

MINUTES

CMDh/EMA Sub-Group Meeting on Paediatric Regulation with Interested Parties

London, Monday 20 September 2010
10.30-12.00, Room 2G

Chairperson: Mrs. Truus Janse-de Hoog

		Action
1.	Agenda of the meeting	
	Agenda Rev.0	Adoption
	The agenda of the meeting was adopted.	
2.	Article 45 Worksharing	
	Recommendations from Assessors Workshop on Paediatric Regulation	Discussion
	Experience with Art. 45 Worksharing	Discussion
	<p>EFPIA gave a presentation on their experiences with Art. 45 worksharing asking for more transparency on the priorities for inclusion of products on the list of Art. 45 procedures and the possibility for MAH to request a product to be assessed under Art. 45. Concerns were raised that the recommendations on paediatric worksharing are not always followed, i.e. with regard to requests for additional studies. EFPIA also asked for an update on the statistics regarding Art. 45 worksharing. Considerations with regard to procedural aspects of the worksharing were also brought forward.</p> <p>EGA also presented their experiences with Art. 45 worksharing. EGA is in favour of the worksharing for an optimal use of resources. EGA proposed to further increase transparency at the end of the procedure and asked for a more coordinated approach between RMS and CMSs with regard to implementation. Questions raised by EGA on grouping for the implementation will be forwarded for discussion to the subgroup on Variation Regulation. Further proposals for improvement with regard to the actual wording to be implemented were presented. The approach of some MS to pro-actively translate the wording was welcomed. EGA also requested a more coordinated approach between Art. 45 worksharing and other procedures, such as PSUR worksharing and Art 30 implementation.</p> <p>UK presented the recommendations as an outcome of the assessors' workshop on Paediatric Regulation. Assessors proposed to ensure appointment of the same Rapporteur for various procedures (e.g. Art. 30 referral, Art. 46, PSUR WS etc). The need for an overview/analysis of the submitted data of the submitted dossier was stressed.</p> <p>A single contact point for the worksharing would facilitate the communication. With regard to old studies, previous assessment should be taken into account. Information to be included in section 5.1 should follow the new SmPC guideline.</p>	

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<p>It was stressed that Art. 45 worksharing is not a harmonisation exercise. The elimination of an indication should be the exemption and handled with the national implementation, at the CMDh or via a referral if sufficiently important. In case of data on off-label use, the involvement of PDCO can be considered.</p> <p>With regard to statistics the group was informed that the published statistics will be updated once per year. At the moment there would be about 50 Art. 45 procedures finalised, about 50 procedures are ongoing and about 40 procedures are not yet started.</p> <p>With regard to the procedural aspects, it was noted that the sending of the preliminary PdAR to the MAH for information has been introduced in the procedure and the public AR should be sent to the MAH for consultation. This will be again stressed to assessors.</p> <p>IP were also informed that in case of different timelines for implementation proposed by RMS and CMS, the RMS timelines should be followed and the CMS should be made aware of this and liaise with the RMS if needed.</p> <p>With regard to priorities of assessment, it was stated that principles have been agreed but also MS were asked to consider priorities at national level. Companies could also inform the CMDh Secretariat if they consider one of their products could be prioritised in the assessment for Art. 45.</p> <p>The EMA informed the group that as of wave 8 the paediatric data under Art. 45 also needs to be submitted to the EMA with a view to be published in EudraCT in the future. The request is included in the letters that are sent to MAHs.</p> <p>Interested Parties were asked for ideas on how to improve the system of Art. 45 assessment in particular the prioritisation of substances (e.g. identification of products that are never used, combination with new studies) as the assessment of all active substances might take more than 10 years.</p>	
<p>3. Article 46 Worksharing</p>	
<p>Experience with Art. 46 Worksharing</p>	<p>Discussion</p>
<p>FR gave a short overview of the procedure and presented the changes introduced in the recent update of the BPG on Art. 46. The main changes concern an update due to the new Variation Regulation. A new section on update of the product information has been introduced and the flowchart has been revised.</p> <p>According to the Variation Regulation the MAH should submit a type IB variation under C.I.3a) of the classification guideline to implement the outcome of the worksharing, if appropriate. This should be done within 30 days after finalisation of the procedure. For MAH with the same active substance and the same pharmaceutical form, a type IB variation should be submitted within 60 days of the publication of the public AR, if this is considered necessary for the safe use of the medicinal product in the paediatric population.</p> <p>FR also addressed the CMDh experience with Art. 46 worksharing. 19 MS have been appointed as Rapporteur so far. Until June 2010, 90 Art. 46 submissions have been received including 140 studies. A decision to start the assessment will take into account the global situation of the product. A mix of Art. 45 and Art. 46 procedures is possible. Also the first public AR for Art. 46 was recently published.</p>	

