

**BEST PRACTICE GUIDE
FOR THE PREPARATION OF THE PUBLIC ASSESSMENT REPORT**

EU Work sharing Procedure in the assessment of paediatric data

June 2006

Revision 2, March 2007

At the HMA meeting held in Amsterdam 30 November 2004 a proposal for Work sharing in the assessment of paediatric data was accepted. The main principle is that two Member States assess the data and prepare an assessment report for the other Member States. After agreement on the proposals for the SPC, a national or MRP variation procedure should be initiated, within 60 days, to update the SPC and PL according to the final paediatric assessment report. This variation procedure should not lead to any further SPC and PL changes.

This procedure includes nationally approved products and products approved via the Mutual recognition or Decentralised procedures.

As the aim of the procedure is to make the paediatric data available for the health care professionals it has been agreed to prepare a public assessment report after finalisation of the procedure. The public assessment report (PaedPAR) will be published on Heads of Medicines Agencies website. National agencies are advised to create hyperlinks to this website.

In the assessors meeting organised on 5 April 2006 at EMEA the writing of the public assessment report in this procedure was discussed. The MHRA experiences were presented and it was agreed to follow the same procedure. The recommendation was to start with the existing final assessment report and to remove confidential information and Annexes. The report should be kept concise, but should be sufficient informative to give the health professionals insight in the available data on the use in children. The Draft report (in Word format) is sent to the marketing authorisation holders to comment in 2 weeks time.

This document addresses the structure and content of the Paediatric Public assessment reports (PaedPAR). Furthermore a table of content and a timetable are given in the Annexes.

1. The rapporteur should draft a PaedPAR after finalisation of the EU Work sharing procedure. The PaedPAR should provide insight in the available data for the specific product and include the information that should be included in the SPC.
2. The basis for the PaedPAR is the integrated assessment report in the procedure with deletion of confidential information. It has been agreed that the template of the paediatric assessment report can be followed.
3. The PaedPAR is written in the English language. It is up to the national agencies to make publicly available a PaedPAR in national language.
4. The rapporteur should ensure that PaedPARs are released within 60 calendar days after finalisation of the Work sharing procedure. The rapporteur may involve the co-rapporteur in the drafting of the PaedPAR, if considered necessary.

5. Information on discussion between Member States on the final proposals for the SPC, if applicable, should be mentioned in the PaedPAR with a short summary of the discussion.
6. To deal with confidentiality issues, the PaedPAR has to be drafted by the rapporteur in consultation with the MAH according to the same principles as applied by EMEA. As a general rule the non-clinical and clinical part of the assessment report are not confidential. Names of assessors and more detailed annexes should be deleted.
7. The final PaedPAR will be circulated via the CMD(h) mailbox for information.
8. A copy of the Final PaedPAR [will](#) be sent by the CMD(h) secretariat, for publication on the CMD(h) website together with the press release and adopted documents.

Annexe I
Table of content

Table of content of the PaedPAR
Public assessment report Paediatric data in EU Worksharing procedure

<i>Coverpage</i>	<i>Information about the product and procedure</i>
1.	Name of the product
2.	Active Substance
3.	Pharmaceutical form
4.	Strength
5.	MA Holder
6.	Agencies that acted as Rapporteurs/Co-rapporteurs in procedure
7.	Timetable

Scientific discussion

1.	Introduction
1.1	Scope of the assessment
II	Scientific discussion
III	Overall conclusion, benefit/Risk assessment
IV	Proposed changes in the SPC

Annexe II
Timetable

Timetable for drafting the Public assessment report

Step	Calendar days after finalisation of the procedure	Action
1	1-14	Drafting PeadPAR Electronic version (Word format) sent to MAH requesting them to comment on matters of fact within 2 weeks
2	14-28	Comments from MAH
3	28-59	Rapporteur completes public report
4	60	Circulate report via CMD mailbox