October 2018

CMDh guidance documents published on CMDh website (http://www.hma.eu/cmdh.html)

Documents

About CMDh

- **CMDh Composition** (http://www.hma.eu/352.html)

- **CMDh Activities** (http://www.hma.eu/205.html)

  CMDh – Rules of Procedure

  Role of the Vice Chairpersons of the CMDh

  CMDh Strategy to 2020

  Outcome of the public consultation on the CMDh Strategy to 2020

  CMDh Multi - Annual Work plan to 2020

  CMDh Work plan for 2013

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CMDh Work plan for 2010

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- **CMDh Reports** (http://www.hma.eu/207.html)

  Summary of CMDh Activities in 2017

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  Summary of CMDh Activities in 2015

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  Summary of CMDh Activities in 2006

Summary of MRFG/CMDh Activities in 2005

2008 Report on the evaluation of the functioning of the CMDh

❖ **Contacts with Representative Organisations** (http://www.hma.eu/208.html)

Recommendations on contacts with Representative Organisations

CMDh meeting with Interested Parties - 29 May 2018

CMDh meeting with Interested Parties - 7 November 2017

CMDh meeting with Interested Parties - 16 May 2017

CMDh meeting with Interested Parties – 8 November 2016

CMDh meeting with Interested Parties on MRP/DCP Improvements – 7 November 2016

CMDh meeting with Interested Parties - 24 May 2016

Meeting with Interested Parties on MRP/DCP Improvements - 23 May 2016

Meeting with Interested Parties on DCP/MRP improvements – 16 November 2015

Meeting with Interested Parties – 19 May 2015

Meeting with Interested Parties on DCP/MRP improvements – 18 May 2015

CMDh Meeting with Interested Parties – 18 November 2014

Meeting with Interested Parties on ASMF – 18 November 2014

Meeting with Interested Parties on DCP/MRP improvements – 17 November 2014

Meeting with Interested Parties – 20 May 2014

Meeting with Interested Parties on DCP/MRP improvements – 19 May 2014

Meeting with Interested Parties – 18 November 2013

Meeting with Interested Parties – 27 May 2013

Meeting with Interested Parties – 12 November 2012

Meeting with Interested Parties – 21 May 2012

Meeting with Interested Parties – 14 November 2011

Meeting with Interested Parties – 20 June 2011

Meeting with Interested Parties on the Self-Medication Project – 20 June 2011

Meeting with Interested Parties – 15th November 2010

Meeting with Interested Parties on Paediatric Regulation – 20th September 2010

Meeting with Interested Parties – 21st June 2010

Meeting with Interested Parties – 16th November 2009

Meeting with Interested Parties on Paediatric Regulation – 21st September 2009

Meeting with Interested Parties – 16th December 2008

Meeting with Interested Parties – 12th November 2007

Meeting with EGA on Work-sharing for patient consultation – 19th June 2007

Meeting with Interested Parties-13th November 2006

Request for Marketing Authorisation Holders to assess the risk of occurrence of contamination with mesilate esters and related compounds in pharmaceuticals

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- **Transparency Measures** (http://www.hma.eu/209.html)

  Position paper on transparency policy of the CMDh

- **Calendar for CMDh** (http://www.hma.eu/115.html)

- **MRFG(1995-2005)** (http://www.hma.eu/89.html)

  Summary of MRFG Activities in 2005

  Introduction to the Mutual Recognition Facilitation Group

Statistics (http://www.hma.eu/87.html)

Agendas and Minutes (http://www.hma.eu/457.html)

Press Releases (http://www.hma.eu/249.html)

BREXIT

Notice to marketing authorisation holders of national authorised medicinal products for human use

Questions and Answers related to the United Kingdom's withdrawal from the European Union with regard to national authorised medicinal products for human use

Practical guidance for procedures related to Brexit for medicinal products for human use approved via MRP/DCP

