

**CO-ORDINATION GROUP FOR MUTUAL RECOGNITION AND
DECENTRALISED PROCEDURES – HUMAN (CMD(h))**

SUMMARY OF ACTIVITIES IN 2008

*Doc. Ref.: CMDh/011/2009
January 2009*

Web Sites:

CMD(h)

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

European product index

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

INTRODUCTION

2008 was the last year of the first three-year term of operation of the Coordination Group for Mutual Recognition and Decentralised Procedures - Human, CMD(h), set up under the revised EU pharmaceutical legislation for the examination of any question relating to marketing authorisation of a medicinal product in two or more Member States, in accordance with the mutual recognition procedure (MRP) or the decentralised procedure (DCP).

The CMD(h) is composed of one representative per Member State, including Norway, Iceland and Liechtenstein and an observer from the European Commission. The list of the CMD(h) Members, together with the respective professional qualifications, has been published on the Heads of Medicines Agencies website. The CMD(h) cooperates closely with the Heads of Medicines Agencies for human medicines.

A list of new and revised CMD(h) documents and questions & answers developed by the CMD(h) in 2008 is included as **Annex** to this document.

GENERAL INFORMATION

The CMD(h) met eleven times in 2008. The meetings were chaired by Mrs. Truus Janse-de Hoog, who was re-elected Chairperson of the CMD(h) in November 2008 for a second term of three years. The Vice-Chairpersons during the Slovenian and French presidencies of the Council of the European Union were, respectively, Mrs. Sabina Zalar and Mr. Alban Dhanani. Press releases with statistics, adopted documents and information on the applications referred to the CMD(h) were published monthly on the Heads of Medicines Agencies website. Two informal CMD(h) meetings were held in 2008, in Kranjska Gora, Slovenia and in Paris, France.

The EMEA supported the chairperson, the CMD(h) and respective sub-groups in their activities. The CMD(h) Secretariat was also in charge of answering the questions received at the EMEA in relation to the MRP and DCP, in liaison with the CMD(h) Chairperson.

The main activities carried out by the CMD(h) in the areas identified as priorities for 2008 in the CMD(h) work plan are summarised below:

Active participation of all members of the CMD(h)

With a view to improving participation of CMD(h) Members in CMD(h) related activities, the CMD(h) has agreed that all Member States should participate as Rapporteur in work-sharing activities, such as work-sharing for paediatric studies submitted according to Articles 45 and 46 of the Paediatric Regulation.

The CMD(h) has also recommended National Competent Authorities to increase the resources at national level for assisting the CMD(h) Member, by e.g. appointment of a CMD(h) Alternate.

The CMD(h) has also agreed to distribute rapporteurship for guidance documents more widely amongst CMD(h) Members and to support co-operation between experienced and new CMD(h) Members.

Improvement and evaluation of existing procedures

The CMD(h) has considered the proposal to evaluate the decentralised procedure in 2008 and agreed that there was no need to introduce changes to the procedure, further to the revision of the Decentralised Procedure SOP in 2007, which had been subject to public consultation and discussion with Interested Parties.

The Working group on Validation issues/National requirements has continued in 2008 to work towards achieving further reduction in the number of national requirements in the MRP/DCP, a similar understanding between MSs on 'level' of validation and facilitating validation of applications in MRP/DCP.

To meet the above mentioned objectives the following documents, prepared by the Working group on Validation issues/National requirements, have been endorsed by the CMD(h) and published on the website:

- Best Practice Guide on the compilation of the dossier for new applications submitted in MRP and DCP;
- Updated table with additional data requested for new applications in the mutual recognition and decentralised procedures;
- Number of electronic copies requested by each National Competent Authority for new applications for marketing authorisation;
- Number of electronic copies requested by each National Competent Authority for renewals and variations within MRP, DCP or national procedures;
- Common grounds seen for invalidation/delaying Day 0 for Variations;
- Common grounds seen for delaying Day 0 Renewals.

