"PHARMACOVIGILANCE: A PERFECT SYSTEM FOR HEALTH CARE FOR BETTER TOMMROW"



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Director Grade Scientist, IICT, Hyderabad

Director, School of Pharmacy,

Anurag Group of Institutions, Hyderabad.

DO WE NEED DRUGS ?



Yes

30,000 diseases / disorders
only 10,000 can be treated

Why?

Therapy unsatisfactory
Viral disease, Cancer and Skin diseases
etc.

Are drugs Safe ????





Paraselsus

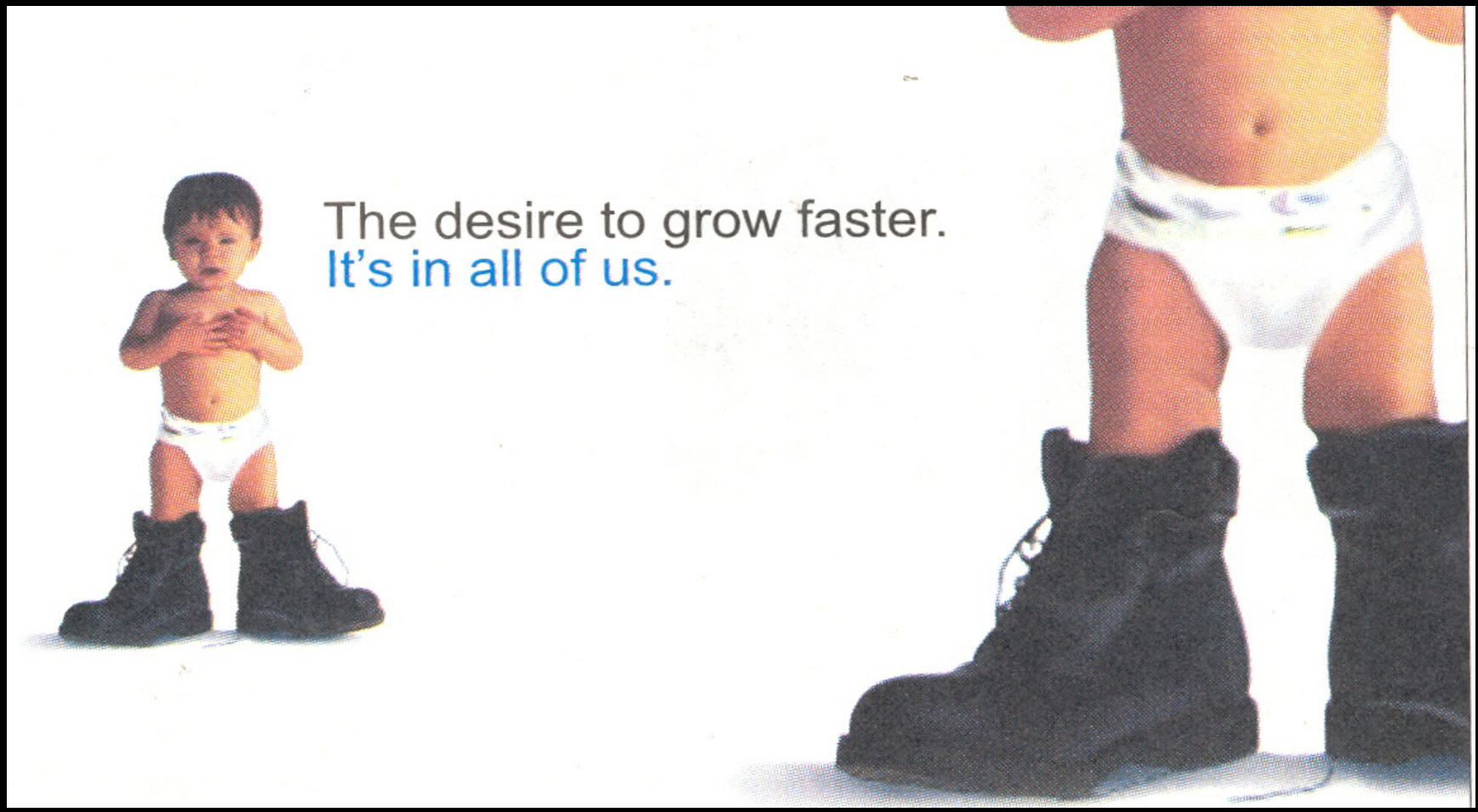
There was no safe drug and there will not be any safe drug in the coming future



Before thirty, men search disease;

after thirty, disease searches men.

Desire to grow !!



Change is inevitable… Move on









Voice of the Patients



“Keep Me Safe”

“Get Me Well”

“Treat Me Nice”

Dying from a disease is sometimes unavoidable; dying from a medicine is unacceptable. *Lepakhin V. Geneva 2005*







Quasthoff's Mother Took Thalidomide- 1960







Recent Drugs Banned

- Sibutramine – Adverse Cardiac Event
- Rimonabant- Suicidal Ideation
- Placental Extract
- Nimsulide below 12 year age- Hepatitis
- Rofecoxib- CVS
- Valdecoxib- CVS
- Rosiglitazone – Heart Attack
- Gatifloxacin – Severe hypo/Hyperglycemia
- Astemizole - Adverse Cardiac Event
- Terfinadine- Adverse Cardiac Event
- Cisapride- Adverse Cardiac Event
- Phenylpropanolamine - Hemorrhagic stroke

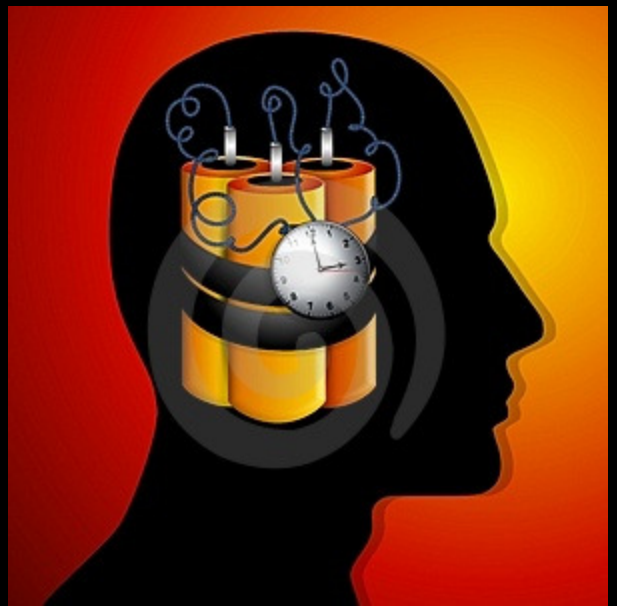






Disease Diagnosis

The patients are really scared of a disease called '**DIAGNOSIS**', where in Pharmacy Journal named the cholesterol estimation as **TIME BOMB**.



Hritik Roshan suffered with Drug Allergy











Figure 2 – Widespread small blisters that arose on erythematous macules appeared on the skin of this patient in whom Stevens-Johnson syndrome developed after she received trimethoprim-sulfamethoxazole. Severe erosions affected the oral and vaginal mucosa.

(Courtesy of Marti Jill Rothe, MD and Jane M. Grant-Kels, MD.)

Antibiotic for Chest pain

Urgent need to develop safe drug !!





Need to know more about...

Pathophysiology?

Phenotypes?

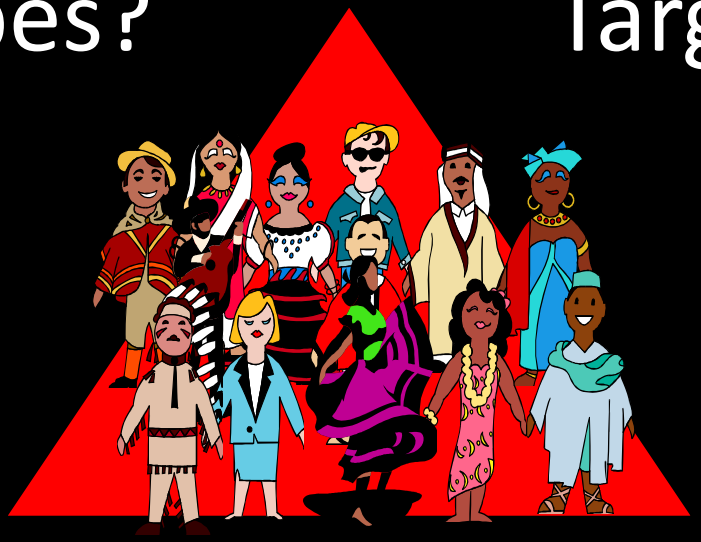
Targets?

Costs?

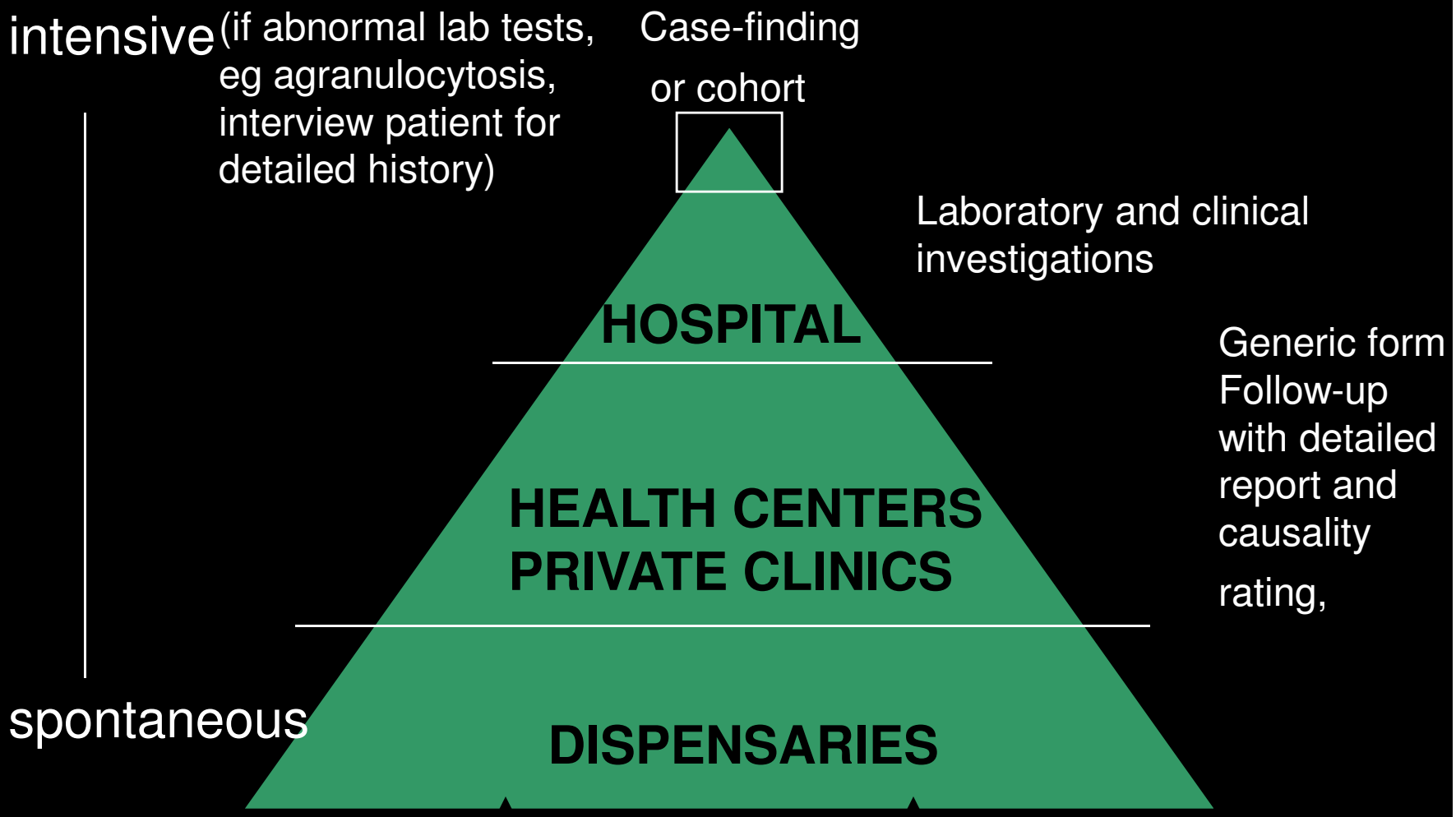
Biomarkers?

QoL?

Outcomes?



Detection of serious drug reactions



Safety Communications - A Patient Perspective

THE TIMES

"Wonder Pills"

Sir, My wife has been prescribed pills. According to the acc
possible side-effects are: sickness, diarrhoea, indigestion,
belching, vertigo, abdominal cramps, dizziness, stomach ul
intestine or blood diarrhoea, ulcerative colitis, sore mouth
constipation, back pains, inflammation of pancreas, mouth
hair loss, sensitivity to sunlight, drowsiness, tiredness, imp
difficulty with sleeping, seizures, irritability, anxiety, depres
tremor, memory disturbances, disorientation, changes in v
bad dreams, taste alteration, allergic reactions, swelling du
palpitations, impotence or tightness of the chest.

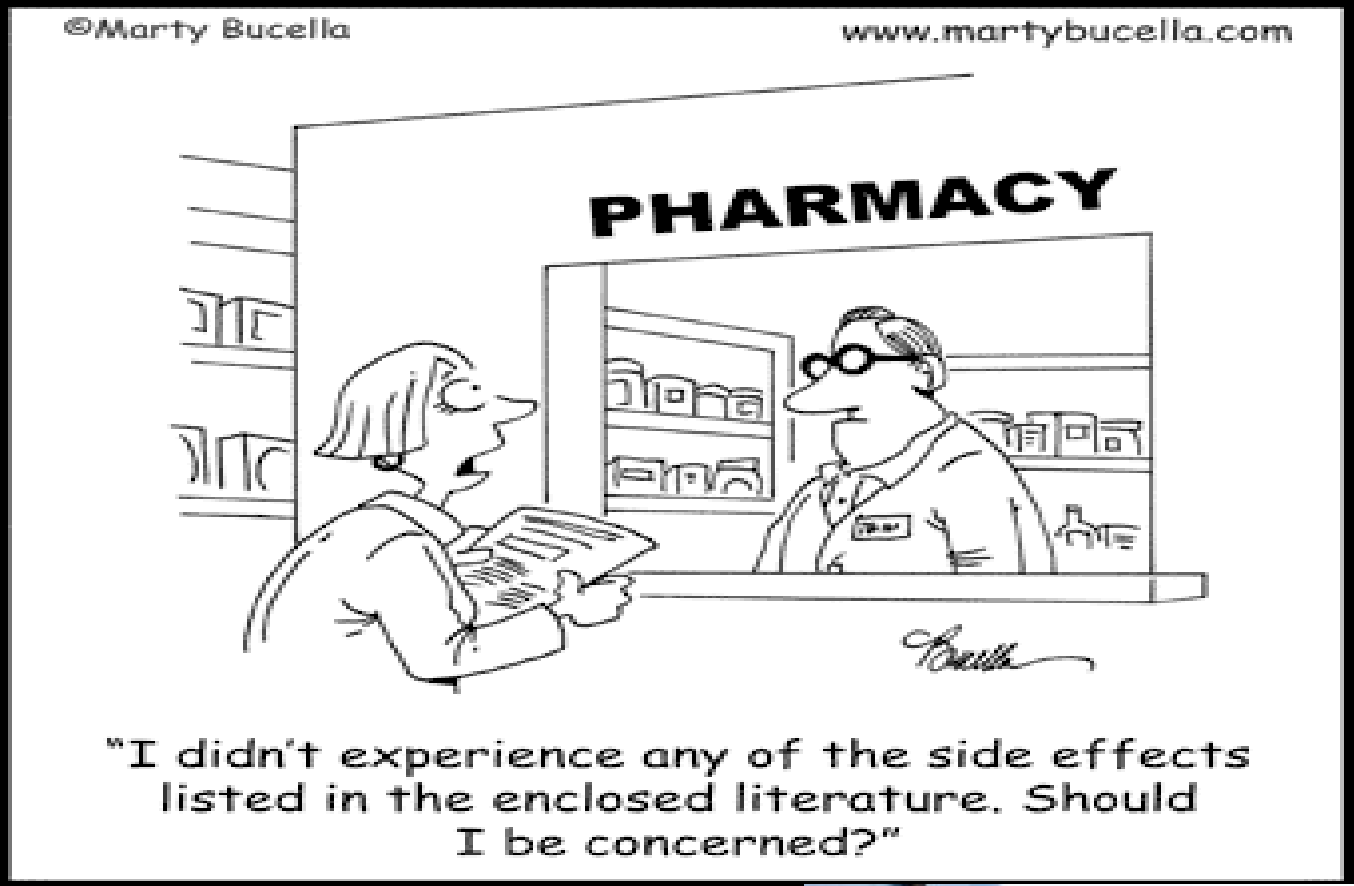
Should she take them?

Yours faithfully,
A D. O.



Letter to the Editor,1996




©Marty Bucella
www.martybucella.com
PHARMACY
"I didn't experience any of the side effects listed in the enclosed literature. Should I be concerned?"









AVOID ADR & get SAFE DRUG

Why do we need pharmacovigilance?





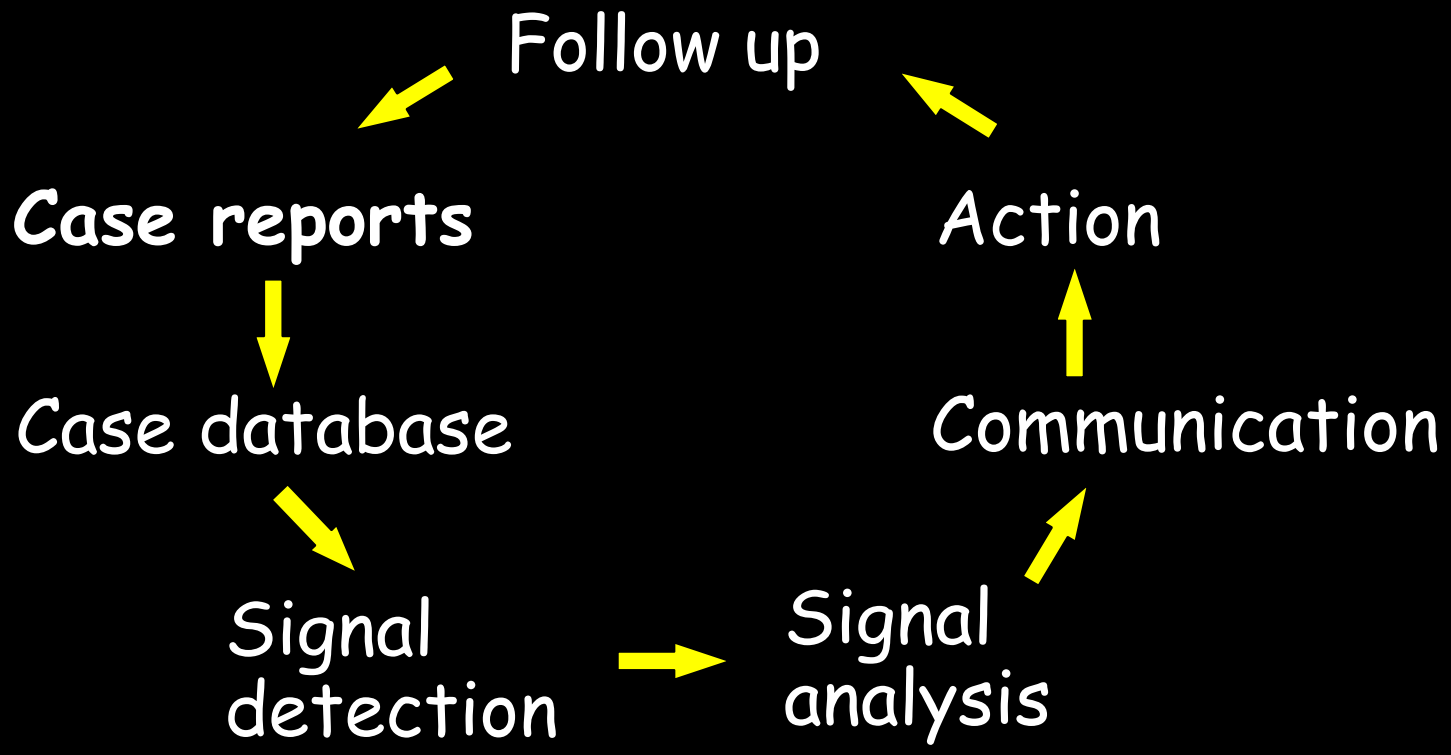
Why do we need pharmacovigilance?

- **Humanitarian concern –**
  - **Insufficient evidence of safety from clinical trials**
  - **Animal experiments**

Why we need PV ???

- In daily practice – real world situation
  - Patients are not selected
  - Diverse patient populations
  - large patient population
  - Poly pharmacy
  - Several underlying disease factors and concomitant medications

The pharmacovigilance process





Rapid Pharmacovigilance Implementation in Developing Countries

"Some remedies are worse than the disease"

Publilius Syrus, Roman writer, 1st century BC.

3 Key Activities of the RaPID™ Program

All India Institute of Medical Sciences

Data Analysis

2

3

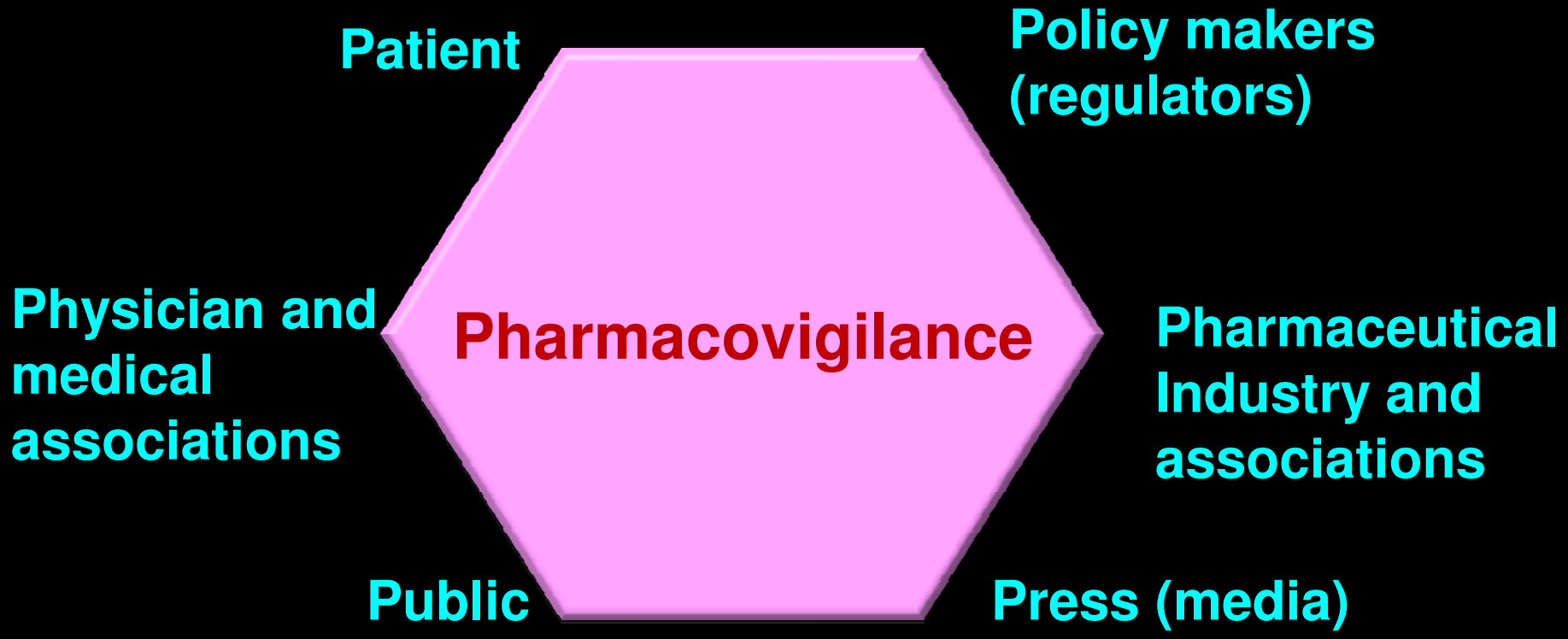
Data Sharing

1

Data Gathering

In-country partners

Seamless synergistic Pharmacovigilance partnership



Team work is need of hour for PV



HERBOVIGILANCE ??

