EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Setting the scene: new European Union Pharmacovigilance legislation

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Introduction to the new European Union Pharmacovigilance legislation

In this talk:

- What is pharmacovigilance?
- Why new legislation was developed
- Objectives of the new legislation
- Key improvements to the EU system
- Impact of the changes

What is pharmacovigilance?

Pharmacovigilance is the science and processes of monitoring the benefits and risks of medicines on the market and taking action to maximise benefit and minimise risk

Process steps in pharmacovigilance:

- Process steps
  - Data collection and management
  - Signal detection
  - Safety issue evaluation
  - Benefit risk assessment
  - Regulatory action / risk minimisation
  - Communication
  - Audit

Current EU system
Who are the key stakeholders:

- Patients
- Doctors, pharmacists, nurses
- Pharmaceutical companies
- Regulators:
  - National Medicines Agencies
  - European Medicines Agency/Commission
- Others

Only those in red have legal obligations in EU law

Opportunities for improvement: Need To Strengthen Pharmacovigilance

Medicines save lives and relieve suffering

However, all medicines also can cause Adverse Drug Reactions (ADRs – also called side effects):

- 5% of all hospital admissions are for ADRs
- 5% of all hospital patients suffer an ADR
- ADRs are the 5th most common cause of hospital death
- Estimated 197,000 deaths per year in EU from ADRs
- EU societal cost of ADRs amounts to Euro 79 Billion per year

Opportunities for improvement: Need To Strengthen Pharmacovigilance

Current EU system recognised as one of the most robust in the world. However, improvements can be made due to:

- Insufficient clarity on roles and responsibilities
- For nationally authorised products, lack of rapid EU decision-making
- Patients and healthcare professionals not included
- Risk and benefit assessed separately
- Need for more EU capacity for post-authorisation studies / monitoring
- Lack of funding for EU pharmacovigilance
- Some duplication of effort
- Need for more planning of safety monitoring
- Limited transparency

New EU Pharmacovigilance Legislation

- Council of Ministers and European Parliament adopt new legislation Autumn 2010
- Both **Regulation (EC) 1235/2010** and **Directive 2010/84/EC** published on 31 December 2010
- July 2012: new legislation applies
- Some provisions become effective later:
  - ADR reporting to EMA only,
  - PSUR reporting to EMA only,
  - Pharmacovigilance System Master File

Why? High Level Objectives

Promote and protect public health by reducing burden of ADRs and optimising the use of medicines:

- Clear roles and responsibilities / robust and rapid EU decision-making
- Engage patients and healthcare professionals
- Science based - integrate benefit and risk
- Risk based/proportionate
- Increased proactivity/planning
- Reduced duplication/redundancy
- Increase transparency and provide better information on medicines

What? - Scope of Changes

- Strengthened coordination
- Authorisation requirements
- Risk Management Plans
- Post-Authorisation Studies
- Measure effectiveness of risk minimisation
- Adverse Drug Reactions reporting
- Signal detection
- Periodic Safety Update Reports
- Pharmacovigilance Risk Assessment Committee
- Decision-making legally binding –
- Transparency /communication
- Coordination of inspections
- Audits
- Better funding - Fees

New legislation impact:

- Biggest change to the legal framework for human medicines in a generation
- Product life-cycle impacted
- Major change project that will take a few years to fully implement.

New legislation impact:

- For patients / consumers:
  - Patient reporting of suspected adverse reactions
  - More studies of safety + benefit risk balance of medicines
  - Patient access to data and better information
  - Participation in the assessment and decision-making:
    - Members of the committee (PRAC)
    - Public hearings for major safety issues
  - Major increase in transparency
  - Faster warnings, restrictions, improvements to product information
  - Optimised safe and effective use

New legislation impact:

- Full implementation estimated to save between:
  - –500 and
  - –5,000 lives per year
- Savings to society between:
  - –250 Million Euros and
  - –2.5 Billion Euros per year

Ref: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=SEC:2008:2671:FIN:en:PDF

New pharmacovigilance legislation conclusion:

- EU regulators are working with industry and patient and healthcare groups to deliver:

Better public health protection

…..through better pharmacovigilance