The Working group has also worked towards reaching a similar understanding on level of validation and developed a regulatory and administrative check-in during the validation phase for new applications/extensions in the DCP/MRP, which has been agreed by the CMD(h).

The CMD(h) endorsed the principle that no scientific evaluation of the documentation/dossier can take place as part of the dossier check-in procedure.

Readability tests – Better guidance for industry and harmonisation in assessment of user tests

The CMD(h) participated in the organisation of a joint DIA-EMEA-CMD(h) Workshop on User Testing, aimed at discussing EMEA and MSs experience in the assessment of user tests and giving recommendations how the test can contribute to improve the quality of a package leaflet.

Implementation of the Paediatric Regulation

The CMD(h) has agreed a Best Practice Guide on the EU work-sharing procedure for paediatric studies submitted according to Article 45 of the Paediatric Regulation, aimed at facilitating assessment of paediatric information in a harmonised and coordinated way for nationally authorised medicinal products, including MRP and DCP.

The CMD(h) has started the first-wave of the work-sharing for the assessment of paediatric studies submitted in accordance with Article 45 of the Paediatric Regulation and published the list of active substances included in the first wave of the work-sharing procedure on the CMD(h) website, for transparency reasons.

The CMD(h) has agreed on the list of active substances for the second wave of the work-sharing, to be started in February 2009.

The CMD(h) developed a procedural advice concerning submission of information on paediatric data according to Article 46 of the Paediatric Regulation, including a cover letter and line listing.

The CMD(h) has also agreed additional questions & answers to address validation of applications and submission of paediatric investigation plans in accordance with Articles 7 and 8 of the Paediatric Regulation in the framework of the mutual recognition procedure and to address when is a medicinal product considered not authorised in the Community and the concept of global marketing authorisation in this context.

With regard to the previous voluntary work-sharing procedure in the assessment of paediatric data, the CMD(h) updated the list of active substances in the EU work sharing procedure with the final agreed text for inclusion in the summary of product characteristics, for transparency reasons.

Implementation of the Variation Regulation

The CMD(h) has set up a Sub-group together with the CMD(v) and the EMEA to take forward the various actions arising from the revision of the Variation Regulation, such as the development of new guidance (e.g. recommendations on the classification of unforeseen variations), update of existing guidance (e.g. CMD(h) referral SOP), input to EC proposals and to provide a forum for a common interpretation of the revised Variation Regulation.

The mandate of the Sub-group has been published on the CMD(h) website.

The Sub-group met monthly in the margins of the CMD(h) meetings, as of July 2008.

Public consultation – ‘Strategy to better protect Public health by strengthening and rationalising EU Pharmacovigilance’

The CMD(h) contributed to the public consultation on the draft legislative proposals on Pharmacovigilance strategy. The CMD(h) supports the Commission legislative proposal aimed at better protecting patients by strengthening the EU system for the safety monitoring of medicines.

To contribute to a truly mutual recognition by Member States with a focus on a targeted approach and elimination of full parallel assessment by CMSs

The CMD(h) has contributed to the HMA task force on resources in MRP/DCP and has been involved, amongst other activities, in reducing parallel assessment by CMSs in MRP/DCP, which could generate a greater capacity for MSs to act as RMS.

The CMD(h) discussed this issue more in depth at the informal meeting in Paris and agreed, as a first step, to share amongst MSs the criteria used by National Competent Authorities for not performing parallel assessment when acting as CMSs.

The CMD(h) agreed also that the assessment of an MRP/DCP application by a CMS should be based on the assessment report prepared by the RMS and not on the dossier itself.

Increase transparency for industry on the outcome of the referral discussions in CMD(h) and CHMP

With the aim of increasing transparency on the outcome of CMD(h) and CHMP referrals and to facilitate search of information by Interested Parties, the CMD(h) has published a table with information on all applications referred to the CMD(h) and, where they resulted in a CHMP referral, the date of the CHMP opinion and a link to the respective Commission Decision.

The table is published under 'CMD(h) referrals' and updated on a monthly basis.