HERBOVIGILANCE ??







Cost of drug development200 million $

Drugs from Natural products

52% of the drugs approved in the U.S. from

-**26 plant based** drugs were approved during 2000-2006,

- **80 %world population uses traditional medicine**

25000 Herbal formulations

More than 1.5 million practitioners use herbs 7800 manufacturing units

Problems associated with use of Herbal medicines

Potential drug interactions

Multiple ingredients

Difficulty in identifying ingredients

Less knowledge of ADRs

Less disclosure by the patients

40- 70 % of the patients do not inform physicians about the use of alternate medicines.

Herbal toxicity

Effedra herb





Popy



Kava Kava



Allergy pepper plant

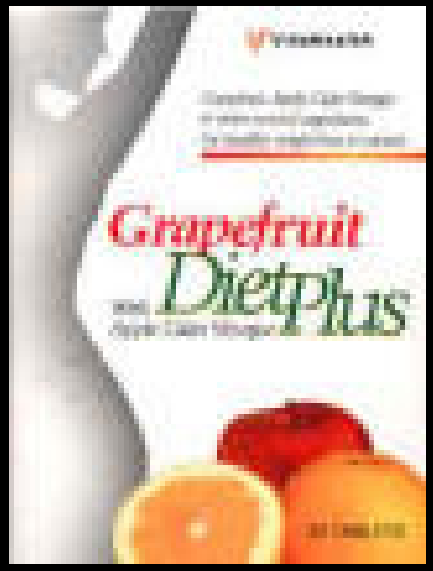
Genseng



Drug-Food interactions







- **Grapefruit juice and Terfenadine**
- **Grapefruit juice and cyclosporin**
- **Grapefruit juice and felodipine**
- **Grapefruit contains : furanocoumarin compounds that can selectively inhibit CYP_3A_4**

Drug-Herb interactions

Ginko biloba









DELIBRATE ADDITION OF MODERN DRUGS

Corticosteroids in Herbal medicines
-Eczema
-Rheumatoid Arthritis
- Bronchial asthma



Deliberate addition of modern drugs…

Antiepileptics (60% commercial samples)
-Sod. Valproate
-Phenytoin
- Carbamazepine

Antidiabetics
-Glibenclamide
-Tolbutamide

“Herbal thalidomide”

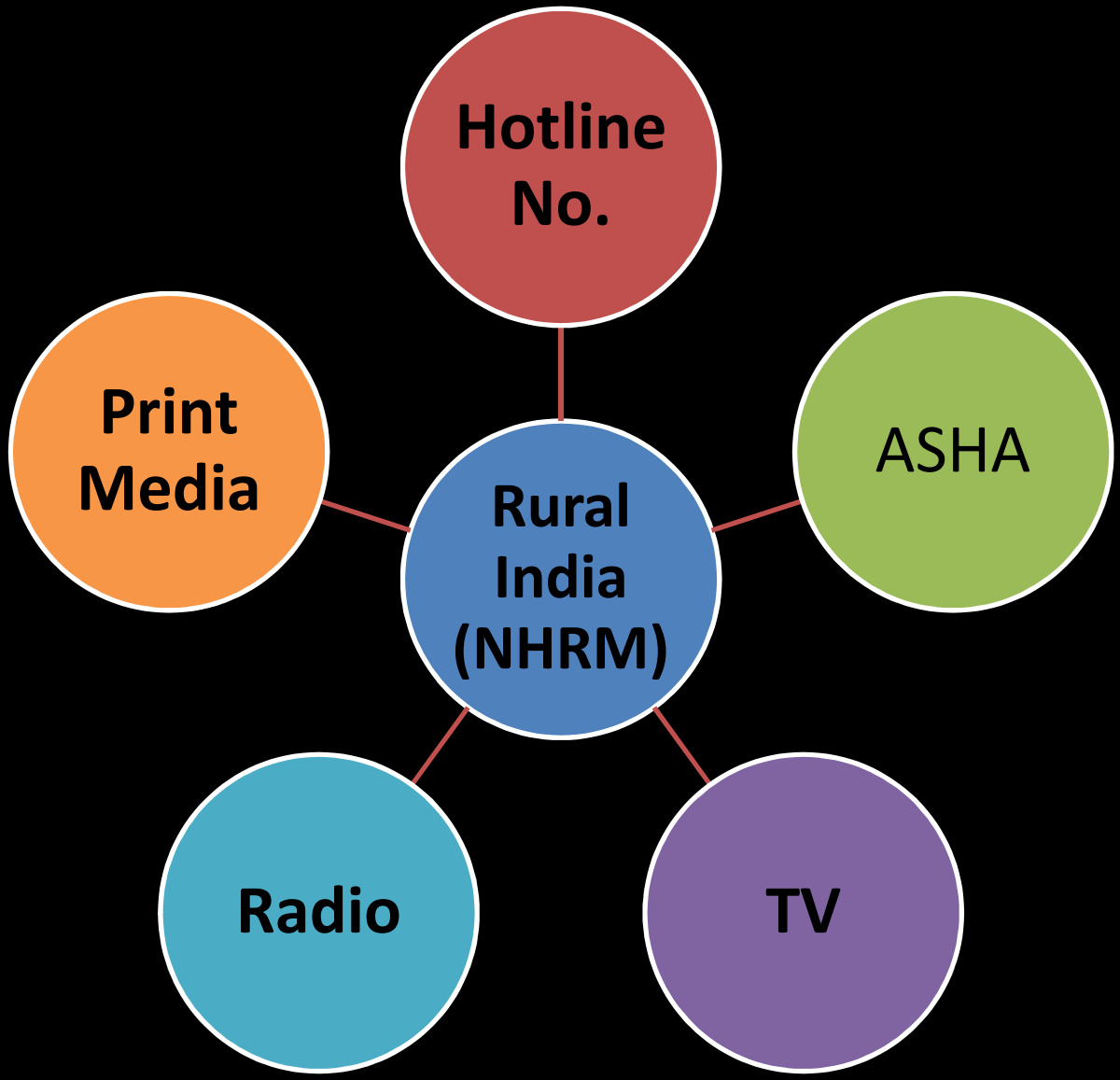
Pharmaco vigilance in herbal medicine is perhaps a LESS THOUGHT of concept as yet But we don't need Herbal Thalidomide.

ADR reported are NEGLIGIBLE

Public Health Problem



Reaching rural India for PV ???




Viagra blindness alert
Britons 'lost sight after taking impotence drug'
Revealed: the danger of taking Prozac
Drug maker knew 60 years ago of possible link to suicide
Newsweek
Ritalin
Are We Overmedicating Our Kids?
12 BUSINESS
300 m
BAD MEDICINE
Merck recalls Vioxx
Heart risk found in arthritis drug
Washington Times
FRIDAY, OCTOBER 1, 2004
FINAL
25 cents
PAINFUL
Merck's stock plunged after the pharmaceutical company said it was taking its arthritis drug Vioxx off the market.
Sept. 30
$33
-$12.07
MERCK
Suicides blamed on acne drug



VIOXX®

STROKE ~ HEART ATTACK ~ DEATH
BLOOD CLOTS ~ PULMONARY EMBOLISM

Merck Pharmaceutical has recalled the popular pain and arthritis medication Vioxx® (rofecoxib) from the market after studies revealed that it may increase the risk of blood clots, stroke, heart attack and death. According to acting FDA commissioner Dr. Lester M. Crawford, "Overall, patients taking the drug chronically face twice the risk of heart attack compared to patients receiving a placebo."

YOU MAY BE ENTITLED TO MONEY DAMAGES

If you or a loved one have suffered a stroke, heart attack or deat
call attorney James Rolshouse toll free at 888-VIOXX-87 (8

James Rolshouse & Associates
Personal Injury Attorney

visit us online at

TOLL FREE 888







Remicade (Infliximab)
Side Effects Lawsuits

Tuberculosis, Multiple Sclerosis, Lupus, and Serious Infections

The-Plavix-Lawyer.com
Ennis & Ennis, P.A.

1-800-856-6405
Nationwide Free Consultations





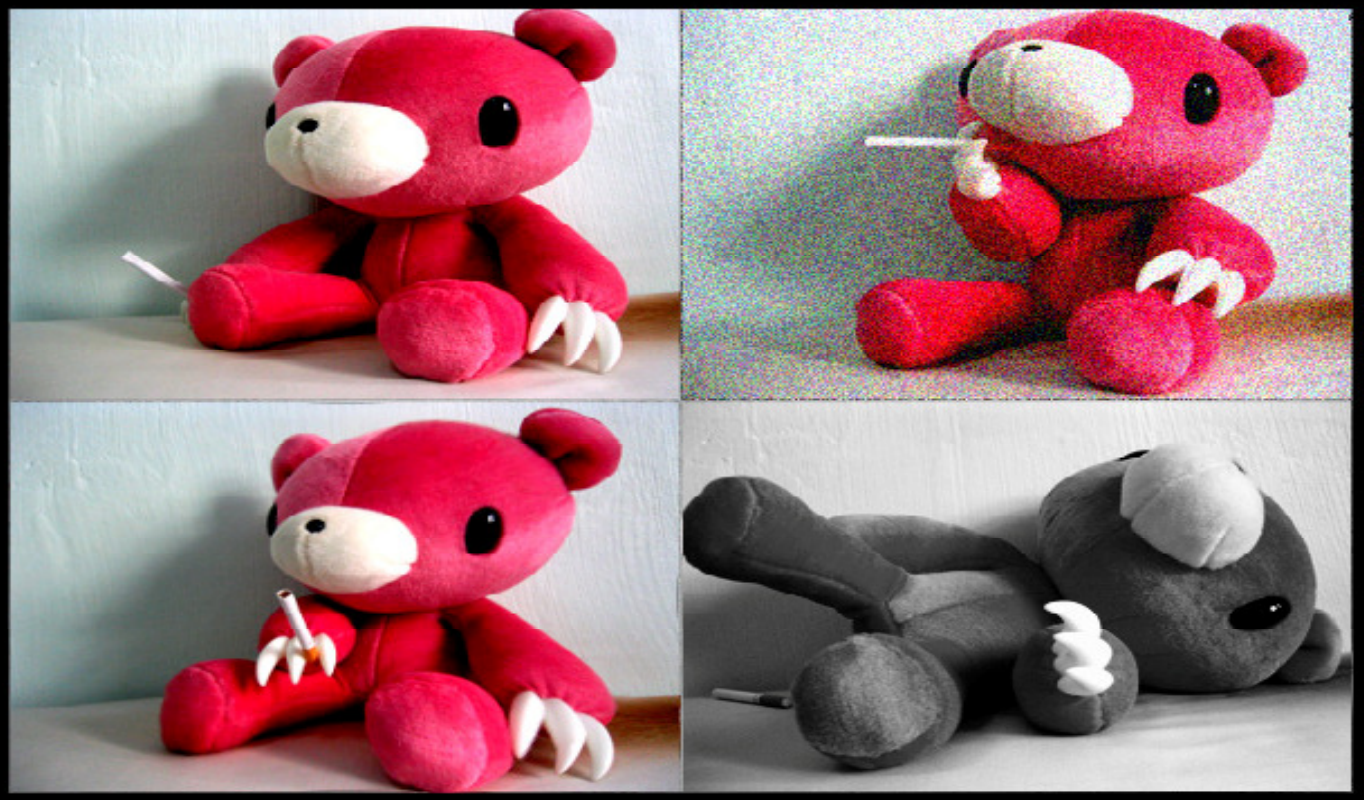
ADR Reporting -Training Session-10

Public health awareness





POLIO FREE NATION



Do not smoke in the bed as the ash may be yours

Need more Health Workers









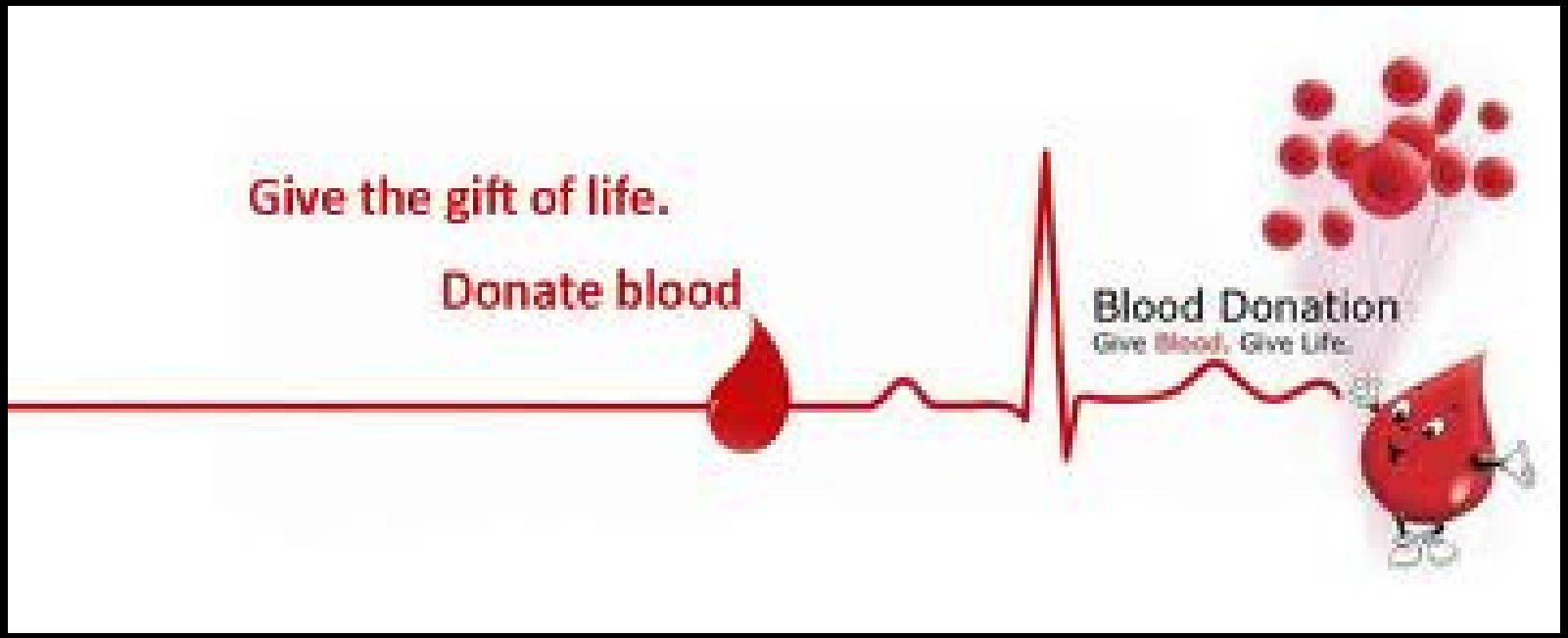
Doctors do not have time to spend

Hence we need people concerned with health to report ADRs or the patients

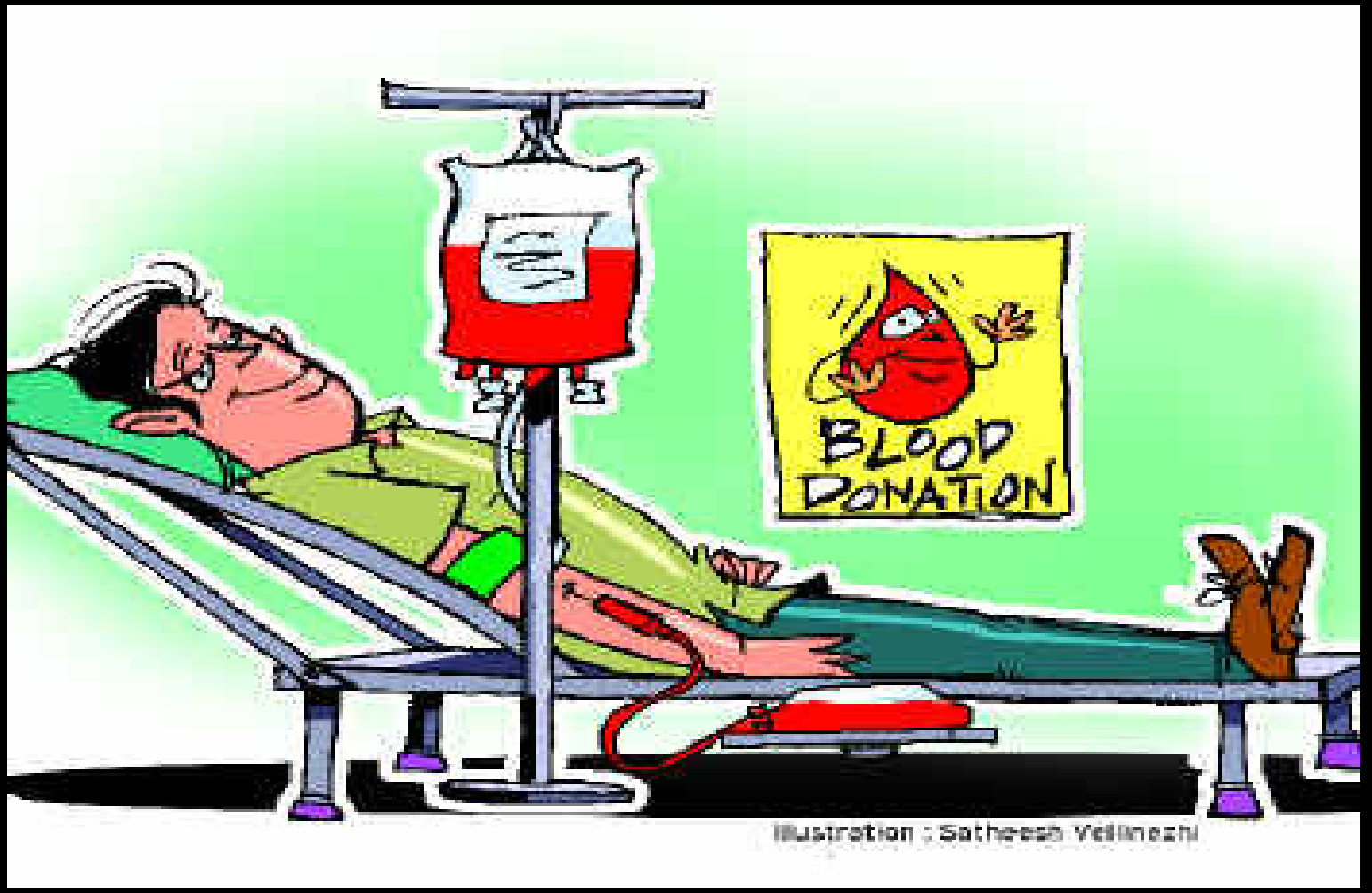




HEAMOVIGILANCE ???



HEMOVIGILANCE SYSTEMS



Negligible attention is given

SCOPE

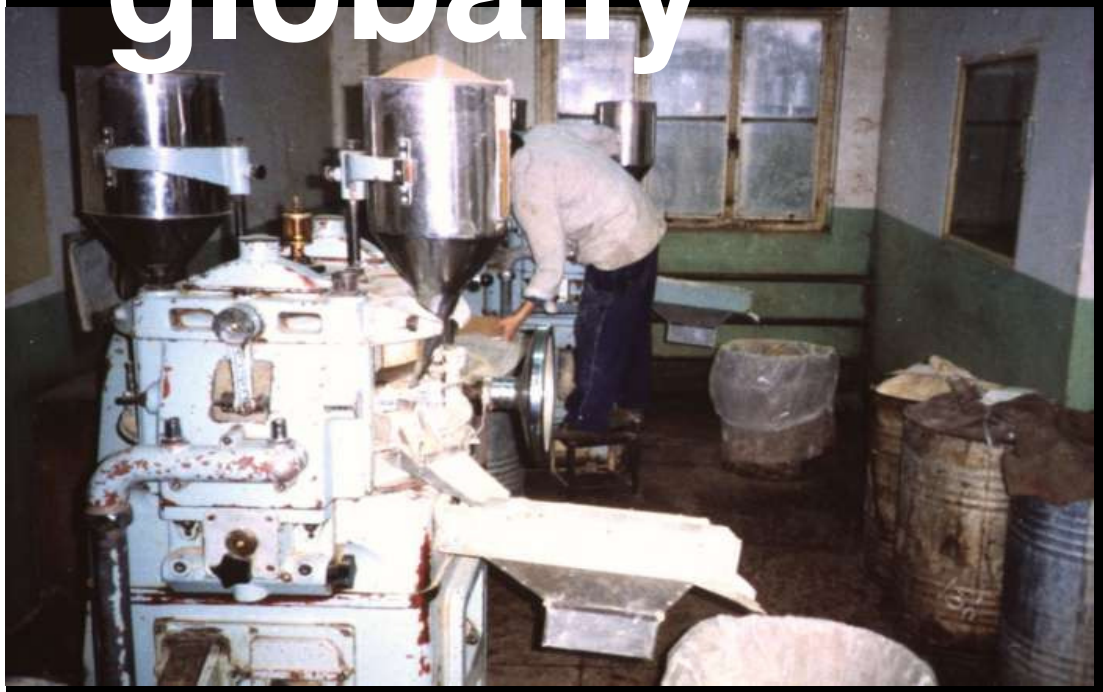
- Products
  - Blood components (mainly)
  - Plasma derivatives
  - Donor safety
    - Incidence of undesirable effects of donations in donors
  - Blood safety
    - Prevalence of ID markers in first-time donors
    - Incidence of ID markers in repeat donors
    - Surveillance of donor exclusion factors

Pharmacovigilance For Counterfeit drugs ???

Up to 25% of the medicines consumed in poor countries are counterfeit or substandard

Annual earnings from the sales of counterfeit globally

US$ 32 billion





Counterfeit drugs

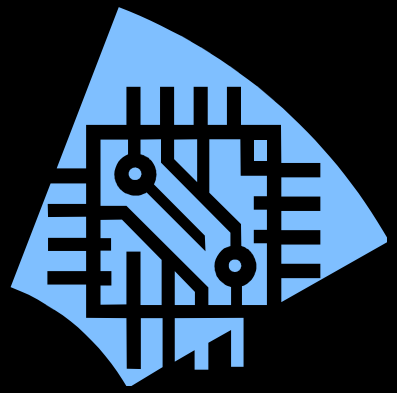






Technology

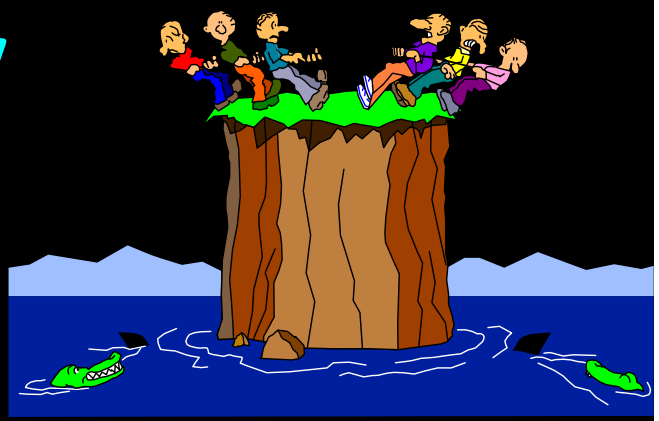
- FDA's Recommendation
  - A multilayered approach that includes radio frequency track-and-trace and authentication features
- Chipless ID
- Issues
  - Cost
  - Availability
  - Reliability
- Other Security Mechanisms
- Pedigree???



