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SCIENCE MEDICINES HEALTH

Pharmacovigilance Impact Evaluation – for better Pharmacovigilance.

Tenth Stakeholder forum on the Pharmacovigilance legislation
21 September 2015

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In this presentation

- Context
- Key elements of PRAC impact strategy
- How does the pharmacovigilance system generate impact?
- Collaborations
- Conclusions

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DIRECTIVES

DIRECTIVE 2010/84/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 15 December 2010

amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use

(Text with EEA relevance)

(2) Pharmacovigilance rules are necessary for the protection of public health in order to prevent, detect and assess adverse reactions to medicinal products placed on the Union market, as the full safety profile of medicinal products can only be known after they have been placed on the market.

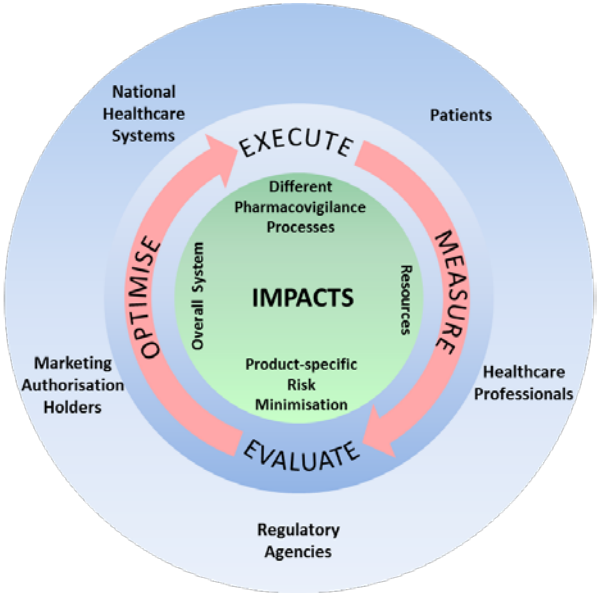
Why measuring impact of regulatory measures?

- To inform the **review of the benefits and risks of individual medicines** that have been the subject of **major risk minimisation efforts**;
- To determine what activities are successful and which are not, and therefore **identifies enablers and barriers for generating positive impacts** which would contribute to the development of proactive pharmacovigilance in the EU;
- Support to **continuously improve and optimise** the functioning of the pharmacovigilance system (‘evidence-based process improvements’);

Measuring pharmacovigilance impact:

The PRAC strategy focusses on 4 key areas:

- Effectiveness of **pharmacovigilance processes** (e.g. ADR reporting, signal management)
- Effectiveness of **product-specific risk minimisation** (e.g. labelling)
- Enablers of effective pharmacovigilance such as **stakeholder engagement**;
- Collaboration on **methodologies**, e.g. modelling methods for measurement of impact on health outcomes;



→ Leverage of ongoing work by regulators (NCAs + EMA), industry and academia;

Two dimensions to the strategy

- **Product risk management**: Collaboration between the EMA and Member States' competent authorities **to continuously develop pharmacovigilance systems** capable of achieving high standards of public health protection for all medicinal products, and monitor the **outcomes of risk minimisation measures.**
- **System / process**: The **EU Regulatory Network** and its **stakeholders** all have a role in collecting data and information on **regulatory measures**
  - to ensure they are **effective and efficient** and
  - to continuously drive **process improvement**.