National information on MAH transfers

Procedural Guidance

- **General Information** (http://www.hma.eu/90.html)

Documents

Best Practice Guide for the Reference Member State in the Mutual Recognition and Decentralised Procedures

CMDh procedural advice on changing the RMS

Template for RMS switches

Best Practice Guide for the exchange of regulatory and administrative information regarding orphan medicinal products between EMEA and National Competent Authorities

CMDh Agreement on sunset clause and its application to marketing authorisations granted in more than one MS

Phasing in EU procedures: MRP and referrals

CMDh recommendation on the Summary of the Pharmacovigilance System and Risk Management Plan in the Mutual Recognition and Decentralised procedures

CMDh Best Practice Guide for the public assessment report and Summary Public Assessment Report in MRP/DCP

CMDh Best Practice Guide on the submission of high quality national translations

Publication of decisions to grant or revoke a marketing authorisation

Transfer of information contained in Notice to applicants, Volume 2A, Chapter 7

CMDh position paper on the use of Quick Response (QR) codes to provide information about the medicinal product

CMDh Best Practice Guidance on collaboration between Member States in relation to serious GMP non-compliance issue

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- **Application for Marketing Authorisation** (http://www.hma.eu/91.html)

Best Practice Guide for Decentralised and Mutual Recognition Procedures

Best Practice Guide on Assessment Report in the Mutual Recognition and Decentralised Procedures

Documents

Best Practice Guide for the Decentralised and Mutual Recognition Procedures

Best Practice Guide on the Assessment Report for Mutual Recognition and Decentralised Procedures

Best Practice Guide on Break-out sessions for Mutual Recognition and Decentralised Procedures

Best Practice Guide for authorisation of non-prescription medicines in the Decentralised and Mutual Recognition procedures

Recommendations on Informed consent applications in Mutual Recognition and Decentralised Procedures

Recommendations on Multiple/Duplicate applications in Mutual Recognition Procedures and Decentralised Procedures

MSs Recommendations on Extension applications in Mutual Recognition and Decentralised Procedures

Position Paper concerning Applicants' request of submission of multiple applications during ongoing decentralised procedures or inclusion of new CMS or additional strength(s) in an already ongoing decentralised procedure (DCP)

Procedural advice on Repeat Use

Declaration form for the submission of DPPS already approved by a competent authority

CMDh guidance for Declaration form submission DDPS already approved by a competent authority

Requirements on submissions (number and formats) for New Applications within MRP, DCP or National procedures

Languages to be used for Marketing Authorisation Application (MAA), Variations and Renewals

Mock-ups, Specimens and Samples for new Applications

'Blue-box' requirements

CMDh SOP on decision-making process for new active substance status or extension of marketing protection or data exclusivity

Documents

User Guide for the electronic Application form for a Marketing Authorisation

Validation Procedure

Member state agreement upon conditions under which the RMS can start MRP/DCP

Procedural advice - Automatic Validation of MR/Repeat-Use/DC Procedures

Additional Data requested for new applications in the MRP/DCP

Common grounds for invalidation/delaying validation

MS recommendations on the Cover Letter for new applications submitted through MRP/DCP

CMDh BPG on the Compilation of the Dossier for New Applications submitted in MRP/DCP

- ***DCP*** (http://www.hma.eu/92.html)

Decentralised procedure - Member States' SOP

Recommendations on submission dates for Applicants of the Decentralised Procedure

Flow chart of the decentralised procedure

Requests to act as RMS in DCP

Common request form for RMS

Links to NCAs webpages - Recommendations for requests to act as RMS

- ***MRP/RUP*** (http://www.hma.eu/93.html)

Flow chart of the Mutual Recognition Procedure

Documents

Recommendations on submission dates for Applicants of the Mutual Recognition Procedure

Procedural Advice on Repeat Use

- **eSubmissions** (http://www.hma.eu/277.html)

