Joint European Commission / EMEA Document: Priorities for Implementation of the Regulation on Medicinal Products for Paediatric Use
(Based on Common Position of the Council amended by second reading agreement): September 2006

The precise dates of adoption, publication and entry into force of the paediatric regulation are not known at the present time. However, based on our best estimates this document assumes entry into force of the paediatric regulation in January 2007

Implementation tasks to be the main focus of work during 2006 and 2007

Implementation task	Reference in the Paediatric Regulation	Output	Lead responsibility
List of expertise required on the Paediatric Committee (PDCO)	Article 4	Informal list to be shared between EMEA, Commission and Member States	**EMEA**
Establish operational PDCO	Article 3(1) + Article 4	Established PDCO (excluding Commission nominees)	**EMEA** + Commission + Member States
Establish full PDCO	Article 4(1)(c) and (d)	Established full PDCO (Commission nominees following a call for expressions of interest).	**Commission** + EMEA + European Parliament
PDCO Rules of Procedure	Article 5(2)	Internal EMEA document	**EMEA,** but Management Board then Commission opinions required
Guidance on significant therapeutic benefit / fulfilling a therapeutic need / significant studies	Article 6(2) + Article 45 (3a)	See row below –included in the Commission guideline	**EMEA** and Commission
Detailed arrangements on format and content of applications for Paediatric Investigation Plans (PIPs), waivers, deferrals and modifications + Compliance check	Article 10	Commission guideline - Combine with Article 45(3)(a) guideline on significant studies and interpretation of Article 6(2) terms significant therapeutic benefit / fulfilling a therapeutic need	**Commission** with input from EMEA, CHMP, CMD + Pharmaceutical Committee
EMEA Decision-Making Process including transparency procedures	Article 25	Internal procedure	**EMEA**

Publish the symbol + explanation in the Package Leaflet	Article 32	'Make the symbol public' + need brief guidance for guidance on how to use it	**Commission** based on 'recommendation of the PDCO'
Post-authorisation guidelines includes pharmacovigilance, deferral reports and long term efficacy and safety	Article 34(4)	EMEA guidelines	**EMEA**
Inventory of rewards and incentives by the Community and Member States	Article 39	Commission 'inventory' on website	**Commission** based on Member State information
Funding of studies into off-patent medicines for children ('MICE')	Article 40	Calls for proposals under the 7th Framework Programme	**Commission** and EMEA
Clinical trials in children - details	Article 41(1)	Need to modify EudraCT and manage information	**EMEA**
Clinical trials in children - results	Article 41(2)	Linked to EudraCT	**EMEA**
Clinical trials in children – guidelines on information to be made public, on submitting information and the EMEA's responsibilities	Article 41 (3)	Commission guidelines	**Commission** (in consultation with the Agency, Member States and interested parties)
Survey of existing uses	Article 42	PDCO guidance	**EMEA**
European paediatric research network	Article 44	EMEA implementing strategy	**EMEA** Management Board to adopt (must consult Commission, Member States and interested parties)
Reduced fee for a PUMA	Article 47(1)	Amendment to the Council Regulation on fees payable to the EMEA	**Commission** proposal for Regulation 297/95