Product: Identifying and Characterising Risks

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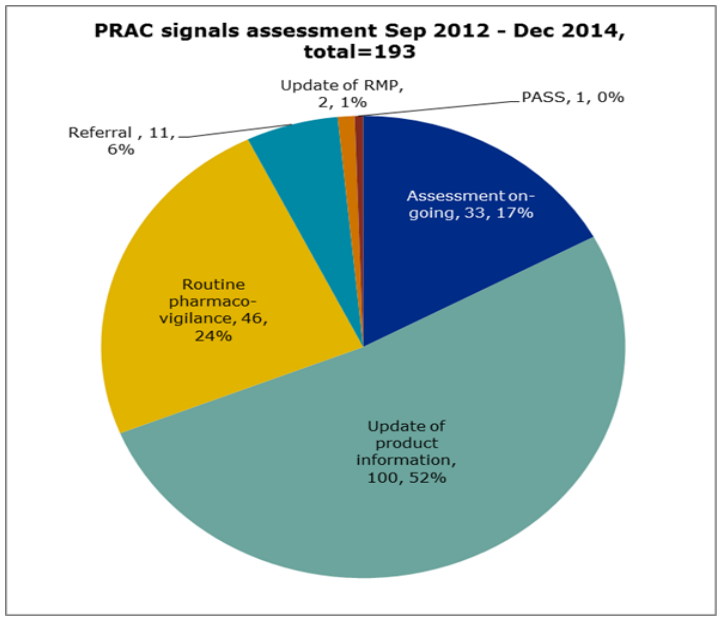
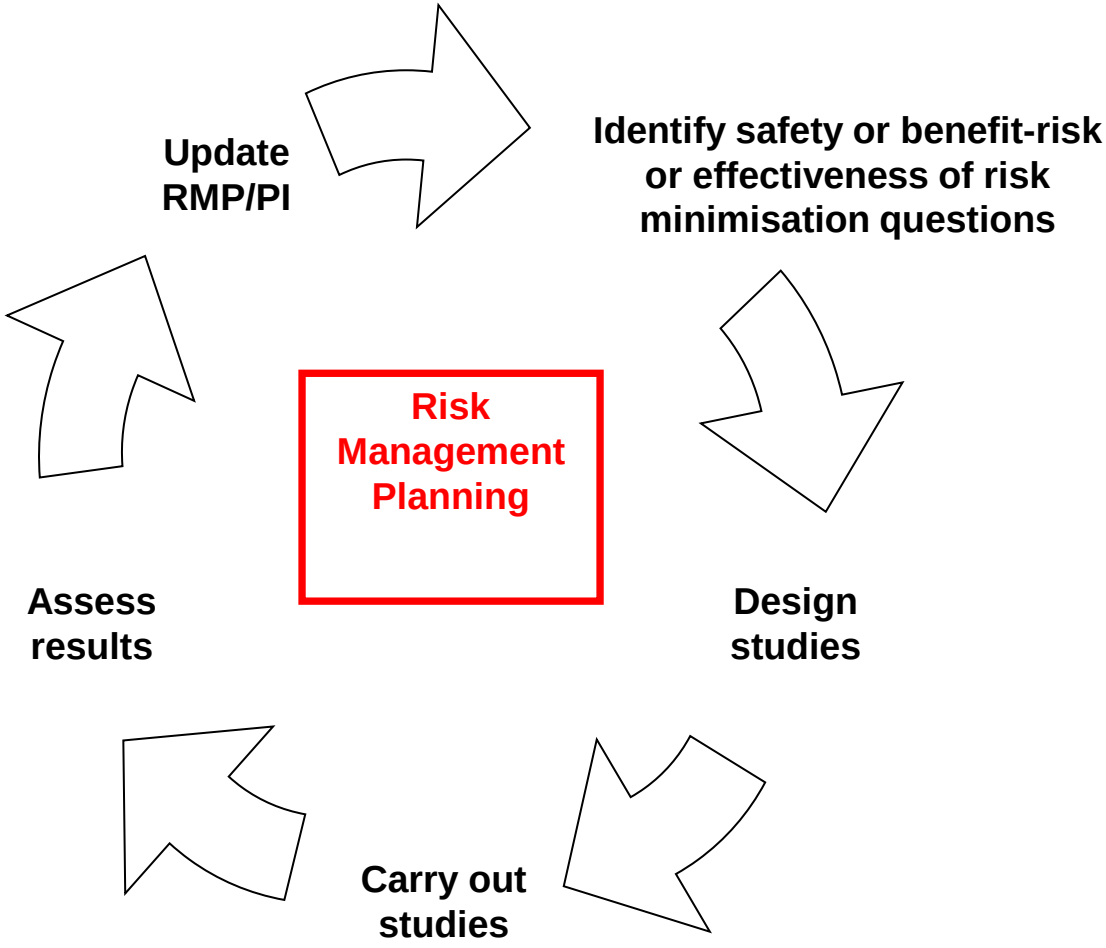