  CMDh BPG on the use of eCTD in MRP/DCP

  Requirements on eSubmissions (number and format) for New MA Applications within MRP, DCP or National procedures

  Requirements on eSubmissions (number and format) for Variations and Renewals within MRP and National procedures

- **Generics in MRP and DCP** (http://www.hma.eu/211.html)

  List of MRP/DCP finalised in 2006-2010 with new active substances

  CMDh Position paper on processing of generic applications when the generic has more indications or fewer indications than the reference product in the CMS

  Information to be submitted by the Member State of the European Reference Medicinal Product

  CMDh Recommendations on Implementation of Article 30 Decisions for Generic /Hybrid/Biosimilar Medicinal Products approved through MRP/DCP

- **Applicants' Responses** (http://www.hma.eu/98.html)

  Applicant's Response Document in Mutual Recognition and Decentralised procedures

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- **Renewal Procedure** (http://www.hma.eu/95.html)

  CMDh Best Practice Guide on the processing of Renewals in the Mutual Recognition and Decentralised procedures

  Common grounds seen for delaying Day 0 Renewals

Documents

Data requested for Variations and/or Renewal Applications in the Mutual Recognition and Decentralised procedures

Requirements on submissions (number and format) for Variations and Renewals within MRPand National procedures

Languages to be used for Marketing Authorisation Application (MAA), Variations and Renewals

Mock-ups, Specimens and Samples for variations and renewals

Member State agreement upon conditions under which the RMS can start renewals

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- **Variation Procedure** (http://www.hma.eu/96.html)

Best Practice Guides for the Submission and Processing of Variations in the Mutual Recognition Procedure

Chapter 1: CMDh BPG for the allocation of the mutual recognition variation number for Type I Notifications, Type II Variations, Grouping and Worksharing

Chapter 2: Procedure for automatic validation of Mutual Recognition Procedures for Variations

Chapter 3: CMDh BPG for the processing of Type IA Minor Variations (Notifications) in the Mutual Recognition Procedure

Chapter 4: CMDh BPG for the processing of Type IB Minor Variations (Notifications) in the Mutual Recognition Procedure

Chapter 5: CMDh BPG for the handling of Type II Variations in the Mutual Recognition Procedure

Chapter 6: CMDh BPG for the processing of Grouped Applications in the Mutual Recognition Procedure

Chapter 7: CMDh BPG on Worksharing

Chapter 8: CMDh BPG on CMDh Recommendations on Unforeseen Variations

Documents

Chapter 9: CMDh BPG on fast track procedure for annual update of Human Influenza Vaccines

European Medicines Agency/CMDh explanatory notes on Variation Application Form (Human medicinal products only)

Examples for acceptable and not acceptable groupings for MRP/DCP products

Position paper on common grounds seen for invalidation/delaying Day 0 for Variations

Data requested for Variations and/or Renewal Applications in the MRP/DCP

Mock-ups, Specimens and Samples for variations and renewals

- ***Art.5 on Unforeseen Variations*** *(http://www.hma.eu/293.html)*

  Timetables for request to CMDh for a recommendation on the classification of an unforeseen variation-Article 5

  CMDh Recommendation for classification of unforeseen variations according to Article 5 of Commission Regulation (EC) No 1234/2008

❖ **Urgent Safety Restriction** (http://www.hma.eu/102.html)

Urgent Safety Restriction Members States' Standard Operating Procedure

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❖ **Art. 61(3) Procedure** (http://www.hma.eu/101.html)

CMDh Standard Operating Procedure for Article 61(3) changes to patient information and the notification for product information amendment under Article 61(3) (not accompanying a variation change)

Flow-chart for the Article 61(3) procedure

Notification Form

❖ **Consultation with target patient groups** (http://www.hma.eu/218.html)

Documents

Consultation with target patient groups: meeting the requirements of Article 59(3) without the need for a full test-Recommendations for bridging

