

CMDh/European Medicines Agency SUBGROUP ON PAEDIATRIC REGULATION WORKPLAN 2010

*Doc. Ref.: CMDh/163/2010
January 2010*

| 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 | Wave 6 Jan 10 Wave 7 Apr 10 Wave 8 Jul 10 Wave 9 Oct 10 |
| | | <ul style="list-style-type: none"> Introduction of fair distribution principle for assessment amongst MSs | Q1, 2010 |
| | | <ul style="list-style-type: none"> Preparation of worksharing schedule for 2011 | Q3, 2010 |
| 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 | NL | <ul style="list-style-type: none"> Best practice guide update | Q1, 2010 |

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| | NL | <ul style="list-style-type: none"> Update of Public assessment report template | Q2, 2010 |
| | Agency | <ul style="list-style-type: none"> Update to priority list in accordance with CMD(h), NCAs and industry recommendations | Q1, 2010 |
| Article 46 Worksharing – optimising procedures | FR | <ul style="list-style-type: none"> Update of Best practice guide | Q3, 2010 |
| Outcome of Article 45 and 46 Worksharing | Agency, 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. | End Q4, 2010 |
| Statistics on rapporteurships | Agency | <ul style="list-style-type: none"> Presentation to sub-group, HMA | Routine |
| | | <ul style="list-style-type: none"> Publication | Q1 2010 |
| Maintenance of web-site Q&As | Agency, 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, 2010 |
| Training and sharing experience with paediatric procedures | UK | <ul style="list-style-type: none"> Publication of Paediatric Work-sharing Assessment guidance | Q1, 2010 |
| | UK (lead) | <ul style="list-style-type: none"> Workshop/seminar for assessors | Q3, 2010 |
| | Agency, Chair | <ul style="list-style-type: none"> Meeting with Industry | Q3, 2010 |

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|--|------------------------------|---|----------|
| 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 29 applications. | Q4, 2010 |
| | | <ul style="list-style-type: none"> Gather and review experience of users | Q3, 2010 |
| | | <ul style="list-style-type: none"> Training / User manual | Q4, 2010 |
| | Agency, DE | <ul style="list-style-type: none"> Link to EudraCT – liaise with EMA on future plans. | Q4, 2010 |
| Tracking of paediatric studies in EudraCT | Agency | <ul style="list-style-type: none"> Information to sub-group | Q1, 2010 |
| Improve link with PDCO | Agency | <ul style="list-style-type: none"> Share experience with PIPs and compliance checks | Q2, 2010 |
| | | <ul style="list-style-type: none"> Oral report from PDCO on topics of mutual interest | Routine |
| Exchange of information about other aspects of the Paediatric Regulation | All CMDh members | <ul style="list-style-type: none"> Share experience of implementation of other aspects of the Regulation as appropriate to Member States | On-going |
| | Agency, nominated rapporteur | <ul style="list-style-type: none"> Practical interpretation of legislative requirements, eg Articles 8, 29 | On-going |