EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

FDA, EuPFI, WHO Collaborations

Paediatric Workshop - 31 May 2010, European Medicines Agency, London, EU

Presented by: Agnes Saint Raymond, Caroline Le Barbier, Piotr Kozarewicz

Agenda

- Objective
- Quality Sector & Paediatric Sector
- Observer at the EuPFI
- Collaboration with FDA - NIH
- Participation in WHO
- Conclusion

Objective

- To present the various collaborations of the EMA regarding paediatric formulations
- Building on synergy and simultaneous initiatives
- To increase the communication between the parties & encourage harmonisation of requirements
- More than a EU project

The Quality & Paediatric sectors

- **Who we are** : scientific admin, assistants (Medical Doctors, Pharmacists, Bio, Chemists)
- **What we do:** Coordination of Centralised procedures, PIPs Clinical & Quality aspects
- **Collaboration:** Internal and External

- **Working together on PIPs** –we are <u>not</u> assessing the MAA- you are the Assessors

Internal & External Collaboration

- Committees (CHMP, PDCO…..)
- Working Parties/Groups (QWP, BWP, …)
- FDA
- EuPFI
- WHO
- External Experts

Collaboration with FDA - NIH

FDA - NIH

- FDA-EMA monthly teleconferences (discussions rarely on formulations)
- FDA fellowships
- NIH Collaboration for BPCA- project on-going
- NIH Collaboration - Teleconference with US PFI (focus on excipients)

Collaboration with EuPFI

European Paediatric Formulation Initiative

Who are they: EuPFI

- Consortium created in 2007, Chair: Dr C. Tuleu, School of Pharmacy
- Discussion forum (experts from industry, academia and clinical pharmacy)

Their objective: to raise awareness and facilitate preparation of better medicines for children

- forum for the exchange of information and expertise
- informing and defining standards for paediatric dosage form development
- publications and discussion papers on paediatric formulation
- education through conferences /workshops

EuPFI continues

Academia	**Industry**	**Organisations**
Royal Liverpool Children's NHS Trust & MCRN	AZ	Association Commercial Specials Manufacturers
	B-I Pharma Gmbh	
	GSK	International Pharmaceutical Excipients Council Europe
The School of Pharmacy, University of London	MSD	
	Novartis	
	Roche	
University of Ghent	Sanofi Aventis	
University of Dusseldorf		

EMA (observer)

Collaborations with US PFI (Eunice Kennedy Shriver NICHD,NIH)

EuPFI continues

The main topics:

- Excipients – to create a searchable safety/toxicity Database of excipients SURVEY www.eupfi.org

- Taste Masking and Testing
- Delivery Devices: Administration- Challenges and Recent Developments
- Extemporaneous preparation – Challenges associated with Extemp. Vs. 'Industry-Verified' preparations
- Age-appropriate formulations - defining basic requirements for industrial dosage form design of paediatric medicines.

EuPFI continues

Our participation:

- Attending meetings (School of Pharmacy, London) 2-3 times/year

- Invited to their Conferences (2009, London + 2010, Berlin)

Collaboration with WHO

‘Make Medicines Children Size’

On 6 December 2007 WHO launched a global campaign '**make medicines child size**' to raise awareness and accelerate action to address the need for improved availability and access to safe child-specific medicines for all children under 15.

World Health Organization

make medicines Child Size

‘Make Medicines Children Size’

The 'make medicines child size' campaign has been endorsed by industry through the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA); civil society through Save the Children and Medicines Sans Frontières, Caritas Internationalis and others; as well as professional associations, the National Institutes of Health, **European Medicines Agency** and UNICEF.

‘Make Medicines Children Size’

We are part of the Initiative!

In partnership with WHO

PmRN –Paediatric Medicines Regulators' Network

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

Steering Committee chaired by the European Medicines Agency

PmRN - Objectives

- Capacity building and exchange forum for **regulatory agencies** from **all regions**
- Provide industry with key information on public health needs
  - Paediatric dosage forms (generics)
  - Clinical trials evaluation
  - Ethics of paediatric trials

PmRN - Objectives

- Facilitate communication between stakeholders
- Provide industry with key information on public health needs
- Prequalification program for medicinal product
- Advise countries on issues of quality, safety and efficacy, and supply management
- Provide the healthcare community with information on dosage and treatment guidelines.

Achievements so far …

The first **Model List of essential Medicines for children** developed in 2007 by a WHO Subcommittee on Selection and Use of Essential Medicines was revised in 2008 to include missing essential medicines for children using evidence-based clinical guidelines.

The **International Conference of Drug Regulatory Authorities**, held a two day pre-conference in September 2008 to discuss the regulation of medicines for children, including clinical trials, streamlining registration procedures and guidance for prescribing medicines for children.

Achievements so far …

The Expert Committee on Pharmaceutical Specifications is **drafting a guidance** document **on the development of paediatric medicines** that will be a resource for industry.

Report of the First Meeting of the paediatric medicines Regulators' Network (15-17 February 2010) published on the website:

http://www.who.int/childmedicines/paediatric_regulators/meetings/Final_PmRN report_2010.pdf

Future steps …

Long term goals include acceptance of and implementing research **guidelines**, establishing credible and feasible outcome measures to assess the impact of interventions and process changes, seeking **regulatory compatibility** across regulated activities such as manufacturing, licensing and research.

All of the goals will rely on culturally aware behavioural changes with new opportunities to explore different types of **partnerships and collaborations** that will extend across disciplines and geographic regions.

Conclusions

- Age-appropriate formulations: needed
- Assessors: stakeholders of major importance
- Additional Expertise: with industry and a few academic groups
- Global development including for formulations
- Balance: 'nice to have' vs 'need to have'
- PIP is binding therefore need for clear message
- All those efforts and synergy ….improve future assessment

Thank you for your attention.
Any question?