Feedback from SAAPI Pharmacovigilance Workshop held on 24 May 2011

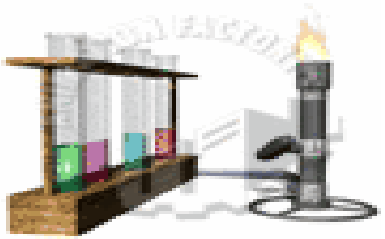
Suheila Abdul-Karrim

Pharmacovigilance (PV) Workshop

- Opening address by Registrar, Ms Mandise Hela
- Emphasized that changes around us need to be taken into account:
  - Climate change
  - Migration within the continent
  - An increase in chronic disease in population
- Patients exposed to medications for a longer period of time.

Opening address (cont.)

- Goal is to increase life expectancy in South Africa
- Biotechnology is the future for non-communicable diseases – “Innovation is for All”
- Perceptions and not effects creates an attitude.



WHO PV & ICH Guidelines

Sten Olssen

- Have moved away from ‘adverse effects’ to ‘any other drug related problem’
- Shift in focus from drug safety to Patient safety
- ICH E2A – expedited reporting
- E2F – new – format of annual report sent to regulator for a clinical trial
- Challenge for industry is each country has its’ own local laws

WHO & ICH (cont.)

- Need more frequent reporting
- Vigibase = WHO database
- WHO dictionary
- Pharmacovigilance Plan: how to follow-up missing information
- ICH E2E – great step forward; bridges the gap between pre-marketing and post-marketing.
- PV inspections – EU Directive 2004/27

WHO PV Programme

Sten Olsson

- Introduction of signal detection methods
- Manual scrutiny becomes unmanageable
- Signal validation:
  - Getting more details from the reporter
  - Opinion from a specialist
  - Assessment of causality in each case

- Consistency in data, Dose-response relationship - “Look for the unexpected”

WHO PV (cont.)

- Other sources of information (Literature) to strengthen signal
- Identify risk populations
- Determine best and worst case scenario
- Benefit/Harm Evaluation
- Feedback loops in place
- Decisions – consider likely degree of risk reductions
- Information to be disseminated to health professionals first

Decentralized PV Plan (possible Future model)

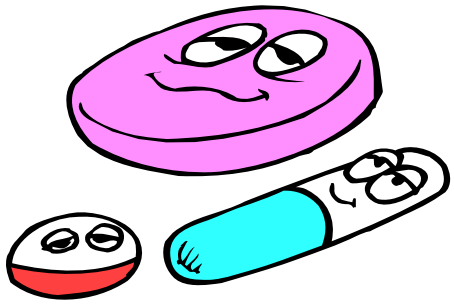
Mukesh Deda

- National Indicators to be reported
- 0% compliance in reporting of key indicators
- Propose a decentralized level of reporting:
  - Health care professionals in direct contact with patients
  - Committee / working group
  - Meet regularly and information disseminated to all
- Brings about a quick turn-around time for responses

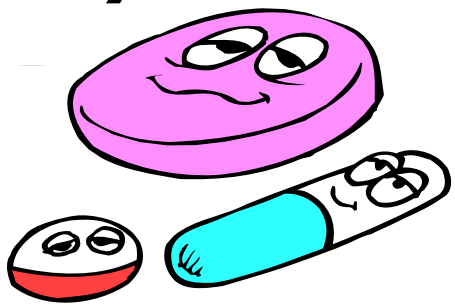
PV & Risk Management

Prof S Banoo

- Purpose of risk management is to ensure that the benefits exceed the risks
- >120 medications withdrawn for safety reasons
- “Need for a culture of safety in the world today”.
- Risk Management Plan



PV & Risk Management (cont).



Risk Management Plan

Safety Specifications

⇩

PV Plan

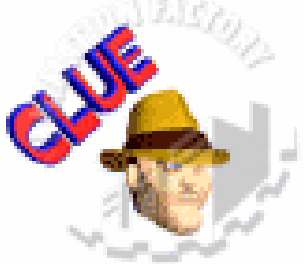
⇩

Risk Minimization Strategies

Good PV Practices. How industry can be prepared?

Abeda Williams

- Concern that companies in S.A. are not sensitized or prepared for PV Audits
- Documents requested
  - Organization Charts
  - Job descriptions
  - Contact details of staff
  - Training records*
- Compliance to Regulations (incl. Africa)
- Handbook on 12 point plan for good PV plan – working group within PIASA currently putting it together.



PV in Pre-Clinical Trials

Gavin Steel

- Regulatory Approach and MCC Guidance Documents
- Regulatory approach: following standard ICH – GCP (IB, protocol, GCP monitoring & inspection, DSMB, final report)
- Reporting of ADRs – Guidance Document: May 2003, Section 5, pages 14-18 (applicable to any type of trial or drug investigation conducted under Section 21 of Act 101)
- Timelines for Expedited reporting.

Summary

- Panel Discussion
- Need for more information
- Health care professionals are obliged to report
- **Patient Safety!**