Position paper on user testing of package leaflets

- **Post referral phase** (http://www.hma.eu/100.html)

  CMDh Recommendation for implementation of Commission Decisions or CMDh agreements following Union referral procedures where the marketing authorisation is maintained or varied

CMDh Referrals (http://www.hma.eu/26.html)

Overview of timetables

CMDh Standard Operating Procedure - Disagreement in procedures - Referral to CMDh

Guidance on oral explanations to CMDh - Annex to CMDh SOP on Disagreement in Procedures, Referral to CMDh

Information on applications referred to the CMDh in accordance with Article 29(1) of Directive 2001/83/EC/Tracking table

Product Information

- **PhVWP Recommendations** (http://www.hma.eu/222.html)

- **CMDh Recommendations** (http://www.hma.eu/245.html)

  Labelling for multi-language packages

  Adrenaline Auto-Injectors

  Azithromycin containing products in patients with severe hepatic impairment

  Combined hormonal contraceptives (CHCs) containing ethinylestradiol

Documents

*Flucloxacilline and risk of liver injury in subjects carrying HLA-B*5701 allele*

Gabapentin containing products

Oxycodone containing medicinal products

❖ **Harmonisation of SmPCs - Article 30** (http://www.hma.eu/261.html)

Information on applications referred in accordance with Article 30 of Directive 2001/83/EC/Tracking table

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Lists of Medicinal Products for Harmonisation of SmPCs

Final list of products for SmPC Harmonisation - 2014

Final list of products for SmPC Harmonisation - 2013

Criteria for selection of products for SPC Harmonisation

❖ **Core SmPC/PL** (http://www.hma.eu/104.html)

Fludeoxyglucose (18F) - Revised Core SmPC and PL

Hormone Replacement Therapy - Core SmPC

Hormone Replacement Therapy - Core Package Leaflet

Hormone Replacement Therapy - MRFG-PhVWP agreed updated core SmPC

Hormone Replacement Therapy - SmPC wording for medicinal products used in HRT with regard to increased risk of venous thromboembolism as agreed by the PhVWP

Hormone Replacement Therapy - SmPC wording for medicinal products used in HRT with regard to increased risk of breast cancer as agreed by the PhVWP

Trivalent influenza vaccines - Core SmPC

Trivalent influenza vaccines - Core Package Leaflet

EMA Explanatory Note on the withdrawal of the note for guidance on harmonisation of requirements for influenza vaccines

Advice from CMDh (http://www.hma.eu/226.html)

Harmonised warning for ferrous sulfate-containing medicinal products on dysphagia and related bronchostenosis due to risk of aspiration

Concomitant use of benzodiazepines/benzodiazepine like products and opioids

Extension of pilot for splitting of MRP/DCPs

CMDh Working Document on Merging and Splitting of MRP/DCPs

Decisions on additional year of market protection/data exclusivity for new therapeutic indication agreed by the CMDh

Deletion of interaction between broad spectrum antibiotics and combined oral contraceptives (COC)
Cover note to Public Assessment Report
Public Assessment Report
List of ATC codes for which the change applies

Harmonised traceability of gadolinium-containing contrast agents - update of Product Information wording regarding electronic patient records

Monitoring of medicines originating from Japa**n**

Bioequivalence studies conducted at GVK Biosciences Private Limited (GVK Bio), Swarna Jayanthi commercial complex, Ameerpet, Hyderabad 500 038, India (new name since 15 July 2014: Clinogent)

Letter to Marketing Authorisation Holders (MAHs) / Applicants
Template for information to be submitted

Abbreviated core Risk Management Plan for bisphosphonates

Guidance on the submission/updating of Risk Management Plans to reflect 'atypical femoral fractures'
Abbreviated core bisphosphonate RMP for atypical femoral fracture

EU Worksharing Procedure

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

Templates

- **Applications for MA** (http://www.hma.eu/219.html)

