

CO-ORDINATION GROUP FOR MUTUAL RECOGNITION AND DECENTRALISED PROCEDURES – HUMAN (CMDh)

SUMMARY OF ACTIVITIES IN 2009

*Doc. Ref.: CMDh/159/2010
January 2010*

Web Sites:

- CMDh: <http://www.hma.eu/cmdh.html>
- European product index: <http://www.hma.eu/mri.html>

INTRODUCTION

2009 was the fourth full year of operation of the Coordination Group for Mutual Recognition and Decentralised Procedures - Human, CMDh, 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 CMDh is composed of one representative per Member State, including Norway, Iceland and Liechtenstein and an observer from the European Commission. The list of the CMDh Members, together with the respective professional qualifications, has been published on the Heads of Medicines Agencies website. The CMDh cooperates closely with the Heads of Medicines Agencies for human medicines.

A list of new and revised CMDh documents and questions & answers developed by the CMDh in 2009 is included as **Annex** to this document.

GENERAL INFORMATION

The CMDh met eleven times in 2009. The meetings were chaired by Mrs. Truus Janse-de Hoog, who was re-elected Chairperson of the CMDh in November 2008 for a second term of three years. The Vice-Chairpersons during the Czech and Swedish presidencies of the Council of the European Union were, respectively, Mrs. Monika Kisacova and Mr. Christer Backman. Press releases with statistics, adopted documents and information on the applications referred to the CMDh were published monthly on the Heads of Medicines Agencies website. Two informal CMDh meetings were held in 2009, in Prague, Czech Republic and in Uppsala, Sweden.

The European Medicines Agency supported the chairperson, the CMDh and related sub-groups in their activities.

The CMDh Secretariat was also in charge of answering the questions received at the European Medicines Agency in relation to the MRP and DCP, in liaison with the CMDh Chairperson.

The main activities carried out by the CMDh in the areas identified as priorities for 2009 in the CMDh work plan are summarised below:

Active participation of all members of the CMDh

With a view to improving participation of CMDh Members in CMDh related activities and to promoting the collaboration between experienced and new CMDh Members, the CMDh has agreed to appoint co-rapporteurs for the development of guidance documents.

Active participation of all Member States in Worksharing procedures

In order to have more Member States involved in the Worksharing procedures such as worksharing for the evaluation of paediatric studies submitted according to Articles 45 and 46 of the Paediatric Regulation, the rapporteurship has been widely distributed amongst CMDh Members. Statistics show that nearly all Member States participated.

Contributing to HMA Taskforce on Resources

Some CMDh Members have taken part of the HMA Taskforce on Resources and have regularly reported to the CMDh on the activities of the group, allowing an active collaboration between the HMA Taskforce on Resources and the CMDh on topics such as a questionnaire on the assessment of applications, an estimation of the workload for the coming years and future capacity of RMSship, document sharing and how to make the best use of the available resources.

In particular, several initiatives were taken to improve the booking system for DCP: a link to NCAs webpages containing information on NCAs priorities to accept assignment of RMS was published on the CMDh website. In addition, a DCP request form template was developed that is used by most of the NCAs.

Elimination of parallel assessment and implementation of a Risk based approach

CMDh Members have shared experiences on the application of a risk-based approach for CMS activities. A feedback form was developed for CMS to give feedback on the Assessment Report prepared by the RMS aimed at improving the quality of the Assessment Report and avoiding parallel assessments. Member States will use the feedback form for a pilot period of 12 months starting in November 2009. Filled-in feedback forms will be for the exclusive use of RMS and will not be disclosed.

Implementation of the Paediatric Regulation

The CMDh has started four waves of the work-sharing for the assessment of paediatric studies submitted in accordance with Article 45 of the Paediatric Regulation and the list of active substances included in the waves of the work-sharing procedure has been published on the CMDh website for transparency reasons. The Assessment Reports containing the final agreed text for inclusion in the summary of product characteristics are published on the CMDh website.

The Best Practice Guide on the EU work-sharing procedure for the assessment of paediatric studies submitted according to Article 45 of the Paediatric Regulation was revised to introduce a fast track implementation procedure for the outcome of the Article 45 procedure.

The CMDh has agreed a Best Practice Guide on the EU work-sharing procedure for the assessment of paediatric studies submitted according to Article 46 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 Questions & Answers document was updated to reflect the experience gained in 2009 with the Paediatric Regulation.

A training session for assessors was held in July with the aim to give further clarification on the scope of the procedures and discuss the first experiences in the assessment of the Paediatric data.

Implementation of the Variation Regulation

In close collaboration with the CMDv and the European Medicines Agency, the CMDh contributed to the implementation of Regulation (EC) No 1234/2008 on variations by sending proposals to the European Commission on the draft Variation “Classification Guideline” and “Procedural Guideline” as well as by making proposals for the revision of the CMDh/CMDv/EMA common Application Form.

The CMDh has revised its Best Practice Guides on submission and processing of variations in Mutual Recognition Procedure to reflect changes introduced by Commission Regulation (EC) No 1234/2008.

The revised Best Practice Guides provide details on the actions undertaken by the Reference Member State (RMS), Concerned Member States (CMS) and the applicant at each step of the variation process, and the involvement of CMDh where applicable. The revised Best Practice Guides have been published on the CMDh website.

Prepare for the new task foreseen with the new legislative proposal on pharmacovigilance

The CMDh has followed the discussion on the proposed legislation on Pharmacovigilance and will continue to closely follow-up in 2010 to anticipate the impact of the proposed legislation on CMDh activities.

Increase transparency

The CMDh has continued to publish on a monthly basis the outcome of CMDh and CHMP referrals. Statistical information were published on the applications referred to and concluded by the CMDh in 2009, according to Article 29(1) of Directive 2001/83/EC, as amended, sorted per type of procedure (MRP vs. DCP), per type of product, per legal basis, per therapeutic area, per grounds and per outcome.

The CMDh is still closely collaborating with the CHMP with a view to publishing positions agreed at EU level on any questions of general interest.

In 2009, the CMDh got actively involved in several multi-disciplinary and/or cross-agency groups working on transparency in order to reach a common approach regarding requests for access to documents.

The CMDh position paper on transparency was revised.

In order to improve access to product information, the CMDh has made proposals to develop a user-friendly version of the Product Index accessible through the CMDh website.

