

## MINUTES

### CMDh/EMEA SUB-GROUP MEETING ON PAEDIATRIC REGULATION WITH INTERESTED PARTIES

London, Monday 21 September 2009  
10.00-12.00, Room 2G

*Doc. Ref.: CMDh/114/2009/Rev0  
November 2009*

		Resp. Action
<b>1.</b>	<b>Agenda of the meeting</b>	
	The agenda of the meeting was adopted.	
<b>2.</b>	<b>Paediatric Subgroup Workplan 2009</b>	
	<ul style="list-style-type: none"> <li>Status of Workplan 2009</li> </ul>	
	A presentation on the status of the workplan 2009 of the Paediatric subgroup was given by the EMEA.	
	<ul style="list-style-type: none"> <li>Recommendation for implementation of compliance statement for the agreed completed PIP</li> </ul>	
	<p>DK gave a presentation on the 'Recommendation for implementation of compliance statement for the agreed completed PIP' which will be published on the CMDh website following the September meeting.</p> <p>The recommendation paper should smooth the NCA's implementation/ amendment of the marketing authorisation.</p> <p>The publication of the recommendation paper was appreciated by EFPIA.</p>	
<b>3.</b>	<b>Article 45 Worksharing</b>	
	<ul style="list-style-type: none"> <li>Statistics on Art. 45 and 46 worksharing</li> <li>Recommendations from Assessors Workshop on Paediatric Regulation</li> <li>Experience with Art. 45 Worksharing</li> </ul>	
	<p>Statistics on Art. 45 and 46 worksharing were presented by the EMEA. The aim is to assess 20 active substances per wave and to include all MS in the worksharing.</p> <p>For the ongoing waves of Art. 45 many procedures are still in clock-stop.</p> <p>For Art. 46, 61 submissions have been received until 14 September 2009 including 102 paed. studies. 19 worksharing procedures have been started.</p>	

UK gave a presentation on the outcome of the assessor's workshop on Paediatric Regulation. It was recommended to develop further guidance for industry to optimise the administrative information and for assessors on the practical application of Art. 45 and 46.

Addressing the questions raised by EFPIA and EGA, it was stated that at the moment it would not be possible to announce the active substances included in one wave further in advance. It could be envisaged to achieve an earlier publication in 2010.

With regard to prioritisation, it was mentioned that PDCO was invited to provide priorities for assessment. Priorities at MS level would also be taken into account. If one MAH considers his product should be prioritised, the CMDh can be approached and the active substance can be taken into account in one of the next waves.

With regard to transparency, Rapporteurs could be mentioned in the published list of active substances included in Art. 45 worksharing.

As some data sets can be huge, a brief summary to guide assessors to the pivotal studies would be appreciated.

Regarding the proposal to have a Co-Rapporteur, it was mentioned that this is not excluded but should only apply in complicated cases and not on a routine basis.

To improve communication, a central company contact point for pediatric issues would be appreciated. A change of the contact point should always be communicated to the EMEA.

Following a question on further workshops for assessors, it was noted that it was important to bring assessors together after the first waves to share experience. A further workshop could be envisaged next year.

EFPIA asked if the PrAR could be shared with MAHs.

This could be discussed, but confidentiality issues should be kept in mind. The Rapporteur should try to summarise the different MS positions at this stage.

To facilitate the submission of variations for the agreed wording, the date of publication of the PAR will be included on the CMDh website.

It was clarified that the worksharing procedure should not be a full harmonisation of the SmPC. It would also not be the intention to delete indications.

Translations of the agreed wording could only be handled at national level.

With regard to synchronisation of parallel procedures, the intention would be to synchronise all ongoing procedures as far as possible, but there are practical difficulties. MAHs should inform the assessors of all ongoing actions to avoid parallel assessment.

Concerns were raised that multiple updates of the SmPC might be requested within a short time due to PSUR WS, Art. 45 WS etc., which are time and resource consuming and expensive.

<b>4.</b>	<b>Article 46 procedure</b>	
	<p>FR gave a presentation on the Art. 46 procedures.</p> <p>The acceptance of English synopses for non-English studies was supported from an Industry point of view. Synchronisation with other ongoing procedures should be envisaged.</p> <p>It was stressed by all parties that good communication between companies and the Rapporteur is essential.</p> <p>Submitted variations should include information in case they are related to a previous Art. 46 submissions.</p> <p>It was mentioned that the route for implementation of the agreed wording after entry into force of the new variation regulation might be different. The publication of the classification guideline would need to be awaited.</p> <p>The wish was to have some flexibility in the interpretation of consequential variations in the context of grouping.</p>	
<b>5.</b>	<b>Recommendations on Paediatric Use Marketing Authorisations</b>	
	<p>UK gave a presentation on the 'Recommendations on Paediatric Use Marketing Authorisations' published on the CMDh website, addressing key attribute, possible legal basis, content of the application and rewards.</p> <p>Companies should be encouraged to develop paediatric products.</p> <p>More experience with PUMAs would need to be gained and shared once the first PUMA application has been submitted.</p>	
<b>6.</b>	<b>Press Release</b>	
	<p>It will be mentioned in the press release that the EMEA/CMDh subgroup on Paediatric Regulation met with Interested Parties.</p>	
<b>7.</b>	<b>A.O.B.</b>	
	<p>N/A</p>	

## **ANNEX I: LIST OF PARTICIPANTS**

- CMD(h) Members
- AESGP
  - Christelle Anquez-Traxler
  - Jerome Gourbeault
- EFPIA
  - Marianne Poulmaire (EFPIA)
  - Gesa Pellier (Novartis)
  - Ali Harrison (AstraZeneca)
  - Angelika Joos (MSD)
- EGA
  - Sue Roach (Arrow)
  - Michel Mikhail (Fresenius Kabi)
  - Carmen Vieira (Teva)
  - Smruti Patel (Teva)
  - Beata Stepniewska (EGA)