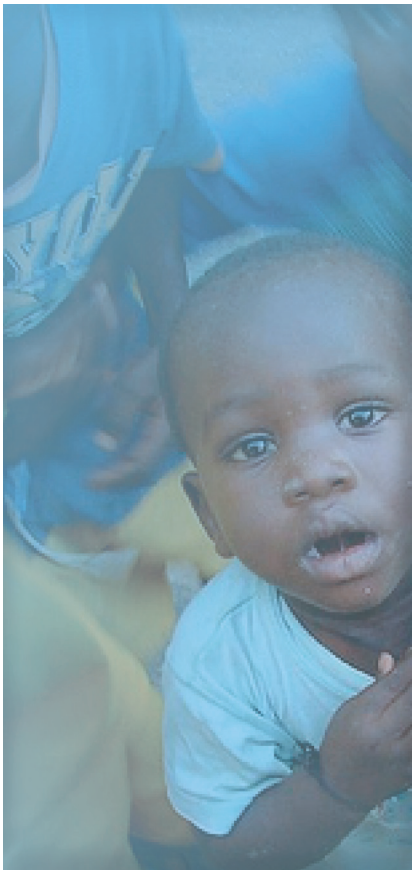

PmRN Newsletter No.1

September 2010

1. Paediatric medicines Regulators' Network (PmRN) in Brief

There is a significant need for research and development on paediatric medicines. Only a limited number of medicines that are currently available have been clinically evaluated for their safety and efficacy in the paediatric population. Following the recommendations from the 13th International Conference of Drug Regulatory Authorities (ICDRA) a Paediatric medicines Regulators' Network (PmRN) has been established with representatives from National Medicines Regulatory Authorities.

Further information on the activities and achievements of the network are provided on the PmRN web site (please see address below). Interested National Medicines Regulatory Authorities are welcome to participate in the PmRN. Authorities from 27 countries from all WHO regions have already registered (members listed on the PmRN web site). To register as a member, please send us an email.

This Newsletter is prepared by WHO, Geneva, on a quarterly basis. Comments and relevant information for possible publication in the Newsletter are welcome.

2. PmRN news

Set-up of PmRN web site

WHO has launched a Paediatric medicines Regulators' Network web site:
http://www.who.int/childmedicines/paediatric_regulators/en/

Formation of the PmRN Steering Committee

A PmRN Steering Committee has been established with regulatory experts from Singapore, the United Republic of Tanzania, the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA).
Dr Agnès Saint Raymond (EMA) was elected as the Chair. The Steering Committee convenes via teleconferences on a monthly basis and can be contacted at: pmr_network@who.int

The Steering Committee coordinates the provision of advice and technical support between PmRN members on key topics in paediatric medicines development and regulation:

- review and assessment of dossiers for application for marketing authorization;
- development of appropriate formulations and dosage forms;
- safety aspects of paediatric medicines.

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World Health Organization

Terms of Reference of the Steering Committee can be accessed on the PmRN web site.

3. Country interview

National requirements and approval procedures for the conduct of clinical trials and application for marketing authorization vary between countries and regions. Interviews will be carried out with PmRN members to reflect the local regulatory environment with the focus on paediatric medicines. The first country interview will discuss the regulatory environment in Tanzania and address the following topics:

- structure and function of the Tanzanian Food and Drug Administration and other relevant authorities;
- resources for ethics review;
- requirements and procedures for applications for conducting clinical trials;
- import of study drugs;
- submission and review of dossiers for marketing authorization;
- resources for paediatric medicines regulation;
- expertise in paediatric medicines and pharmacology;
- capacity building needs;
- links and contacts.

4. Publications from WHO

WHO Model Formulary for Children

The first WHO Model Formulary for Children was launched at the Palais de Nations in Geneva on 18 June 2010.
http://www.who.int/selection_medicines/list/WMFc_2010.pdf

UNICEF/WHO: Sources and Prices of Selected Medicines for Children

The 2nd edition of Sources and Prices of Selected Medicines for Children has been launched. It provides up-to-date information on the sources of selected child-specific medicines and nutrition products, as well as their indicative prices.
http://www.who.int/medicines/publications/sources_prices/en/index.html

5. Other publications

Reflection Paper on Ethical and GCP Aspects of Clinical Trials of Medicinal Products for Human Use Conducted in Third Countries and Submitted in Marketing Authorization Applications to the EMA

The European Medicines Agency launches public consultation on ethical and good clinical practice (GCP) aspects of clinical trials conducted in countries that are not member states of the European Union or the European Economic Area.
http://www.ema.europa.eu/
http://www.ema.europa.eu/Inspections/docs/71239709en.pdf

6. Quality and safety of paediatric medicines

Information on quality and safety of paediatric medicines is provided on the PmRN web site.

7. Upcoming events

ICDRA meeting

The 14th International Conference of Drug Regulatory Authorities (ICDRA) will be held in Singapore from 30 November to 3 December 2010. A paediatric workshop has been scheduled for Tuesday, 30 November 2010, 16:00 to 17:30.
http://www.icdra2010.sg/

Paediatric medicines Regulators' Network
Medicine Access and Rational Use (MAR)
Department of Essential Medicines and Pharmaceutical Policies (EMP)
Health Systems and Services (HSS)
World Health Organization
20 Avenue Appia
1211 Geneva 27, Switzerland

pmr_network@who.int

http://www.who.int/childmedicines/paediatric_regulators/en/