Reduction of national requirements

The CMDh worked with the national agencies to reduce the additional data requested for New Applications in the Mutual Recognition and Decentralised Procedures. The updated list has been published on the CMDh website and has been communicated to the European Commission.

Implementation of e-CTD in MRP and DCP

The CMDh has started to follow the status of the implementation of the e-submissions in the Community to communicate the information relating to this status to interested parties. A list of national requirements was also established and made available, which is updated regularly.

The CMDh in close collaboration with the TIGes and the interlinking group has identified major hurdles preventing the applicant to use the e-CTD format and has put forward proposals to HMA to facilitate the use of e-CTD by applicants. HMA has accepted the CMDh proposal to handle national translations outside of the e-CTD.

The CMDh has revised the Best Practice Guides for use of e-CTD to reflect these changes and give practical information on how to handle the e-submission. The revised BPG will be published on the CMDh website.

Implementation of the use of Vitero

The Vitero conferencing tool has been used 3 times in 2009 for joint CMDh/CMDv meetings. The CMDh has agreed to use Vitero for some of the CTS working group meetings and for Break out Sessions as well in situations where CMDh members cannot travel.

Scientific memory for outcome on product related issues and regulatory questions

The CMDh agreed on the User Requirements for the Scientific and Regulatory Database for CMD Decisions and CMD Memory. The agreed document has been forwarded to the Executive Director of the European Medicines Agency.

Pandemic preparedness

The CMDh has agreed on a pandemic plan which outlines a framework for maintenance of core and critical business functions within CMDh in the event of an outbreak of the pandemic influenza according to the WHO pandemic phase system and defines the rules for its implementation. The CMDh pandemic plan was published on the CMDh website under "Procedural Guidance".

ORGANISATIONAL MATTERS

The meeting calendar and relevant procedure dates have been published on CMDh website.

The Secretariat is keeping track of the expiry dates of nominations of CMDh members, whilst the Member States are responsible for sending in renewals or new nominations on time.

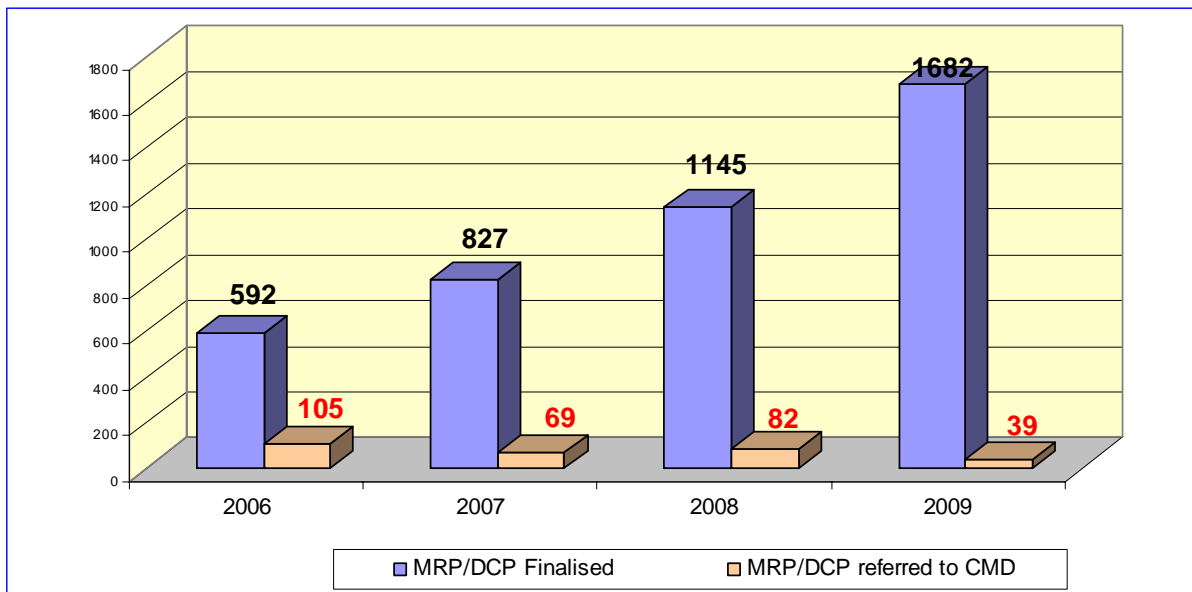
The CMDh has also recommended National Competent Authorities to increase the resources at national level for assisting the CMDh Member, by e.g. appointment of a CMDh Alternate.

The Rules of Procedure of the CMDh have been revised in 2009 to reflect the experience gained in the first four years of operation and to be prepared for the coming years.

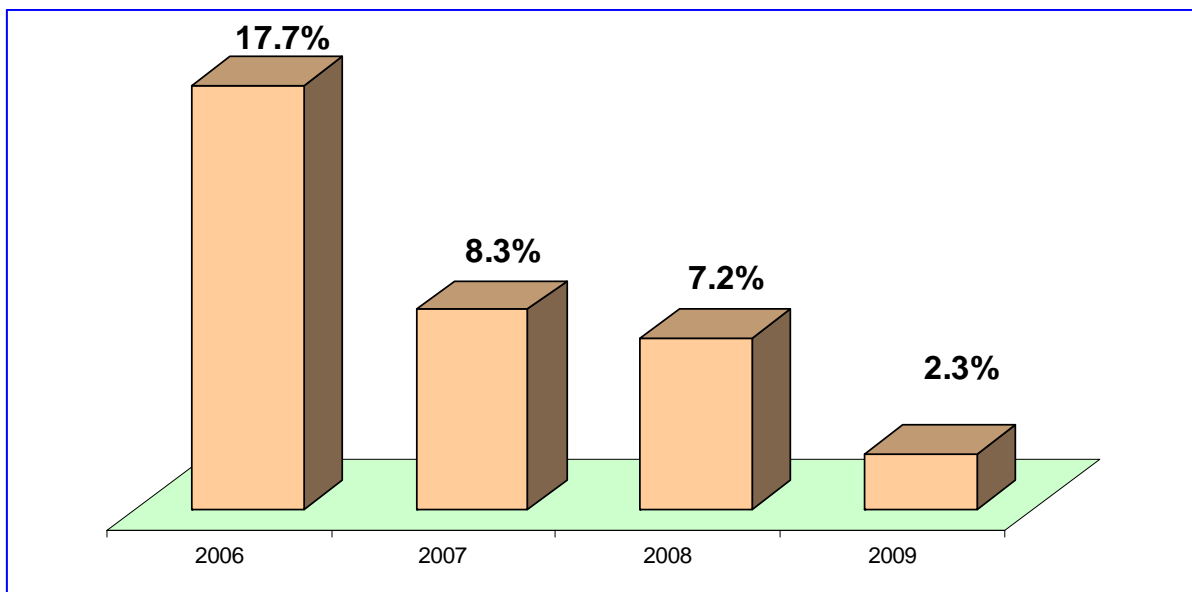
REFERRALS TO CMDh

The CMDh has continued to devote in 2009 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.