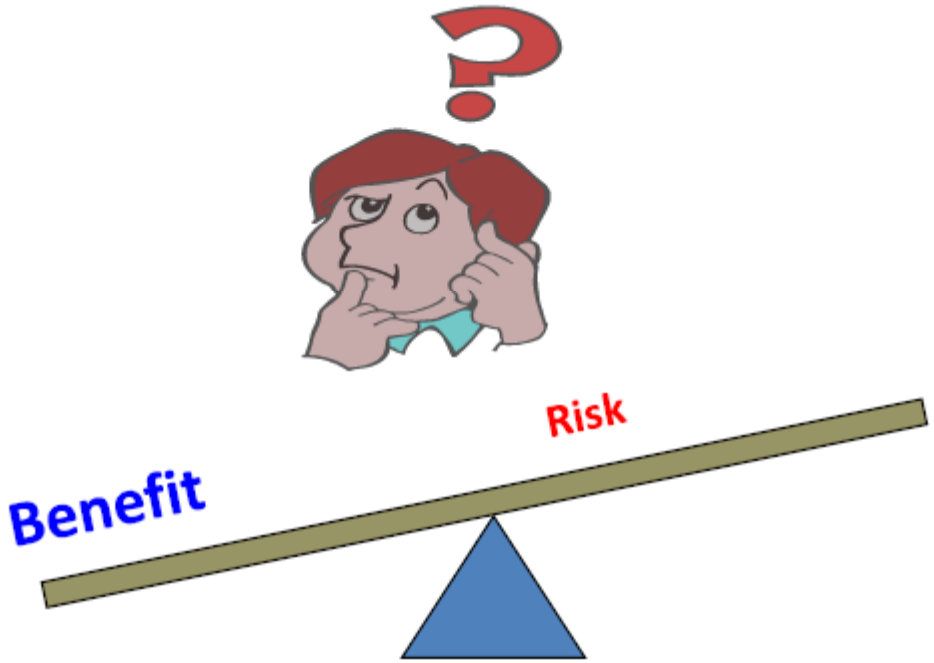
Risk Management
&
International Harmonization

International harmonization is wonderful in theory

…….but everyone is harmonizing differently



Compute risk-benefit ratio



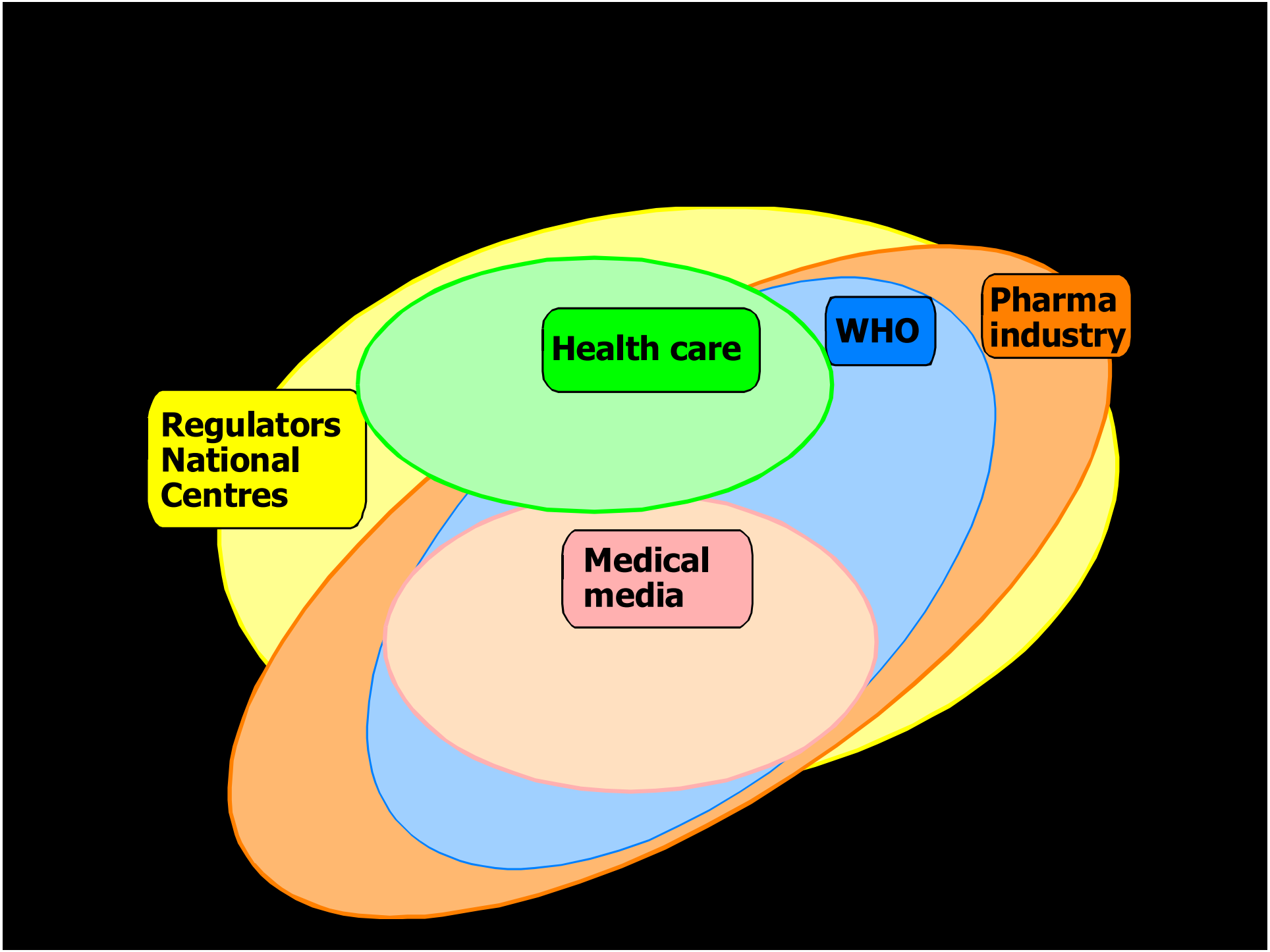
One man's meat is another man's poison !!!

Risk Management and Planning

"In preparing for battle I have always found that plans are useless, but planning is indispensable."

Dwight D. Eisenhower




Regulators
National
Centres
Health care
WHO
Pharma
industry
Medical
media

Risk Management – A Shift in Emphasis

"Old Model"

Pre-marketing Safety Analysis

- Pre-clinical toxicology
- Clinical trial safety data
- Laboratory data
- ECGs/other data
- Targeted safety studies

ISS

- Integrated safety analysis
- SADRs
- AEs
- Laboratory/other data

Approval

- Regulatory approval for labelled use
- Risks included in label (disclosure)

"See what happens in real world use"

- Ongoing surveillance and signal assessment of serious/ unexpected ADRs
- Post-marketing safety studies
- Update label
- Ad hoc HCP communications (Dear Dr. letters)
- Product restrictions/ withdrawal

Risk Management – A Shift in Emphasis

"New Model"



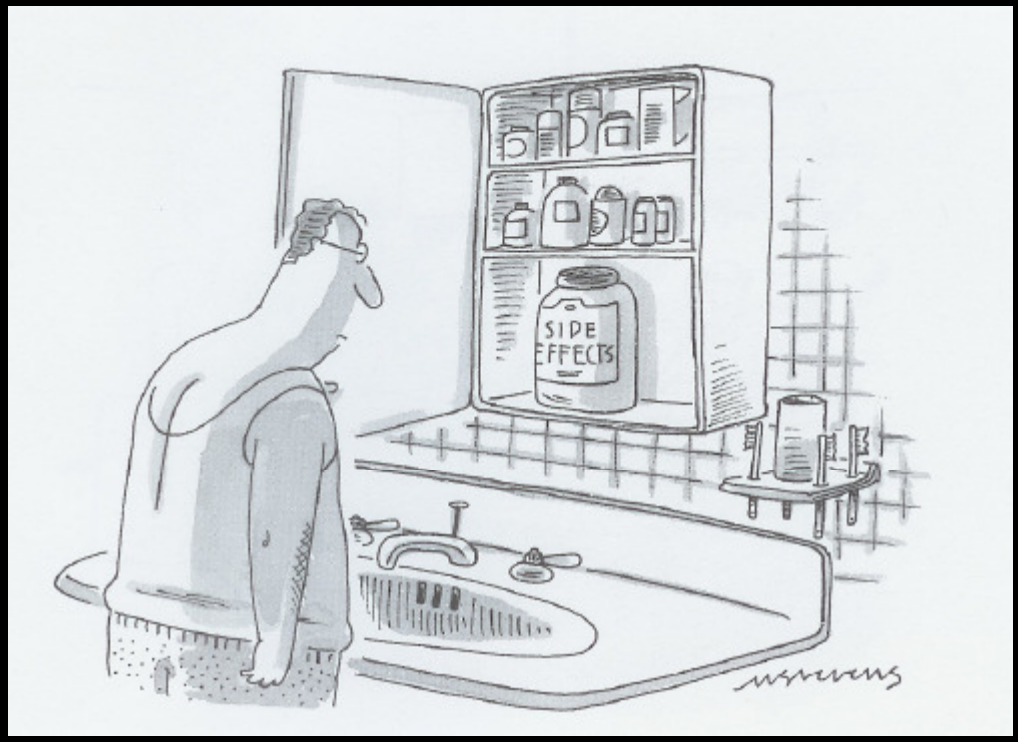
- Traditional analyses plus
- Anticipated conditions of use
- Intrinsic/extrinsic risks (identified and potential)
- Epidemiology of disease
- Benefit : risk assessment

Global Plan and US RMP Relationships



- New information on the benefits and risks of any drug may be generated at any time after marketing
- Continuously monitor the safety of the compound/drug throughout the life cycle product
- Continuously assess the benefit risk profile in order to guarantee patient safety

Better Patient Focus



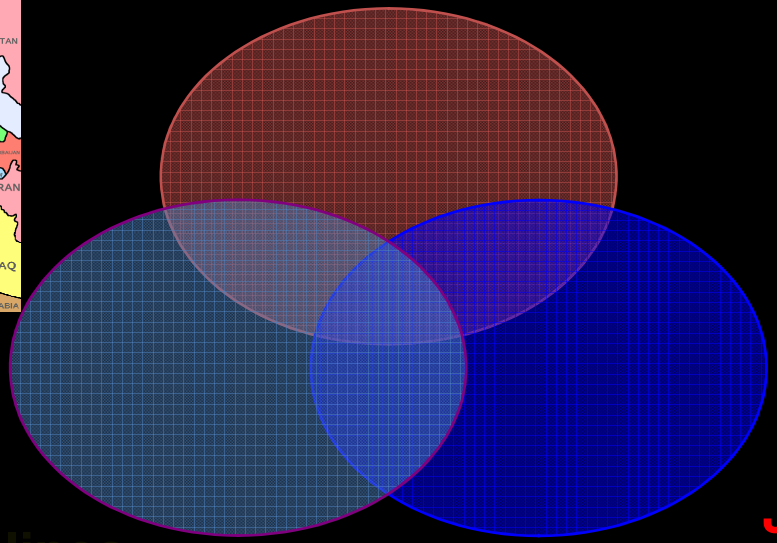
Pharmacovigilance is now accepted to be a continuous process of evaluation accompanied by steps to improve safe use of medicines

Global Risk Management Planning
The Challenge of Reconciling the Differences



Europe

E2E +/- Risk Minimization Plans



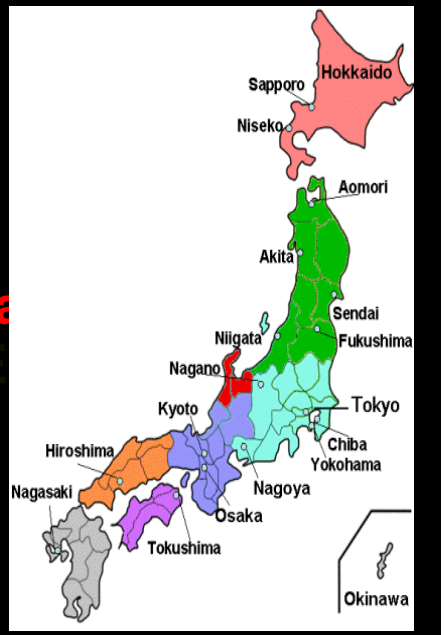
US



Ja

ICH E2E

kMAP/REMs



Industry and Academic Partnership

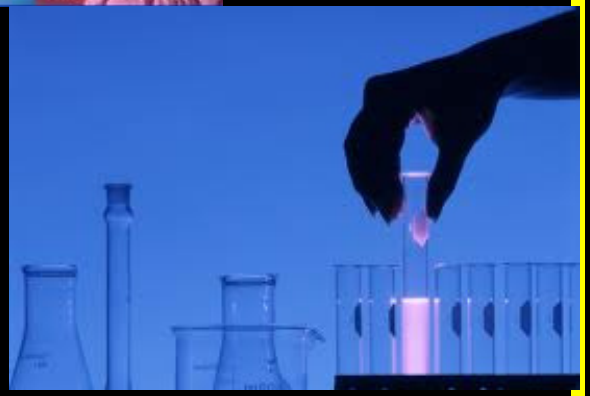






Need for Translation





Research



Practice

BIOPHARMACEUTICALS: A RECENT INDUSTRY WITH HIGH POTENTIAL



DNA Molecule Deciphered



Genetic Code Cracked



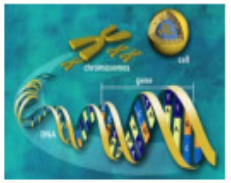
Basic Biotechnology Enabling Discoveries

XOMA
A Leader in Therapeutic Antibodies
Genentech
IN BUSINESS FOR LIFE
biogen
Applied Biosystems
AMGEN

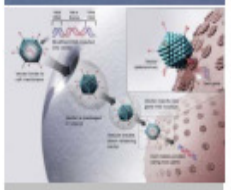
Commercial Biotech Companies Formed

Enbrel
Remicade
Rituxan
PROCRIT EPREX
Aranesp
EPOGEN
Neulasta
Herceptin
AVONEX
AVASTIN (bevacizumab)
NutropinAq
Dysport

Leading Biotech Products







1950s | 1960s | 1970s | 1980s | 1990s-Today | Tomorrow

… LINKED TO MANY ENTREPRENEURIAL RISKS



Long development cycles (over 10 years)



Very complex products : High risk of failure



Science and technology continue to evolve

… NEED OF A PROACTIVE PHARMACOVIGILANCE SYSTEM

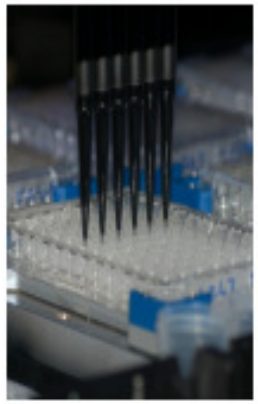
PREDICTIVE IMMUNOLOGICAL ASSAYS

HLA class II binding assays

APC Recognition

HLA II alleles	Frequency
DRB1*0101	9,3
DRB1*0401	5,6
DRB1*1101	9,2
DRB1*0701	14,0
DRB1*0301	10,9
DRB1*1301	6,0
DRB1*1501	8,0
DRB5*0101	7,9
DRB3*0101	9,2
DRB4*0101	28
DPB1*0401	40
DPB1*0402	11





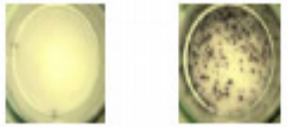
Quantitative predictive T cell assays

T Cell Priming



Quantification of pre-existing antigen-specific T cells in naïve donors

Antigen specificity

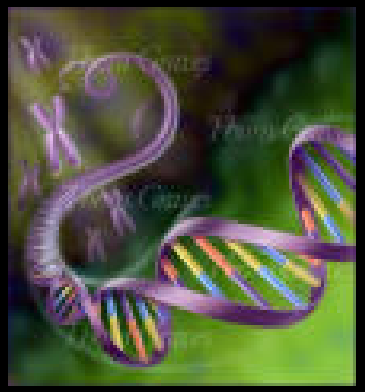


Control + peptide

Problem in medical practice



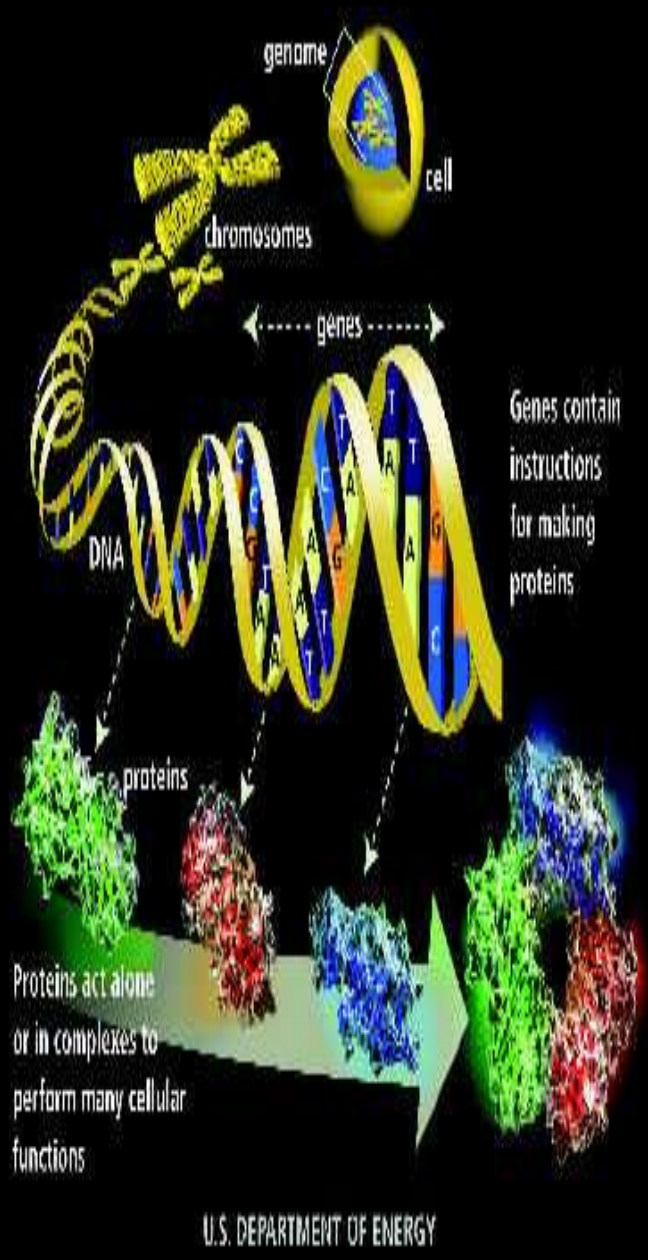
- same complaints
- same finding
- same diagnosis
- same treatment
- but differential effect ????



- **Possible reasons**
  Physiological factors
- Pathological factors
- Food
- Drug interaction

DNA polymorphism

- Changes in the DNA sequence such as
  - **Nucleotide mutation**
    - **The most frequent DNA variation found in the human genome is single nucleotide polymorphism (SNP)**
  - **Nucleotide deletion**
  - **Nucleotide insertion**
  - **Gene deletion**
  - **Gene duplication**




Base on your genetic profile you should take Drug A instead of Drug B

Pharmacovigilance

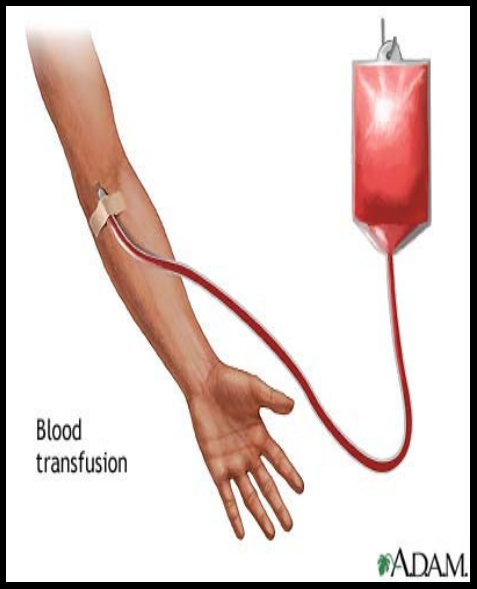






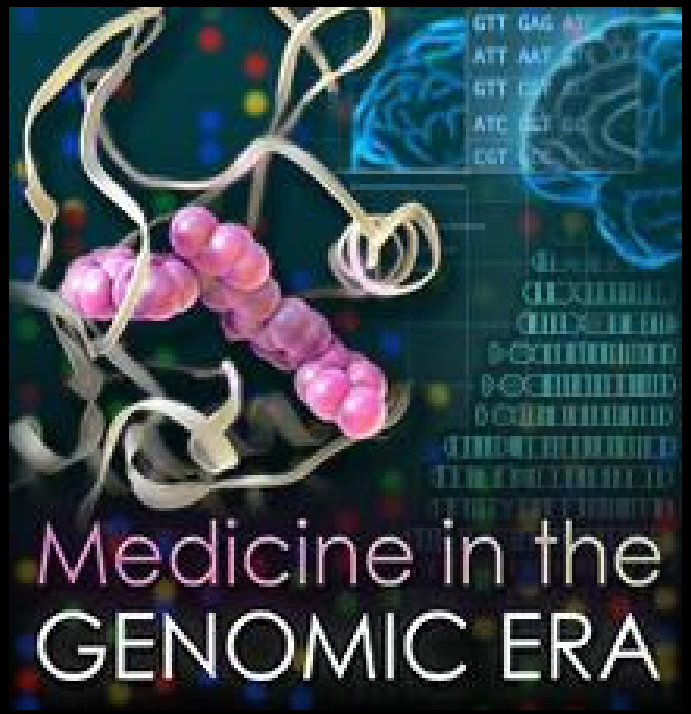






IT solutions are "a must" to help with drug safety monitoring





Pharmacovigilance in a genomic era pharmacogenomics research should be developed.

Success in this field will require a prudent and scientific approach, with the avoidance of hype



Human resource development is a key feature for the success PV

Right ways to use the drugs

- The Right medicine to
- the right person
- in the right dosage
- at the right time
- at the right route of the administration.

USING INFORMATION THERAPY



TO PUT PATIENTS FIRST

DR ANIRUDDHA MALPANI, MD

EDITED BY ROHAN PASRICHA

Pharmaco vigilance is Essential



Roadmap of Pharmacovigilance Programme of India (PVPI) (Year 2010 - 2015)



Despite of recent implementation of a well structured pharmacovigilance program in India in agreement with the recommendations and objectives of WHO by CDSCO, desired success is still a distant dream





•CONCLUSIONS

Risk benefit planning is a must

Synergy between PHP and PV

Importance for herboPV

Heamovigilance

PV for genomic Era

Global harmonisation

Active participation of team of PV

30 Years of Essential Medicines



Where is my essential medicine?

¿Donde está mi medicamento esencial?

Et moi?

Pharmacovigilance

does not get the deserved Attention !!

WHY

59% ADR should have been avoided


IDEA OF
PRESENTATION IS
NOT TO OVERLOAD
YOU LIKE THIS
HTTP://JOKES.GLOWPORT.COM/

GLOBAL AWARENESS ON PV

Thanks
To Organisers for an opportunity to share my experience !!

