EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Pharmacovigilance

Training session for patients and consumers involved in EMA activities, 25 November 2014

Presented by: Priya Bahri

Pharmacovigilance
- the science concerned with the risks of medicines

Risks with medicines endangering patient and/or public health

- Adverse reactions (side effects), inc toxicity for unborn child, non-fitness to drive
- Overdose, misuse and abuse
- Medication errors
- Off-label use (medical intention, but not as authorised)
- Quality defects
- SSFFC (Substandard/spurious/falsely-labelled/falsified/counterfeit medical products)
- Lack of efficacy
- Underuse due to public scare

What is risk?

- Harm occurred or potential for harm?
- Identified and potential risks - Cave: We don't know what we don't know.
- Probability and frequency -> Quantitative risk measures
- Multifactorial -> Qualitative aspects and risk factors
- Serious and non-serious risks

Quantitative risk measures

- Relative risk

  = Multiplicative factor, applied to a reference risk for an occurrence, associated with an exposure in a population

- Absolute risk

  = Number of exposed persons experiencing an occurrence (the risk for this population had it not been exposed + the risk induced by the exposure)

Cave: Different definitions

Safety concern

= An important identified risk, important potential risk or missing information

Signal

= Information arising from one or multiple sources, including observations and experiments, which suggests a new potentially causal association, or a new aspect of a known association between an intervention and an event or set of related events, either adverse or beneficial, that is judged to be of sufficient likelihood to justify verificatory action

Adverse reaction

= Response to a suspected medicinal product which is noxious and unintended

Reaction means that it is thought to be not just a coincidental event but that a causal relationship is suspected.

Serious adverse reaction

= An adverse reaction which results in death, is life-threatening, requires in-patient hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or is a congenital anomaly/birth defect

Frequency categories for adverse reactions

- Very common: > 1/10
- Common: ≥ 1/100 to < 1/10
- Uncommon: ≥ 1/1000 to < 1/100
- Rare: ≥ 1/10000 to < 1/1000
- Very rare: < 1/10000


Risk

Pharmacovigilance

= Science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem

Pharmacovigilance Risk Assessment Committee (PRAC)

= Committee at the European Medicines Agency that is responsible for assessing and monitoring safety issues for human medicines

Pharmacovigilance post-authorisation – Why?

- Wider use in different population
- Other risk factors
- Healthcare practice

Clinical trials are small and controlled and hence do not allow for identifying all risks prior to marketing authorisation.

REAL LIFE!

Pharmacovigilance integrated work flow

- Data collection
- Data analysis / Identification of safety concerns and signals
- Risk assessment and assessment of benefit-risk balance
- Option analysis and decision-making on risk minimisation / regulatory action
- Communication
- Evaluation of the effectiveness of risk minimising action

Pharmacovigilance tools and processes 1/2

- Spontaneous reporting of adverse reactions
- Additional monitoring
- Post-authorisation safety and other studies
- Signal management
- Periodic safety update reports
- Risk management plans
- Incident management
- Continuous conduct of pharmacovigilance and monitoring/evaluation of benefit-risk balance

Pharmacovigilance tools and processes 2/2

- Public participation and hearings
- Safety communication
- International collaboration
- Pharmacovigilance systems with quality management, master files
- Audits and inspections

Spontaneous report

= An unsolicited communication by a healthcare professional or consumer to a company, regulatory authority or other organisation (e.g. the World Health Organization, a regional centre, a poison control centre) that describes one or more adverse reactions in a patient who was given one or more medicinal products and that does not derive from a study or any organised data collection scheme

Additional monitoring

To enhance spontaneous reporting by an inverted triangle and encouraging text in the product information

Individual case safety report (ICSR) synonym: Adverse (drug) reaction report

= Format and content for the reporting of one or several suspected adverse reactions to a medicinal product that occur in a single patient at a specific point of time

Post-authorisation safety study (PASS)

= Any study relating to an authorised medicinal product conducted with the aim of identifying, characterising or quantifying a safety hazard, confirming the safety profile of the medicinal product, or of measuring the effectiveness of risk management measures

May be an interventional clinical trial or may follow an observational, non-interventional study design

Signal management

= Signal detection, signal validation, signal confirmation, signal analysis and prioritisation, signal assessment and recommendation for action

Periodic safety update report (PSUR)

= Format and content for providing an evaluation of the risk-benefit balance of a medicinal product for submission by the marketing authorisation holder at defined time points during the post-authorisation phase

- To present a comprehensive and critical analysis of the risk-benefit balance taking into account new information in the context of cumulative data
- Assessed to determine whether there are new risks or whether risks have changed or whether there are changes to the risk-benefit balance

Risk management system

= A set of pharmacovigilance activities and interventions designed to identify, characterise, prevent or minimise risks relating to a medicinal product, including the assessment of the effectiveness of those interventions

Risk management plan (RMP):

A detailed description of the risk management system

Incident

= A situation where an event occurs or new information arises, irrespective whether this is in the public domain or not, in relation to (an) authorised medicinal product(s) which could have a serious impact on public health

Patients' role in pharmacovigilance

- Raison d'être!
- User of information for safe use of medicine
- Regulatory review of product information and safety announcements
- Spontaneous reporting
- Study participant
- Provide information, e.g. at public hearings
- Patient expert at regulatory fora


We Want
YOU!