Role of Industry in the improvement of Pharmacovigilance System

Dr Pranjal Bordoloi MD
Outline

• History
• Responsibilities
• Drivers of the System
• The Process
• Governance – Structure & Steps
• Changing Environment
• Process Implementation
• Conclusion
Thalidomide Disaster

- Launched - 1957
- First reports of birth defects - 1959
- 10000 infants affected by Phocomelia.
- Withdrawn the market - Nov 1961

Outcome
1. Birth of Pharmacovigilance
2. Drug development programs cannot provide full safety information
“All things are poison, and nothing is without poison: the dose alone makes a thing not poison,”

**Paracelsus** (1493 - 1541)
Pharmacovigilance - A Shared Responsibility

1. Company
   - legally and morally responsible for monitoring their product.

2. Regulatory authorities
   - Ensure safety of licensed drugs.

3. Doctors
   - Prescription of safe drugs & Educate patients.

4. Pharmacist & Nurse
   - Monitoring, Identification and reporting of ADRs.

5. Consumer
   - Reporting to Health Care Providers
Drivers of the System...

- Guidelines / Policies / Directives
- Ethics / Social Responsibility.
  - Updating Safety information / Black box warning / Withdrawal
- Audits / Inspections
- Rules / Fines / Compensation

*Merck Vioxx settlement cost - $4.85 billion*

* http://www.drugwatch.com/vioxx/lawsuit/
Pharmacovigilance Process

HCP Consumer

Spontaneous Reports

Literature Reports

Data In

Database Entry

Data Review & Evaluation

Output

Action

PMS Data

Regulatory Reports

Regulatory Submission

Safety Updates – PSUR/PADER

Signal Generation
Pharmacovigilance Process – Who is doing what

Company/Industry plays a very vital role in the process
Governance - Structure & Steps

- Identify - AE - Failure
- Analyse - Cause
- Prioritise & Plan - Risk Index
- Control & Report
- Monitor
- Technology

Governance Structure

People

Process
Changing Environment – Expectations from Industry

• Compliance to Proactive Safety

• Constantly evolving regulatory environment demands
  – Updation of systems and processes
  – Continuous training and development programs

• Increased interest in drug safety by stakeholders

  Desire for more transparency
Industry evolution to changing environment

Present/Future

- Risk Management
- Signal Detection
- Periodic Reporting
- AE Handling

Past

- Risk Management
- Signal Detection
- Periodic Reporting
- AE Handling

Risk Reduction

Case Management

Surveillance
Implementation Steps

• Align and simplify SOPs across all operating companies
• Increase employee awareness of safety responsibilities
• Improved capability e.g. safety risk mgt, signal detection
• Defining global roles and responsibilities in partner agreements
• Improve automation
Conclusion

• Pharmacovigilance
  – is a shared responsibility of all the stakeholders
  – is shifting from meeting compliance to a proactive safety approach
• Companies should have
  – Aligned approach to policies, Quality System for all partners
  – Global infrastructure (people, process & technology) in place

*Obsession to collect each and every safety information is the mantra for a successful Pharmacovigilance Program*
‘People who are vigilant do not die; people who are negligent are as if dead’. 
- Gautama Buddha

THANK YOU
Why it is difficult

- Identifying Rare (<1/10000 and >= 1/1000) and Very rare (>= 1/10000) events
- At least 30,000 patients need to be exposed to detect a very rare ADR (1 in 10,000)
- Every event is a critical safety information