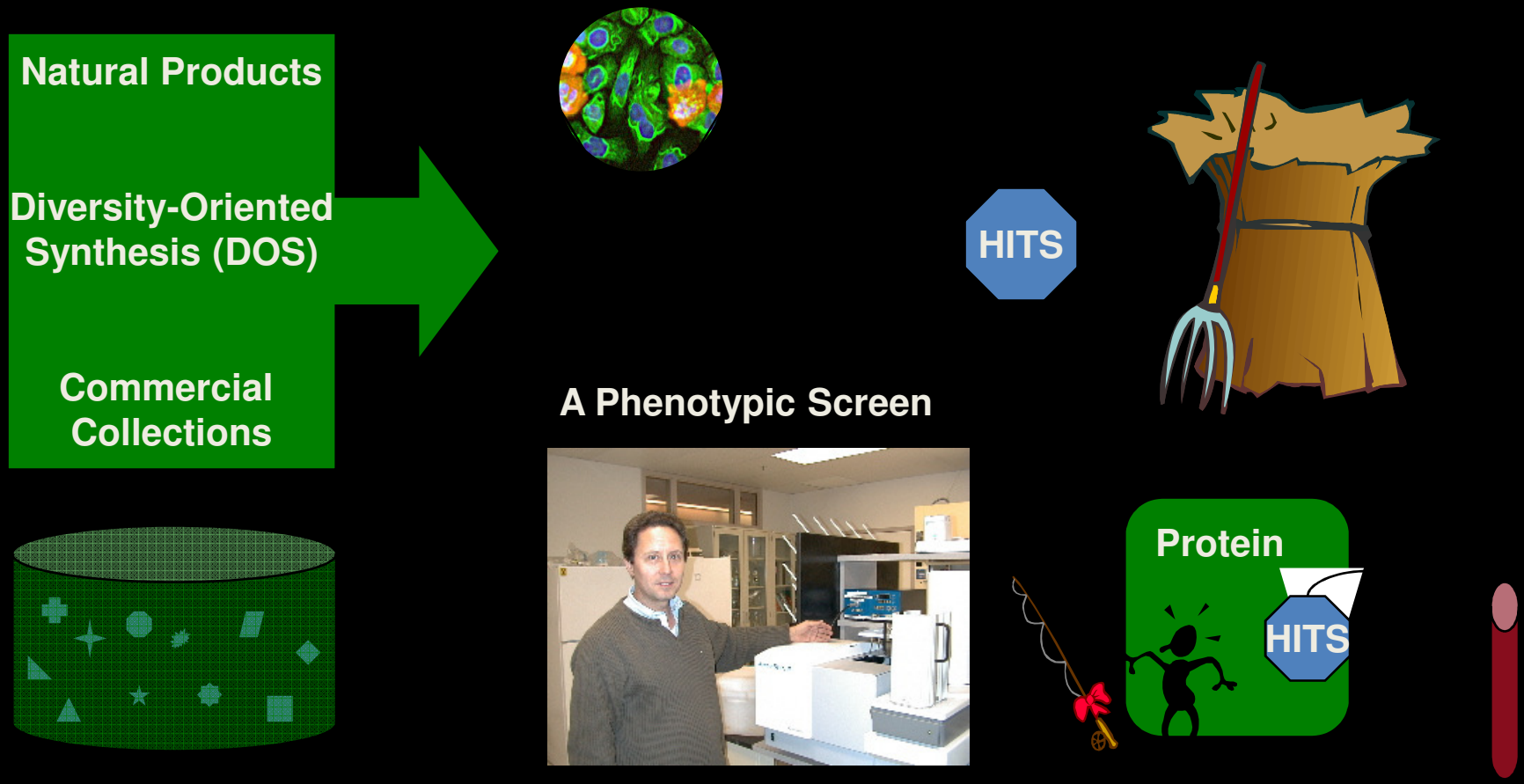
Thanks

Conclusions

- Signal detection **a**nd Risk Management is a fascinating field, which is now more often used in PV in majority of the MNCs
- Databases provide a powerful tool for early detection of safety signals
- Ddomain knowledge is essential for assessing causality between a drug & an event
- Risk management should start early during clinical drug development process
- Risk Management Plans should be for all drugs and submitted to RA
- Urgent need for synergistic collaboration between PHP &PV

Forward chemical genetics involves 3 basic stages:

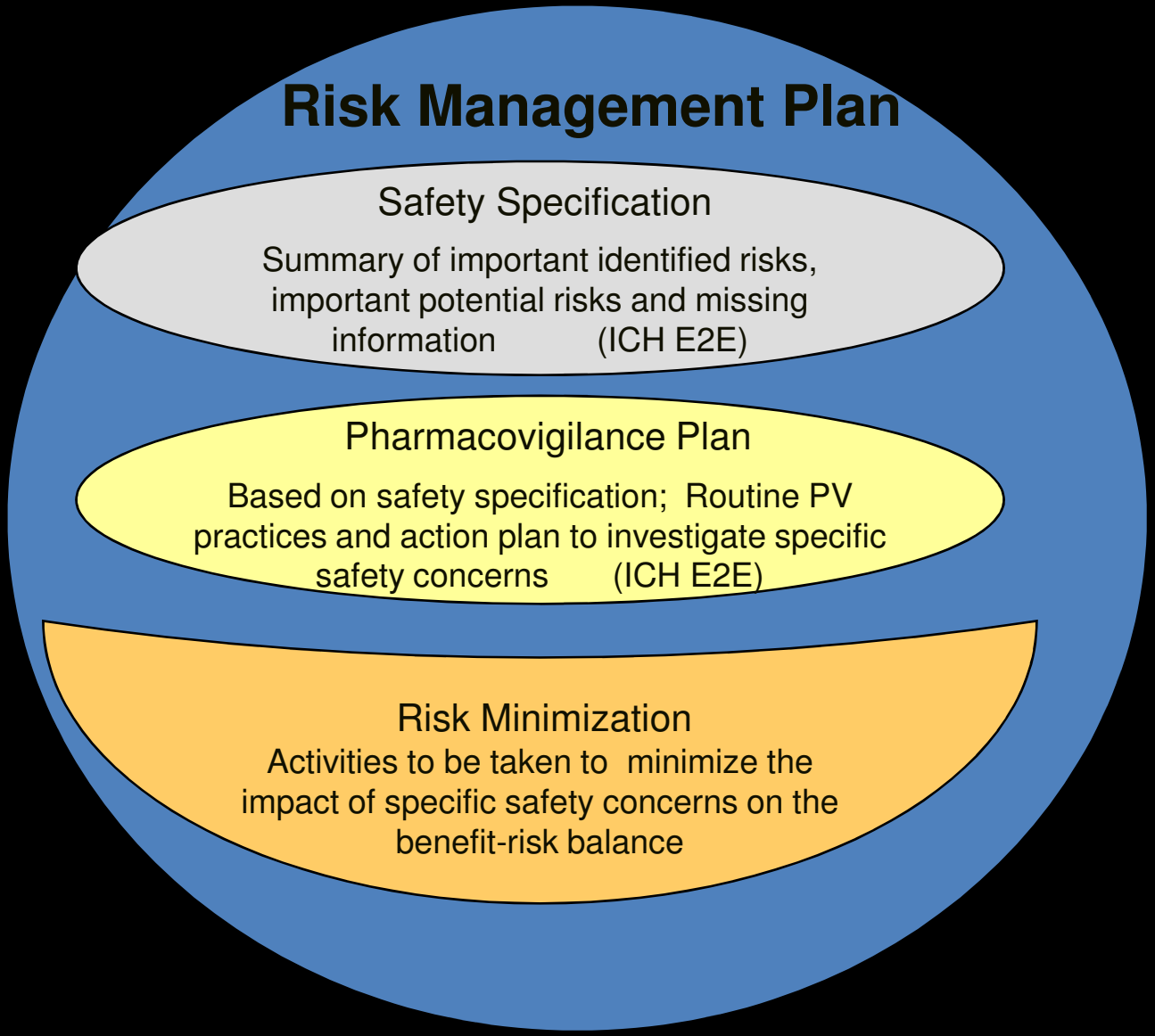
- a library of compounds
- an assay, usually a phenotypic assay
- a strategy to trace an active compound to its biological target



In most developing countries

PHP	PV
Crucial and critical	Seen as a luxury discipline
Long standing	Not fully established
Technically performed	No spontaneous reporting culture, no PV competence
Good financial support	Poor support

Basic Components of a Risk Management Plan



Components of a Risk Management



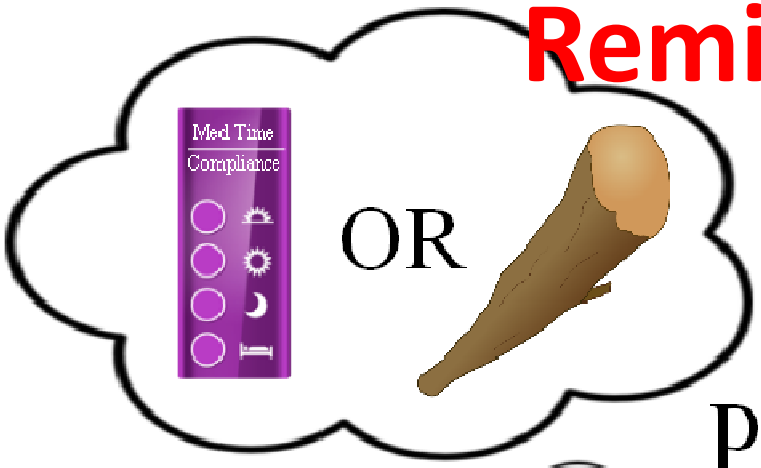
FDA's February 2004 Report

"Practical ways to report PV"

Best seller in 1999 book



Reminder device for Rx



PHARMACY



Pharmacist: "and which medication reminder device would you like to use with this prescription?"

Team for implementation : **PV**



Process of PV

Process in Pharmacovigilance

- Collect and record of AEs / ADRs
- Causality assessment and analysis of ADRs
- Collate and code in database
- Compute risk-benefit and suggest regulatory action
- Communicate for safe use of drugs among stakeholders



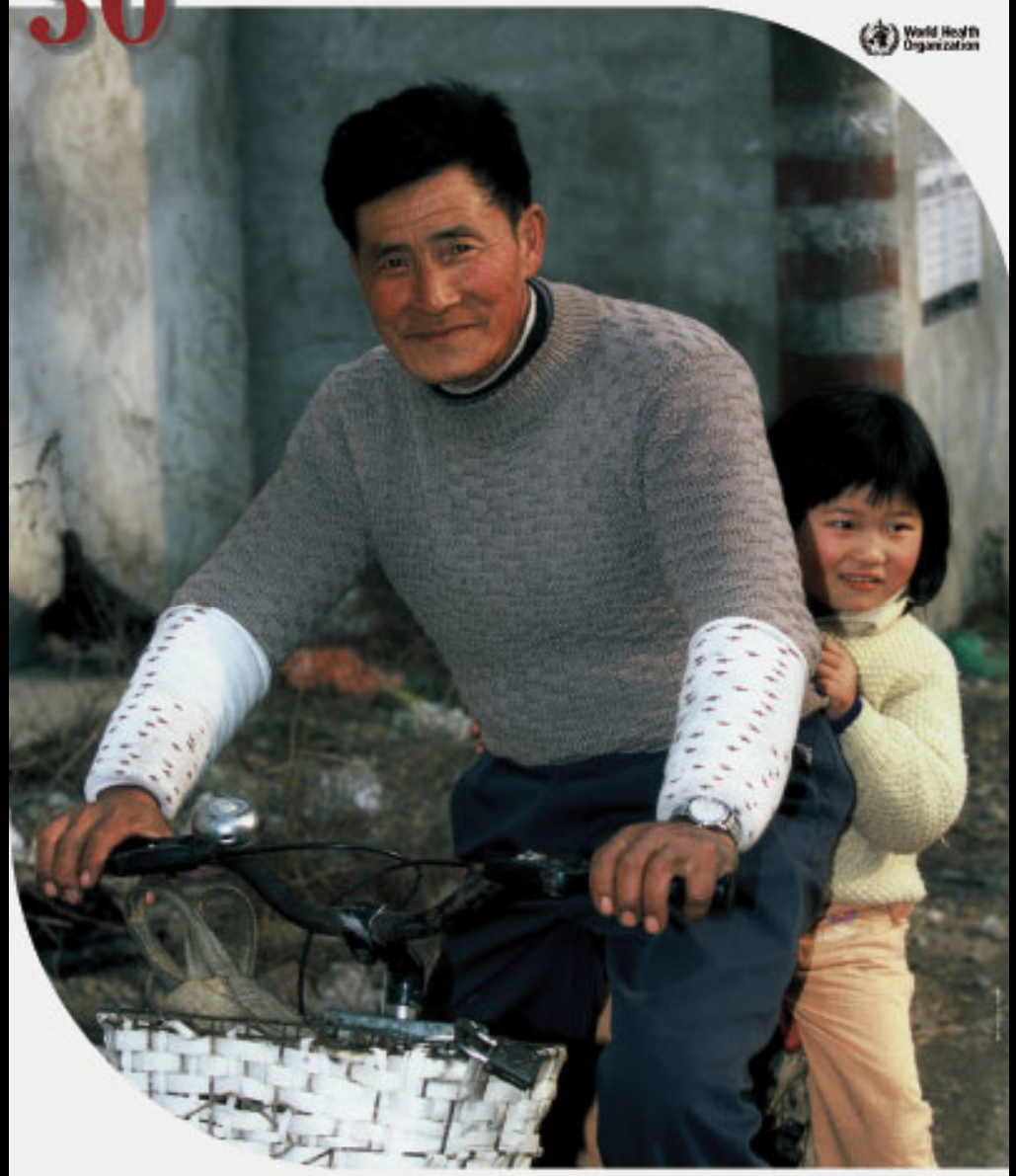
John's wort: CYP3A4 inducer







30 Years of Essential Medicines



Safe medicines save lives

Los medicamentos seguros salvan vidas

Des médicaments sûrs pour sauver des vies

PHP

opportunity to implement PV activities

Offer a cohort of patients under controlled conditions to be monitored for safety over a period of time

PV

detect, evaluate, and prevent adverse events

promote rational use of drugs in mass treatment programmes

Evaluate the impact of the programmes

improve acceptability of the programme

- FDA Serious ADR
  - Result in death
  - Life-threatening
  - Require hospitalization
  - Prolong hospitalization
  - Cause disability
  - Cause congenital anomalies
  - Require intervention to prevent permanent injury

Type A (Augmented)

- Extension of pharmacologic effect
- Predictable
- Mechanism based Adverse reaction
- Dose dependent
- Responsible for at least two-thirds of ADRs
- Side effect, Toxic Effect
- More Common
- Mostly preventable and reversible

Type B (Bizarre)

- idiosyncratic or immunologic reactions
- rare and unpredictable
- Less Common
- More serious
- Non dose related
- Can only be predicted and prevented if Genetic basis is known (Pharmaco-genetics)
- Allergy, idiosyncasy, intolrance

QUALITY REPORTS



To translate ADR information into Safe Clinical Practice

Risk Management – A Shift in Emphasis

"New Model"



Smoking is injurious to lungs





Scope of the Problem

- WHO
- **60% of counterfeit medicine cases occurred in poor countries and 40% in industrialized countries from January 1999 to October 2000**
- **Counterfeits make up more than 10% of the global medicines market and are present in both industrialized and developing countries.**
- **Up to 25% of the medicines consumed in poor countries are counterfeit or substandard**
- **Annual earnings from the sales of counterfeit and substandard medicines estimated at over US$ 32 billion globally**
- **Up to 25% of medicines consumed in developing nations are estimated to be fake or substandar**



Pharmacovigilance is now accepted to be a continuous process of evaluation accompanied by steps to improve safe use of medicines which involves pharmaceutical companies, regulatory authorities, health professionals and patients. The methodologies have broadened to encompass many different types of study, with spontaneous reporting remaining the cornerstone. The concern for ADRs in highly vulnerable populations is of even greater concern.Pharmacovigilance is especially important since most of the adverse effects are reversible by modifying the dosage or omitting the offending medicine. All medicines (pharmaceuticals and vaccines) haveside effects.





Adverse drug reactions

Lip gloss or lipstick especially should not be used by more than one person.

The herpes cold sore virus can be present on the lips of people even if a sore is not present.







Bacteria in foundation can sometimes result in red, acne-like bumps on the face.



What is a Signal?

- Reported information on a possible causal relationship between an adverse event and a drug, the relationship being unknown or incompletely documented previously.

  WHO Definition
- Hypothesis generating
- Does not establish any causal relationship between the drug and the event
- Suggests further studies
- Should be quick and credible

Other Definitions of Signal

- Early identification of suspected signals with subsequent generation of hypothesis
- Hypothesis of a signal can be generated by identification of:

  - unexpected SAE (also non-serious) or change in its severity

  - Increases in reporting frequency of an expected event

  - AEs experienced in special population groups (i.e. Paediatric, elderly, hepato-renal compromised patients etc)


... YOU'RE RIGHT, MORPHING INTO A HIDEOUS MONSTER IS NOT LISTED AS A POSSIBLE ADVERSE REACTION
©DOLISHAN.
© 2010 - CFHI

http://www.youtube.com/watch?v=XdFBaA0KH2g

Pharmacovigilance of Herbal Drugs

The number of adverse reactions to Herbal drugs reported in the National Pharmacovigilance Program in India is

Negligible

Due to:

- The strong belief that Herbal medicines are safe.
- The lack of knowledge about the concept and importance of Pharmacovigilance in Herbal medicine

Drug Safety, making the conference a perfect platform to share experience, foster collaborations across industry, academia, serve the humanity and make a better future for mankind by share emerging scientific updates across the globe by means of thought provoking Keynote

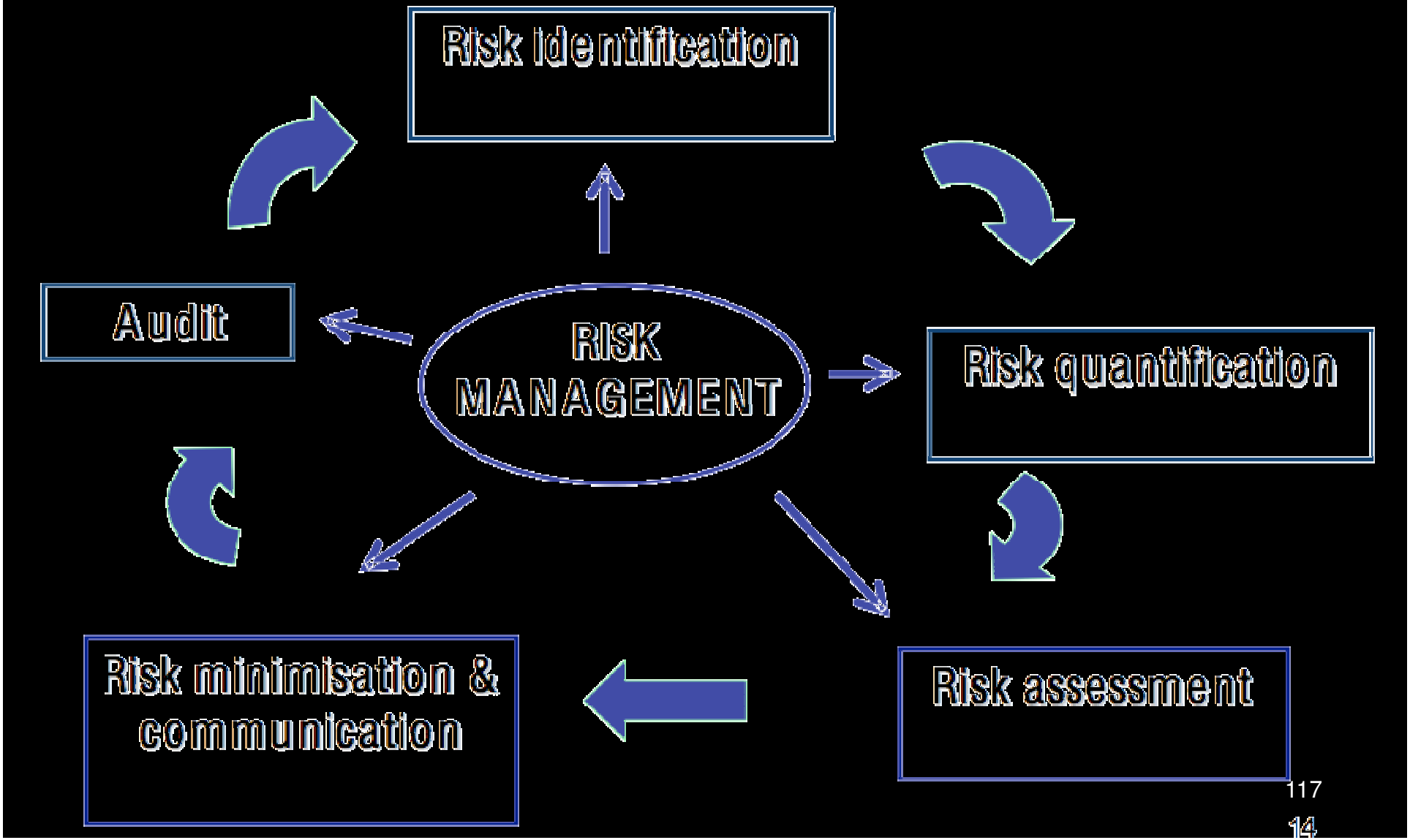
Hrithik Roshan Suffered Drug Allergy

- By SUNIL Sonkar November 22 — Bollywood actor Hrithik Roshan was hospitalised on Sunday to Kokilaben Dhirubhai Ambani Hospital in Mumbai after his lungs practically collapsed. Hrithik was unable to breathe and his lips became ten times bigger and face was also swollen. The problem started when he took an antibiotic after complain of chest infection, which led to strong allergy. He took the tablet on Saturday. Though he was discharged in the evening, but was kept under observation. He said, "It was an allergic reaction to the antibiotics I was taking. Lungs and throat went into spasm. I reached hospital just in time…All cool now. I'm under observationIt was an allergic reaction to the antibiotics I was taking. Lungs and throat went into spasm. I reached hospital just in time…All cool now. I'm under observation."
- Hrithik also revealed later that a delay of about 15-minute would make the condition fatal.
- He complained of temperature, headache, backache, muslce pain and tiredness earlier.
- Family members of the star are quite shocked and also scared over his condition

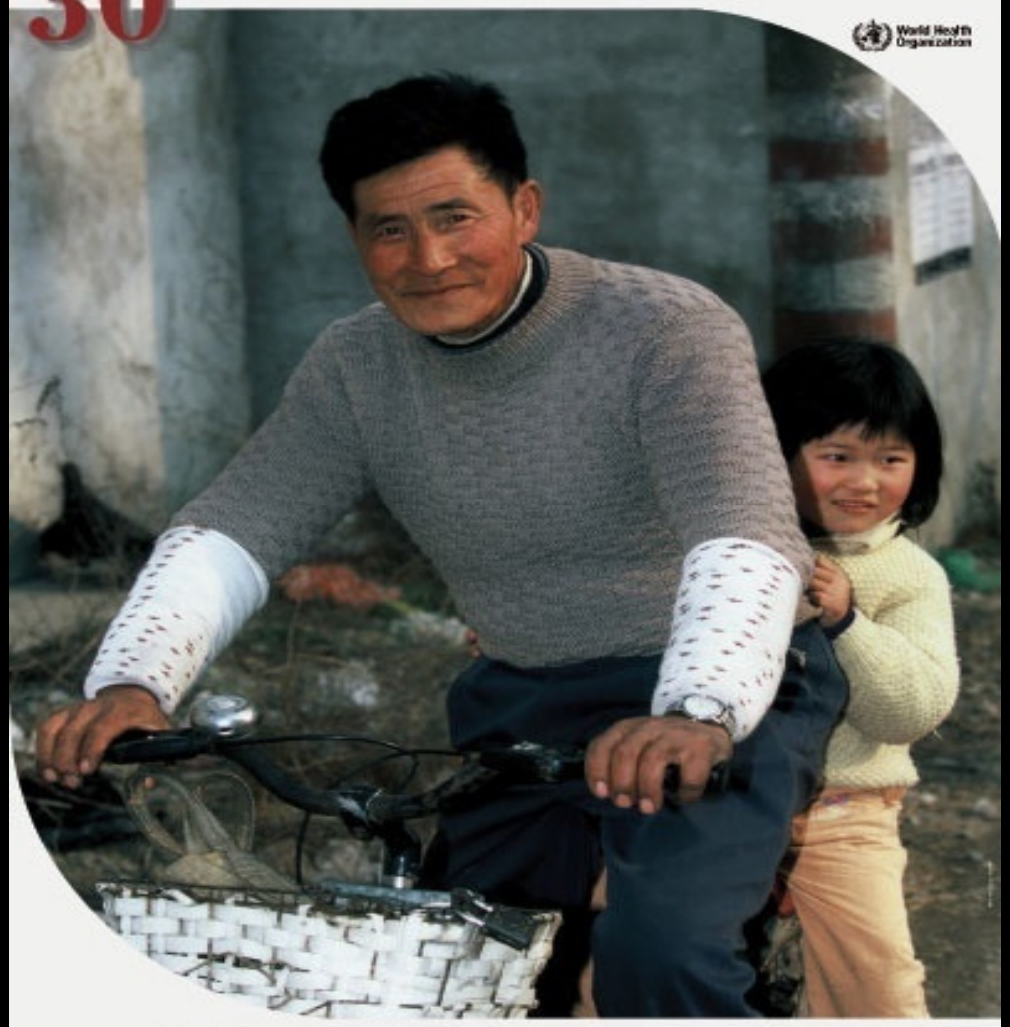


"Can you give me a non-drowsy medication for my insomnia?"