The CMD(h) has also published, for the medicinal products included in the lists for SPC harmonisation in accordance with Article 30(2) of Directive 2001/83/EC, as amended, a table with information on the status of the CHMP referral and, for the finalised referrals, the date of the CHMP opinion, a link to the respective Commission Decision and the assigned Reference Member State.

In addition, the CMD(h) has published statistical information on the applications referred to and concluded by the CMD(h) in the first semester of 2008, according to Article 29(1) of Directive 2001/83/EC, as amended, addressing referrals to CMD(h) per type of procedure (MRP vs DCP), per type of product, per legal basis, per therapeutic area, per grounds and per outcome.

The CMD(h) is also working with the CHMP with a view to publishing positions agreed at EU level on specific questions in relation to pharmacokinetic evaluation and, in particular, the requirements and assessment of bioequivalence studies that might be of general interest.

ORGANISATIONAL MATTERS

The October 2008 CMD(h) meeting was the last one of the first three-year term of the CMD(h).

The CMD(h) Secretariat prepared the election of the CMD(h) Chairperson, held in November 2008, and oversaw the nomination of CMD(h) Members for a new three year-term.

Mrs. Truus Janse-de Hoog was re-elected Chairperson of the CMD(h) by an absolute majority of CMD(h) Members for a second term of three years.

EVALUATION OF THE FUNCTIONING OF THE CMD(h)

The CMD(h) has agreed as one of the priorities for 2008 to conduct, before the end of the first three-year term of the CMD(h), an evaluation of how the Group is functioning in view of the agreed mandate and new responsibilities and discuss how further improvements in the operation of the CMD(h) can be achieved.

Questionnaires to collect the views of the CMD(h) Members and of Interested Parties have been prepared by a Working Group of the CMD(h) and the results of the questionnaires including an action plan to address the main issues identified by CMD(h) Members and Interested Parties were presented and discussed at the informal CMD(h) meetings.

A report with the outcome of the assessment on the functioning of the CMD(h) will be published on the CMD(h) website.

REFERRALS TO CMD(h)

The CMD(h) has continued to devote in 2008 considerable time and resources to trying to reach agreement for MRP and DCP applications, in the situations where a Member State cannot approve the assessment report, the summary of product characteristics (SPC), the labelling and the package leaflet (PL) on the grounds of potential serious risk to public health, in accordance with Article 29(1) of Directive 2001/83/EC, as amended.

The percentage of MRP and DCP applications referred to the CMD(h) in 2008 (7.2%) has decreased by 1% compared to 2007 and by 10% compared to 2006.

Of the Mutual Recognition Procedures finalised in 2008 (411), 9% (39) were referred to the CMD(h). This represents a decrease of 1% and 10% in the percentage of finalised MRP referred to CMD(h) in comparison with 2007 and 2006, respectively.

The percentage of MRP applications referred to the CMD(h) seems to have stabilised around 10%.

Of the Decentralised Procedures finalised in 2008 (733), 5.8% (43) were referred to the CMD(h) in this time period. The percentage of DCP applications referred to the CMD(h) seems to have stabilised around 6%.

The lower percentage of DCP applications referred to the CMD(h) in comparison with MRP applications referred to the CMD(h) might be due to an early involvement of CMS(s) in the DCP applications and the possibility for the Applicant to address the issues raised by the RMS and CMS(s) in the clock-stop.

The number of oral explanations from Applicants with the CMD(h) in 2008 (31) has increased by 48% in comparison with previous years.

Of the 81 referral procedures finalised by the CMD(h) in 2008 (which includes 13 applications referred to CMD(h) in 2007), the CMD(h) was able to reach agreement for 77% of the procedures (62) and referred to the CHMP 23% of the procedures (19).

The percentage of applications referred to the CHMP has decreased slightly over the past years, i.e. from 29% in 2006, 26% in 2007 to 23% in 2008. It is expected that the percentage of applications referred to the CHMP will be kept between 20-25%.

The 19 applications referred to the CHMP for arbitration in 2008 include 3 multiple applications and thus correspond to 16 different applications for 15 different active substances.

