

CMDh/EMA PAEDIATRIC SUB-GROUP WORKPLAN 2011

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January 2011*

Work item	Rapporteur	Action(s)	Deadline
EU Worksharing for assessment of paediatric data in accordance with Article 45	All CMDh members	<ul style="list-style-type: none"> 4 waves per year; each wave including 20 active substances Preparation of worksharing schedule for 2012 	Wave 10 Jan 11 Wave 11 Apr 11 Wave 12 Jul 11 Wave 13 Oct 11 Q3, 2011
EU Worksharing for assessment of paediatric data in accordance with Article 46	All CMDh members	<ul style="list-style-type: none"> On-going assessment 	On-going
Article 45 Worksharing – optimising procedures	EMA	<ul style="list-style-type: none"> Update to priority list in accordance with CMDh, NCAs and industry recommendations Review of Art. 45 list with regard to priorities Update of BPG on Art. 45/46 	Q2, 2011 Q2, 2011 Q3, 2011

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Outcome of Article 45 and 46 Worksharing	EMA, Chair	<ul style="list-style-type: none"> Preparation of report and conclusions to date on outcomes and implementation of changes resulting from paediatric Work-sharing. 	Q1, 2011
		<ul style="list-style-type: none"> Increase transparency on outcome of Art. 45/46 procedures on the website 	Q1, 2011
Statistics on rapporteurships	EMA	<ul style="list-style-type: none"> Presentation to sub-group, HMA 	Routine
		<ul style="list-style-type: none"> Publication 	Q1, 2011
Maintenance of web-site Q&As	EMA, all CMDh members	<ul style="list-style-type: none"> Identify new issues for guidance 	On-going
		<ul style="list-style-type: none"> Annual review of all Q&As 	Q4, 2011
Training and sharing experience with paediatric procedures	UK	<ul style="list-style-type: none"> Update of Paediatric Work-sharing Assessment guidance 	Q4, 2011
	UK (lead)	<ul style="list-style-type: none"> Workshop/seminar for assessors 	Q3, 2011
	EMA, Chair	<ul style="list-style-type: none"> Meeting with Industry 	Q3, 2011
Paediatric Art. 29 procedure	UK	<ul style="list-style-type: none"> Update of recommendations for implementing Commission Decisions following an Art. 29 Application under the Paediatric Regulation 	Q2, 2011
CTS tracking – optimise system	DE	<ul style="list-style-type: none"> CTS WG report on proposals for changing the PdWS in CTS; to incorporate, amongst others, a proposal for logging finalised PUMA and Article 	Q1, 2011

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	EMA, DE	<p>29 applications.</p> <ul style="list-style-type: none"> • Gather and review experience of users • Training / User manual • Link to EudraCT – liaise with EMA on future plans 	<p>Q1, 2011</p> <p>Q1, 2011</p> <p>Q4, 2011</p>
Publication of paediatric studies as long as EudraCT is not operational	EMA	<ul style="list-style-type: none"> • Information to sub-group 	By Q4, 2011
Improve link with PDCO	EMA	<ul style="list-style-type: none"> • Share experience with PIPs and compliance checks • Oral report from PDCO on topics of mutual interest 	<p>Q2, 2011</p> <p>Routine</p>
Exchange of information about other aspects of the Paediatric Regulation	<p>All CMDh members</p> <p>EMA, nominated rapporteur</p>	<ul style="list-style-type: none"> • Share experience of implementation of other aspects of the Regulation as appropriate to Member States • Practical interpretation of legislative requirements, e.g. Articles 8, 29 	<p>On-going</p> <p>On-going</p>