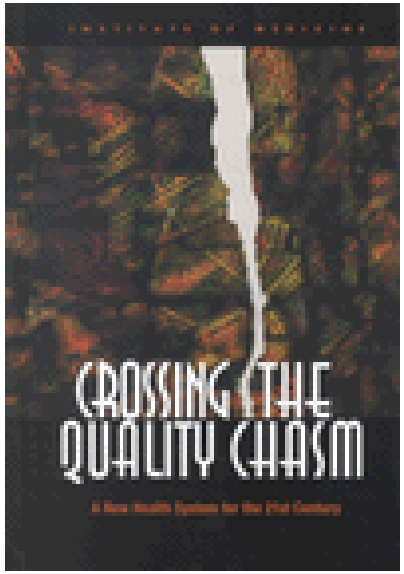


Iterative, incremental, essential.

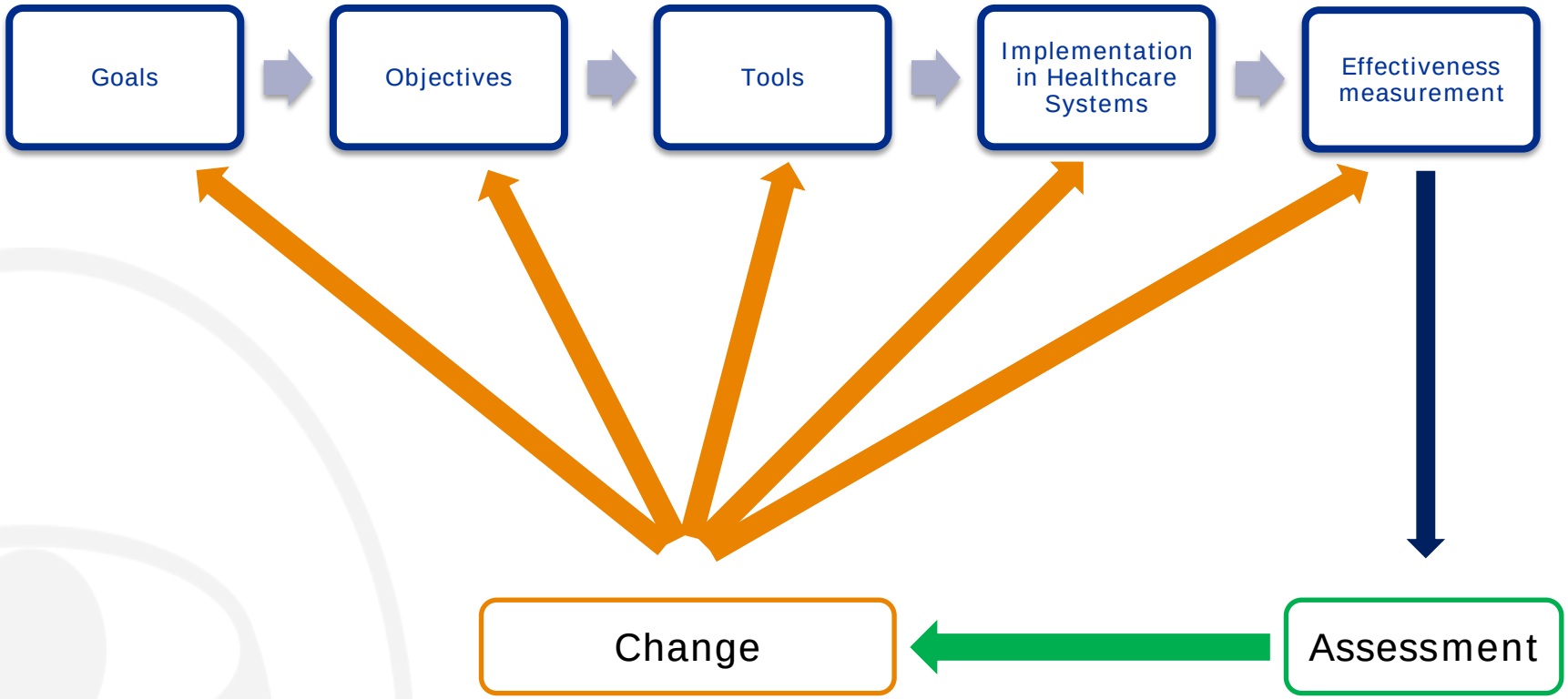
RMP = Risk Management Plan
PI = Product Information