8 of the applications referred to the CHMP were for generic medicinal products, 4 for hybrid medicinal products, 5 for full dossiers, 1 for a well-established use medicinal product and 1 for a fixed-combination.

The CMD(h) has agreed an updated guidance document with the timetables for MRP/DCP applications referred to the CMD(h) for the 60-days referral procedure for 2009.

The CMD(h) has discussed at the informal meeting the number of CMD(h) referrals. Although referrals are considered a useful procedure to discuss different positions between Member States, it was proposed to develop general recommendations to reduce the number of 'unjustified' referrals to CMD(h).

CMD(h) SUB-GROUPS/WORKING GROUPS

A number of CMD(h) subgroups meetings were held during 2008.

The Communication tracking system (CTS) Working Group (Hum + Vet), which is in charge of the MRP and DCP tracking system, met 4 times in 2008.

The CTS WG was also involved in the drafting of the specifications for updating CTS in line with new procedures following implementation of the Paediatric Regulation.

The CMD(h) Sub-group on harmonisation of SPCs, set up in view of the role of the Co-ordination group to lay down a list of products for which a harmonised SPC should be drawn up, met 5 times in 2008.

The Sub-group has agreed a new list of products for SPC harmonisation, in accordance with Article 30(2) of Directive 2001/83/EC, as amended, which was published on the CMD(h) website for an eight week period for public consultation.

The Joint CMD(h)/Pharmacovigilance Working Party Working Group, set up to discuss issues of common interest to the CMD(h) and PhVWP, e.g. PSUR work sharing project, evaluation of EU Risk management plans and Pharmacovigilance systems, met 3 times in 2008.

The CMD(h) has discussed the reports prepared by the PhVWP on safety related issues, including the proposed implementation plan, as foreseen in the document on interaction between PhVWP and CMD(h), and has published a proposal for implementation of the agreed product information, following the PhVWP recommendations on the following:

- Warnings on suicidal thoughts and behaviour for antidepressants;
- Warnings on antiepileptics and suicidal behaviour;
- Carbamazepine related Stevens Johnson Syndrome and associations with HLA-B* 1502;
- SPC changes (sections 4.5 and 5.1) on Ibuprofen and low dose aspirin interaction;
- Implementation of SPC/PL changes on Biphosphonates and Atrial fibrillation;
- Angiotensin Converting Enzyme (ACE) inhibitors and Angiotensin II Receptor Antagonists (AIIAs): Use during pregnancy and lactation

The CMD(h)/EMA Sub-group on Paediatric Regulation met 9 times in 2008, to organise the work-sharing for the assessment of paediatric studies submitted according to Articles 45 and 46, including the development of guidance documents on Articles 45 & 46 and additional questions and answers.

The CMD(h)-GCP Inspections Sub-group met 4 times in 2008. The Sub-group developed a guidance for coordination of GCP inspections and co-operation between GCP inspectors, the RMS and CMS and CMD(h) in the context of the evaluation of the GCP compliance of marketing authorisation applications for MRP and DCP.

The Sub-group developed also a reflection paper on advice to Applicants/Sponsors/CROs of Bioequivalence Studies aimed at increasing awareness with the responsible parties that the data submitted in a marketing authorisation should be of high quality, safety and should be verifiable and to give guidance to the applicant on how to obtain more certainty on the trial data.

The Working group on Validation issues/National requirements met 7 times in 2008 to continue its work towards achieving further reduction in the number of national requirements in the MRP/DCP, a similar understanding between MSs on 'level' of validation and facilitating validation of applications in MRP/DCP.

Transparency

The CMD(h) continued to work on the improvement of the CMD(h) website, to ensure a better structure and easy access to the information published.

The proposals for improvement of the website, including the comments received from Interested Parties, were presented at the informal meeting in Paris.

The question and answers section of the CMD(h) website was updated in 2008 and the update of the other sections of the website should be concluded by Q1, 2009.

The CMD(h) and the EMA met in 2008 with representatives of AESGP, EFPIA and EGA to discuss transparency of agendas and minutes and of on-going applications.