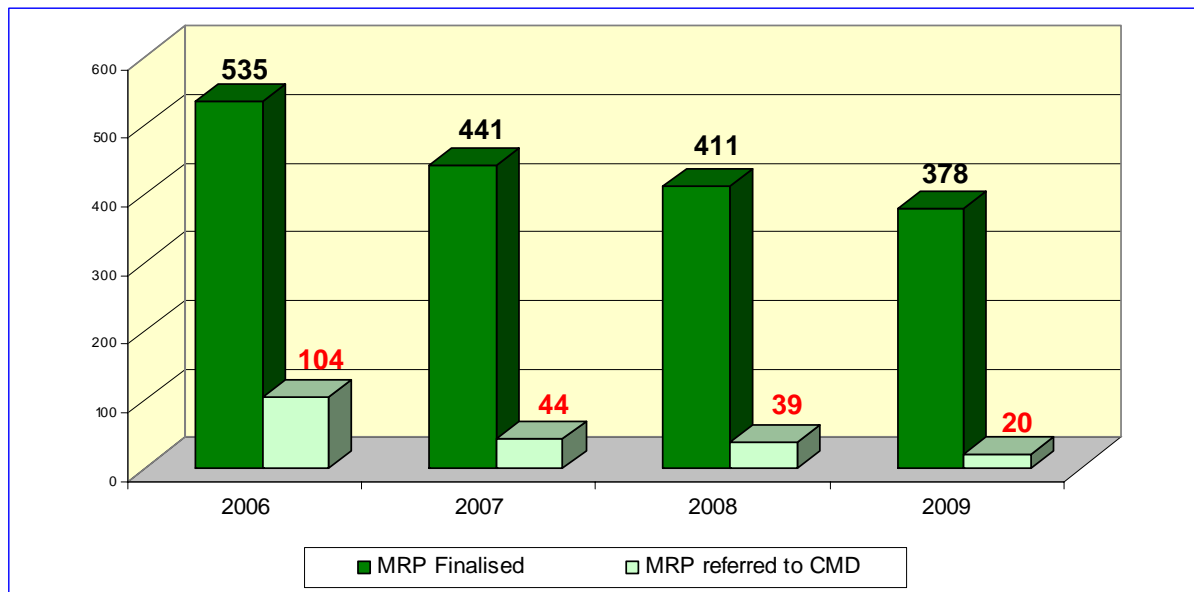
Finalised MR/DC Procedures vs. MR/DC Procedures referred to the CMDh since 2006



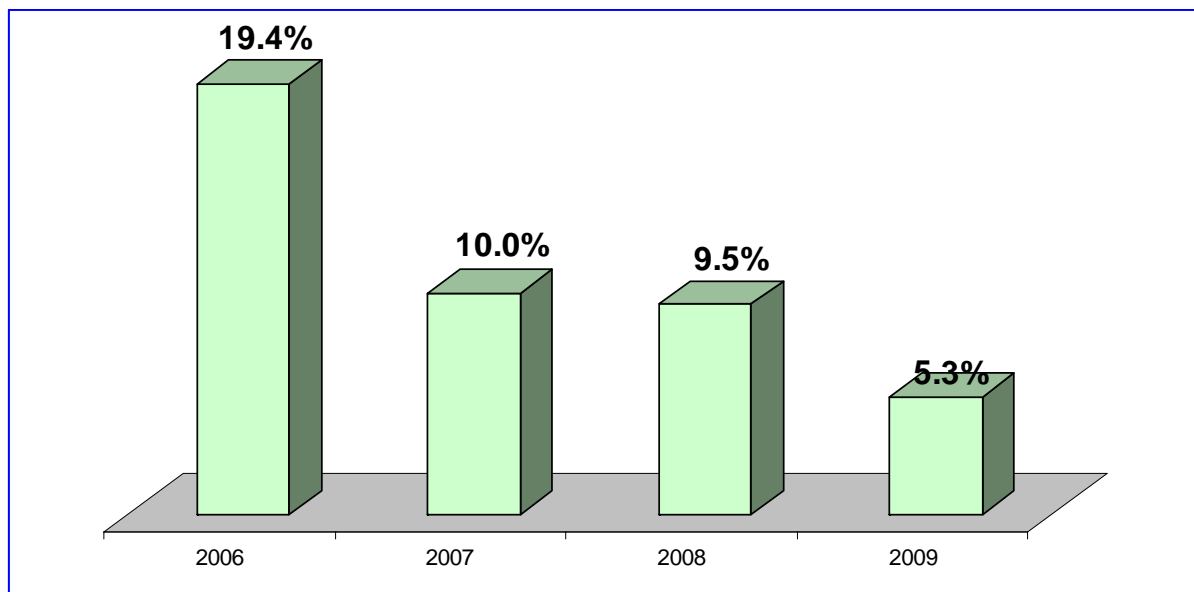
Percentages of MR/DC Procedures referred to the CMDh since 2006:



Finalised MRPs vs. MRPs referred to the CMDh since 2006

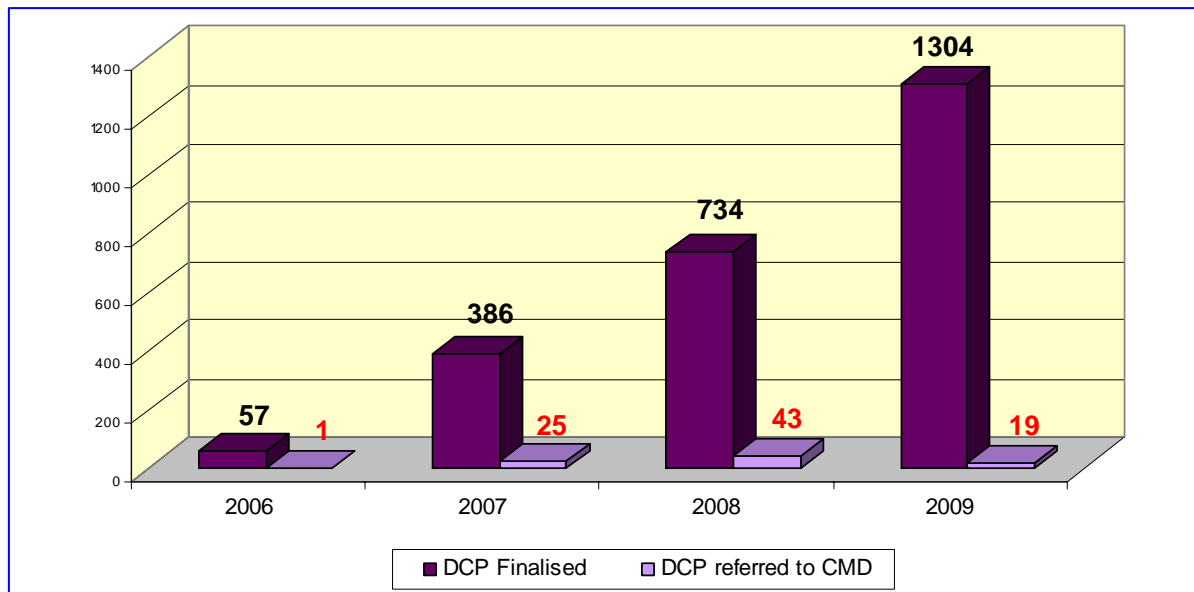


Percentages of MR Procedures referred to the CMDh since 2006:

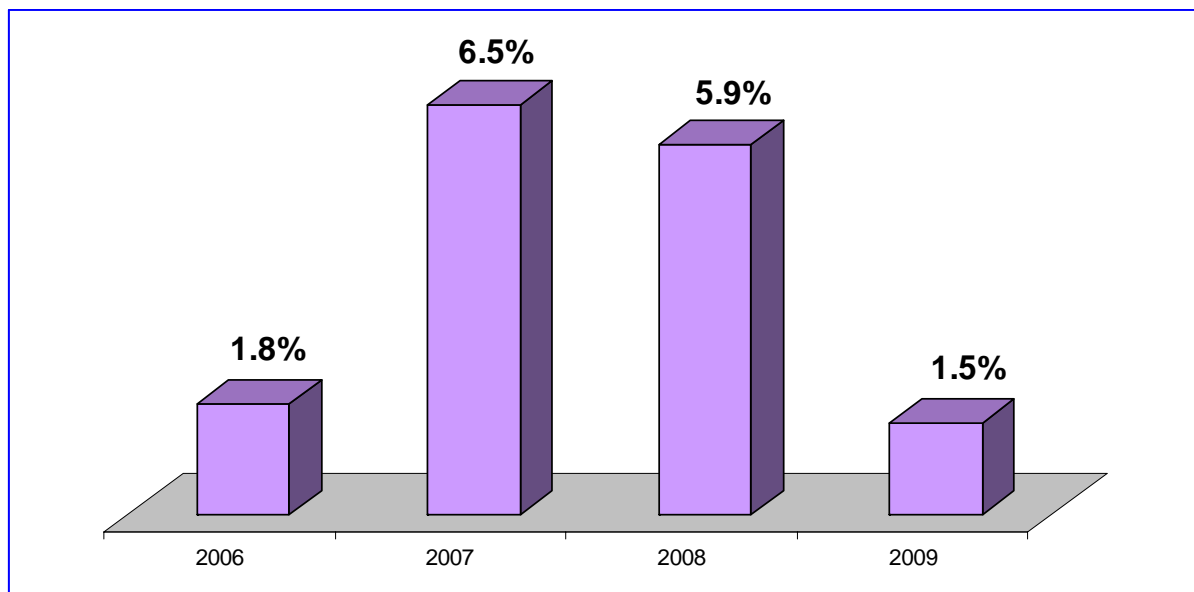


The percentage of MRP applications referred to the CMDh has further decreased compared to previous years.

Finalised DCPs vs. DCPs referred to the CMDh since 2006



Percentages of DCPs referred to the CMDh since 2006:



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

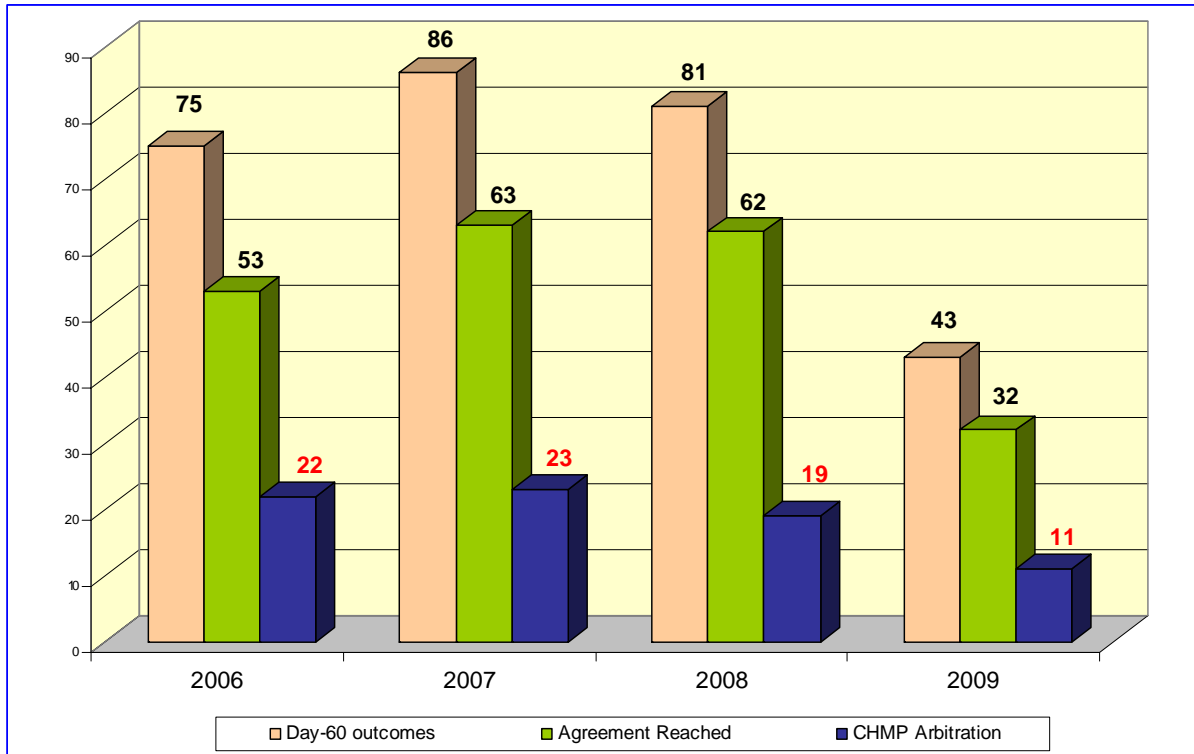
Oral Explanations

The number of oral explanations from Applicants with the CMDh in 2009 (10) has decreased by 68% in comparison with the previous year (31).

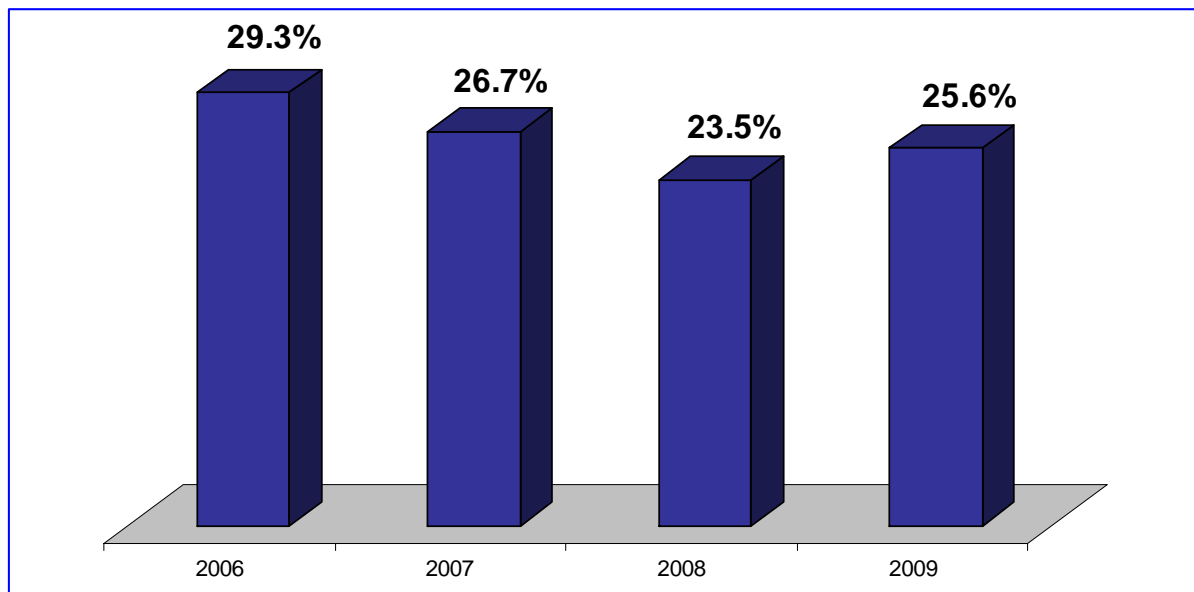
Outcomes at Day 60

Of the 43 referral procedures (excluding 4 withdrawals) finalised by the CMDh in 2009 (which includes 11 applications referred to CMDh in 2008), the CMDh was able to reach agreement for 74.4% of the procedures (32) and referred to the CHMP 25.6% of the procedures (11).

MRPs/DCPs referred to CMDh vs. Agreement Reached/CHMP Arbitration since 2006:



Percentages of Arbitrations to CHMP at Day 60 of CMDh referral procedures, since 2006:



The percentage of CMDh referrals referred to the CHMP remains around 25%.

The 11 applications referred to the CHMP for arbitration in 2009 include 2 multiple applications and thus correspond to 9 different applications for 8 different active substances. 8 of the applications referred to the CHMP were for generic medicinal products, 3 for full dossiers and 1 for a bibliographic.

Guidance documents/Recommendations

The CMDh has agreed an updated guidance document with the timetables for MRP/DCP applications referred to the CMDh for the 60-days referral procedure for 2010.

CMDh WORKING PARTIES

A number of CMDh subgroups meetings were held during 2009.

The **Communication Tracking System (CTS) Working Group (Hum + Vet)**, which is in charge of the MRP and DCP tracking system, met 4 times in 2009.

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 and regarding the new Variation Regulation. A new client was made available end of 2009.

The **CMDh 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 2009.

After public consultation, the CMDh has adopted 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 CMDh website.

The **Joint CMDh/Pharmacovigilance WP Working Group**, set up to discuss issues of common interest to the CMDh and PhVWP, e.g. PSUR work sharing project, evaluation of EU Risk management plans and Pharmacovigilance systems, met 6 times in 2009.

The mandate of the joint CMDh/PhVWP Working Group was published on the CMDh website, under CMDh Sub-groups.

The CMDh 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 CMDh, and has published a proposal for implementation of the agreed product information, following the PhVWP recommendations on the following:

- Additional hypotensive effects following co-administration of non-selective alpha-blockers and phosphodiesterase-5-inhibitors;
- Hydrochlorothiazide and use during pregnancy;
- Ceftriaxone and the risk of precipitation when given with calcium-containing solutions;
- Adverse events to be included in the Product Information of HMG CoA Reductase Inhibitors;
- Apomorphine containing products and risk of QT interval prolongation;
- Short-acting beta agonists and risk of myocardial ischemia;
- Vigabatrin and MRI abnormalities and movement disorders;
- Conventional (Typical) Antipsychotics and increased mortality;
- Antipsychotics and VTE;
- Alendronic acid and the risk of stress fractures of the proximal femoral shaft
- Cyproterone acetate and the risk of meningiomas;
- Phenytoin-induced Stevens-Johnson syndrome (SJS) in association with HLA-B*1502 allele in individuals of Thai or Han Chinese origin;

The **CMDh/EMA Sub-group on Paediatric Regulation** met 11 times in 2009, 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 subgroup also worked on guidance documents for Article 29 of the Paediatric Regulation, paediatric use marketing authorisations (PUMA) and gave guidance on the implementation of the compliance statement of an agreed completed PIP.

