EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Risk minimisation for patient safety – update on policies and practices

PCWP + HCPWP February 2024

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Priya Bahri, European Medicines Agency, H-QS-PhV

We need you

Patient safety is a continued collaborative effort

Initiatives at EMA for improving risk minimisation

- Strengthening guidance to marketing authorisation holders and competent authorities
- Enhancing engagement with patient and healthcare professional representatives
- Investing in research

EU Good Pharmacovigilance Practices (EU-GVP) – Module XVI on Risk Minimisation Measures (RMM) Revision 3

Comprehensive view on RMM with clarified relationships between different RMM tools

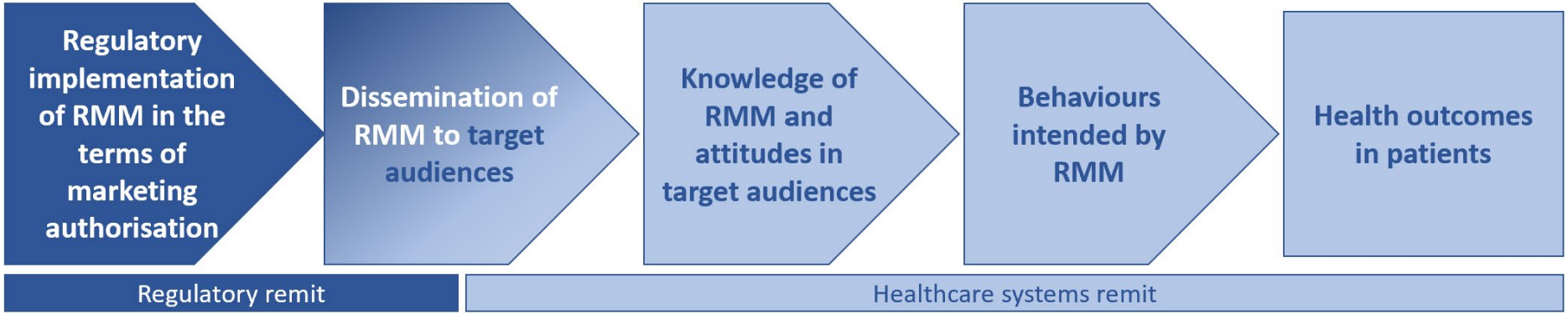
Iterative approach to RMM within the benefit-risk management cycle

Mixed-methods research approaches

Implementation pathway with intended RMM-outcomes

Engagement of patient and healthcare professional representatives in RMM within appropriate frameworks

RMM implementation pathway in GVP M XVI rev 3



Opportunities for engagement of patient and healthcare professional representatives in RMM in GVP M XVI rev 3

- Provide input on RMM options, their implementability and target audiences
- Contribute to designing/tailoring to target audiences, user-testing and planning for implementation of RMM in healthcare
- Support the dissemination of RMM via multiple channels and further implementation in healthcare
- Advise and participate in the evaluation of RMM

PRAC Risk Minimisation Alliance (PRISMA) Group

Looking at RMM options in different lights

= perspectives of all stakeholders

with a focus on barriers and enablers of

RMM implementation in healthcare; and

Advising on stakeholder engagement

Collating a knowledge base for

RMM development, implementation and evaluation

across medicinal products from a systems perspective

PRISMA group membership and practicalities

- Pilot working group
- PRAC patient and healthcare professional members/alternates, PRAC (co-)chairs and further members, HCPWP member from PGEU and two representatives from the EMA's GP Forum
- Monthly meetings of one hour online

PRISMA group achievements under pilot Jul 2022 - Dec 2023

- High interest from PRAC rapporteurs and members and important dialogue fostering:
  - ❖ Clinical mindset
  - ❖ Patient perspectives
  - ❖ Healthcare systems insight
- Proposals on PRAC lists of questions to stakeholders regarding RMM and for competent authorities in support of RMM implementation
- Conduct of two surveys:
  - ❖ Integration of RMM in dispensing and prescribing software
  - ❖ Internet access to RMM materials
- Development of a new patient journey-based PRISMA discussion framework and testing for specific RMM-tool in general terms; this provided useful input for PRAC

PRISMA group plans for 2024

- Report on survey on integration of RMM in dispensing and prescribing software with proposals for potential opportunities for collaboration

- Proposal for an EMA webpage on RMM with links to the webpages of national competent authorities for access to RMM materials

- Mapping of RMM tools and their enablers, using and further developing the PRISMA discussion framework

EMA-commissioned research 2022-2023

"Implementation of EU risk minimisation measures for medicinal products in clinical guidelines" (EUPAS 47588)

- Report to be published in a scientific journal

Future updates for PCWP and HCPWP members

- Online launch event for GVP Module XVI rev 3 in Q2 2024: *We will announce it to PCWP and HCPWP, please join if feasible*

- Updates from the PRISMA group and presentations on the PRISMA group and EMA-commissioned research reports: *We will add this to future PCWP + HCPWP agendas for discussion*

Discussion points for today

- Do you see more training needs on regulatory RMM policies and guidance?
- How do you see capacities of patient and healthcare professional organisations for user testing in RMM materials?
- Which engagement frameworks for marketing authorisation holders towards patient and healthcare professional organisations for the purpose of RMM development do you see as appropriate?

Thank you

priya.bahri@ema.europa.eu
Address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands
Send us a question Go to www.ema.europa.eu/contact
Telephone +31 (0)88 781 6000

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