	Action
<p>EGA gave similar feedback for Art. 46 as for Art. 45 procedures, i.e. alignment of ongoing procedures and provision of final SmPC/PL wording and translations. EGA noted that experience with Art. 46 procedures is limited so far.</p> <p>EFPIA stressed that the different procedures between the centralised procedure and MRP/DCP lead to issues in the internal compliance system of companies and recommended an alignment.</p> <p>EFPIA also informed the CMDh that they will shortly start a survey among their members on experience with the Paediatric Regulation including Art. 45 and 46 procedures. Results should be available in Q1 2011.</p> <p>EFPIA was reminded that if the survey is done anonymously it would be difficult to draw conclusions. A direct feedback is appreciated.</p> <p>Companies were encouraged to discuss with the Art. 46 Rapporteur if a combined Art. 45/46 worksharing could be started in case Art. 45 data is available related to a product with an Art. 46 submission.</p>	
<p>4. Article 29 of Paediatric Regulation</p>	
<p>Experience with Paed. Art. 29 procedure</p>	Discussion
<p>Compliance statement</p>	Discussion
<p>UK gave a presentation with lessons learned from the experience so far. The CMDh has published recommendations for implementing EC decisions following Paediatric Art. 29 procedures (under revision) and guidance and a template regarding the compliance statement.</p> <p>UK noted that the implementation of Paed. Art. 29 EC decision is an unforeseen variation and has been discussed in an Art. 5 (of Variation Regulation) procedure. The interim position is to classify it as a type IB (C.I.1z) variation, but the situation is under further review.</p> <p>MAHs are advised in the recommendation document to liaise early (between CHMP opinion and EC decision) with the RMS. The need for a timely implementation within 30 days is also stressed.</p> <p>EFPIA welcomed the clarifications in the updated CMDh guidance and stressed the need for an implementation in 30 days and the inclusion of the compliance statement in the MA. EFPIA also presented overviews of recent Paed. Art. 29 procedures with regard to the national approval time for each procedure.</p> <p>It was noted that the situation would be difficult in case there is no RMS for the procedure.</p> <p>EGA welcomed the increased visibility of the Paed. Art. 29 procedures on the EMA website.</p> <p>It was noted that experience was limited. The role and responsibilities of generic companies were not clear. Further guidance for generics is needed.</p> <p>The questions from EGA will be further discussed internally.</p>	

		Action
5.	Press Release	
		Discussion
	The meeting of the subgroup on Paediatric Regulation with Interested Parties will be mentioned in the press release.	
6.	A.O.B.	
		Discussion
	Interested Parties were asked to update the EMA about any changes in their contact points for Art. 45/46 submission/worksharing.	

ANNEX I: LIST OF PARTICIPANTS

- CMDh Members
- AESGP
Christine Bautz (Bayer) – AESGP Representative
- EFPIA
Ali Harrison (AstraZeneca)
Christine-Lise Julou (EFPIA)
Gesa Pellier (Novartis)
Elisabeth Fournier Quezari (Sanofi-Aventis)
- EGA
Smurti Patel, TEVA
Kim Clover, Arrow
Beata Stepniewska, EGA secretariat