EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Updates on pharmacovigilance
- new initiatives for risk minimisation and updates on EU-GVP

PCWP & HCPWP Joint Meeting

22 September 2022

Priya Bahri, European Medicines Agency

Plans for pharmacovigilance engagement

PCWP + HCPWP June 2022:

Re-start with new experiences for enhancing engagement of Pharmacovigilance Risk Assessment Committee (PRAC):

- Commissioning a study on integration of risk minimisation measures (RMM) in clinical guidelines with examples for 5 major disease areas: *Study protocol evaluated in September 2022 and study report expected at the end of 2023*
- Piloting of the PRAC Risk Minimisation Alliance (PRISMA): *Started in July 2022 and expected to run until mid-2023 and be transitioned into a regular process*
- Drafting a reflection paper on digital support to risk minimisation: *first meeting of multistakeholder drafting group scheduled for 6 October 2022 and draft for public consultation expected to be available in 2024*

1 Priya Bahri: Pharmacovigilance updates

PRAC Risk Minimisation Alliance (PRISMA)

Looking at RMM options in different lights - perspectives of all stakeholders with a focus on barriers and enablers of RMM implementation in healthcare

- Pilot working group on enhancing PRAC's engagement with patients and healthcare professionals (PRAC members/alternates and two representatives from the EMA's GP Forum; PRAC rapporteurs; EMA)
- Monthly meetings to discuss risk minimisation measures (RMM) early in the assessment to allow stakeholder PRAC members to contribute to PRAC on selected products
- Collating a knowledge base for RMM development and implementation across products

Concept of pharmacovigilance engagement for knowledge exchange
Reviews of past engagement events, including valproate public hearing

PRAC Risk Minimisation Alliance (PRISMA) – 1st and 2nd meeting

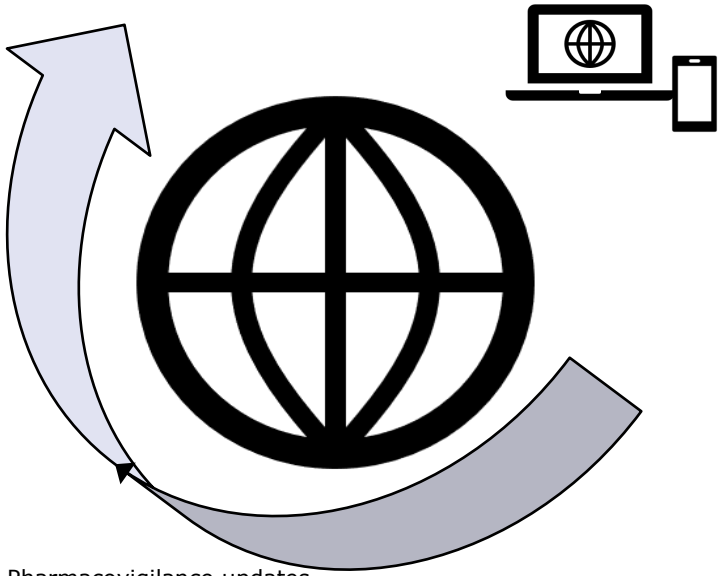
- Piloting PRISMA for widely used products with significant preventable risk

Products discussed so far:

- Topiramate and valproate: mainly antiepileptics with risks of congenital and long-term neuro-developmental disorders after in-utero exposure
- Discussion focus for topiramate: to inform, from healthcare and patient perspectives, on the implementability of RMM options for decision-making in an ongoing referral procedure
- Discussion focus for valproate: to explore how healthcare and patient communities could possibly support the implementation of RMM imposed by the 2017/8 referral procedure
- Kick-off discussions; to be discussed further in October and November 2022

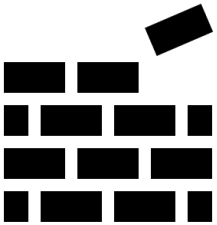
Reflection paper on digital support to risk minimisation

Opportunities of digitilisation for support to risk minimisation flagged by stakeholders



- Support to diverse patients (e.g. with disabilities, or children by explanatory game-like videos)
- Targeting digitally-oriented patients
- Dissemination of risk information and safe use advice healthcare professionals
- Data collection for evaluation of risk minimisation measure effectiveness
- Timeliness of information (e.g. experiences with QR codes on package to latest product information)

Reflection paper on digital support to risk minimisation: Principles



Electronic product information (ePI):

- Health benefit and diverse patient inclusiveness
- Dissemination and open access via www, e-platforms and printing
- Complementing paper PI
- For use in other e-health systems (e.g. e-health records, e-prescribing) and interoperability with EU and global initiatives
- EU electronic standard (e.g. mark-up language, controlled vocabularies, interoperability specifications)
- Personal data protection when using ePI
- High-level governance
- Flexible implementation across EU Member States
- Multi-lingual
- Efficient (regulatory) information management
- Research resource

Guidance on mobile technology

Data security policies and processes

Personal data protection:

- Information relating to an identified or identifiable natural person
- Right to privacy under EU Charter of Fundamental Rights
- General Data Protection Regulation (GDPR), the Data Protection Law Enforcement Directive and other rules

Reflection paper on digital support to risk minimisation

Good Pharmacovigilance Practices (EU-GVP)

Work 2022/23:

- **GVP Module XVI Rev 3 on risk minimisation measures (RMM), Addendum II on RMM evaluation and Addendum III on pregnancy prevention programmes**: Finalisation post-public consultation, aiming at publication in 2023
- **GVP Chapter P III on pregnancy and breastfeeding**: Finalisation of post-consultation, to be published in 2023
- **GVP Annex I Rev 5 on definitions**: published Rev 4 includes latest definitions from clinical trial legislation; previous definitions will be deleted in Rev 5, aiming at publication in 2023
- **Concept Paper on digital support to RMM and their evaluation**: Development by multi-stakeholder drafting group, aiming at launch of public consultation in 2024
- **GVP Module VIII Rev 4 on post-authorisation safety studies**: to be started in 2022/3
- **GVP Module V Rev 3 on risk management plans**: possibly to be started in 2023

Thank you

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