The **CMDh-GCP Inspections Sub-group** met 3 times in 2009. The Sub-group developed a Guidance for coordination of GCP inspections and co-operation between GCP inspectors, RMS, CMS and CMDh in the context of the evaluation of the GCP compliance of marketing authorisation applications for MRP and DCP. In addition, a Guidance on selection of trials/sites to be inspected was finalised.

The **CMDh/CMDv/EMA Sub-group on Variation Regulation** met 10 times in 2009 to prepare for the implementation of the new Variation Regulation. The Best Practice Guides for the submission of variations and the Q&A document have been revised to reflect the changes made in the legislation.

TRANSPARENCY

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

The CMDh and the EMA met in 2009 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 CMDh 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 CMDh in case of disagreement between the involved MSs in a MRP or DCP application.

CMDh Observers have continued to participate in the EMA/Human Scientific Committees WP with Patients' and Consumers' Organisations and in the EMA/CHMP Working Group with Health Care Professionals' Organisations.

INTERACTION WITH INTERESTED PARTIES

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

The CMDh held a meeting with EFPIA in July 2009 to discuss the results of a survey on the timing to issue national marketing authorisations following MRP/DCP and the implementation of Article 46 of Regulation (EC) No 1901/2006.

The CMDh also held a meeting with representatives of AESGP, EFPIA and EGA in September 2009 to discuss the following topics:

- Paediatric Subgroup Workplan 2009
- Article 45 Worksharing
- Article 46 procedure
- Recommendations on Paediatric Use Marketing Authorisations

A report from the meeting is published on the CMDh website for transparency reasons.

Finally the CMDh held another meeting with representatives of AESGP, EFPIA and EGA in November 2009 to discuss the Standard Operating Procedure for DCP, electronic submissions, the task force on resources and the variation regulation & CMDh overview of documents to be developed/revised.

A report from the meeting will be published on the CMDh website for transparency reasons.

MRP/DCP STATISTICS

The number of new applications submitted in 2009 via MRP and DCP (1658) has decreased by 13% compared to 2008. The number of new applications submitted in 2009 via MRP (326) has decreased by 25% compared to 2008. The number of new applications submitted in 2009 via DCP (1332) has decreased by 9% compared to 2008.

The number of applications finalised via MRP and DCP (1682) in 2009 has increased by 47% compared to 2008. The number of new applications finalised via MRP (378) in 2009 has decreased slightly (8%) in comparison with 2008 whilst the number of applications finalised via DCP in 2009 has increased by 78%.

The number of variations submitted and finalised in 2009 has increased by 16% and 19%, respectively, compared to 2008.

Statistical information on applications under the MRP and the DCP was provided by the EMEA and presented in the monthly CMDh press releases.

	Total started in 2009*	Under evaluation in 2009*	Ended in 2009*	Referrals to CMDh in 2009**	Referrals to CHMP in 2009**
New applications MRP (including Repeat Use)	326	68	378	15	2
New applications DCP	1332	1685	1304	19	7
Type-IA variations	7493	371	7019	N/A	N/A
Type-IB variations	3821	409	3627	N/A	0
Type-II variations	3335	994	3007	N/A	6

**The numbers include multiple procedures as stated at 31 December 2009.*

***Referred renewals are excluded*

ANNEX

NEW DOCUMENTS

Document reference	Revision number	Heading on website	Date of creation	Dates of revision	Title
CMDh/011/2009	Rev0	About CMDh-CMDh Reports	January 2009	N/A	Summary of CMDh Activities in 2008
CMDh/018/2009	Rev0	About CMDh-CMDh Reports	February 2009	N/A	Summary of assessment on the functioning of the CMDh
CMDh/012/2009	Rev0	About CMDh-CMDh Workplan	January 2009	N/A	CMDh Work plan for 2009
CMDh/009/2009	Rev0	About CMDh-Contact with Representatives-Organisations	January 2009	N/A	Minutes and Presentations from the CMDh meeting with representatives of Interested Parties – 16th December 2008
CMDh/114/2009	Rev0	About CMDh-Contact with Representatives-Organisations	November 2009		Minutes and Presentations from the CMDh/EMEA subgroup meeting on paediatric regulation with interested parties – 21 September 2009
CMDh/013/2009	Rev0	About CMDh-Contact with Representatives-Organisations	January 2009	N/A	Request for Marketing Authorisation Holders for medicinal products presented as pressurised metered dose inhalers (pMDI)
CMDh/EMEA/145/2009	Rev0	CMD Subgroups/Working Groups	June 2009	N/A	Mandate for the CMDh Subgroup on Paediatric Regulation
CMDh/PhVWP/146/2009	Rev0	CMD Subgroups/Working Groups	June 2009	N/A	EMEA / CMDh Paediatric Regulation Subgroup workplan 2009
CMDh/013/2009	Rev0	CMD Subgroups/Working Groups-Joint CMDh/PhVWP WG	July 2009	N/A	Cooperation CMDh-PhVWP and Mandate Joint Subgroup CMDh-PhVWP Revision 2/3 June 2009 JOINT CMDh/PhVWP Working Group
CMDh/010/2009	Rev0	CMD Subgroups/Working Groups-SPC Harmonisation	January 2009	N/A	2008 List of Products for SPC Harmonisation

