Role of Risk Management in Pharmacovigilance

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Confidence about the safety

POST MARKETING

LAUNCH

Information
RISK MANAGEMENT

- RISK MANAGEMENT is a set of pharmacovigilance activities and interventions designed to identify, characterise, prevent or minimise risks relating to medicinal products, including the assessment of the effectiveness of those interventions.

- Risk Management = Risk Assessment + Risk Minimisation
Aim of Risk management

To ensure that the benefits of a particular medicine (or a series of medicines) exceed the risks by the greatest achievable margin for the individual patient and for the target population as a whole.
Purpose

- To **identify the risks** associated with a medicinal product
- **Develop methods** to clarify further the safety profile of a product
- **Plan ways** to minimise risk to individual patients in clinical use.
Which products???

- **New active, biosimilar or generic** with risk minimisation for reference substance
- **New dosage form, route, indication**, manufacture process for biotech product
- **On request** of authorities
- If **Marketing Authorization Holder (MAH)** identifies a safety concern
- Other situations for **centrally authorised product**, e.g. fixed combination
Risk Management

Detection

Communication

Assessment

Minimization

STEPS

Risk Management
RISK DETECTION AND ASSESSMENT

Identify

Understand

Monitor
Communicate

Act to reduce

Measure outcome of interventions
<table>
<thead>
<tr>
<th>ICH</th>
<th>EU</th>
<th>FDA</th>
<th>Japan</th>
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<tbody>
<tr>
<td>ICH E2E: Pharmacovigilance Planning</td>
<td>Eudravigilance Database Implemented</td>
<td>PDUFA III</td>
<td>EPPV Introduced</td>
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<td>Guideline on Risk Management Systems for Medicinal Products for Human Use</td>
<td>FDA Risk Management Guidance Documents FDA Amendments Act (FDAAA) FDA REMS Guidance</td>
<td>•Committee on Drug Disas...</td>
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Safety Specification

Clinical

Limitations of the human safety database

Populations not studied in the PAP

AE/AR

Identified and potential

Epidemiology

Important identified risks

Important potential risks

Important missing information
Pharmacovigilance Plan

Safety concern

Monitoring by the MAH

Milestones for evaluation and reporting

Objective of proposed actions

Actions proposed
Pharmacovigilance

- Post marketing Pharmacovigilance
- Targeted safety studies
- Observational/Epidemiological studies
- Descriptive studies
- Active surveillance
- Drug utilization studies
- Additional educational material about the medicine and its use
- Training programs
Risk minimization plan

Routine risk minimization activities

Additional risk minimization activity
Pharmacovigilance and risk management are an essential part of pharmaceutical product development and commercialization.

Risk Management:
- Through life-cycle of products
- Involve all related stakeholders
- Transparency
- Utilization of existing data: Safer, more beneficial, and more optimal
- Epidemiological study: General safety study, collect information in large sample, Specific safety study, determine frequency of ADR.
- A move away from reliance on spontaneous reporting towards more reliable evidence.
- For building PV capacity requires a systemic approach to ensure that all safety aspects are monitored and addressed properly.
References


- Suzanne Gagnon*, Peter Schueler**, James (Dachao) Fany. Pharmacovigilance and Risk Management; 151-159

- Kazuhiko Mori. Pharmacovigilance in Japan and Risk Management Plans (RMP); Regulator Perspective [Internet] [cited 2012] available at http://www.diahome.org

“It is not the strongest of the species that survive, nor the most intelligent, but the one most responsive to change.”

Charles Darwin, 1859

THANK YOU