Applications for Marketing Authorisation

Cover letter for new applications submitted through MRP/DCP

Letter of access for informed consent applications

Request for RMS in a Decentralised Procedure, medicinal products for human use

Common request form

Validation

Validation for Application on Marketing Authorisation

- **QRD** (http://www.hma.eu/126.html)

CMDh QRD annotated template for MRP/DCP

Addendum to the Quality Review of Documents templates for SmPC, Labelling and Patient Leaflet on Mutual-recognition and Decentralised procedures specific for (Traditional) Herbal Medicinal Products ((T)HMPs)

- **Assessment Reports** (http://www.hma.eu/108.html)

  - ***DCP (AR/Comments)*** *(http://www.hma.eu/127.html)*

    Non Clinical / Clinical AR for Generics - MRP & DCP

    D70 Preliminary AR

    D100 CMS Comments

    D105 Clock stop

    D120 Draft AR

    D120/D180 Quality AR

    D145 CMS comments

    D205 CMS Comments

    End of procedure

  - ***MRP/RUP*** *(http://www.hma.eu/110.html)*

    Template Assessment Report MRP Overview

    Template CMS comments in MRP

    Template Non Clinical / Clinical AR for Generics - MRP & DCP

    Request for MRP/RUP for Medicinal Products for Human Use

Appendix 1 - Request for MRP/RUP for Medicinal Products for Human Use

Update Assessment report for Repeat Use Procedures

- ***Renewals*** *(http://www.hma.eu/238.html)*

  Template - Preliminary Renewal Assessment Report

  Template - RMS End of Renewal Procedure

- ***Variations*** *(http://www.hma.eu/112.html)*

  Type II variation
  Preliminary Variation Assessment Report

  Type II variation
  Final Variation Assessment Report

- ***Art. 61.3 Procedure*** *(http://www.hma.eu/128.html)*

  Notification form

- ***Public AR*** *(http://www.hma.eu/114.html)*

  Public Assessment Report Scientific discussion

  Summary of public assessment report - Generics

  Public Assessment Report update

  Summary of Public Assessment Report for non-generics

  Public Assessment Report for refused marketing authorisation application

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- ***Paediatric Data*** *(http://www.hma.eu/193.html)*

Paediatric Regulation: Article 45

AR for paediatric studies submitted in accordance with Article 45 of Regulation (EC) No 1901/2006, as amended

Public AR for paediatric studies submitted in accordance with Article 45 of Regulation (EC) No 1901/2006, as amended

Paediatric Regulation: Article 46

AR for paediatric studies submitted in accordance with Article 46 of Regulation (EC) No 1901/2006, as amended

Public AR for paediatric studies submitted in accordance with Article 46 of Regulation (EC) No 1901/2006, as amended

Comments from the competent authority on the Paediatric work sharing ARs

MSs comments on the Paediatric work sharing ARs for Article 45 & 46

- ***ASMF*** *(http://www.hma.eu/334.html)*

  Assessment Report on Active Substance Master File (ASMF) Type IB Variation

  Assessment Report on Active Substance Master File (ASMF)

❖ **Art.29 Referrals to CMDh** (http://www.hma.eu/262.html)

Referral to CMDh (RMS)

D90/210 referral request (CMS)

❖ **PSUR** (http://www.hma.eu/345.html)

Cover letter for the submission of PSURs under the EU PSUR synchronisation scheme

Cover letter for the submission of the PSUR overview table to P-RMS, when specific MAH product is not authorised in P-RMS

Overview of Marketing Authorisations for the Medicinal Product(s) containing <active substance name(s)> for which the PSUR(s) is submitted

Concerned Member State's Comments on Lead Member State's Preliminary assessment report

Template - PSUR Assessment Report

<Preliminary> <Updated> <Final> Lead Member State PSUR Follow-Up assessment report

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- **Variations** (http://www.hma.eu/265.html)

