16 November 2023
EMA/CMDh/498582/2023

Report from the CMDh meeting held on 7-8 November 2023

Election of CMDh Vice-chair

The CMDh re-elected Susanne Winterscheid (Germany) as its vice-chair by consensus of the CMDh members, for a second three-year mandate starting from the December 2023 CMDh meeting. The elected vice-chair will join efforts with the appointed vice-chairperson of the presidency of the Council of the European Union in supporting the CMDh chairperson in her tasks.

Questions & Answers on the implementation of the Medical Devices and In Vitro Diagnostic Medical Devices Regulations ((EU) 2017/745 and (EU) 2017/746)

The CMDh in liaison with the EMA and the European Commission has agreed an update of the joint EMA/CMDh Q&As on the implementation of the Medical Devices and In Vitro Diagnostic Medical Devices Regulations ((EU) 2017/745 and (EU) 2017/746). Questions 2.10 has been updated to specify that for MRP/RUP the previously assessed documentation according to MDD for legacy devices can be accepted in the absence of device related significant changes of the integral DDC authorised in the RMS since the entry into application of the MDR.

The updated Q&A document will be published on the EMA website and linked from the CMDh website under "Questions and Answers".

A further, more comprehensive update of the Q&As is currently ongoing and will be published in the near future.

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

The CMDh updated its guidance document "Data requested for Variations and/or Renewal Applications in the MRP/DCP which are not stated in the current EU legislation and/or in Volume 2B, Presentation and format of the dossier Common Technical Document (CTD) and/or in the EEA approved Guidelines/ Recommendation papers". The update takes into account the new renewal process, published in February 2023. It is also now specified in the document if a requirement is related to variations or renewals or both. A new line has been included to indicate which Member States require full

documentation for standard renewals for legislative reasons. The existing national requirements have been reviewed and reduced by Member States, as far as possible.

The updated document will be published on the CMDh website under "Procedural Guidance> Variation".

CMDh position on PASS results according to Art. 107q of Directive 2001/83/EC concerning valproate - EMEA/H/N/PSR/J/0045

The CMDh, having considered the results of a non-interventional imposed post-authorisation safety study (PASS) on the basis of the PRAC recommendation and the PRAC assessment report, agreed by consensus that the benefit-risk balance of medicinal products containing valproate is unchanged, but recommends that the terms of the marketing authorisation should be varied as follows:

- The obligation to perform PASS VALNAC09344 to investigate the therapeutic strategies after discontinuation of valproate and related substances in clinical practice is considered fulfilled; valproate risk management plan (RMP) should be updated accordingly at the next regulatory opportunity.

CMDh positions following PSUSA procedures for nationally authorised products only

The CMDh, having considered the PSURs on the basis of the PRAC recommendations and the PRAC assessment reports, agreed by consensus on the variation of the marketing authorisations of medicinal products containing the following active substances:

- fluconazole
- furosemide / spironolactone
- oxycodone

Further information regarding the above mentioned PSUSA procedures, including information on the implementation, will be published on the EMA website.

Outcome of PSUR Follow-up procedures

Montelukast - FI/H/xxxx/WS/112

The CMDh endorsed the outcome of the WS variation (FI/H/xxxx/WS/112) for montelukast-containing medicinal products as a follow-up to the PSUSA (PSUSA/00002087/202107).

Based on the review of data submitted, an update of the SmPC section 4.4 and of section 2 of the PL in relation to neuropsychiatric events was agreed.

All MAHs of concerned medicinal products are requested to update their product information in accordance with the recommendation.

The agreed CMDh recommendation, including the PI wording to be implemented, will be published on the CMDh website under "Pharmacovigilance > PSUR > Outcome of PSUR Follow-up procedures".

EU Worksharing Articles 45 & 46 of the Paediatric Regulation – Public Assessment Reports

The CMDh has agreed a public assessment report for paediatric studies submitted in accordance with Article 46 of the Paediatric Regulation for:

- Trileptal (oxcarbazepine)

The public assessment report will be published on the CMDh website under "Paediatric Regulation > Assessment reports".

Working Party on Paediatric Regulation

The CMDh agreed to discontinue the Working Party on Paediatric Regulation. All topics previously discussed in the Working Party, like Art. 45 and 46 worksharing, will continue to be discussed in the CMDh plenary meetings. The CMDh thanks the Working Party chair as well as any previous chairs and all Working Party members for their efforts throughout the years.

Update of website on PSUR work sharing and synchronisation project

The CMDh agreed updated text to be published on the subpage of the CMDh website on the PSUR work sharing and synchronisation project. The PSUR work sharing project was officially declared concluded in December 2019. More than 1.500 WS procedures were finalised and allowed a more than significant reduction of the administrative burden, both from NCAs and MAHs side.

NEW APPLICATIONS

Mutual Recognition Procedure

Table 1. New applications in Mutual Recognition procedure started in October 2023

Member State	Number of times involved in a procedure as RMS	Number of times involved in a procedure as CMS
Austria	1	6
Belgium		3
Bulgaria	1	2
Croatia		7
Cyprus		2
Czech Republic	2	4
Denmark	1	4
Estonia		2
Finland	2	4
France	1	4
Germany	5	3
Greece		6
Hungary	1	3

Member State	Number of times involved in a procedure as RMS	Number of times involved in a procedure as CMS
Iceland		2
Ireland	1	4
Italy		2
Latvia	2	3
Liechtenstein		
Lithuania		5
Luxembourg		3
Malta	1	2
Netherlands	5	6
Norway	2	3
Poland		2
Portugal	2	2
Romania		2
Slovak Republic		2
Slovenia		2
Spain	1	6
Sweden		6
United Kingdom (Northern Ireland)		

Decentralised Procedure

Table 2. New applications in Decentralised procedure started in September 2023

Member State	Number of times involved in a procedure as RMS	Number of times involved in a procedure as CMS
Austria		14
Belgium		4
Bulgaria		10
Croatia	1	8
Cyprus	1	8
Czech Republic	4	14
Denmark	2	11
Estonia	1	9
Finland	4	4
France		9
Germany	12	20
Greece		8
Hungary	4	8
Iceland	1	5
Ireland	4	1
Italy		16
Latvia	1	9

Member State	Number of times involved in a procedure as RMS	Number of times involved in a procedure as CMS
Liechtenstein		
Lithuania	2	7
Luxembourg		4
Malta	5	6
Netherlands	10	7
Norway		12
Poland	2	15
Portugal	4	9
Romania		14
Slovak Republic	2	10
Slovenia	2	8
Spain	1	17
Sweden	8	8
United Kingdom (Northern Ireland)		

Information on the above-mentioned issues can be obtained:

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