INTERACTION WITH EMA SCIENTIFIC COMMITTEES AND WORKING PARTIES

The CMD(h) has liaised regularly with EMA Scientific Committees and Working Parties and sent requests for scientific opinions and/or for interpretation of scientific guidelines or guidance documents, mainly arising from discussions for applications referred to the CMD(h) in case of disagreement between the involved MSs in a MRP or DCP application.

The CMD(h) welcomed the publication on the EMA website of the draft Guideline on the investigation of Bioequivalence for a 6 months public consultation.

CMD(h) Observers have continued to participate in the EMEA/Human Scientific Committees WP with Patients' and Consumers' Organisations and in the EMEA/CHMP Working Group with Health Care Professionals' Organisations.

INTERACTION WITH INTERESTED PARTIES

The CMD(h) has liaised regularly with representatives of Interested Parties, through public consultation of CMD(h) documents and discussion of questions raised by Interested Parties.

The CMD(h) held a meeting with representatives of Interested Parties in 2008, to discuss Member States' resources in the Mutual Recognition and Decentralised Procedures & CMD(h) contribution to the Task force on resources, a report on the status of the on-going Article 45 and 46 work-sharing procedures, electronic submissions and information on the Variation Regulation Sub-group & overview of documents to be developed/reviced.

A report from the meeting will be published on the CMD(h) website for transparency reasons.

The CMD(h) held also a meeting with AESGP to discuss experience with the use of mutual recognition and decentralised procedures for non-prescription medicinal products.

The CMD(h) has collaborated with EGA in the organisation of the 2nd EGA-CMD(h) Symposium on Bioequivalence – “Bioequivalence guideline revision, regulatory procedures and Good Practices: Paving the way towards an even more efficient regulatory framework”, held in Paris, 7-8 October 2008.

MRP/DCP STATISTICS

The number of new applications submitted in 2008 via the MRP and DCP (1899) has increased by approximately 33% and 81% compared to 2007 and 2006, respectively.

The number of new applications submitted in 2008 via the MRP (433) has increased by 9% compared to 2007.

The number of new applications submitted in 2008 via the DCP (1466) has increased by 42% in comparison with 2007.

The number of applications finalised via the MRP and DCP (1144) in 2008 has increased by 38% compared to 2007 (827) and 90% compared to 2006 (592). The number of applications finalised via the MRP in 2008 has decreased slightly (7%) in comparison with 2007 whilst the number of applications finalised via the DCP in 2008 has increased by 95%.

The number of variations submitted and finalised in 2008 has increased by 18% and 14%, respectively, compared to 2007.

Statistical information on applications under the MRP and the DCP was provided by the EMEA and presented in the monthly CMD(h) press releases.

	Total started in 2008*	Under evaluation in 2008*	Ended in 2008*	Referrals to CMD(h) in 2008	Referrals to CHMP in 2008
New applications MRP	433	82	411	39	12

New applications DCP	1466	1709	733	43	7
Type-IA variations	6757	616	6275	N/A	N/A
Type-IB variations	2846	492	2590	N/A	0
Type-II variations	3020	1508	2642	N/A	0

**The numbers include multiple procedures as stated at 31 December 2008.*

ANNEX

NEW DOCUMENTS

Document	Adoption
<u>About CMD(h)</u>	
CMD(h) Work plan	
CMD(h) Work plan for 2008	January, 2008
CMD(h) Reports	
Summary of CMD(h) Activities in 2007	January, 2008
Contacts with Representative Organisations	
Minutes from the CMD(h) meeting with representatives of Interested Parties (November 2007)	January, 2008
Request for Marketing Authorisation Holders to assess the risk of occurrence of contamination with mesilate esters and related compounds in pharmaceuticals	February, 2008
<u>CMD(h) Subgroups</u>	
Subgroup on Variations Regulation	
Mandate for the CMD(h)-(v) Subgroup on Variation Regulation	November, 2008
CMD(h) Subgroup on Harmonisation of SPCs	
Final 2007 List of Products for SPC Harmonisation	January, 2008
Tracking table for information on applications referred to CHMP in accordance with Article 30(2) of Directive 2001/83/EC, as amended	October, 2008

