CMDh Work Plan 2026–2028 including transparency measures related to pharmacovigilance

21st Industry Stakeholder Platform – Operation of EU Pharmacovigilance

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General objective to be included in the MAWP to 2028:

- Optimize information from CMDh on safety outcomes
- Find new ways how CMDh informs on safety:
  - stakeholders
  - health care professionals
  - patients
- Be more transparent in providing information what topics on safety is CMDh discussing

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1.6. Transparency on safety outcomes for NAPs

Action points

Actions	Lead	Performance indicators	Priority/Timeline
Publish the outcomes of safety variations for NAPs	SOS WG/ CTS WG *See also Chapter 2.3 of the MAWP*	Dedicated website with safety variations outcomes	Short term
Publish the outcomes of PRAC advice to MS on the CMDh Pharmacovigilance website	SOS WG	Publishing the outcomes of PRAC advice to MS in a more structured and visible manner (under CMDh/ Pharmacovigilance)	Short term
Publish information on the List of Safety Concerns (LoSC)	PhV WS WP	1. Process of publishing of LoSC is in place for continuous publications 2. Dedicated website with LoSC uploaded via CTS is ready	Short term
Publish CMDh guidance on how to deal with additional risk minimisation measures (aRMM) in MR/DC procedures	PhV WS WP	Publishing the CMDh Best Practice Guide on aRMM in MR/DC procedures (under CMDh/ Pharmacovigilance)	Medium term

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Publishing the outcomes of PRAC advice to MS on the CMDh PhV website

- Proposal to systematically publish the outcome of PRAC advice to MSs in a more structured and visible manner than currently only in CMDh Minutes
- Information will be published under the Product Information/ PhV procedure outcomes section
- How: Excel table containing a compilation of outcomes of PRAC advice to Member States
- The initial PRAC advice and the final outcome will be reflected for transparency

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Active substance	Medicinal product	Request for PRAC advice	CMDh meeting minutes	Outcome
active substance	*medicinal product name*	*request for PRAC advice in very short terms as described in PRAC agenda*	*links to the CMDh minutes*	***Possible outcomes***
lithium	Lithionit	Update the product information regarding the development of Darier disease following administration of lithium containing products		Update of PI

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Publishing the Outcomes of Important Safety variations for NAPs

- The intention is to publish – on the dedicated webpage – approved safety changes in Product Information that have been based on new data submitted by the MAH

- All NAPs regardless of legal basis and procedure (MRP variations + WS variations for MRP/DCP/pure NAPs)

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Publishing the Outcomes of Important Safety variations for NAPs

- For each safety variation that qualifies for publication two key elements will be published:

Safety summary

Prepared by NCA

"Clean" PI changes

Prepared by MAH

- Guidance for the MAHs how to prepare anonymized, track changes PI or a summary of the PI changes is planned

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Publishing the information on the List of Safety Concerns (LoSC)

- List of Safety Concerns available in a webpage integrated with CTS client
- Info on products' LoSCs to be uploaded by MAHs via a dedicated webpage
- Go live deadline: 2026/2027
- HaRP project AR included in the system

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Publishing CMDh guidance how to deal with aRMM in MR/DC procedures

- Best Practice Guide on how to deal with additional Risk Minimisation Measures in MR/DC procedures
- Will contain a section on patient cards
- First step to revise and improve aspects regarding the management of patient cards in the various EU procedures

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Thank you for your attention

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