December 2020

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

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  - 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
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- CMDh position paper on the use of Mobile scanning and other technologies to be included in labelling and PL in order to provide information about the medicinal product
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  - CMDh BPG on the use of eCTD in MRP/DCP
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  - CMDh Recommendations on Implementation of Article 30 Decisions for Generic /Hybrid/Biosimilar Medicinal Products approved through MRP/DCP

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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**

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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

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  - **Urgent Safety Restriction** ([http://www.hma.eu/102.html](http://www.hma.eu/102.html))
    
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  - **Art. 61(3) Procedure** ([http://www.hma.eu/101.html](http://www.hma.eu/101.html))
    
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  - **Consultation with target patient groups** ([http://www.hma.eu/218.html](http://www.hma.eu/218.html))
    
    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](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](http://www.hma.eu/26.html))
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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

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

- **CMDh Recommendations** ([http://www.hma.eu/245.html](http://www.hma.eu/245.html))
  
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  *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](http://www.hma.eu/261.html))

  *Information on applications referred in accordance with Article 30 of Directive 2001/83/EC/Tracking table*
Lists of Medicinal Products for Harmonisation of SmPCs

Final list of products for SmPC Harmonisation - 2014

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Criteria for selection of products for SPC Harmonisation

- Core SmPC/PL ([http://www.hma.eu/104.html](http://www.hma.eu/104.html))
  - Fludeoxyglucose (18F) - Revised Core SmPC and PL
  - Hormone Replacement Therapy - Core SmPC
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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](http://www.hma.eu/226.html))

Information on nitrosamines for marketing authorisation holders

Notice to marketing authorisation holders

Questions and answers on “Information on nitrosamines for marketing authorisation holders”

CMDh practical guidance for Marketing Authorisation Holders of nationally authorised products (incl. MRP/DCP) in relation to the Art. 5(3) Referral on Nitrosamines

Templates:
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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 Japan

**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)**

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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’
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QRD (http://www.hma.eu/126.html)

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- **MRP/RUP** ([http://www.hma.eu/110.html](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
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  - Update Assessment report for Repeat Use Procedures

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  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

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

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- **Joint CMDh/PhVWP WG** ([http://www.hma.eu/275.html](http://www.hma.eu/275.html)) - RETIRED
  Mandate Joint Subgroup CMDh-PhVWP
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- **CTS Working group** ([http://www.hma.eu/294.html](http://www.hma.eu/294.html))
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**Paediatric Regulation** ([http://www.hma.eu/213.html](http://www.hma.eu/213.html))

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

  *Paediatric Regulation: Article 45 and Article 46*

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- **Assessment Reports** ([http://www.hma.eu/187.html](http://www.hma.eu/187.html))
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  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 Assessment**
    
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  - **PSUR worksharing and Synchronisation Project**
    
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    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 PSUR Follow-up procedures**
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**Falsified Medicines** ([http://www.hma.eu/489.html](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


- 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


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- Impact of EU-USA Mutual Recognition Agreement on marketing authorisation applications and relevant variations
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Variations to an existing pharmacovigilance system as described in DDPS

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

**Contact points for:**

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- Submission of new applications, variations and renewals
- Submission of electronic response documents in MRP and DCP
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- Submission of Responses to List of Questions for Applications referred to the CMDh
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- PSUSA/PSUR Worksharing Project
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- 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

Switch of the RMS

Requests to act as reference authority in a variation worksharing procedure

Publication of product information by NCAs

What’s New History ([http://www.hma.eu/186.html](http://www.hma.eu/186.html))