NEW DOCUMENTS

Document

Adoption

Procedural Guidance

General Information

Application for MA

CMD(h) BPG on the Compilation of the Dossier for New Applications submitted in MRP/DCP

March, 2008

eSubmissions

CMD(h) BPG on the use of eCTD in MRP/DCP

April, 2008

Requirements on eSubmissions for NA within MRP, DCP or National procedures

January, 2008

Requirements on eSubmissions for Renewals and Variations within MRP, DCP or National procedures

December, 2008

Renewal Procedure

Common grounds seen for delaying Day 0 Renewals

July, 2008

Variation Procedure

Common grounds seen for invalidation/delaying Day 0

September, 2008

CMD(h) Referrals

Tracking table for information on applications referred to the CMD(h) in accordance with Article 29(1) of Directive 2001/83/EC, as amended

July, 2008

NEW DOCUMENTS

Document

Adoption

Pharmacovigilance / PhVWP Recommendations

Antidepressants and suicidal thoughts and behaviour

Recommendations from the PhVWP Antidepressants and suicidal thoughts and behaviour - SPC wording agreed in January 2008

January, 2008

Antidepressants and suicidal thoughts and behaviour - PhVWP PAR

January, 2008

Angiotensin Converting Enzyme (ACE) inhibitors and Angiotensin II Receptor Antagonists (AIIRAs): Use during pregnancy & lactation

Angiotensin Converting Enzyme (ACE) inhibitors and Angiotensin II Receptor Antagonists (AIIRAs) - Agreed wording SPC and PL

December, 2008

Antiepileptic medicines (risk of suicidal thoughts and behaviour)

Key statement

July, 2008

Agreed SPC & PL wording

July, 2008

Q&As

July, 2008

Carbamazepine related Stevens Johnson Syndrome and association with HLA-B*1502

Agreed SPC & PL wording

July, 2008

Ibuprofen & Aspirin

Agreed SPC & PL wording

September, 2008

Bisphosphonates and Atrial fibrillation

Agreed SPC & PL wording

October, 2008

NEW DOCUMENTS

Document

Adoption

Paediatric Data Assessment

BPG Article 45 of Paediatric Regulation (EU Worksharing procedure)

September, 2008

Procedural guidance concerning submission of information on paediatric data according to Art.46 of the Paediatric Regulation

November, 2008

Product Information

Oxycodone containing medicinal products

Labelling & Package Leaflet warning - Taking alcohol

November, 2008

Core SPCs

[Trivalent Influenza Vaccines] Core PL

November, 2008

Templates

[Renewals] End of Renewal Procedure

September, 2008

Advice from CMD(h)

Public Assessment Report - Change in qualitative and quantitative composition of rubber stoppers of West Pharmaceutical Services

July, 2008

NEW QUESTIONS & ANSWERS

Document		Adoption	Last Update
<u>FAQs</u>			
[FAQs – Harmonisation SPCs]	Following an Article 30 or 31(1) referral procedure involving medicinal products authorised nationally in more than one MS, should the mutual recognition procedure be used to maintain the harmonisation achieved?		February, 2008
[Generics]	Does the requirement in Article 3.3 c) of Regulation (EC) No 726/2004 that a generic of a reference medicinal product authorised by the Community should be authorised under the same name in all the Member States where the application has been made apply to generic applications submitted via the Mutual Recognition or Decentralised Procedures?		October, 2008
[Generics]	Following a successful concluded MRP/DCP, a Generic of a reference medicinal product authorised by the Community is authorised in all MS concerned with the same name. Is it possible to change the name of the Generic following the transfer of the MA in one or several MS to a new MAH?		November, 2008