Cyclical model: Risk Management



30 Years of Essential Medicines



Safe medicines save lives

Los medicamentos seguros salvan vidas

Des médicaments sûrs pour sauver des vies



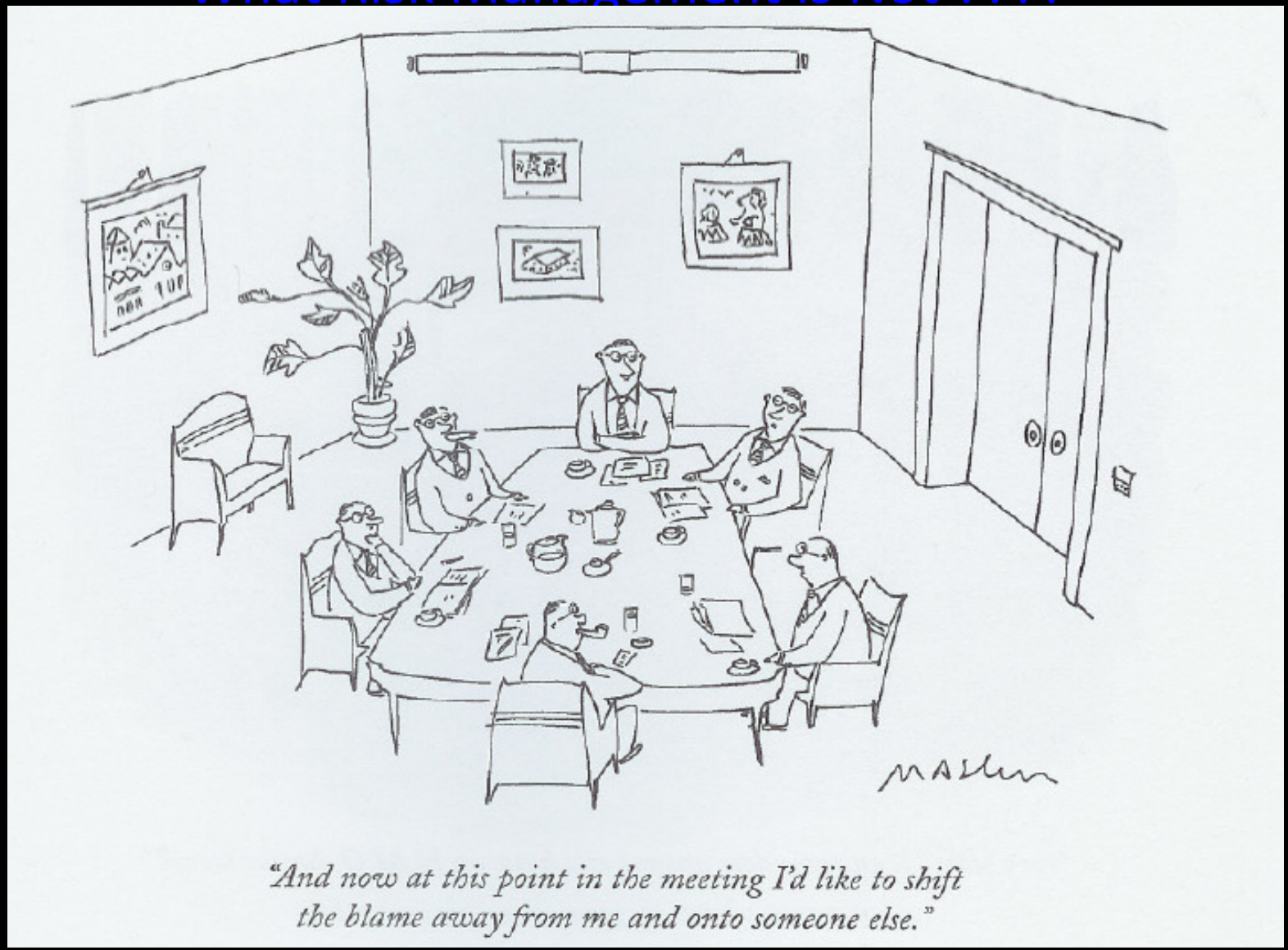








What Risk Management is Not ????



"And now at this point in the meeting I'd like to shift the blame away from me and onto someone else."

Addressing the needs of public health programs

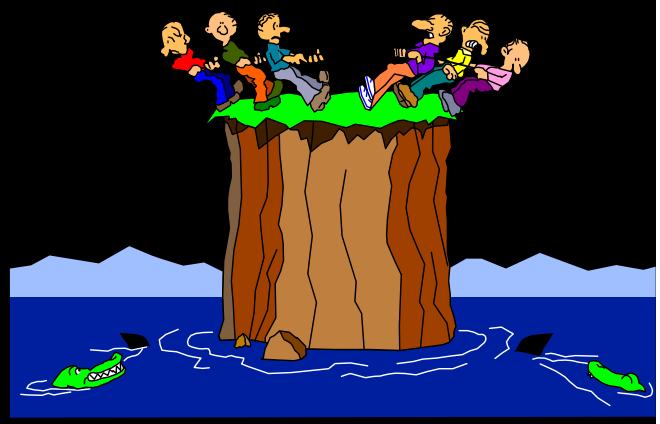
Neutropenia with ACTs in malaria-HIV co-infected ?
Result of repeated treatment with ACTs?
ia with As-Aq? SJS susceptibility

Delete d4t? NVP in women?
Can we use TDF without renal monitoring?
Risk of severe anaemia in children with AZT?
Use NVP & rifampicin concomitantly in HIV/TB patients?

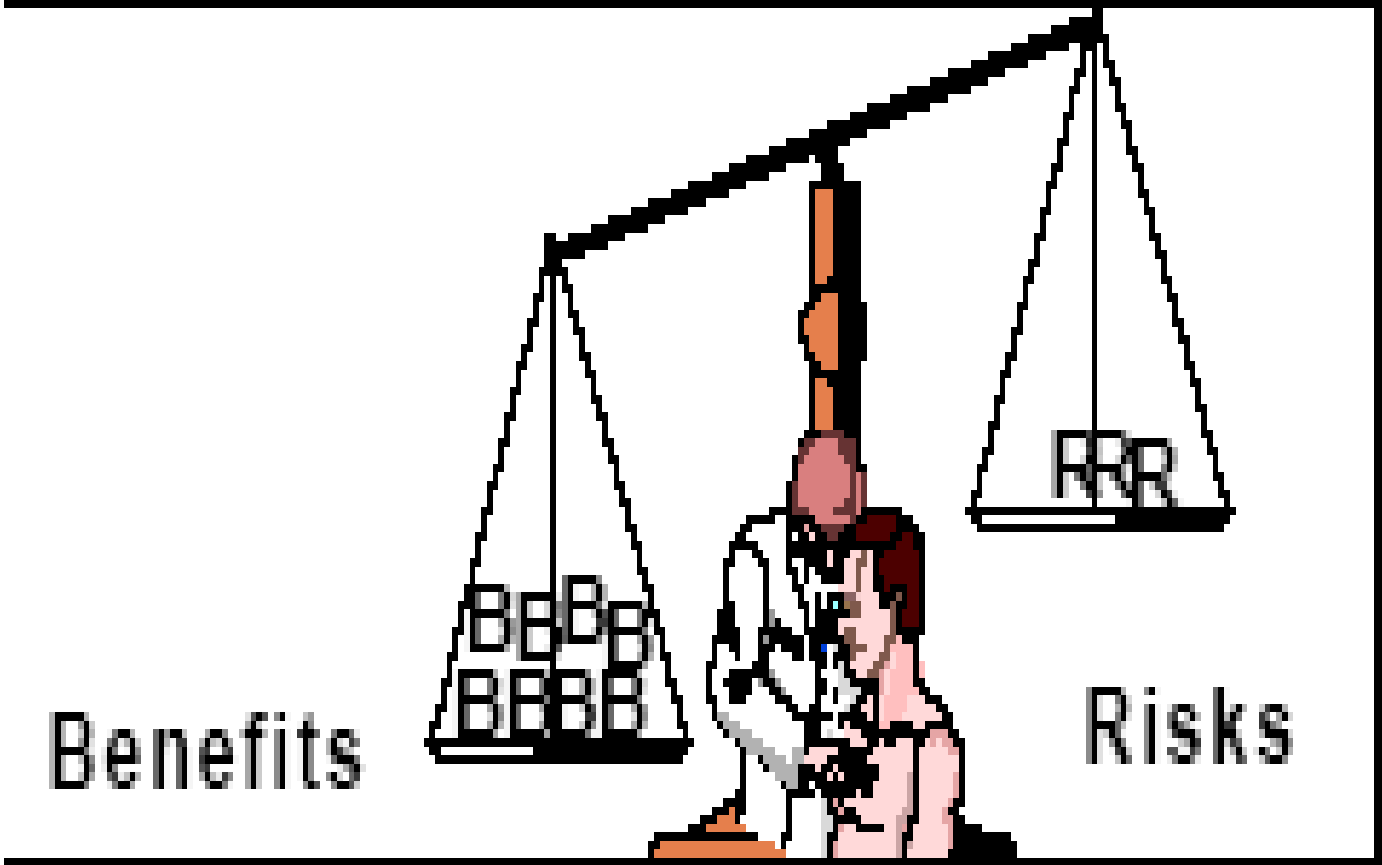
Management and International Harmonization

International harmonization is wonderful in theory

…….but everyone is harmonizing differently



Overall Objectives of Risk Management Planning
Benefit - Risk Optimization



- Literacy of reporters
- Clearly defined responsibilities
- Adequate training and education
- Public awareness of the new medicine
- Public awareness on reporting safety problems of all medicines
- Awareness of pharmacovigilance system within informal sector
  - Community & religious leaders, shopkeepers, traditional healers, community health workers and school teachers
- Quality control of laboratories
- Open communication between public, health care providers and policy makers
  - Judicious and pro-active use of the media, professional and general
- Presence of national coordinator/s

PHP ORGANIZATION

INTERNATIONAL

SPONSORS
WHO
OTHERS

NATIONAL

PROGRAMME MANAGERS

LOCAL

LOCAL COORDINATOR FOR HEALTH PROGRAMMES



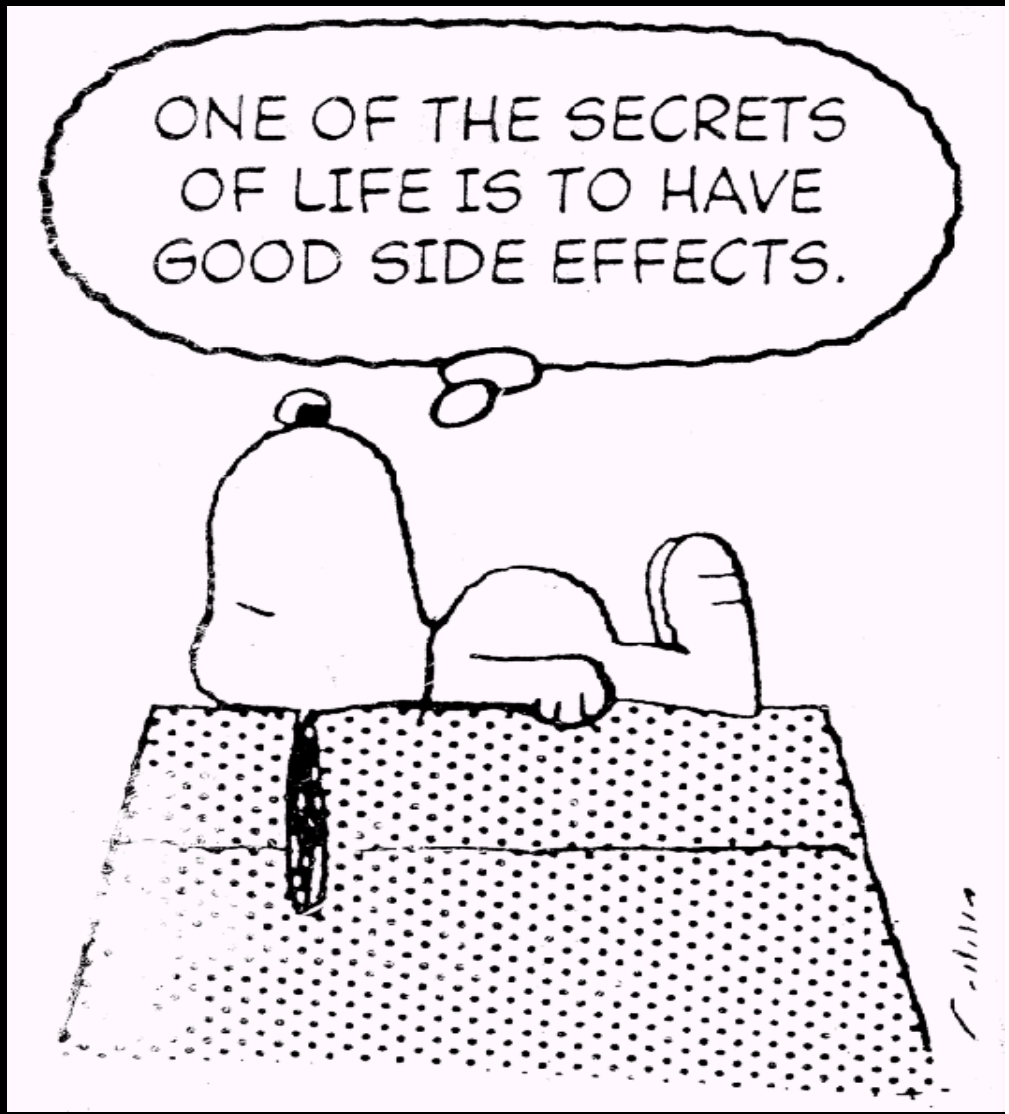
HEALTH WORKERS

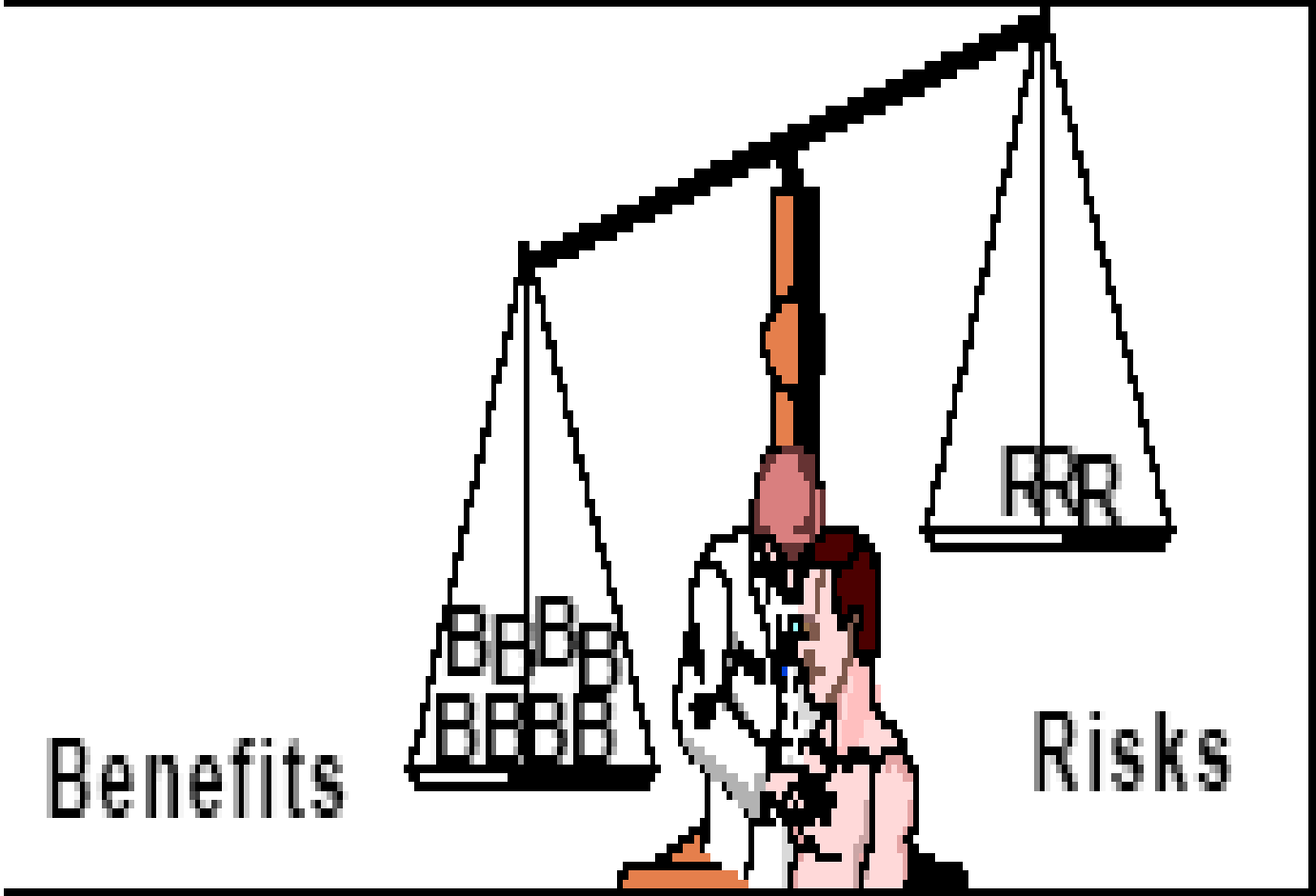
PATIENTS

Need to monitor PHPs…

To detect, evaluate and prevent ADRs related to:

- ✓ Harm
  Acceptance and tolerance
  Misuse
  Dependence
  Effect on pregnancy and children
  Therapeutic failures (resistance, quality defects, counterfeits)


ONE OF THE SECRETS OF LIFE IS TO HAVE GOOD SIDE EFFECTS.


Benefits
Risks

Principles of Signal Detection & Risk Management in Pharmacovigilance

- Dr Pipasha Biswas
- MD MFPM DM MRQA
- Principal Consultant & Director
- Symogen Limited, UK.

- ISPRT & SOPI Conference, Lady Hardinge Medical College, New Delhi
- 26 – 28 November 2010

What can be done in the United States?

- Trafficking in counterfeit, unapproved, adulterated, or misbranded products is a felony violation of the U.S. Federal Food, Drug, and Cosmetic Act (FDCA)
- FDA's "Long Arms"
  - Cease & Desist Orders
  - Import Alerts
  - Warning Letters
  - Civil Monetary Penalties
  - "Cybersmuggling"



- Patent Infringement
- Business & Professional Code Violations

Internet Pharmacies")

- If impact in U.S. (example: shipping products to U.S.)
- Injunctions against or criminal prosecutions of foreign nationals
- Seizures of product, injunctions, criminal prosecutions, and civil penalties
- Conspiracy Laws
- 18 USC 1001 (False Reports to the Government Act)
- 18 USC 542 (relating to entry of goods by means of false statements)
- 18 USC 545 (relating to importation contrary to law and smuggling)
- Money laundering charges

FDA Recommendations – Summary

- Multilayered approach; no “magic bullet”
- New Technologies
- Stricter Licensing Requirements
- Tougher Penalties
- More Secure Business Practices
- Reporting and Response
- Increase Education
- International Collaboration

30 Years of Essential Medicines



Safety comes first

La seguridad es lo primero

La sécurité d'abord

Why do we need pharmacovigilance?