Focus on Risk Minimisation – monitoring use

Transfer of knowledge from research to practice and policy.



Implementation Science and Assessment of the Risk Management Process



Strategy Pillars

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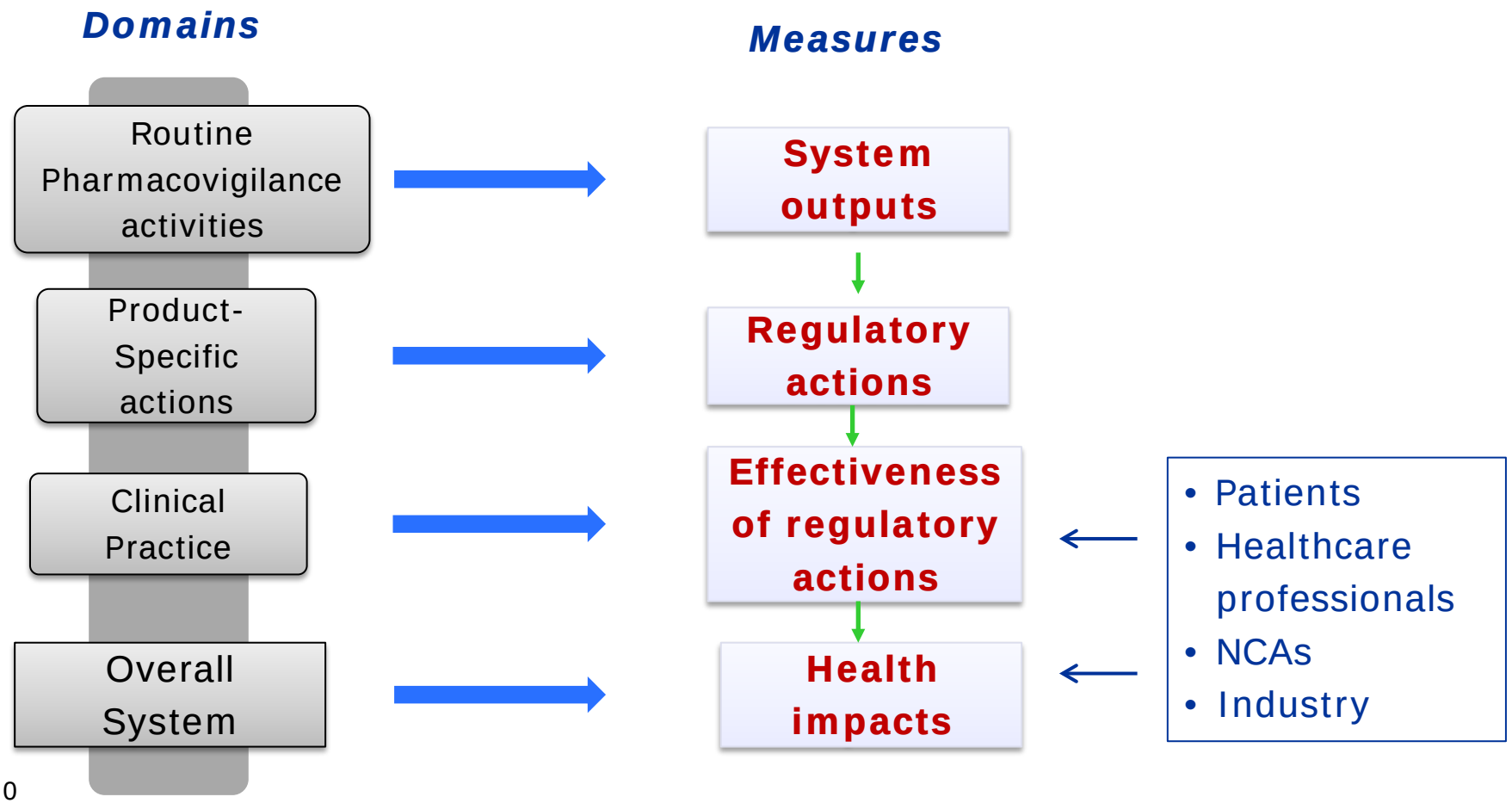
System level