REVISED DOCUMENTS

Document	Adoption	Last Update
<u>Procedural Guidance</u>		
Application for Marketing Authorisation		
Additional data requested for new applications in the MRP/DCP	July, 2007	July, 2008
MS recommendations on the Cover Letter for new applications submitted through MRP/DCP	July, 2007	April, 2008
[DCP] Guidance on submission dates for Applicants of the Decentralised Procedure	October, 2005	December, 2008
Renewal Procedure		
CMD(h) BPG on the processing of renewals in the MRP/DCP		November, 2008
Variation Procedure		
CMD(h) Best Practice Guides for the Submission and Processing of Variations in the Mutual Recognition Procedure	June, 2003	February, 2008 <i>(Chapter 5)</i>
Post referral phase		
Recommendation for Mutual Recognition Procedure after finalisation of an arbitration procedure with a positive decision by the EU-Commission	September, 2001	October, 2008 <i>For consultation until 5th January 2009</i>

REVISED DOCUMENTS

Document	Adoption	Last Update
<u>Paediatric Data Assessment</u>		
Cover letter for submission of information on paediatric data according to Article 46 of the Paediatric Regulation	June, 2008	November, 2008
Line listing – Submission of information on paediatric data according to Article 46 of the Paediatric Regulation	June, 2008	November, 2008
Q&A on the Paediatric Regulation (Regulation of the European Parliament and of the Council (EC) No 1901/2006, as amended)	October, 2007	November, 2008
Worksharing project		
List of active substances and agreed SPC wordings - EU Worksharing procedure in the assessment of paediatric data	May, 2008	July, 2008
<u>Templates</u>		
AR		
[DCP] Templates AR/Comments	February, 2006	February, 2008 <i>(Overview D70 PrAR; Overview D120 DAR; NC-C AR for Generics)</i>
[MRP] Template on Assessment Report MRP CTD format	January, 2003	February, 2008 <i>(Overview MRP AR; NC-C AR for Generics)</i>
Application for MA		
Cover letter for new applications submitted through MRP/DCP	November, 2007	April, 2008

REVISED DOCUMENTS

Document	Adoption	Last Update
<u>FAQs</u>		
[FAQs – Harmonisation SPCs]	How can compliance with the Commission decision be achieved for generics following an Article 30 referral procedure?	February, 2008
[FAQs – Harmonisation SPCs]	How to proceed if following an Article 30 or 31(1) referral the chosen RMS has not authorised all the strengths, pharmaceutical forms and/or duplicates?	February, 2008
[FAQs – Fees]	Which is the best way to get information on the fees payable to every MS when they act as RMS or CMS in the Mutual Recognition Procedure or Decentralised Procedure?	February, 2008
[FAQs – Miscellaneous]	How should the communication in a MRP/DCP be directed?	February, 2008
[FAQs – Miscellaneous]	Where can I find general information regarding national requirements for MRP/DCP?	February, 2008
[FAQs – Miscellaneous]	How should variations to ASMFs of MRP/DCP marketing authorisations be introduced?	February, 2008
[FAQs – Miscellaneous]	Can a medicinal product, which is not licensed in the EEA be used as reference product in bioequivalence studies?	February, 2008

REVISED DOCUMENTS

Document	Adoption	Last Update
[FAQs – Miscellaneous] Is the decentralised or mutual recognition procedure optional for bibliographical applications, submitted in accordance with Article 10(a), Directive 2001/83/EC, as amended?		February, 2008
[FAQs – Miscellaneous] The Decentralised or Mutual Recognition Procedure is compulsory when the same applicant intends to market a medicinal product in more than one Member State. Can you clarify when two or more companies are considered to be the same applicant?		February, 2008
[FAQs – Miscellaneous] Is it optional for a Company to submit a bibliographic application when there is an original/reference medicinal product to which essential similarity can be claimed, or is an application, in accordance with Article 10(1) or 10(3) the appropriate legal basis for such an application?		February, 2008
[FAQs – Miscellaneous] How should applicants deal with a transfer of MA for a product registered through MRP or DCP?		February, 2008
[FAQs – Miscellaneous] Are medicinal products authorised by Mutual Recognition or Decentralised Procedures listed?		February, 2008