Reason 5: Ensuring public confidence

If something can go wrong, it will – Murphy's law

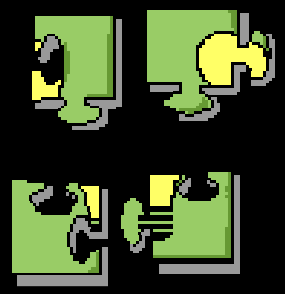
Definition

- WHO
  - response to a drug that is *noxious and unintended* and that occurs at doses used in humans for prophylaxis, diagnosis, or therapy of disease, or for the modification of physiologic function
  - excludes therapeutic failures, overdose, drug abuse, noncompliance, and medication errors


Patient with drug-induced
toxic epidermal necrolysis


IMPROVE PATIENT HEALTH

Risk Management Planning



Industry Experience in Implementation

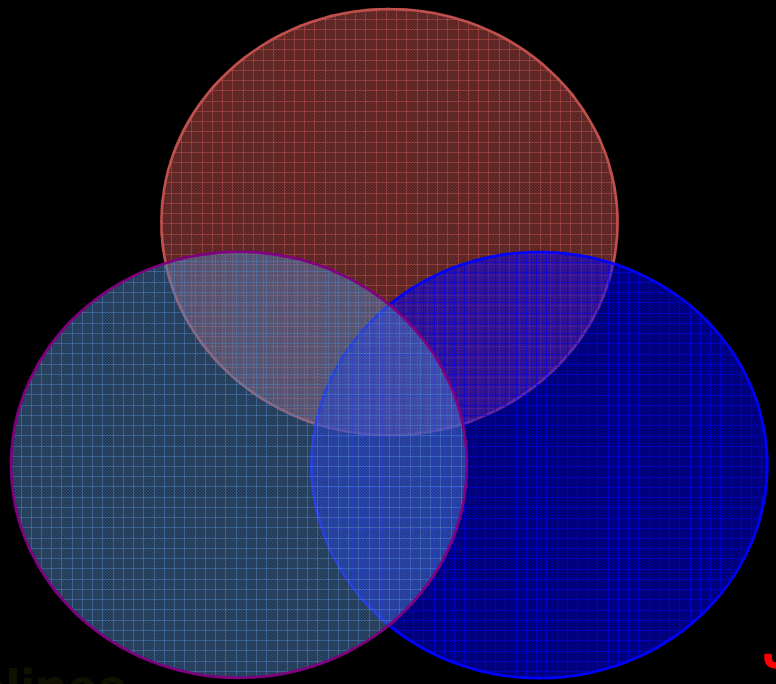
Val Simmons, MD FFPM

EU QPPV Executive, Eli Lilly

Global Risk Management Planning
The Challenge of Reconciling the Differences

Europe

ICH E2E +/- Risk Minimization Plans



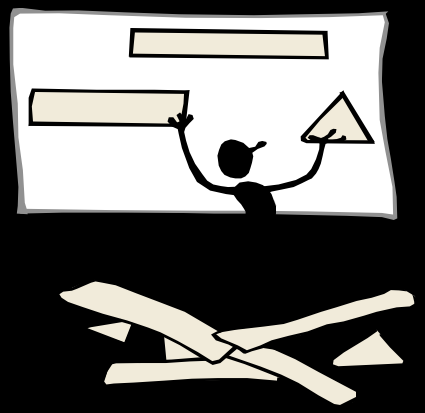
US

RM Guidelines
ing RiskMAP/REMs

Japan

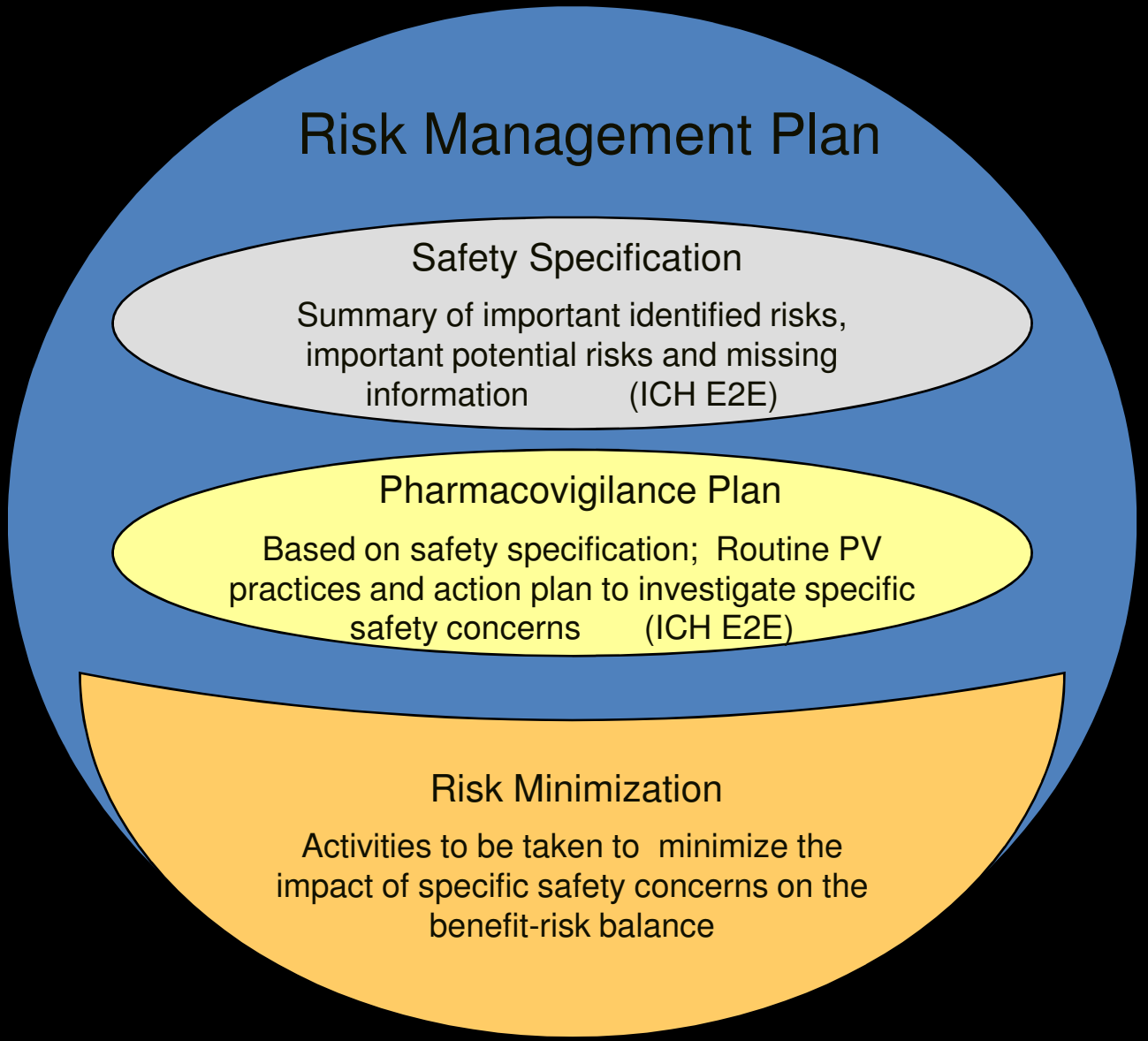
ICH E2E + EPPV(?)

Risk Management in Industry





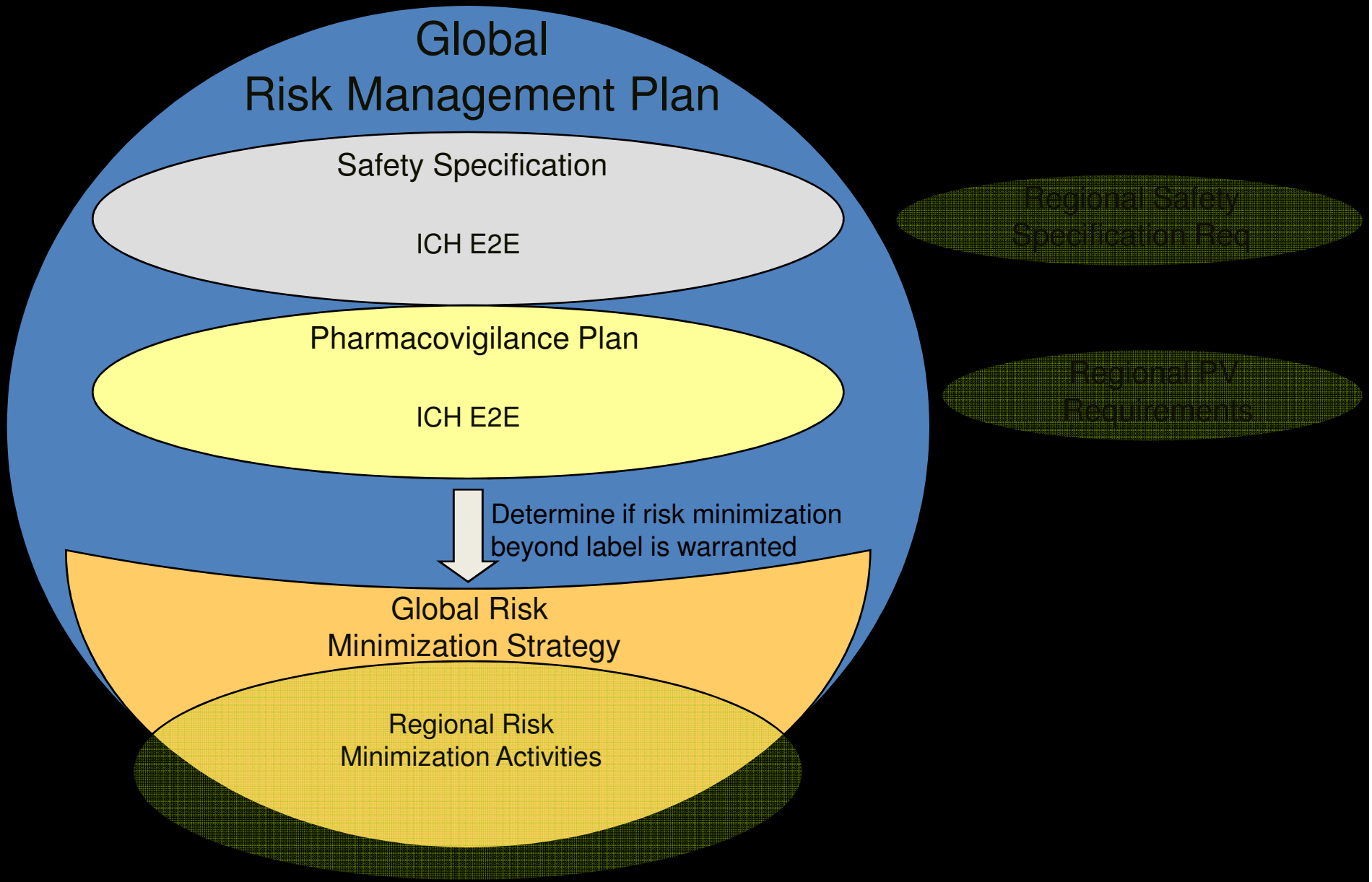
Basic Components of a Risk Management Plan



Global Plan and EU RMP Relationships



RMP Regional Variations



SCOPE….2

- Transfusion process
  - Errors at blood center
    - Blood center tracking systems
    - MERS-TM system
  - Errors at the hospital
    - Near-misses
    - MERS-TM system, UK SHOT, Canadian TESS
  - Blood utilization
  - Traceability

- Hemovigilance is now an integral part of a quality system in transfusion
- Hemovigilance covers donors, processes and recipients
- Hemovigilance helps identify priorities for transfusion safety and monitors effects of preventive measures
- Hemovigilance works

Institut national de santé publique Québec

The Problem

- According to WHO:
  - Fake packaging, correct quantity of correct ingredient (clone)
  - Fake packaging, wrong ingredient
  - Fake packaging, no active ingredient
  - Fake packaging, incorrect quantity of correct ingredient
  - Genuine packaging, wrong ingredient
  - Genuine packaging, no ingredient
  - Genuine packaging, incorrect quantity of correct ingredient

Challenges of pharmacotherapy in PHPs ….

- may use agencies and staff with a wide variety of skills and patients may not be seen by a physician
- insufficient diagnosis and follow up
- large numbers exposed, may include special populations i.e. pregnant &breast feeding mothers

Challenges of pharmacotherapy in PHPs ….

- use of new drugs with limited experience, i.e. ARVs, ACTs; use of substandard drugs;incorrect use of drugs;counterfeit drugs
- weak health care systems, often poor drug control/legislation

SWOT analysis of PHPs and PV

Strengths of PHPs

- well established roles
- usually well funded
- technical guidelines
- monitoring and evaluation procedures
- good databases

SWOT analysis of PHPs and PV ……

Strengths of PV

- new drugs , high interest in drug safety
- exists in a few African countries
- expertise in assessment of drug safety
- training in benefit/risk assessment
- good international support, WHO, UMC

SWOT analysis of PHPs and PV ……

Weaknesses of PHPs

- lack experience in drug safety monitoring
- drugs used in PHPs considered safe
- lack of coordination between PHPs, duplication
- may cover special populations

SWOT analysis of PHPs and PV ……

Weaknesses of PV

- relatively new concept
- role not well recognised
- poorly funded, considered a luxury
- not seen as a component of PHPs

SWOT analysis of PHPs and PV ……

<u>Opportunities</u>

together, PV and PHPs may greatly benefit each other. PV will assist in the early identification and prevention of ADRs and product quality problem ……..

SWOT analysis of PHPs and PV ……

<u>Opportunities</u>

PHPs may provide resources, reliable databases,M&E tools leading to …….

SWOT analysis of PHPs and PV ……

<u>Opportunities</u>

1. rationale drug use
2. better patient adherence
3. improved drug procurement

All this will lead to …….

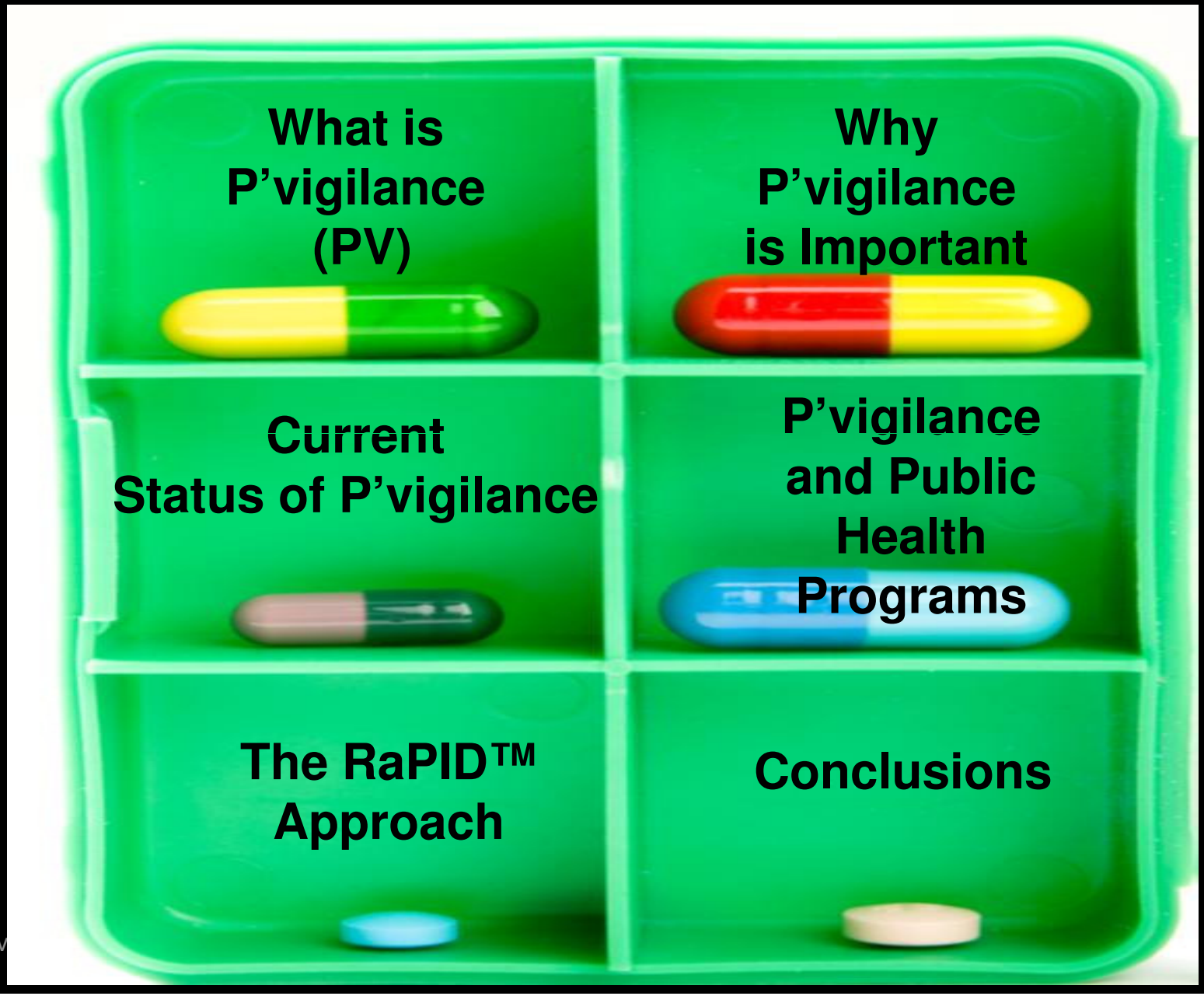
SWOT analysis of PHPs and PV ……

BETTER HEALTH
OUTCOMES AND
RESOURCE SAVINGS

SWOT analysis of PHPs and PV …..

Threats

- lack of political/public support
- funding shortfalls
- misunderstanding of each other's roles


What is P'vigilance (PV)
Why P'vigilance is Important
Current Status of P'vigilance
P'vigilance and Public Health Programs
The RaPID™ Approach
Conclusions

- UK:

It has been suggested that ADRs may cause 5700 deaths per year in UK.

Pirmohamed et al, 2004

- US:

ADRs were 4th-6th commonest cause of death in the US in 1994

Lazarou et al, 1998

Journal of Clinical Pharmacy and Therapeutics (2006) **31**, 335–341

ORIGINAL ARTICLE

Adverse drug reactions in hospital in-patients: a pilot study

E. C. Davies*‡ MPharm MRPharmS, C. F. Green† BSc Hons PgDipClinPharm PhD MRPharmS, D. R. Mottram‡ BPharm PhD, FRPharmS and M. Pirmohamed*§ MBChB PhD FRCP

(59%) were avoidable

Why do we need pharmacovigilance?

Adverse drug reactions as cause of admission to hospital: prospective analysis of 18 820 patients

Munir Pirmohamed, Sally James, Shaun Meakin, Chris Green, Andrew K Scott, Thomas J Walley, Keith Farrar, B Kevin Park, Alasdair M Breckenridge

Reason 3: ADRs are expensive !!

- 6.5% of admissions are due to ADRs
- Seven 800-bed hospitals are occupied by ADR patients

Cost £446 million per annum

BMJ 2004;329:15–19

Pharmacovigilance in India: Brief History

- 1982 & 1989 - ADR monitoring system for India proposed (12 regional centres)
- 1997 - India joined WHO-ADR monitoring programme (3 centres: AIIMS, KEM, JLN)
- 2004 – 2008 - National Pharmacovigilance Programme
- **2010 – Pharmacovigilance Programme of India**
-



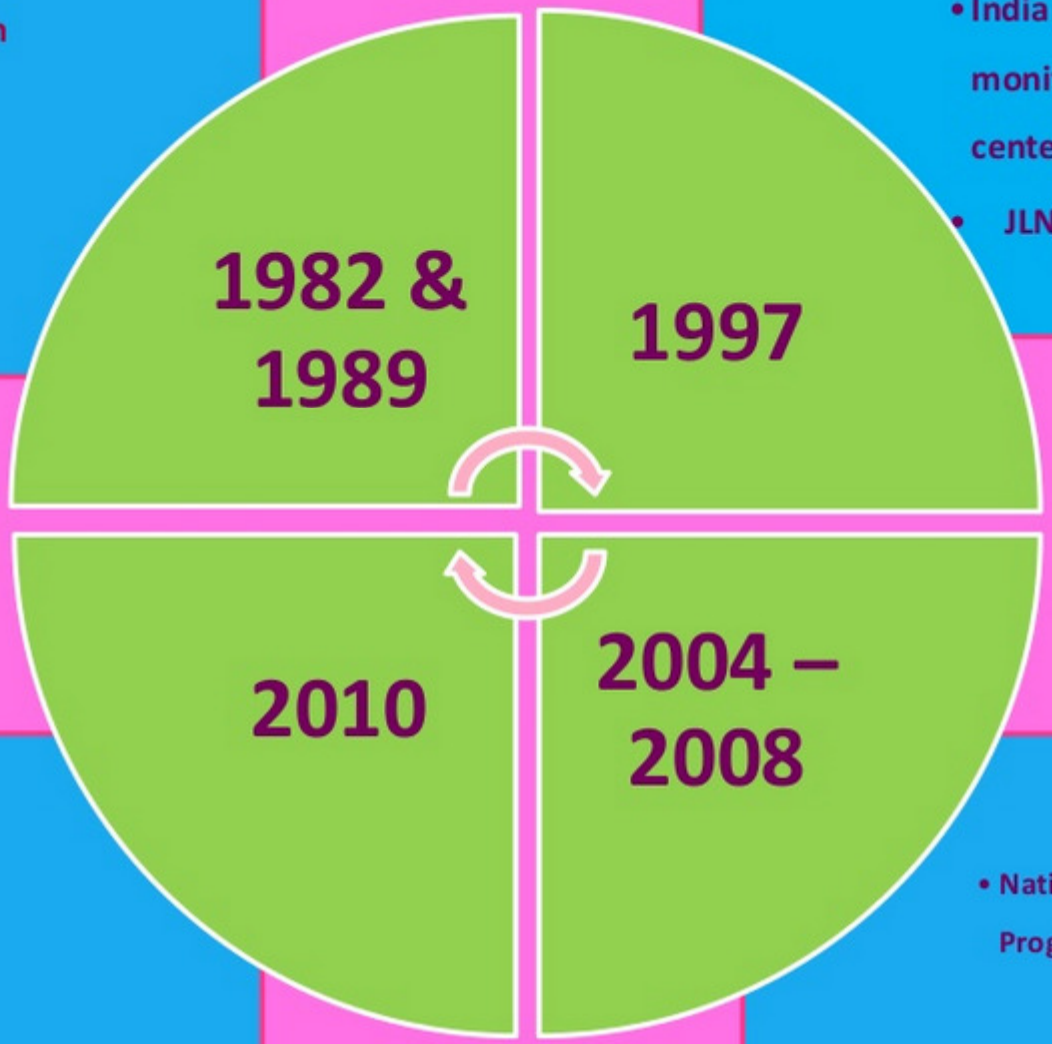
GOD & DRUG



WORD GOD END'S WITH ALPHABET "D"

WORD DRUG END'S WITH ALPHABET "G"

Pharmacovigilance in India: A Brief History



- ADR monitoring system for India proposed (12 regional centers)

- India joined WHO-ADR monitoring programme (3 centers: AIIMS, KEM, JLN)

- Pharmacovigilance Programme of India

- National Pharmacovigilance Programme

What is Pharmacovigilance?

WHO definitio

The scie *a* *c* *atin* *to the* ***detection* *d* *es* *der* *nding,*** ***reporting* *d p* *en* *j* *c* *erse* *fects or any other* *g-re* *d prob* *.*

Aims & Scope

Patient Care	• To improve patient care & safety in relation to medicines & all medical & para-medical interventions
Public Health	• To improve public health & safety in relation to the use of medicines
Risk Benefit Assessment	• To contribute to the assessment of benefit, harm, effectiveness and risk of medicines
Communication	• To promote understanding, clinical training & effective communication to health professionals & the public

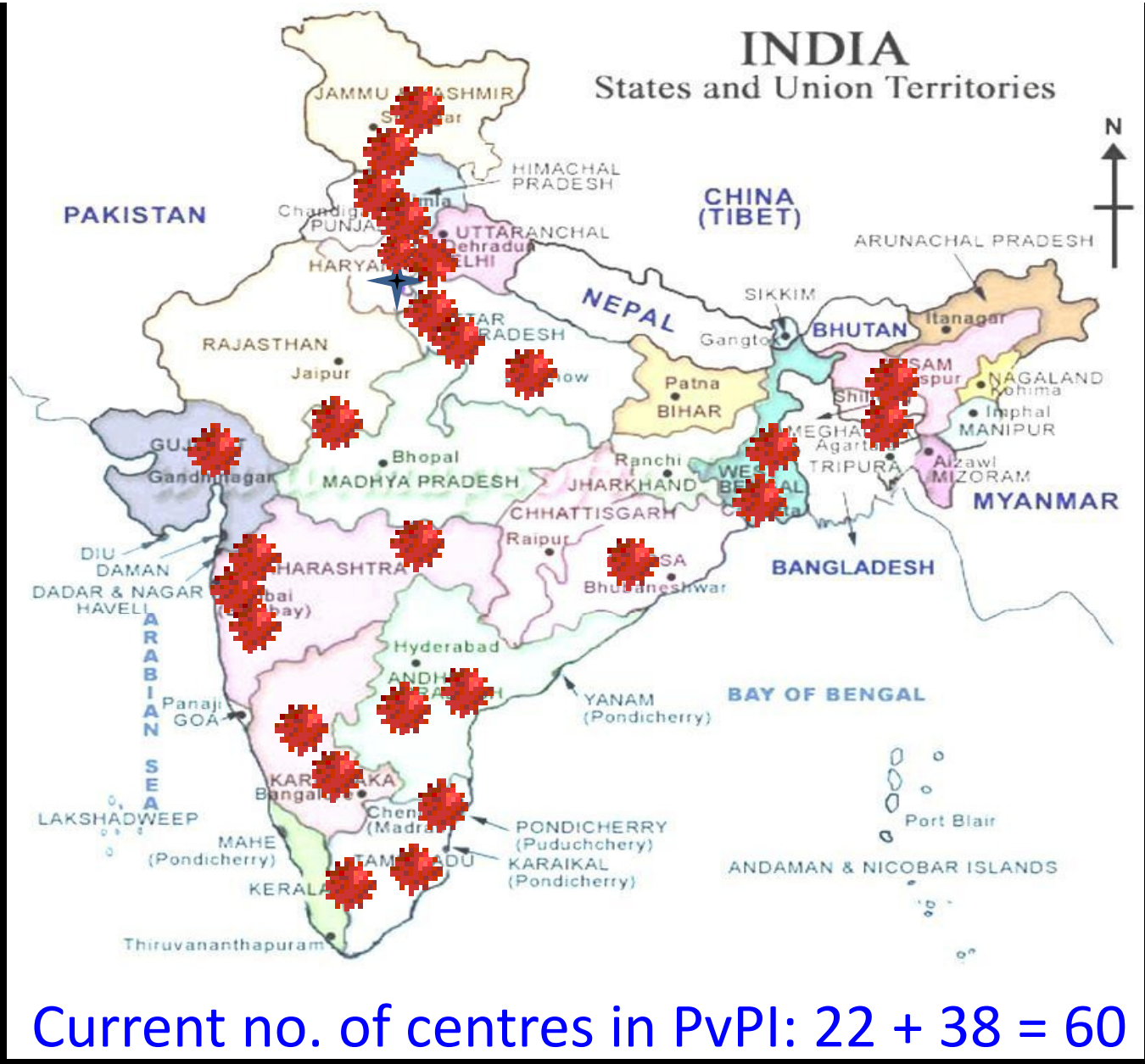


Destruction is easier but its consequences should be thought of



“A destruction , an annihilation that only man can provoke , only man can prevent”

Serious ADR to Estrogen Contraceptive 1960



Current no. of centres in PvPI: 22 + 38 = 60

Hindustan Times

January 13, 2003

IMA ends debate: Nimesulide is safe

Arun Kumar and Sutirtho Patranobis New Delhi



More than 50 doctors country-wide participated in an **opinion poll** organised by the IMA and submitted **data** on the use of nimesulide on nearly 5.3 lac patients.