Variation applications

Cover letter for Variation Applications in the Mutual Recognition Procedure

Worksharing procedure to the CMDh according to Article 20 of Commission Regulation (EC) No 1234/2008

Letter of intent for the submission of a worksharing procedure

Outcome of variation worksharing procedures

Grouping of type IA variations according to Article 7 of Commission Regulation (EC) No 1234/2008

Letter of intent for the submission of a type IA grouped procedures ("Supergroup")

Recommendation of the CMDh on the classification of an unforeseen on variations to the terms of the marketing authorisation

Recommendation form - Article 5

Request form for recommendation - Article 5

- **Renewals** (http://www.hma.eu/562.html)

Cover letter template for renewals

- **RMP** (http://www.hma.eu/480.html)

  Form for providing list of safety concerns of new approved RMPs/updates to list

- **RUP** (http://www.hma.eu/481.html)

  Request for MRP/RUP for Medicinal Products for Human Use

  Appendix 1 to Request for MRP/RUP for Medicinal Products for Human Use

  Update Assessment report for Repeat use procedures

CMD Working Parties / Working Groups (http://www.hma.eu/86.html)

- **Working Group on Active Substance Master File Procedures** (http://www.hma.eu/306.html)

  Mandate of the Working Group on Active Substance Master File Procedures

  EU ASMF number request form

  The worksharing procedure for the assessment of Active Substance Master File (ASMF)

  Training presentations on Active Substance Master File (ASMF) work sharing procedure

  - ASMF worksharing - Introduction to the procedure
  - Requesting an EU_ASMF repository number
  - Submitting an initial worksharing ASMF
  - Determining the parent procedure
  - Assessment report template
  - Sharing assessment reports
  - Submitting a variation to an ASMF
  - Use of an approved ASMF in a new procedure

- **Process Improvement Working Party** (http://www.hma.eu/279.html)

Mandate, objectives and rules of the Process Improvement Working Party

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- **Working Party on Paediatric Regulation** (http://www.hma.eu/272.html)

  Working Party on Paediatric Regulation

  Mandate for the Working Party on Paediatric Regulation

  Statistics on Paediatric Regulation

  Statistics on Member States acting as rapporteurs in Paediatric worksharing procedures

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- **Working Party on Variation Regulation** (http://www.hma.eu/243.html)

  Mandate for the Working Party on Variation Regulation

- **PSUR Work-Sharing Working Party** (http://www.hma.eu/330.html)

  Mandate of the PSUR Work-Sharing Working Party

- **Joint CMDh/PhVWP WG** (http://www.hma.eu/275.html) - RETIRED

  Mandate Joint Subgroup CMDh-PhVWP

  CMDh and PhVWP Best Practice Guide on communication and implementation of safety information

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- **CTS Working group** (http://www.hma.eu/294.html)

  Mandate for CTS Working Group

- **Joint CMDh/GCP Inspectors Working Party** (http://www.hma.eu/307.html)

  Mandate for the GCP Inspectors Working Group/CMDh Working Party

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Paediatric Regulation (http://www.hma.eu/213.html)

- **Guidance Documents** (http://www.hma.eu/216.html)

Paediatric Worksharing

Recommendations on submission and assessment in paediatric worksharing

Paediatric Regulation: Article 45

Best Practice Guide Article 45 - EU Worksharing procedure

Paediatric Regulation: Article 46

Best Practice Guide Article 46 - EU Worksharing procedure

Cover letter- Submission of information about paediatric studies completed after 26 January 2007 in accordance with Article 46 of Regulation No 1901/2006

Line listing

Paediatric Regulation: Article 29

Recommendations for implementing Commission Decisions following an Art. 29 Application under the Paediatric Regulation

Compliance statement for the agreed completed PIP

Recommendation for implementation of compliance statement for the agreed completed PIP

Template on compliance statement for the agreed completed PIP

PUMA

Recommendations on Paediatric Use Marketing Authorisations

- **Article 45 and previous Worksharing** (http://www.hma.eu/99.html)