NEW DOCUMENTS

Document reference	Revision number	Heading on website	Date of creation	Dates of revision	Title
CMDh/150/2009	Rev0	CMD Subgroups/Working Groups-SPC Harmonisation	July 2009	N/A	Draft list of products for SPC Harmonisation - 2009 In accordance with Article 30(2) of Directive 2001/83/EC, as amended
CMDh/158/2009	Rev0	CMDh Referrals	September 2009	N/A	Overview of timetables 2010 – CMDh 60 day procedures for MPR/DCP Applications
CMDh/019/2009	Rev0	Paediatric Regulation-Guidance Documents	February 2009	N/A	Recommendations for implementing Commission Decisions following an Article 29 application under the Paediatric Regulation
CMDh/138/2009	Rev1	Paediatric Regulation-Guidance Documents	March 2009	October 2009	BPG Article 46 - Paediatric Regulation EU worksharing Procedure
CMDh/152/2009	Rev0	Paediatric Regulation-Guidance Documents	July 2009	N/A	Recommendations on Paediatric Use Marketing Authorisations
CMDh/161/2009	Rev0	Paediatric Regulation-Guidance Documents	September 2009	N/A	Recommendation for implementation of compliance statement for the agreed completed PIP
CMDh/141/2009	Rev0	Paediatric Regulation-Guidance Documents	December 2009	N/A	Recommendations on submission on assessment in paediatric worksharing
CMDh/151/2009	Rev0	Paediatric Regulation-Article 45 and previous Worksharing	December 2009	N/A	List of Active Substances for which data has been submitted in accordance with Art.45 of the Paediatric Regulation
CMDh/020/2009	Rev2	Procedural Guidance-Application for MA	February 2009	March 2009 April 2009 June 2009	Links to NCA websites - National Recommendations for requests to act as RMS
CMDh/153/2009	Rev0	Procedural Guidance-Pandemic Plan	July 2009	N/A	CMDh Pandemic Plan and Annexes

NEW DOCUMENTS

Document reference	Revision number	Heading on website	Date of creation	Dates of revision	Title
CMDh/139/2009	Rev0	Procedural Guidance-Variations	April 2009	N/A	Timetables for request to CMDh for a recommendation on the classification of an unforeseen variation-Article 5 of Commission Regulation (EC) No.1234/2008
CMDh/096/2009	Rev1	Procedural Guidance-Variations	January 2009	December 2009	Cover letter for Variation applications in MRP
CMDh/135/2009	Rev0	Procedural Guidance-Variations	February 2009	N/A	CMDh recommendations on unforeseen variations
CMDh/136/2009	Rev0	Procedural Guidance-Variations	February 2009	N/A	Flow chart for Recommendations on unforeseen variations – Request to CMDh
CMDh/137/2009	Rev0	Procedural Guidance-Variations	February 2009	N/A	Request to CMDh/CMD(v)/EMA for a recommendation on the classification on unforeseen variation under article 5
CMDh/132/2009	Rev0	Procedural Guidance-Variations	December 2009	N/A	Q&As for the submission of Variations according to the Commission Regulation (EC) 1234/2008
CMDh/EMA/133/2010	Rev0	Procedural Guidance-Variations	December 2009	N/A	European Medicines Agency/CMDh explanatory notes on Variation Application Form (Human medicinal products only)
CMDh/PhVWP/002/2009	Rev0	Product Information-PhVWP Recommendations	February 2009	N/A	Non-selective alpha-blockers and phosphodiesterase-5-inhibitors - Agreed wording SPC and PL
CMDh/PhVWP/004/2009	Rev0	Product Information-PhVWP Recommendations	April 2009	N/A	Alendronic acid and the risk of stress fractures of the proximal femoral shaft - Agreed wording SPC and PL
CMDh/PhVWP/005/2009	Rev0	Product Information-PhVWP Recommendations	September 2009	N/A	Ceftriaxone and the risk of precipitation when given with calcium-containing solutions - Agreed wording SPC and PL

NEW DOCUMENTS

Document reference	Revision number	Heading on website	Date of creation	Dates of revision	Title
CMDh/PhVWP/006/2009	Rev0	Product Information-PhVWP Recommendations	November 2009	N/A	Association of HMG CoA reductase inhibitors with the following safety concerns: sleep disturbances; memory loss; micturition disorders; sexual disturbance; depression; and interstitial pneumopathy - PhVWP Report
CMDh/PhVWP/007/2009	Rev0	Product Information-PhVWP Recommendations	October 2009	N/A	Apomorphine containing products and the risk of QT interval prolongation - Agreed wording SPC and PL
CMDh/PhVWP/008/2009	Rev0	Product Information-PhVWP Recommendations	October 2009	N/A	Short-acting beta agonists and risk of myocardial ischaemia - Agreed wording SPC and PL
CMDh/PhVWP/009/2009	Rev0	Product Information-PhVWP Recommendations	October 2009	N/A	Vigabatrin and MRI abnormalities and movement disorders - Agreed wording SPC and PL
CMDh/PhVWP/010/2009	Rev0	Product Information-PhVWP Recommendations	October 2009	N/A	Antipsychotics and the risk of increased mortality - Agreed wording SPC and PL
CMDh/PhVWP/011/2009	Rev0	Product Information-PhVWP Recommendations	October 2009	N/A	Antipsychotics and the risk of venous thromboembolism - Agreed wording SPC and PL
CMDh/PhVWP/012/2009	Rev0	Product Information-PhVWP Recommendations	November 2009	N/A	Cyproterone acetate and the risk of meningiomas - PhVWP Report
CMDh/PhVWP/014/2009	Rev0	Product Information-PhVWP Recommendations	November 2009	N/A	Phenytoin-induced Stevens-Johnson Syndrome (SJS) in association with HLA-B*1502 allele in individuals of Thai or Han Chinese origin
CMDh/PhVWP/013/2009	Rev0	CMD Subgroups/Working Groups-Joint CMDh - PhVWP WG	July 2009	N/A	Cooperation CMDh-PhVWP and Mandate Joint Subgroup CMDh-PhVWP
CMDh/042/2009	Rev0	CMD Subgroups/Working Groups-Working Party on Future of the CMDh	November 2009	N/A	Mandate for the Working Party on the Future of the CMDh