The **data clearly showed** that the side-effects of the drug were nothing more than common GI problems …

THE TIMES OF INDIA

January 14, 2003

Nimesulide not safe, *insist* doctors



By Kalpana Jain **Times News Network**

New Delhi: Doctors have questioned an **"opinion poll"** conducted by the Indian Medical Association (IMA) to declare the controversial fever drug, Nimesuilde, "safe".

… a leading paediatrician who is the former head of the pediatrics department at the All India Institute of Medical Sciences, told The Times of India … that severe side effects of the drug have been **documented** and it needs to be used with caution.

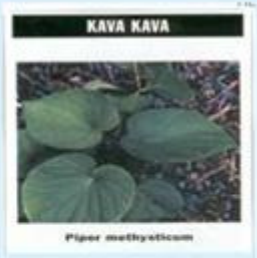
Ephedra *sinica* (mahaung)



- **Anorexiant, Decongestant, 1% ephedrine**
- **Palpitations, MIs, death**
- **Drug interactions**
  - **Theophylline, digoxin, caffeine**

- Products containing ephedra accounted for 64% of all adverse reactions to herbs in the USA
- FDA announced ban on manufacturing dietary supplements that contain ephedrine and related alkaloids (12/30/2003)

Kava Kava
(Piper methysticum)



Kava Kava (Piper me

, stress, sleep disorders
e for short-term treatment of anxiety
ermopathy : Photosensitivity and phototoxic
toxicity: liver failure
warning; removal from the market from USA
no > 4 weeks
lcohol/sedating medications
ion when driving or operating machinery

S

ohn's Wort (*Hypericum perforatum*)



verse Effects:

- Photosensitivity/Phototoxicity
- *nsomnia*, vivid dreams, headache, dizziness

g Interactions: (through induction of Cytochrome P450 enzyme CYP3A4, but also CYP2C9 induction of the P-glycoprotein (P-gp) efflux transporter)

- MAOIs, selective serotonin reuptake inhibitors (SSRIs), : ncreased serotonin (Serotonin Syndrome)
- Cyclosporine : Decreased levels
- Warfarin : Decreased INR
- Oral contraceptives or hormone replacement therapy:



Ginseng (Panax notoginseng)



- **Adverse Effects:**
  - Nervousness, insomnia, excitation, palpitations, lowers blood glucose, alters immune function
  - Ginseng abuse syndrome? (long-term use)
- **Drug Interactions:**
  - Antidiabetics
  - Warfarin

Ginkgo *biloba*



dverse Effects:

- Hypersensitivity reactions
- Gastrointestinal disturbances
- Spontaneous bleeding

rug Interactions:

- Anticoagulants
- Antiplatelets
- Ginkgo inhibits monoamine oxidase



AERS

(Adverse Event Reporting System)

- FDA has maintained a database of spontaneous reporting system case reports since 1969
- Number of modifications made, including coding dictionary, search interface, and expanded database capacity

Factors Affecting Reporting

- Nature of the adverse event
- Type of drug product and indication
- Length of time on market
- Media attention
- Extent and quality of manufacturer's surveillance system
- Prescription or over-the-counter drug status
- Reporting regulations

monitoring the safe use of drugs in this field in which pharmacotherapy is affected by high incidence of drug-related complications and by a narrow benefit/risk ratio.

Why do we need pharmacovigilance?

Reason 4:

Promoting rational use of medicines and adherence

Why do we need pharmacovigilance?

Reason 5: Ensuring public confidence

If something can go wrong, it will – Murphy's law

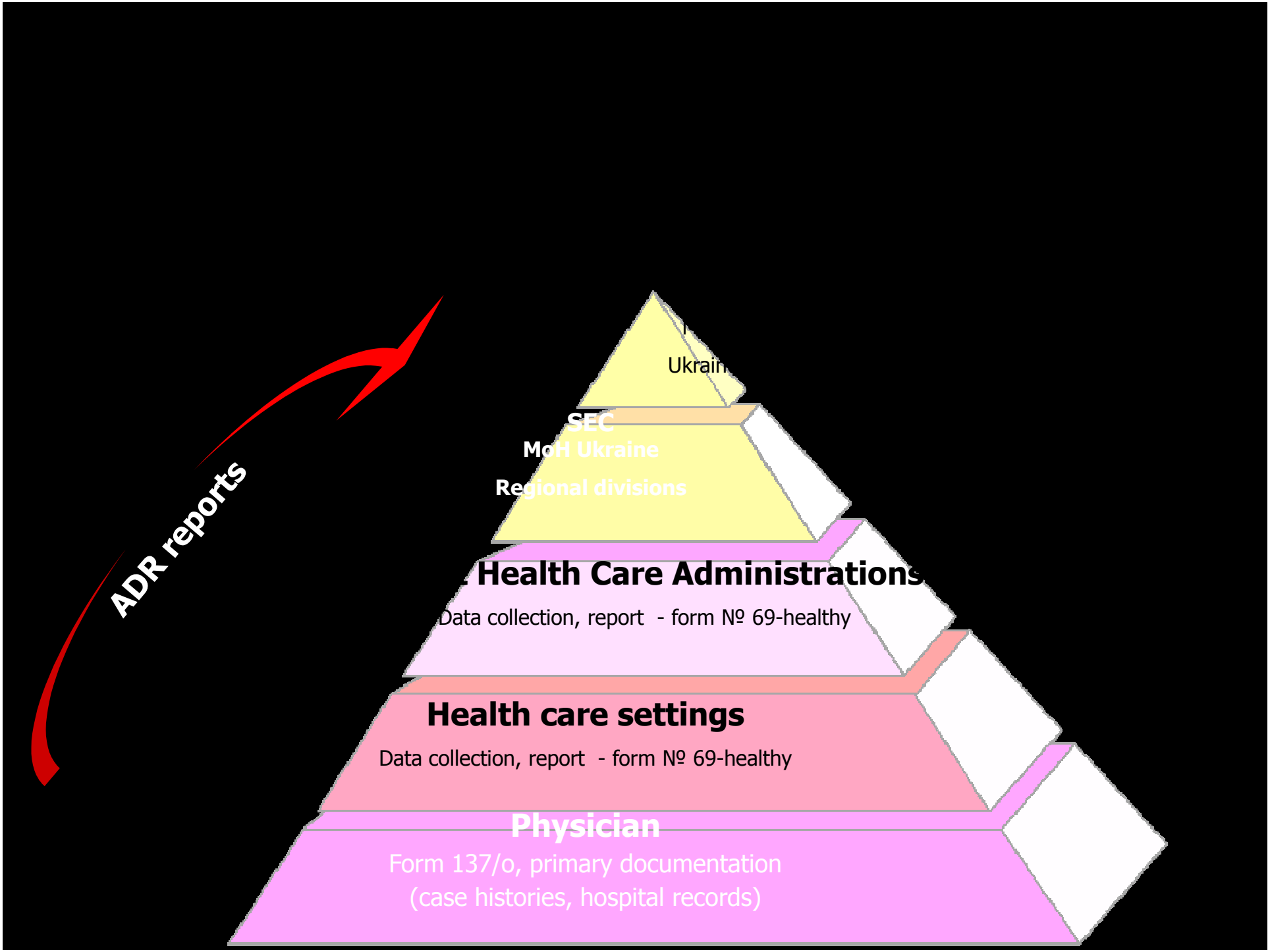
Why do we need pharmacovigilance?

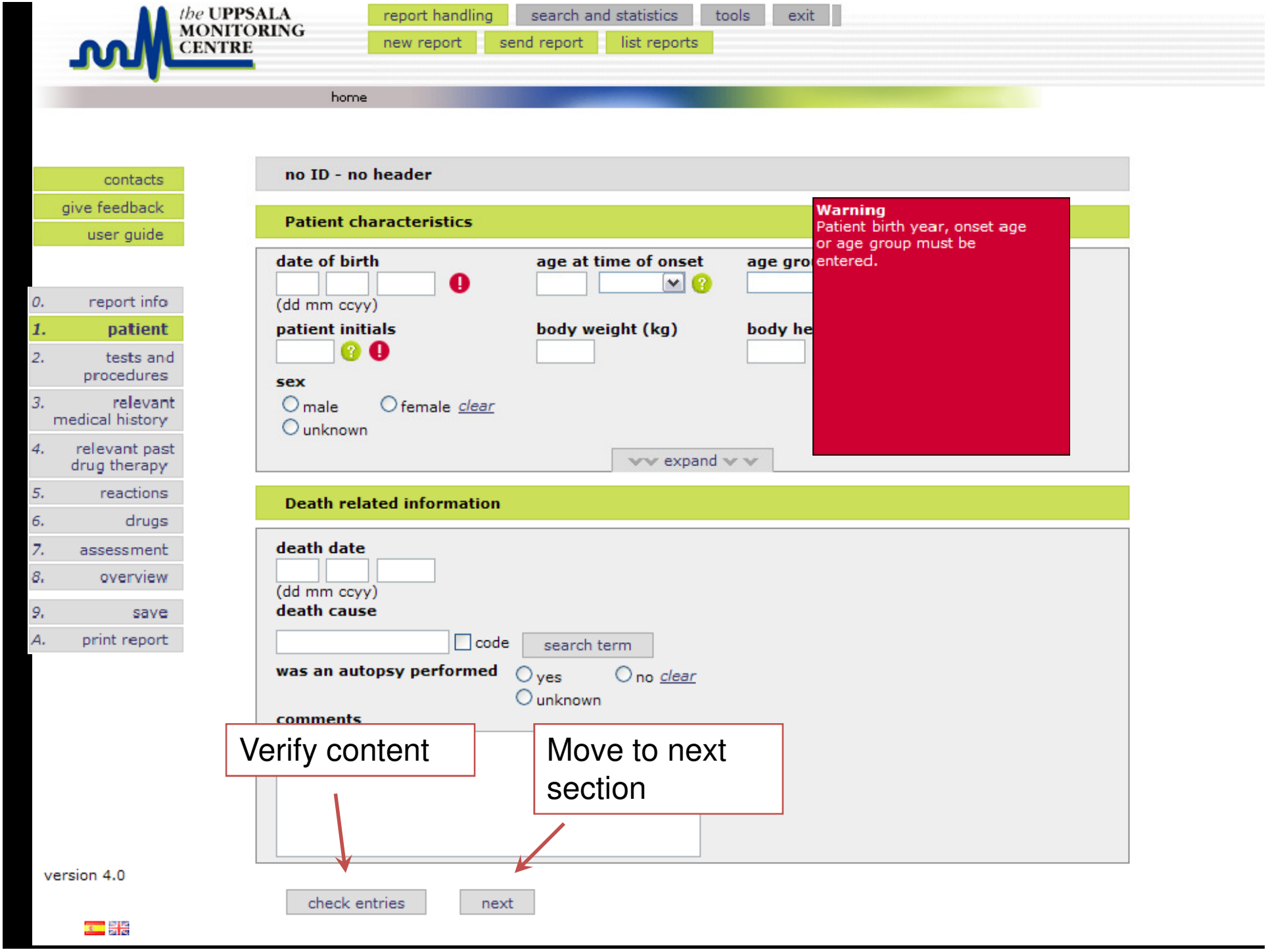
Reason 6: Ethics

To know of something that is harmful to another person who does not know, and not telling, is unethical

Not reporting a serious unknown reaction is unethical

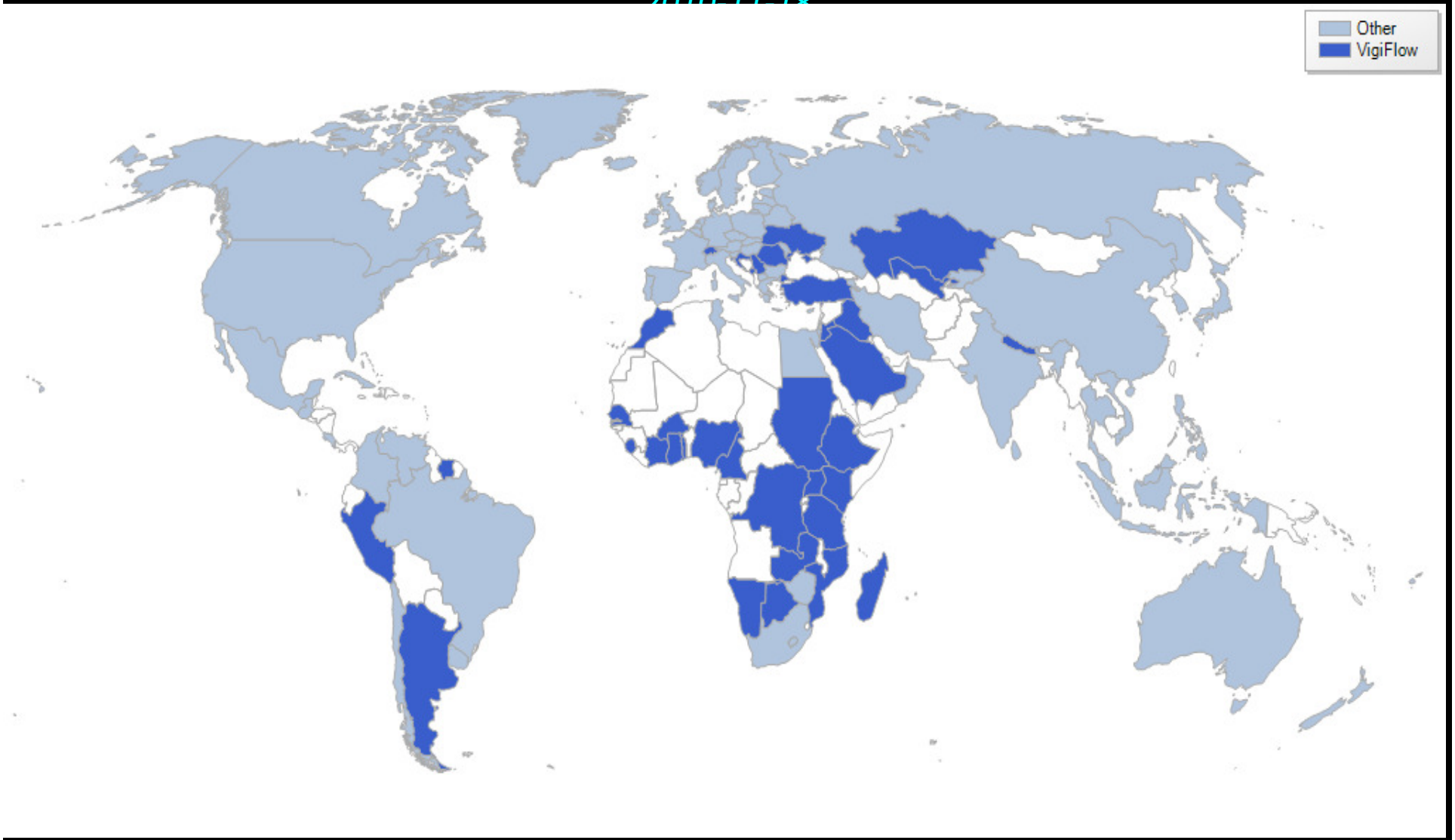
- valid for everyone
- patient
- health professional
- manufacturer
- authorities


ADR reports
Ukrain
SEC
MoH Ukraine
Regional divisions
Health Care Administrations
Data collection, report - form № 69-healthy
Health care settings
Data collection, report - form № 69-healthy
Physician
Form 137/o, primary documentation
(case histories, hospital records)


the UPPSALA MONITORING CENTRE
report handling
search and statistics
tools
exit
new report
send report
list reports
home
contacts
give feedback
user guide
0. report info
1. patient
2. tests and procedures
3. relevant medical history
4. relevant past drug therapy
5. reactions
6. drugs
7. assessment
8. overview
9. save
A. print report
no ID - no header
Patient characteristics
Warning
Patient birth year, onset age or age group must be entered.
date of birth
(dd mm ccyy)
age at time of onset
patient initials
body weight (kg)
sex
male
female
clear
unknown
expand
Death related information
death date
(dd mm ccyy)
death cause
code
search term
was an autopsy performed
yes
no
clear
unknown
comments
Verify content
Move to next section
version 4.0
check entries
next

VigiFlow Countries

2010-11-18



Drug bans revoked…

- Phenylpropanolamine
- Human Placental extract

DATA ON INDIAN POPULATION ?

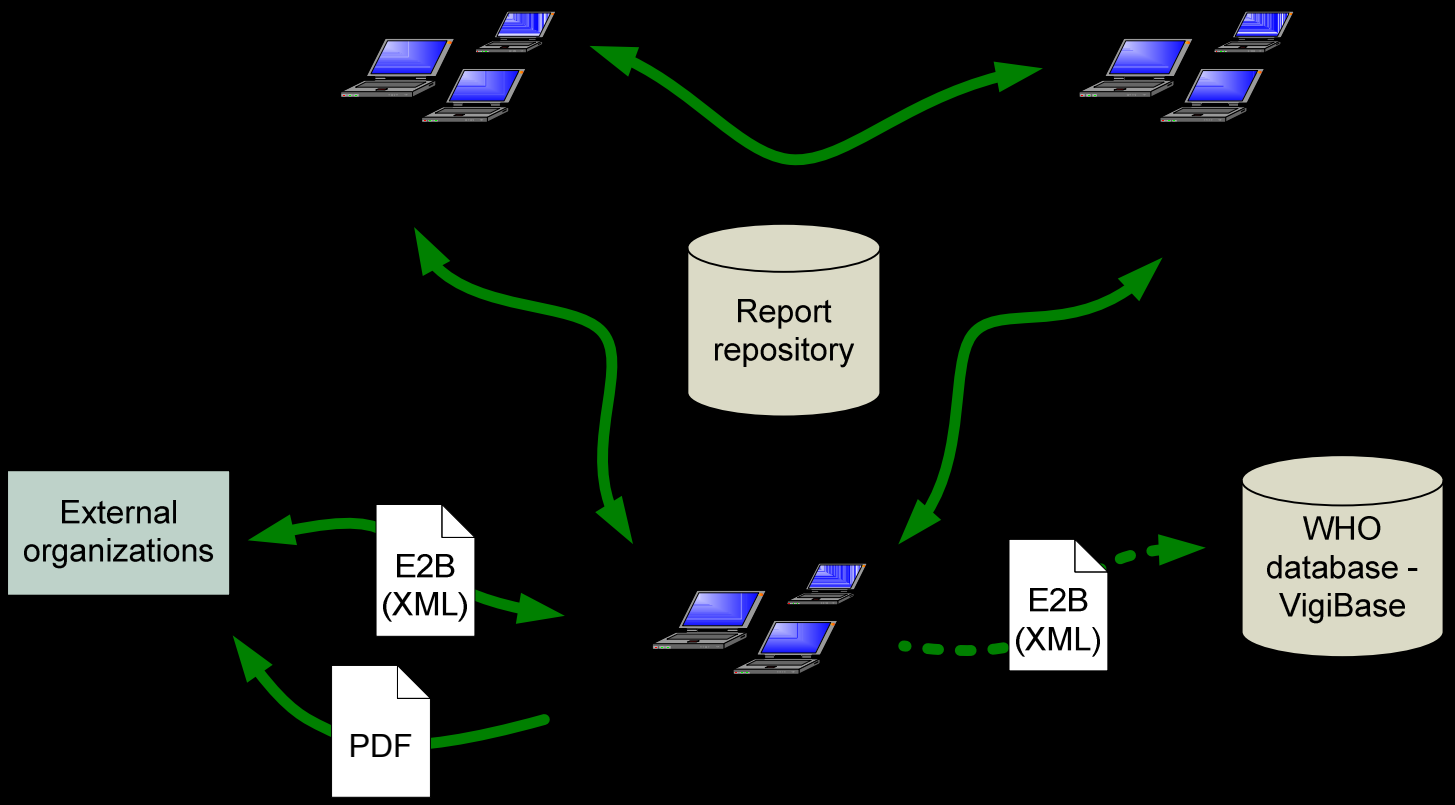
Classification

- Onset of event:
  - Acute
    - within 60 minutes
  - Sub-acute
    - 1 to 24 hours
  - Latent
    - > 2 days

Classification - Severity

- Severity of reaction:
  - Mild
    - bothersome but requires no change in therapy
  - Moderate
    - requires change in therapy, additional treatment, hospitalization
  - Severe
    - disabling or life-threatening

Flow of reports in VigiFlow



GOVERNANCE STRUCTURE - PVPI

Steering Committee

Strategic Advisory Committee

- Signal Review Panel
- Core Training Panel
- Quality Review Panel

MINISTRY OF HEALTH & FAMILY WELFARE (MOHFW)

Central Drugs Standards Control Organisation (CDSCO)

Pharmacovigilance Programme of India (PVPI) –

National Coordinating Centre (NCC)

Indian Pharmacopoeia Commission, Ghaziabad

M	O	NC	IE	ATN	DOT	RRR	IE	NS	G

SIGNAL:

New Safety Information

- A new Signal
  - Unidentified
  - Unlabelled
- New information from an existing signal
  - Change in frequency
  - Change in severity
- Information on risk factors

Sources of Signals

- Premarketing Trials Database
- Spontaneous Reports of ADRs
  - Individual company database
  - AERS database
  - WHO-UMC
  - EMEA
  - National & Regional RA database
- Published Literature
- Epidemiology/Registries
- Automated Databases
  - GPRD
  - IMS
  - Medicaid
  - Kaiser Permanante
- Others
  - PEM
  - MEMO

Principles

Pharmacovigilance


Viagra blindness alert
Britons 'lost sight after taking impotence drug'
Revealed: the danger of taking Prozac
Drug maker knew 20 years ago of possible link to suicide
Newsweek
Ritalin
Are We Overmedicating Our Kids?
12 BUSINESS
300 mi
BAD MEDICINE
Washington Times
FINAL
FRIDAY, OCTOBER 1, 2004
25 cents
Merck recalls Vioxx
Heart risk found in arthritis drug
PAINFUL
Merck's stock plunged after the pharmaceutical company said it was taking its arthritis drug Vioxx off the market.
Suicides blamed on acne drug



VIOXX®

STROKE ~ HEART ATTACK ~ DEATH
BLOOD CLOTS ~ PULMONARY EMBOLISM

Merck Pharmaceutical has recalled the popular pain and arthritis medication Vioxx® (rofecoxib) from the market after studies revealed that it may increase the risk of blood clots, stroke, heart attack and death. According to acting FDA commissioner Dr. Lester M. Crawford, "Overall, patients taking the drug chronically face twice the risk of heart attack compared to patients receiving a placebo."

