



Report from the Informal MRFG meeting held on 3 and 4 October 2005, Dorking, UK

The MRFG convened for an informal meeting on 3 and 4 October 2005 in Dorking, Surrey. The meeting was held as part of a programme of events organised under the UK Presidency of the EU. The MRFG took the opportunity to overview its preparation work in readiness for the implementation of the new legislation from 30 October 2005. The Group reviewed the documents developed in this regard, considered the detailed responses received from Interested Parties concerning the draft decentralised procedure and the Co-ordination Group referral procedure, and considered plans and future work programmes for the new Co-ordination Group for human medicinal products (CMD(h)).

List of MRFG Guidance on the implementation of the new legislation

In the interest of transparency, the MRFG would like to inform Interested Parties of the guidance documents in preparation on the implementation of the new legislation. The documents in the attached list have been or will be published shortly on the Heads of Medicines Agencies website.

Timelines for the update of MRFG Guidance documents in the Mutual Recognition Procedure

The MRFG has agreed to update the MRFG Guidance documents, currently published on the Heads of Medicines Agencies website, in accordance with the new legislation and to consider, where appropriate, the new decentralised procedure.

Meanwhile, MRFG guidance should be considered as MRFG/CMD(h) guidance and the mutual recognition procedure (MRP) should be considered alongside the new decentralised procedure, unless specific guidance exists for the decentralised procedure or MRP guidance cannot be applied, by analogy, to the decentralised procedure.

Meeting schedule

The last MRFG meeting will be held on 10 and 11 October 2005.

Documents mentioned in this press release can be found at the MRFG website at the European Medicines Authorities Windows under the heading *MRFG Guidance*.

Information on the above mentioned issues can be obtained from the presiding chair of the MRFG:

*Ms. Shirley Norton
Medicines and Healthcare products Regulatory
Agency
1 Nine Elms Lane – Market Towers
London SW8 5NQ
United Kingdom*

*Phone: + 44 207084 2390
Fax: + 44 207084 2293
e-mail: Shirley.norton@mhra.gsi.gov.uk*

*Or you could visit the **MRFG web site** at the EUROPEAN NATIONAL MEDICINES AUTHORITIES WINDOW:*

<http://heads.medagencies.org/>



Publication and consultation of MRFG/CMD(h) Guidance documents on the Implementation of the New Legislation

Topic	Title of Document / Subject	Consultation	Status / Additional Information
<u>Transitional arrangements</u>	Questions and Answers on the implementation of the new legislation	N/A	Publication September 2005 Further Q&As in preparation for October 2005 MRFG
<u>Decentralised procedure</u>	Early proposal for decentralised procedure	End: 29.04.05	Amended following consultation
	Flow chart of the decentralised procedure	N/A	Publication July 2005
	Decentralised Procedure (DCP) – Member States’ SOP	End: 28.09.05	Finalisation and publication October 2005
<u>60 days pre-referral procedure in the CMD(h)</u>	CMD SOP – Disagreement in procedures – referral to CMD	End: 21.09.05 (with Interested Parties)	Finalisation and publication October 2005 with updated Notice to Applicants chapters
<u>Patient information</u>	MRFG/CMD(h) Concept paper Achieving harmonised patient information	End: 21.07.05	Publication of final paper September 2005
	Assessment and approval of the PL and labelling in DCP	N/A	Included in the DCP SOP - Finalisation and publication October 2005
	Assessment and approval of the PL and labelling in MRP	See BPG for MRP	To be included in the BPG for MRP - Draft update for publication October 2005
	Procedure for Article 61(3) changes to patient information	Start: Oct 05	Draft for publication October 2005 Review in 3 months in light of experience and initial comments from Interested Parties
	Annotated template for MR/DC procedures	N/A (QRD Template end: 20.05.05)	Finalisation and publication October 2005
	Usage patent common statement in PL	Start: Oct 05	Draft for publication October 2005

Topic	Title of Document / Subject	Consultation	Status / Additional Information
<u>Renewals</u>	Guideline on the processing of renewals in the MR and DC procedures	End: 28.09.05	Finalisation and publication October 2005
<u>Submission dates for DC/MR procedures</u>	Guidance on submission dates for Applicants of the DC/MR procedures	N/A	Publication October 2005
<u>Transparency issues</u>	BPG for the Public Assessment report in MR/DCP	Start: Oct 05	Draft for publication October 2005
<u>Update of MRP Guidance</u>	Best Practice Guide for the Mutual Recognition Procedure	Start: Oct 05	Draft update for publication October 2005
	Procedure for automatic validation of MR procedures for new applications	Start: Oct 05	Draft update for publication October 2005
	Best Practice Guide on Break-out sessions	Start: Oct 05	Input of Interested Parties to be requested
<u>Urgent Safety Restriction</u>	Urgent Safety Restriction – Member States’ Standard Operating Procedure	Start: Oct 05	Draft update for publication October 2005 (to replace USR MS’ SOP; Chapter 6 of MRFG BPG for variations in the MRP will be removed)