



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Strengthening the planning and implementation of risk minimisation

Workshop on risk minimisation measures

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EMA

An agency of the European Union





In this presentation

A vertical timeline graphic on the left side of the slide, consisting of a grey line with five blue circular markers at each step.

How to analyse the opportunities

Focus of process

Prioritisation

Key messages

Acknowledgements



Objective of our work

- Promote and protect public and individual health
 - Enable safe and effective use of medicines
 - Fulfil unmet medical needs of patients



How to analyse the opportunities

- Time axis – next year; five years; ten years
- Stakeholder axis – patients; professionals; industry.....
- Product axis – OTC; chemical; biological
- Process axis– from planning to measuring effectiveness

This analysis – organised by process



Focus on process (while engaging all stakeholders)

- Planning
- Collecting detecting evaluating
- Supporting decisions
- Measuring effectiveness and impact



Planning the monitoring and risk minimisation of medicines

- Planning is key to success – principles:
 - Start early
 - Clear objectives
 - Proportionality
 - Feasibility
 - Effective and sustainable
- Involve stakeholders; hear their voices:
 - work on patient involvement at CHMP
 - Patients and Healthcare Professionals on PRAC
- Scientific advice pilot with PRAC members
- GVP V revision – focus on important risks

Collecting data and information

- Initiatives to strengthen:
 - Patient reporting of suspected adverse reactions – analysing the patient data in EudraVigilance – HAI work: <http://haieurope.org/wp-content/uploads/2015/09/Direct-Patient-Reporting-in-the-EU.pdf>
 - Registries initiative
 - Medication errors initiative of Heads of Agencies
 - PASS – better planning and feasibility
 - PAES – use of observational methods
 - Apps
 - Social media



Detecting issues

- New EudraVigilance with more public access – further access 2017
- Implementing PROTECT results for signal detection (signals of new or changing safety issues) – key role of regulatory sciences research to improve our work

Evaluating

- Patient and healthcare professional involvement – hear the voice.
- Work to develop and implement methods for structured benefit risk assessment
- Feasibility, effectiveness and sustainability assessment –a routine step in consideration of additional risk minimisation activities



Supporting Decisions

- Product information is our key output – continuously improve – European Commission review
- Information distributed via patient and healthcare professional associations
- Work on health literacy
- Websites – EU medicines Web-portal
- Dear Healthcare Professional communications - DHPCs
- Prescribing and dispensing systems
- Smart phones



Social media

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Strengthening the planning and implementation of risk minimisation

Continuously improve methods

Measuring effectiveness and impact

- Key to success – reducing the burden of adverse reactions and enabling safe and effective use
- PRAC strategy on Impact
- Review industry work in risk management plans and periodic reports
- Collaboration and surveys with stakeholders:
 - Survey with patients and HCPs to be discussed in plenary tomorrow
- Further develop methods (science)

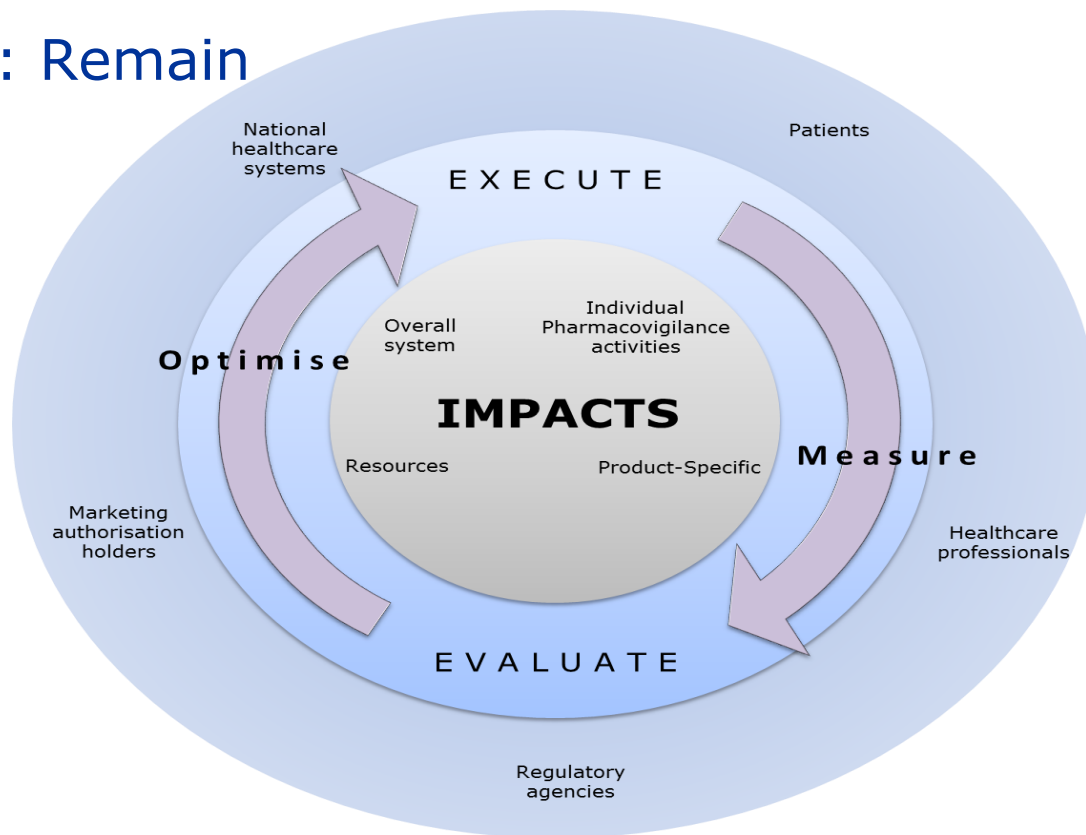


Prioritisation

- Need to prioritise – panel discussion to follow
- Identify quick wins
- Longer-term plan: HCPWP topic groups + patient input + CHMP + PRAC



Key message: Remain on target



Key messages and priorities

- Remember our goal: promote, protect
- Collective effort: engage, communicate, coordinate
- We have opportunities to do better
- Key success factor: planning; feasibility; sustainability, proportionality, collaboration
- Priorities for next year:
 - Improving consistency of decision-making
 - Ensuring risk minimisation measures are proportionate and effective
 - Input from patients & HCPs: what works and what does not
 - Progressing benefit risk methods
 - Progressing impact work



Acknowledgements

HCPWP

PCWP

PRAC

CHMP

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