NEW DOCUMENTS

Document reference	Revision number	Heading on website	Date of creation	Dates of revision	Title
CMDh/036/2009	Rev0	Templates-Applications for MA	January 2009	N/A	Request for RMS in a decentralised procedure, medicinal products for human use
CMDh/160/2009	Rev0	Templates-AR-DCP	September 2009	N/A	Assessment Report Feedback Form
CMDh/021/2009	Rev1	Templates-AR-Paediatric Data	February 2009	October 2009	Rapporteur's <Preliminary> <Final> Assessment Report for paediatric studies submitted in accordance with Article 45 of Regulation (EC) No1901/2006, as amended
CMDh/022/2009	Rev1	Templates-AR-Paediatric Data	February 2009	October 2009	Rapporteur's <Preliminary> <Final> Assessment Report for paediatric studies submitted in accordance with Article 46 of Regulation (EC) No1901/2006, as amended
CMDh/147/2009	Rev0	Templates-AR-Paediatric Data	June 2009	N/A	Template on comments from the Competent authority on the Paediatric work sharing preliminary AR

NEW QUESTIONS & ANSWERS

Heading on website	Date of creation	Title
Questions & Answers- Homeopathics	January 2009	Number of application forms for registration of homeopathic medicinal products
Questions & Answers- Variations	January 2009	New Variation Regulation (Article 5)
Questions & Answers- Applications for MA	April 2009	Article 18 of Directive 2001/83/EC, as amended
Questions & Answers- Generics&Usage Patents- Usage Patents	May 2009	Legal basis for products for local use
Questions & Answers- Post referral phase	June 2009	Submission of translations following an article 29(4) Referral

REVISED DOCUMENTS

Document reference	Revision number	Heading on website	Date of creation	Dates of revision	Title
CMDh/014/2008	Rev6	Paediatric Regulation-Article 45 and previous Worksharing	October 2008	December 2008 January 2009 February 2009 March 2009 June 2009 September 2009 December 2009	Worksharing on Art.45 - List of the active substances included in the work-sharing procedure
CMDh/124/2008	Rev3	Paediatric Regulation-Article 45 and previous Worksharing	May 2008	July 2008 May 2009 December 2009	List of active substances and agreed SPC wordings - EU Worksharing procedure in the assessment of paediatric data
CMDh/EMEA/007/2007	Rev6	Paediatric Regulation-Guidance Documents	October 2007	December 2007 May 2008 September 2008 November 2008 June 2009 October 2009 November 2009	Questions and answers on the paediatric regulation (regulation of the european parliament and of the council (EC) No 1901/2006, as amended)
CMDh/037/2009	Rev2	Paediatric Regulation-Guidance Documents	September 2008	February 2009 October 2009	BPG Article 45 of Paediatric Regulation (EU Worksharing procedure)
CMDh/008/2009	Rev6	Procedural Guidance-Application for MA		January 2009	Procedural advice on Repeat Use
CMDh/040/2001	Rev2	Procedural guidance-Application for MA	November 2001	December 2005 March 2009	Procedural advice: Automatic validation of MR/Repeat-use/DC Procedures
CMDh/043/2007	Rev3	Procedural guidance-Application for MA	July 2007	July 2008 March 2009 September 2009	Additional data requested for new applications in the MRP/DCP
CMDh/072/2001	Rev5	Procedural Guidance-Application for MA	March 2001	July 2006 December 2009	Best Practice Guide on Break-out sessions for Mutual Recognition and Decentralised Procedures

REVISED DOCUMENTS

Document reference	Revision number	Heading on website	Date of creation	Dates of revision	Title
CMDh/078/2005	Rev2	Procedural Guidance-Application for MA	October 2005	November 2007 December 2009	Decentralised procedure - Member States' SOP
CMDh/079/2005	Rev4	Procedural Guidance-Application for MA	October 2005	December 2006 October 2007 December 2008 November 2009	Recommendations on submission dates for Applicants of the Decentralised Procedure
CMDh/082/2002	Rev2	Procedural Guidance-Application for MA	October 2002	September 2007 November 2009	Recommendations on submission dates for Applicants of the Mutual Recognition Procedure
CMDh/100/2007	Rev1	Procedural Guidance-Consultation with target patient groups	October 2007	April 2009	Consultation with target patient groups – Meeting the requirements of Article 59(3) without the need for a full test recommendations for bridging
CMDh/006/2008	Rev2	Procedural Guidance-esubmissions	December 2008	April 209 July 2009	Requirements on eSubmissions for Renewals and Variations within MRP, DCP or National procedures
CMDh/085/2008	Rev4	Procedural Guidance-esubmissions	January 2008	April 2009 July 2009 September 2009 November 2009	Requirements on eSubmissions for NA within MRP, DCP or National procedures
CMDh/039/2002	Rev3	Procedural Guidance-General Info	December 2002	May 2005 February 2006 March 2009	CMDh procedural advice on changing the RMS
CMDh/087/2006	Rev1	Procedural Guidance-Generics	November 2006	November 2009	CMDh agreement regarding processing of generic applications when the generic has more indications or fewer indications than the reference product in the CMS

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CMDh/089/2002	Rev2	Procedural Guidance-Generics	July 2002	May 2006 May 2009	CMDh Recommendation for Applications submitted according to Article 10 when the strength and/or the pharmaceutical form of the reference medicinal product differs between RMS/CMS(s)
CMDh/090/2003	Rev3	Procedural Guidance-Generics	January 2003	April 2009	CMDh Recommendation on Implementation of Article 30 Decisions for Generic Products
CMDh/101/2001	Rev4	Procedural Guidance-Post Referral Phase	September 2001	May 2009	Recommendation for Mutual Recognition Procedure after finalisation of an arbitration procedure with a positive decision by the EU-Commission
CMDh/094/2003	Rev6	Procedural Guidance-Variation	June 2003	February 2008 (Chapter 5) October 2009 (All chapters)	CMDh Best Practice Guides for the Submission and Processing of Variations in the Mutual Recognition Procedure <i>Revision 6 of the Best Practice Guides for the Submission and Processing of Variations in the Mutual Recognition Procedure, taking into account Commission Regulation No 1234/2008, is published as a draft document and subject to review following the publication of the relevant Commission guidelines.</i>
CMDh/128/2003	Rev3	Product Information-Core SPC/PL	October, 2003	December 2006 September 2009	Trivalent Influenza vaccines: revision of the core SPC
CMDh/129/2008	Rev1	Product Information-Core SPC/PL	November, 2008	September 2009	Trivalent Influenza vaccines: core PL
CMDh/140/2008	Rev8	Product Information-Harmonisation of SPCs Article 30 referrals	October 2008	April 2009 May 2009 June 2009	Information on applications referred in accordance with Article 30(2) of Directive 2001/83/EC