  Worksharing on Article 45

  List of active substances for which data has been submitted in accordance with Article 45 of the Paediatric Regulation

  Worksharing project on paediatric data

  List of active substances and agreed SmPC wordings - EU work sharing procedure in the assessment of paediatric data

- **Assessment Reports** (http://www.hma.eu/187.html)

  - ***Article 45 work-sharing*** *(http://www.hma.eu/269.html)*
  - ***Article 46 work-sharing*** *(http://www.hma.eu/291.html)*
  - ***Previous worksharing project*** *(http://www.hma.eu/270.html)*

Pharmacovigilance legislation (http://www.hma.eu/310.html)

- **General information**
- **Referrals**
- **PSURS**

  Best Practice Guide on (1) Introduction of substances/combinations onto the EURD list and setting the initial PSUR DLP and frequency and (2) Assessment of PSURs of products where the EU Reference Date is not yet legally binding

  CMDh Guidance on the Informal Work-Sharing procedure for follow-up for PSUSA for NAPs

  Overview of comments received and responses on "CMDh Guidance on the Informal Work-Sharing procedure for follow-up for PSUSA for NAPs"

  - ***PSUR Single Asessment***

CMDh SOP on the processing of PSUR single assessment for nationally authorised products

- ***PSUR worksharing and Synchronisation Project***

  PSUR worksharing and Nationally Authorised Products with a DLP Synchronised

  List of substances under PSUR worksharing scheme and other substances contained in Nationally Authorised Products with DLP synchronised

  Assessment of Periodic Safety Update Reports for National Authorised Products - Cover note

  PSUR worksharing - other guidance documents

  CMDh Best Practice Guide for Transitional Arrangements for PSUR worksharing

- ***Outcome of Informal PSUR worksharing procedures***

  Summaries of assessment reports

- ***Outcome of PSUFU procedures***

  Summaries of assessment reports

❖ **RMPs**

Cover Note

List of safety concerns per approved Risk Management Plan (RMP) of active substances per product

Falsified Medicines (http://www.hma.eu/489.html)

Implementation plan for the introduction of the safety features on the packaging of nationally authorised medicinal products for human use

Guidance published by Member States on the implementation of the Falsified Medicines Directive

IGDRP (http://www.hma.eu/451.html)

Information Sharing Pilot for the Evaluation of Generic Drug Applications involving the Decentralised Procedure of the European Union (IGDRP)

Questions & Answers on IGDRP information sharing pilot

Questions and Answers (http://www.hma.eu/20.html)

- Active Substance Master File
- Advice from CMDh
- Applications for MA
- Biologicals
- CMDh Referrals
- eSubmissions
- EU-enlargement
- Generics
- Homeopathics
- Impact of EU-USA Mutual Recognition Agreement on marketing authorisation applications and relevant variations
- Paediatric Regulation
- Pharmacovigilance Legislation
- Post-Authorisation Efficacy Studies (PAES) in MRP/DCP

- Post referral phase
- Product Information / Information on medicinal products
- QP Declaration
- Renewals
- Traditional Herbal Medicinal Products
- Usage Patents
- Variations
- Variations to an existing pharmacovigilance system as described in DDPS

Contact Points (http://www.hma.eu/69.html)

Contact points for:

Advice on MRP and DCP

Submission of new applications, variations and renewals

Submission of electronic response documents in MRP and DCP

Submission of Translations in MRP and DCP

Submission of Responses to List of Questions for Applications referred to the CMDh

Submission of Paediatric information in Member States

Request for Variation Grouping Number

Address for advice on fees

Terms of payment

PSUSA/PSUR Worksharing Project

Request for EU ASMF number

Technical validation of e-Submissions

Requests for the composition of a product used in a bioequivalence study

Requests for information on a product for which a parallel import license is requested

What's New History (http://www.hma.eu/186.html)