EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Need for collaboration in pharmacovigilance to ensure effective health protection and promotion

Measuring the impact of pharmacovigilance decisions

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An agency of the European Union

Pharmacovigilance

- '*The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems*' (WHO)

- Post-marketing surveillance of marketed medicines includes:
  - ADR reporting
  - Periodic Safety Update Reports (PSURs)
  - Post-Authorisation Safety/Efficacy Studies

Objectives of Pharmacovigilance

- Protect and promote public health
  - Reduces uncertainty regarding known risks
  - Generates new information regarding unknown risks.

Pharmacovigilance Actions

- When new information warrants action, regulators have several tools available:
  - Update patient information/Summary of Product Characteristics (SmPC)
  - Inform patients and/or healthcare professionals (DHPC, educational material)
  - Review of benefit-risk profile of medicine (referral)
  - Restrict access to medicine

Measuring Impacts

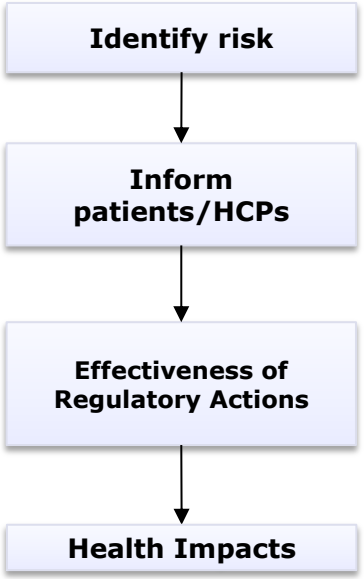
- To determine whether regulatory actions have been successful
  - Effectiveness of risk minimisation

- Identify barriers and enablers for effectiveness of regulatory actions:
  - What works and what does not?
  - Enables improving pharmacovigilance decisions

Role of Patients and Healthcare Professionals in Pharmacovigilance

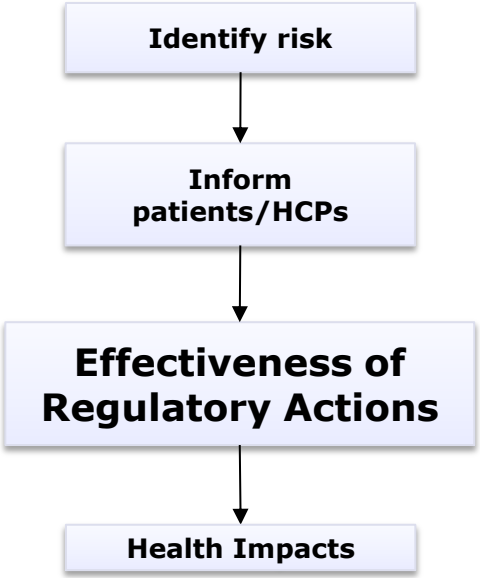
- Patients and healthcare professional are essential part in key stages from reporting to pharmacovigilance decisions
- Effects ultimately are achieved in clinical practice
- Effects can only be achieved by patients and/or healthcare professionals

How do individual pharmacovigilance activities result in health impacts? **An example:**



1. A new risk is identified for a marketed product through signal detection
2. As a result, the product's SmPC is changed and patients and healthcare professionals are informed of the risk
3. A study is performed to measure what proportion of patients and healthcare professionals have changed their behaviour as advised
4. The reduced incidence of the ADR in patients using the marketed product (and potential unintended consequences)

How do individual pharmacovigilance activities result in health impacts?



Part of the strategy on measuring impact of pharmacovigilance decisions:

- Awareness of patients/HCPs of regulatory actions and communicated advise
- Changes in use of medicines?
- Adherence with communicated advice?
- Attitudes of patients/HCPs
- Reasons for not following communicated advice

Survey Development

- Ways to measure stakeholder (patients/healthcare professionals) awareness/attitudes/impacts of pharmacovigilance decisions will be developed

- Annual survey

- Set-up of virtual collaboration group for input in survey

Survey Patient Reporting

- Study to measure patient reporting of ADRs in the EudraVigilance database will be performed in 2015

Conclusions

- Patients and healthcare professional engagement is essential in generating positive health impacts through pharmacovigilance

- Strategy to measure impact of pharmacovigilance therefore prioritises targeted surveys of patients/HPCs to measure effectiveness of regulatory actions

- Next steps: survey development with help of virtual collaboration group / input from PCWP and PHCWP