- Effectiveness of specific pharmacovigilance processes e.g. signal detection
- Enablers of effective pharmacovigilance including stakeholder trust and engagement.
- Method identification and development.

Product level

- Effectiveness of risk minimisation actions
- Enablers of effective pharmacovigilance including stakeholder trust and engagement.
- Method identification and development.

How does the pharmacovigilance system generate impacts?



Key Aspects underpinning Criteria for identifying topics for Impact Research

I Public Health Importance of the Risk to be Managed

Nature and severity of the risk in the affected population

Magnitude of the risk in population exposed.

Public concern, vulnerability of population.

II Potential Impact on Clinical Practice – Change element

Extent of the regulatory intervention e.g. contraindication

III Delivery of decision relevant data

Feasibility, interpretability, generalizability, likely contribution to iterative process of risk management (taking account of already planned studies and gaps to be filled).

Interfaces

PRAC and other committees

- PRAC: prioritise topics for collaborative impact research
- Identify domains of collaboration – method development

Patients and Health Care Professionals

- Measure trust & engagement (e.g. patient-reported ADRs, website views, social media monitoring) - **Collaboration with PCWP and HCPWP**

Academia

- Collaboration with the European Network of Centres on Pharmacovigilance and Pharmacoepidemiology (ENCePP) on the development of new methodologies for measuring impact of pharmacovigilance activities (e.g. modelling health outcomes)

Industry

- Studies on the effectiveness of additional risk minimisation measures in EU RMP
- Collaboration on methodologies and criteria for successful risk minimisation

Areas for development and collaboration

The approach of pharmacovigilance impact measurement may be applicable to specific activities, such as:

- Paediatrics e.g.
  - Signal detection in specific age groups
  - Paediatric PASS
  - Risk minimisation – risk communication
- Use of medicines during pregnancy
- Biologicals - vaccines
  - Traceability
- Authorisation approaches (orphans, adaptive pathways)
  - Impact of safety monitoring through registries

Collaborative process

Workshop: Measuring impact of Pharmacovigilance Activities, 5-6 Dec 2016

- Call for EoI to participate closes 30 Sep'16 (>140 pre-registrations so far);
- Draft programme published:
  - **Session 1** - Importance of measuring the impact of pharmacovigilance
  - **Session 2** - Approaches for measuring impact of pharmacovigilance and regulatory decisions
  - **Session 3** - Parallel breakout sessions:

    3.1 Enablers and barriers to measuring impact – patient and HCP engagement.

    3.2 From regulatory outputs to health outcomes.

    3.3 Measures of impact of pharmacovigilance processes.
  - **Session 4** - Reports from breakout sessions: gaps and observations.
  - **Session 5** - Way forward and next steps

Conclusions

- Standard approach of pharmacovigilance impact measurement: health-focused, science-based, stakeholders-oriented
- Common endeavour of the EU Regulatory network
- Three-year plan of activities
- The approach of pharmacovigilance impact measurement may be applicable to specific activities, such as paediatrics, medicines exposure during pregnancy, traceability of biologicals.

Acknowledgments

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