



U.S. Food and Drug Administration



European Commission
Enterprise and Industry Directorate General



European Medicines Agency

Principles of Interactions: Between EMEA and FDA Pediatric Therapeutics

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Introduction

This document "Principles of Interactions: Between EMEA and FDA Pediatric Therapeutics" has been developed and agreed in the framework of the Confidentiality Arrangements concluded on 12 September 2003 between the EU (European Commission and EMEA) and the U.S. FDA of the U.S. Department of Health and Human Services in the context of regulatory co-operation and transparency between the U.S. Government and the European Commission. These Confidentiality Arrangements were extended for a period of five years on 15 September 2005.

ICH E-11 states that "Pediatric patients should be given medicines that have been appropriately evaluated for their use in those populations. Safe and effective pharmacotherapy in pediatric patients requires the timely development of information on the proper use of medicinal products in pediatric patients of various ages. Obtaining knowledge of the effects of medicinal products in pediatric patients is an important goal. However, this should be done without compromising the well-being of pediatric patients participating in clinical studies. This responsibility is shared by companies, regulatory authorities, health professionals, and society as a whole."

It is the responsibility of the regulatory authorities that are implementing the programs for product development in pediatrics to ensure that the rights, safety, well-being and dignity of children participating in research are the most important considerations and that only when scientifically and ethically justified will children be included in trials.

Therefore considering the Paediatric Regulation now implemented in the EU and the already existing US Paediatric Regulations/legislations, and in the context of the Confidentiality Arrangements, the three parties have taken a further step in agreeing on principles for interactions in relation to pediatric matters.

Objectives:

The EMEA and FDA are committed to develop a framework:

- to facilitate regular exchange of scientific and ethical issues and other information on pediatric development programmes in Europe and the US to avoid exposing children to unnecessary trials.
- to aim at global pediatric development plans based on scientific grounds, and compatible for both Agencies.

Although the different legal/regulatory requirements may prevent receiving identical applications for pediatric development plans, this framework will allow for administrative simplification.

Scope:

This framework includes:

A. INFORMATION EXCHANGE

- on product-specific pediatric development (Paediatric investigation plans/Written requests/deferrals) and waivers from the obligations to perform such pediatric development. This may include for example discussion on trial design issues.

- ad-hoc exchange on general issues related to pediatric development including sharing at an early stage draft guidance documents of pediatric relevance.

- on safety issues in particular in relation to:

- reporting of adverse drug reactions (ADRs) occurring in children
- exchange of statistics from ADRs database

B. OBSERVER STATUS AT MEETINGS OF PEDIATRIC RELEVANCE:

- Individuals from the EMEA may attend the FDA's Pediatric Implementation Team meetings, and FDA staff may attend the EMEA's Pediatric Committee meetings to enable regulators from either group to observe operational activities, and to better inform each other on optimal mechanisms and timing of exchanges.

Methods

To ensure information exchange, the following actions are proposed:

- Monthly conferences/Teleconferences (T-con) to provide an opportunity for discussion of issues. Both agencies will contribute agenda items prior to the T-con. Additional T-Cons and relevant meetings as needed.
- Monthly line-listing of EU applications for Paediatric Investigation Plans (PIPs) (including deferral) and waivers and requests for modification submitted to the EMEA, and of FDA PPRS and requests for waivers.
- Monthly line-listing on EU decisions on Paediatric Investigation Plans (PIPs) (including deferral) and waivers granted by the EMEA, and of issued FDA Written Requests or any other relevant FDA decisions such as waivers and deferrals.
- Upon request, final Paediatric Committee Opinions and/or (WR)FDA Written Requests will be sent to respective Agencies, where issues have been identified and require discussion.
- Ad-hoc discussions on a product-specific pediatric development may be organized.
- Access to the EMEA's public database of clinical trials (EUDRACT), currently under development. As this database can be a common source of information, the FDA will need to receive training to access this database.

- Issues relating to safety reporting in children, to be a regular part of the monthly EMEA/FDA agenda.
- Additional means for exchange of information in relation to safety to be further explored, including information from safety databases.
- Information on any scientific meetings related to pediatric matters with the possibility for the other party to attend the meeting.

Exchange of documents should be through a secure link (e.g. Eudralink) and should be channeled through the EMEA/FDA contact points. In the future, the possibility of having an intranet accessible to both parties only should be explored.

Each Agency will include on its webpage a link to the other Agency's webpage to facilitate the search of information by interested parties.