

Experience with Article 46 Paediatric Worksharing

**Meeting with representatives of
Interested Parties**
- 20th September 2010 -

Alban DHANANI – AFSSAPS (FR)

Scope of Article 46

- All MAH-sponsored paediatric studies completed **after 26 January 2007**
- Whether or not these studies are part of a PIP
- Deadline for submission of information:
 - For the cover letter & line-listing: **within 6 months of completion of the paediatric studies**

- New paediatric studies (**art. 46**) will have to be forwarded to the Rapporteur, once appointed:
 - within **one month of request**,
 - in **electronic format** only.
- A dedicated Paediatric mailbox is used by the Member States for circulation of information (timetable, assessment reports, comments...)

- Timetable based on a **90-day Type II variation**
- Conclusion of the assessment with a **proposal for inclusion of information in the SmPC and PL**, if appropriate
- **Submission of a Variation application** by the MAH to update the product information

Best Practice Guide

- Last update published in **June 2010**
- Mainly changes related to the implementation of the **new Variation Regulation**
 - Creation of a new section: Update of the product information
 - Update of the Flow-Chart

For the MAH concerned by the worksharing procedure

- **A Type IB** procedure shall be submitted within **30 days** by the concerned MAH after the end of the procedure in order to update the product information in accordance with Section C.I.3 a) of the Classification Guideline, if appropriate.

For other MAHs

If considered necessary to guarantee safe use in the paediatric population of the medicinal products with the same active substance

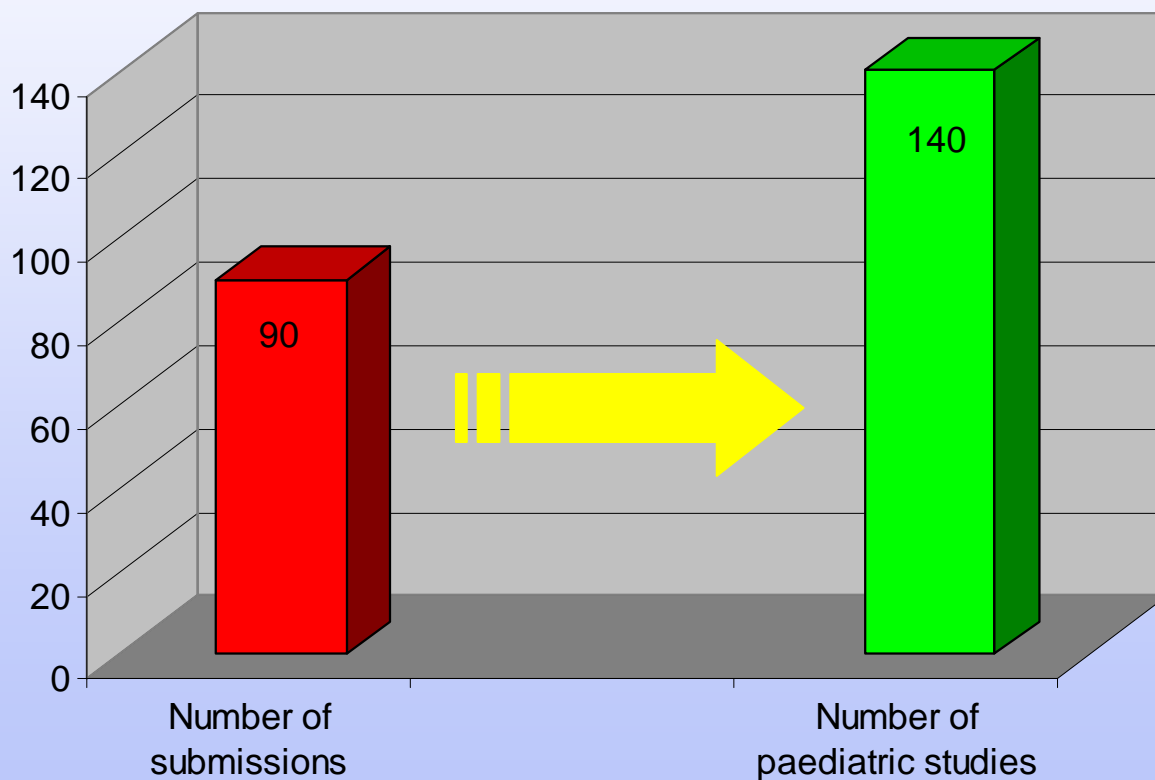
- submission of **type IB variations** within **60 days of publication of the public assessment report** will be requested from other MAHs
- in order to add text agreed during the paediatric assessment procedure to the SmPC/PL of products with the same active substance and pharmaceutical form

Experience with Art. 46

- Appointment of Rapporteur **the month following the submission of information** (*cover letter & line-listing*) by the MAH
- **Main criteria** used for appointment of Rapporteurs:
 - Identified RMS
 - Same Rapporteur as for Art. 45
 - Same Rapporteur as for SPC harmonisation referral (Art. 30)
 - Same PIP Rapporteur
- **19 Member States** have been appointed as Rapporteurs for Art. 46 paediatric WS

Submission of Paediatric data according to Art. 46

1st October 2008 – 30th June 2010



- **Flexibility of the procedure:**
 - The decision to start the evaluation of paediatric data will be taken considering the global situation of the product:
 - possibility to postpone the start of the worksharing procedure in specific situations
 - paediatric data can be submitted as part of a variation / extension or new MAA
 - Possibility **to mix both worksharing procedures** (art. 45 & art. 46) **in one procedure** in agreement with the Rapporteur

- **Improvement of transparency:**



First Public Assessment Reports (PAR) published in 2010

Agreement between Member States to facilitate the publication of the PARs for Art. 46

- **Update of the product information:**



Sensitive step after the end of the WS procedure, especially for other MAHs due to different approaches from Member States

A clear message should be given in order to know whether changes are expected or not for other MAHs

Information published on CMDh website:

<http://www.hma.eu/cmdh.html>

- **BEST PRACTICE GUIDE ARTICLE 46 –
PAEDIATRIC REGULATION - EU WORKSHARING
PROCEDURE (*June 2010*)**
- **Q&As ON THE PAEDIATRIC REGULATION**