

FLOW CHART FOR THE MUTUAL RECOGNITION PROCEDURE

May 2007
Rev1 – November 2011

Approx. 90 days before submission to CMS	Applicant requests RMS to update Assessment Report (AR) and allocate procedure number.
Day -14	Applicant submits the dossier to CMS. RMS circulates the AR including <u>S_mPC</u> , PL and labelling to CMSs. Validation of the application in the CMSs.
Day 0	RMS starts the procedure
Day 50	CMSs send their comments to the RMS, <u>CMSs</u> and applicant
Day 60	Applicant sends the response document to CMSs and RMS
Until Day 68	RMS <u>evaluates and</u> circulates <u>a their report/assessment on f</u> the <u>applicant's</u> response document to CMSs.
Day 75	CMSs send their remaining comments to RMS, <u>CMSs</u> and applicant. <u>A break-out session can be organised between day 73 – 80).</u>
<u>Until Day 80</u>	<u>A break-out session (BOS) can be organised around Day 75 (but may take place between days 73 – 80).</u>
Day 85	CMSs send any remaining comments to RMS, <u>CMSs</u> and applicant.
Day 90	CMSs notify RMS and applicant of final position (and in case of negative position also the CMDh secretariat of the EMEA). If consensus is reached, the RMS closes the procedure. If consensus is not reached, the points for disagreement submitted by CMS(s) are referred to CMD(h) by the RMS within 7 days after Day 90.
Day 150	<u>Final position adopted by their procedures referred to</u> CMD(h): If consensus is reached at the level of CMD(h), the RMS closes the procedure. If consensus is not reached at the level of CMD(h), the RMS refers <u>immediately</u> the matter to <u>EMACHMP</u> for <u>CHMP</u> arbitration
5 days after close of procedure	Applicant sends high quality national translations of <u>S_mPC</u> , PL and labelling to CMSs and RMS.
30 days after close of procedure	Granting of national marketing authorisations in the CMSs subject to submission of acceptable translations.

All days mentioned in this document should be regarded as calendar days.