EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Pharmacovigilance Impact Strategy of the Pharmacovigilance Risk Assessment Committee (PRAC) –

Valproate case study on engagement of patients and healthcare professionals

12th Pharmacovigilance Stakeholder Forum September 2018

Presented by Priya Bahri

Measuring Pharmacovigilance Impact: The PRAC Strategy

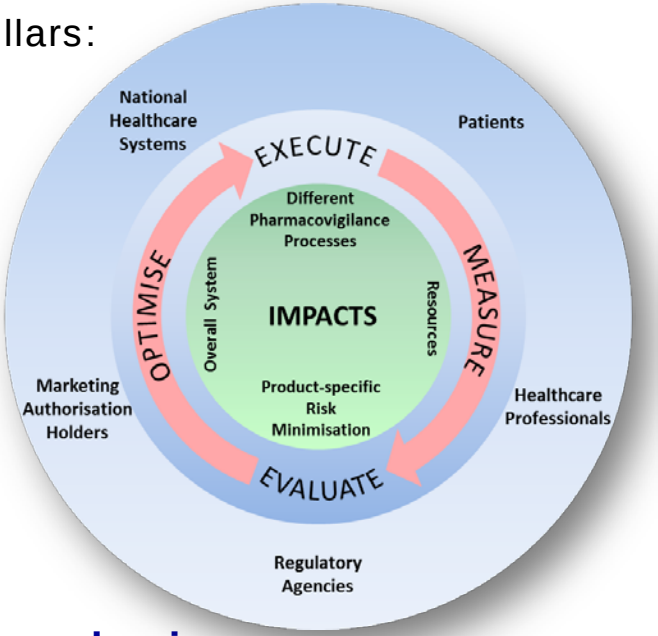
The PRAC Strategy Rev 1 (EMA/165407/2017) focusses on 4 pillars:

I. Effectiveness of **product-specific risk minimisation** (e.g. measures following major referrals)

II. Effectiveness of **pharmacovigilance processes** (e.g. post-authorisation studies)

III. Enablers of effective pharmacovigilance and **stakeholder engagement**

IV. Identification and development of **analytical methods** (e.g. for modelling impact on health outcomes)



→ Leverage of ongoing work by regulators, industry and academia

Thanks for slide to Thomas Goedecke, EMA

Valproate case study - Objectives

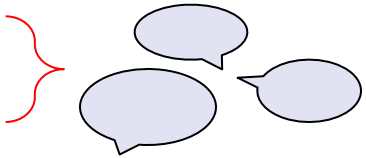
(1) **To analyse the *content* of the input of patients and healthcare professionals** in the evaluation of risk minimisation measures (RMM) during the 2017 regulatory procedure for valproate

(2) **To develop good practice recommendations** for enabling future **systematic** input from patients and healthcare professionals (HP) that are **relevant for decision-making** on medicinal product-specific RMM

Involvement during the procedure

Involvement of patient and HP organisations through all available mechanisms in 2017, i.e.

- Written consultation – evidenced issues with implementation of risk minimisation measures (RMM)
- Public hearing NEW
- Dedicated meeting



Step 1: Content analysis framework adapted from implementation science: New AAA-CIT tool developed and proposed

Background: - Smith MY, Morrato E, 2014
- SMART criteria from strategic management and health communication
- Refinement through testing with stakeholder input in 2014

Six criteria created as relevant to pharmaceutical risk management:

1. **A**ppropriateness of proposed RMM to reduce harm
2. **A**cceptability in terms of impact of RMM on access to appropriate treatment
3. **A**udience-tailored approach of RMM
4. **C**ompatibility of RMM with healthcare structures and resources
5. **I**mplementability of RMM in healthcare processes
6. **T**imebound requirements for implementation of RMM

→ **21 themes subordinated for granularity to compare input**

Step 2: Content analysis summary

- Patients' and healthcare professionals' agreement on need for access to valproate
- Patients' and healthcare professionals' majority agreement on informed choice of the female patient
- Identification of a lack of coordination, resources and processes in healthcare for implementation of RMM
- Many RMM proposals with plausible expectations but little evidence on appropriateness/effectiveness and little convergence on practicalities of implementation
- RMM information tool preferences (incl. pictogram) expressed but limited evidence on effectiveness or success factors

Valproate case study – Preliminary recommendations to the PRAC Impact Group

- **Engage** as input from patients and healthcare professionals is important and useful for regulatory decision-making on RMM
- **Communicate with the public** about rationales and dilemmas of regulatory decision-making
- **Listen to what one can hear and not hear** for limited input e.g. for evidence-based appropriateness, agreement and leadership for implementation in healthcare
- **Ask specific implementation- and practical solution-focussed questions** for filling areas of limited input as may be facilitated by the AAA-CIT tool
- **Connect pharmacoepidemiology with health service research**
- **Outreach and catalyse implementation of RMM** as expected by the public

Declarations:

It is not the objective of this presentation to explain the outcome of the EU referral procedure on valproate, as this is published, together with the assessment report, on the EMA website.

Thank you for your attention

Further information

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