YOU MAY BE ENTITLED TO MONEY DAMAGES

If you or a loved one have suffered a stroke, heart attack or deat
call attorney James Rolshouse toll free at 888-VIOXX-87 (

James Rolshouse & Associates
Personal Injury Attorney

visit us online at

TOLL FREE 888







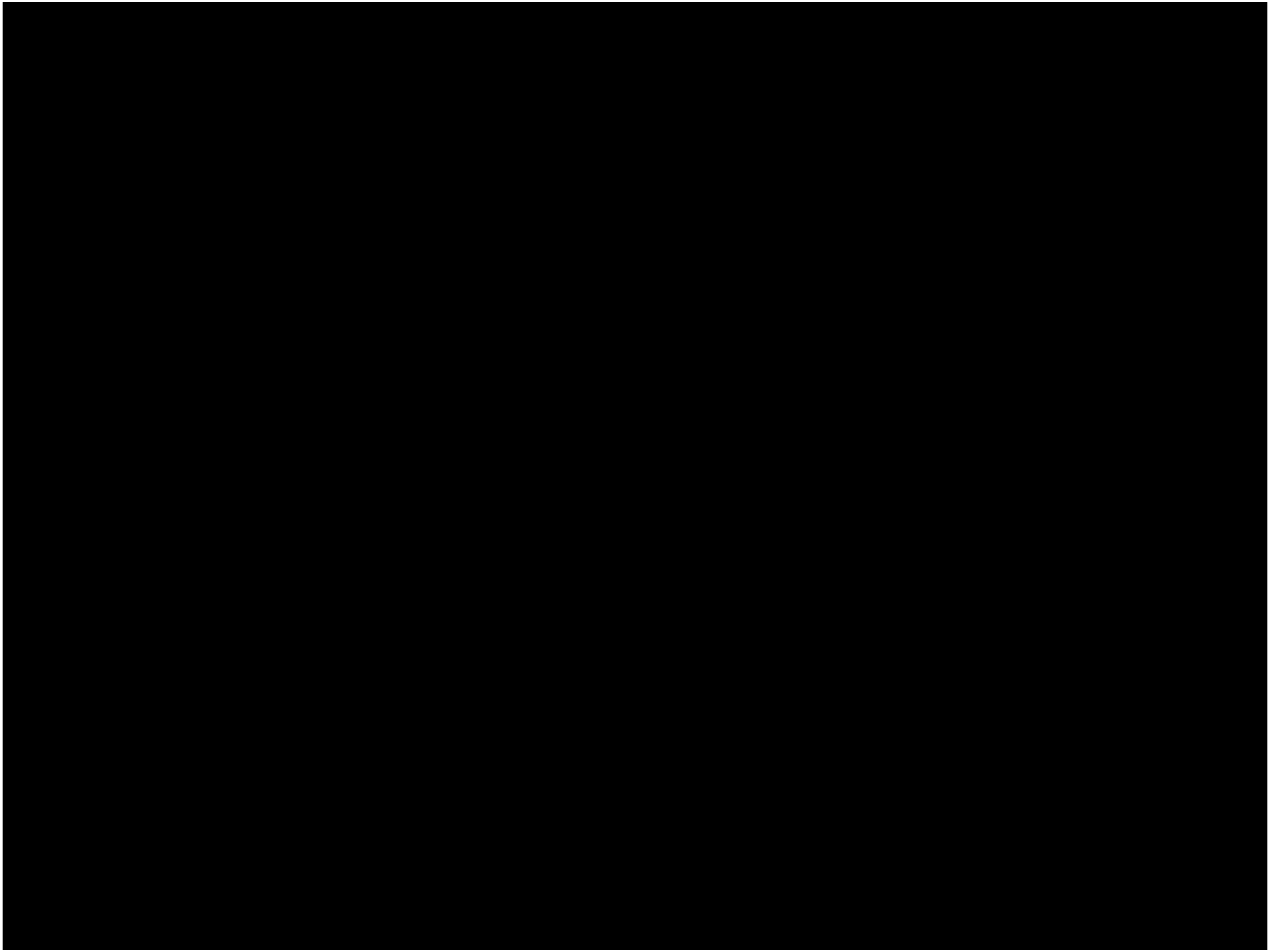
Remicade (Infliximab)
Side Effects Lawsuits

Tuberculosis, Multiple Sclerosis, Lupus, and Serious Infections

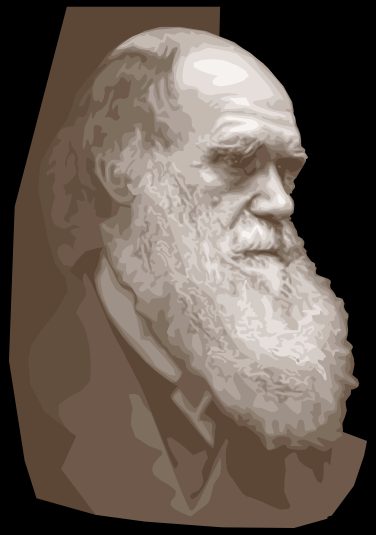
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1-800-856-6405
Nationwide Free Consultations





Risk Management - Conclusion
Embracing Change



WHO-UMC Causality Categories

Certain

Event or laboratory test abnormality, with plausible time relationship todrug intake

- Cannot be explained by disease or other drugs
- Response to withdrawal plausible (pharmacologically, pathologically)
- Event definitive pharmacologically or phenomenologically (i.e. an objective and specific medical disorder or a recognised pharmacologicalphenomenon)
- Rechallenge satisfactory, if necessary

Probable /Likely

Event or laboratory test abnormality, with reasonable time relationship todrug intake

- Unlikely to be attributed to disease or other drugs
- Response to withdrawal clinically reasonable
- Rechallenge not required

Possible

- Event or laboratory test abnormality, with reasonable time relationship todrug intake
- Could also be explained by disease or other drugs
- Information on drug withdrawal may be lacking or unclear

Unlikely

- Event or laboratory test abnormality, with a time to drug intake that makes a relationship improbable (but not impossible)
- Disease or other drugs provide plausible explanations

Conditional /Unclassified

- Event or laboratory test abnormality
- More data for proper assessment needed, or
- Additional data under examination

Unassessable/Unclassifiable

Report suggesting an adverse reaction

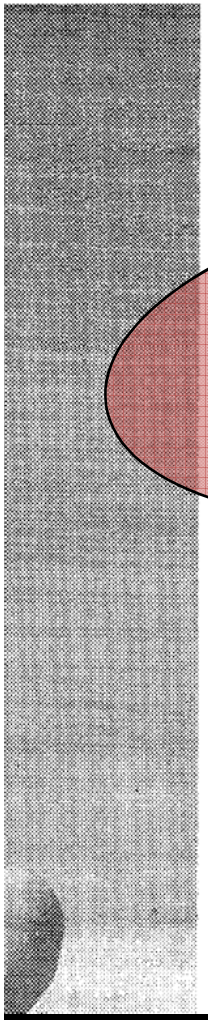
- Cannot be judged because information is insufficient or contradictory
- Data cannot be supplemented or verified

* All points should be reasonably complied with

...liers Scottish
engineering
...rks & Spencer

...mation after
...ng, Downing

...The ombudsman ruled that such blanket secrecy was unacceptable, saying information should be released unless there was a good reason not to. She criticised officials for frustrating her investigation.



Drug safety body accused of cover-up

disaster!!

Sarah Boseley

The chief executive of the mental health charity Mind resigned last week from a high-profile review of modern antidepressant drugs, accusing the British medicines regulatory body of negligence.

Richard Brook had a unique position as a lay member of the expert working group on the class of antidepressants that includes Seroxat and Prozac.

His resignation came in protest at what he considered a cover-up by the regulators, after months of pressure on him not to reveal the review's findings that Seroxat has for years been prescribed by doctors in an un-

ALLEGATION:

Known about SSRI prescribing at unsafe doses for a decade

Guardian Weekly

March 18-24 2004

• To be continued

Artesunate Amodiaquine - A killer drug or curer?

• The personal experience of a patient

By John Nketia

MALARIA is a dangerous disease. It accounts for about 44 per cent of all deaths in Africa.

The inconveniences inflicted by malaria on its victims include but not limited to loss of appetite, headache, fever, general body pains, among others.

When malaria strikes, it sends its victims running helter-skelter, seeking refuge in traditional, as well as orthodox, medicine. People have resorted to all sorts of drugs and herbs to cure themselves of this ailment.

In Ghana, we have, at one time or the other, administered Camoquine, Nevaquine, Artesunate, Chloroquine or Halfan to malaria patients.

Each of these malaria drugs has its own known side effects. The thrust of this article is, however, to discuss the debilitating side effects of Artesunate Amodiaquine — a new malaria drug recently introduced on the Ghanaian market.

I am not a medical doctor and I do not pretend to be one. However, as a patient, I wish to highlight my personal experience with Artesunate-Amodiaquine after a brief encounter with malaria.

I had malaria on Friday, October 20, 2006. I was given a packet of tablets containing two sets of drugs called Artesunate-Amodiaquine. Each set had three tablets.

I was asked to take one of each set at regular intervals for three consecutive days, namely, Friday, Saturday and Sunday. I dutifully took the drugs as prescribed.

The side effects were, however, quite devastating. I experienced dizziness, nausea, general body pains and a low blood pressure recorded as 80/40.

I immediately became an emergency case, leading to my detention in a private clinic for three hours. I was resuscitated through intensive care and three drips of glucose.

After that traumatic experience, I went back to the hospital to do a malaria test. I tested positive and was given Halfan. So the questions that arise are:

- What is the therapeutic efficacy of Artesunate-Amodiaquine?
- Is it a curing or a killing drug?
- What is the safety profile of the drug?
- Should such a drug be administered in Ghana in the light of the danger it poses?
- Should the drug enjoy the wide media coverage it currently enjoys?
- Should it be withdrawn?

From my personal experience, I think the efficacy of Artesunate-Amodiaquine is in serious doubt. How else can a drug meant to cure us of malaria incapacitate its user and leave the malaria parasites to enjoy a field day? In other words, the drug seems to brutalise its user and allow the malaria parasites more room to operate and break down the resistance of the patient.

A thorough scientific analysis ought to be carried out on the drug to determine its true therapeutic and curative efficacy. We do not have to wait for lives to be lost before we start thinking about what to do.

After narrating my horrifying experience to some colleagues and friends, I was informed that many more patients had suffered one side effect or the other from the use of the drug. I personally know the cases of three patients who suffered similar side effects as I did.

Be that as it may, the Ministry of Health, the Ghana Standards Board and the Food and Drugs Board owe the public the duty to ensure that safe and efficacious drugs are put on the market for consumption. This calls for a critical look at the drug to ascertain whether it is a curing or a killing drug.

I am reliably informed that Artesunate-Amodiaquine was brought to Ghana on the recommendation of the World Health Organisation (WHO). If that is the case, are we supposed to apply the prescriptions of the WHO slavishly without regard to the peculiar socio-cultural and bio-demographic characteristics of the Ghanaian?

I also learnt that Artesunate-Amodiaquine is the official drug for the treament of malaria under the National Health Insurance Scheme (NHIS). With all due respect, the Ministry of Health should consider a review of the use of the drug before it kills Ghanaians.

In any case, is the Ministry of Health satisfied with the safety profile of the drug? My research has revealed that doctors know the safety profile of Artesunate and Camoquine as separate drugs but the safety profile of a drug which is a combination of Artesunate and Camoquine is yet to be confirmed.

I am not aware wether Artesunate-Amodiaquine has been tested on a pilot basis and its safety profile determined.

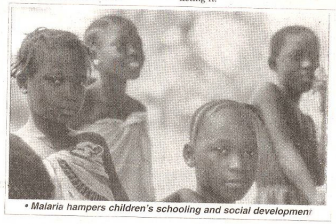
I suggest that the drug should first be tested on rabbits or monkeys before being administered on humans.

It may not be surprising that some of us were used as the guinea pigs. We are even told that camoquine is a banned drug in Europe and the Americas.

If that is true, why should it be used in Ghana? Is our country the dumping ground for banned drugs and substances?

Given the effect it has on innocent patients, it is surprising that Artesunate-Amodiaquine is still in circulation in Ghana. It ought to have been withdrawn by now.

A wide media campaign was recently launched to popularise the use of the drug. For those of us who have suffered severe side effects from the use of the drug, we firmly believe that once bitten, twice shy.



• Malaria hampers children's schooling and social development

No amount of persuasion will convince me to take the drug the second time. I would prefer using herbal medicine if Artesunate-Amodiaquine is the only drug for the treatment of malaria.

The media hype and publicity the drug enjoys is unwarranted. I think we need to place a temporary ban on the use of the drug until all the necessary scientific research and background checks are done.

We must satisfy ourselves as to its efficacy, safety profile and correct usage and dosage before unleashing it on the poor Ghanaian malaria patient. Above all, we need to test the drug on guinea pigs before marketing it.

New Malaria drug backfires

Contd. from Pg. 1

prescription for Artesunate Amodiaquine, I was afraid to take both due to the complaint of some of my colleagues, so I took only the Amodiaquine and I was Okay".

One case that has received some prominence is that of John Nketia, a patient whose personal experience was published on page 9 of the Saturday December 10, 2005 edition of the Daily Graphic. The article raised a number of questions bothering on the efficacy and suitability of the drug.

According to the article, he was given Artesuante-Amodiaquine after catching malaria on Friday October 20, 2005, and then his woes started. John described the side effects of the drug as devastating after observing the procedure for its administration.

"I dutifully took the drugs as prescribed. The side effects were, however, quite devastating. I experienced dizziness, nausea, general body pains and a low blood pressure recorded as 80/40", he stated.

"I immediately became an emergency case, leading to my detention in a private clinic for three hours. I was resuscitated through intensive care and three drips of glucose. After that traumatic experience, I went back to the hospital to do a malaria test. I tested positive and was given Halfan", he further recounted.

The Deputy Nursing Officer of the Accra Psychiatric, David Maculey told Public Agenda that there is need for a proper research and investigations into the new drug and its effects on the body before."

Meanwhile officials of the Food and Drugs Board and the Malaria Control Board were not forthcoming when Public Agenda contacted them for comments on the drug. Several calls at the offices were met with 'we are busy, the person to speak to you is not available, come tomorrow' etc.

Further investigations with some drug companies revealed that there are three major importers of the drug, namely, KAMA Health Services, Ernest Chemist Ltd and Kinapharma Company Limited. An official at the KAMA Health services who refused to go on record hinted that the drug is a generic drug and is manufactured and marketed by several companies. He declined to comment on the basis that he is not sure which particular brand is causing the problem. At the Ernest Chemist wholesale division, the security man simply refused our reporters entry after hearing they were journalists seeking information on the drug.

However, adverts continue to run on our television and radios, extolling the good side of the rather deadly Artesuante Amodiaqine The question is will the drug be withdrawn or be allowed to kill many more people since, importers invested billions of cedis to import it.



NEWS

Secret report reveals 18 child deaths following vaccinations



THE TIMES

£1.50

The Beatles Miscellany

By Ben Schott 4-page special Pages 10-13

Free inside

Get the children off the couch

Plus

50 best places to eat outside

Travel

High-tech holidays - where to go and how to get there

Alert over counterfeit high street medicines



24 REGIONAL NEWS

Pregnant women urged to avoid self-medication

Story: Victor Kwesekumu, Kpetoe

THE Executive Director of the Strength of Women Foundation, Madam Margaret Chiriboruo, has advised pregnant women to desist from self-medication and resort to hospitals and health centres for professional medical attention when sick.

"When you have any health problem during your pregnancy, don't just sit at home, assume what is wrong and self-medicate because it can be very dangerous," she stressed.

Madam Chiriboruo gave the advice when she addressed over 100 pregnant and nursing women, as part of a malaria intervention programme at Kpetoe in the Adaklu-Anyogbe District of the Volta Region.

The programme was organised by the Strength of Women Foundation, based in Ho.

She observed that malaria in pregnancy was very dangerous and could lead to the death of pregnant women, as well as babies adding that it was, therefore, very important that when a pregnant woman fell sick, she sought professional medical attention at a health centre.

"Malaria in pregnancy could lead to anaemia, jaundice and other complications which can ultimately lead to the death of the pregnant woman and the unborn baby," she emphasised.

She said that it was the target of the programme that all pregnant women in the Adaklu-Anyogbe District would be protected against malaria, and that it was their vision also that in the near future all children in the area would be sleeping under insecticide treated nets.

Madam Chiriboruo urged the women to attend antenatal clinics at least three times before delivery as a preventive measure against malaria.

The Principal Nursing Officer for the Adaklu-Anyogbe District, Madam Patience Nunoo, noted that malaria was the leading ailment in the district and that as at mid-year 2000, 4,125 cases had been recorded, representing 65.5 per cent of all out-patient cases.

She said from June to December last year, 5,867 cases of malaria in pregnancy were recorded, adding that the situation called for effective measures as a means of reducing cases of malaria in pregnancy in the district.

Under the Malaria Control Programme, she said that IPTs were being distributed to pregnant women and children under

• Continued on Page 2



STOP SALE

Story: Edmund Kofi Yeboah

• Ministry orders withdrawal of two brands of new malarial drugs

THE Ministry of Health has directed the withdrawal of two brands of the new malarial drug, Artesunate-Amodiaquine, from the market.

The brands in question are the 600mg Amodiaquine and the 200mg Artesunate, which are taken as a combination.

All health facilities have, consequently been instructed to stop the prescription of the two drugs, while the public have also been advised not to patronise or use them.

The decision was taken at a meeting of the health ministry and its partners last Thursday, in response to the numerous complaints by some members of the public about the side effects of the drugs.

Malaria is the number one killer disease in many African countries including Ghana, and statistics show that the disease constitutes about 40 per cent of all reported cases at health facilities in the country.

Artesunate-Amodiaquine was introduced on January 2005, to replace chloroquine as the first line of malaria treatment in the

• Continued on Page 2

Naranjo ADR Probability Scale

Naranjo CA. Clin Pharmacol Ther 1981;30:239-45

To assess the adverse drug reaction, please answer the following questionnaire and give the pertinent score.

		Yes	No	Do Not Know	Score
A1.	Are there previous *conclusive* reports on this reaction?	+1	0	0	____
2.	Did the adverse event appear after the suspected drug was administered?	+2	-1	0	____
3.	Did the adverse reaction improve when the drug was discontinued or a *specific* antagonist was administered?	+1	0	0	____
4.	Did the adverse reactions appear when the drug was readministered?	+2	-1	0	____
5.	Are there alternative causes (other than the drug) that could on their own have caused the reaction?	-1	+2	0	____
6.	Did the reaction reappear when a placebo was given?	-1	+1	0	____
7.	Was the drug detected in the blood (or other fluids) in concentrations known to be toxic?	+1	0	0	____
8.	Was the reaction more severe when the dose was increased, or less severe when the dose was decreased?	+1	0	0	____
9.	Did the patient have a similar reaction to the same or similar drugs in *any* previous exposure?	+1	0	0	____
10.	Was the adverse event confirmed by any objective evidence?	+1	0	0	____
				Total Score	____

Total Score	*ADR Probability Classification*
9	Highly Probable
5-8	Probable
1-4	Possible
0	Doubtful

Risk Management and Planning



RM Planning in Industry - Critical Success Factors

- Safety governance – support from the top
- Comprehensive change management plan
- Defined process and roles/responsib
- Tools and skills to support the proces
- Partnership, education and training
- Early planning in development
- Financial planning




Patient with drug-induced
toxic epidermal necrolysis

ADR Reporting -Training Session-3
District Hospitals



+





Why pharmacovigilance? Factors influencing change

- Toxicity (adverse drug reactions)
- Lack of patient adherence

Adverse Event reporting Form

ADVICE ABOUT REPORTING

- **Report adverse experiences with medications**
- **Report serious adverse reactions. A reaction is serious when the patient outcome is:**
  - death
  - life-threatening (real risk of dying)
  - hospitalization (initial or prolonged)
  - disability (significant, persistent or permanent
  - congenital anomaly
  - required intervention to prevent permanent impairment or damage
- **Report even if:**
  - You're not certain the product caused adverse reaction
  - you don't have all the details, however, point nos. **1, 5, 7, 8, 11, 15, 16 & 18** (see reverse) are essentially required.
- **Who can report:**
  - Any health care professional (Doctors including Dentists, Nurses and Pharmacists)
- **Where to report:**
  - Please return the completed form to the nearest ***Adverse drug reaction Monitoring Centre (AMC)*** or to ***National Coordinating Centre***
  - A list of nationwide AMCs is available at: http://cdsco.nic.in/pharmacovigilance.htm
- **What happens to the submitted information:**
  - Information provided in this form is handled in strict confidence. The causality assessment is carried out at Adverse Drug Reaction Monitoring Centres (AMCs) by using WHO-UMC scale. The analyzed forms are forwarded to the National Coordinating Centre through the ADR database. Finally the data is analyzed and forwarded to the Global Pharmacovigilance Database managed by WHO Uppsala Monitoring Center in Sweden.
  - The reports are periodically reviewed by the National Coordinating Centre (PvPI). The information generated on the basis of these reports helps in continuous assessment of the benefit-risk ratio of medicines.
  - The information is submitted to the Steering Committee of PvPI constituted by the Ministry of Health and Family Welfare. The Committee is entrusted with the responsibility to review the data and suggest any interventions that may be required.

Suspected Adverse Drug Reaction Reporting Form

For VOLUNTARY reporting of suspected adverse drug reactions by health care professionals

Central Drugs Standard Control Organization
Directorate General of Health Services,
Ministry of Health & Family Welfare, Government of India,
FDA Bhawan, ITO, Kotla Road, New Delhi -110002
www.cdsco.nic.in

Pharmacovigilance Programme of India for *Assuring Drug Safety*

Pharmacovigilance Programme of India (PvPI)
National Coordinating Centre,
Department of Pharmacology,
All India Institute of Medical Sciences
Ansari Nagar, New Delhi – 110029
Phone no: 011-26593282, 26588422
Fax no: 011- 11-26588663, 26588641
Email: pvpi.ncc@gmail.com

Confidentiality: The patient's identity is held in strict confidence and protected to the fullest extent. Programme staff is not expected to and will not disclose the reporter's identity in response to a request from the public. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction.

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

For VOLUNTARY reporting of Adverse Drug Reactions by healthcare professionals

CDSCO
Central Drugs Standard Control Organization
Directorate General of Health Services,
Ministry of Health & Family Welfare, Government of India,
FDA Bhawan, ITO, Kotla Road, New Delhi -110002
www.cdsco.nic.in

AMC/ NCC Use only
AMC Report no.
Worldwide Unique no.

A. Patient information

1. Patient initials
2. Age at time of event or date of birth
3. Sex: ☐ M ☐ F
4. Weight: _____Kgs

B. Suspected Adverse Reaction

5. Date of reaction started (dd/mm/yy):
6. Date of recovery (dd/mm/yy):
7. Describe reaction or problem

12. Relevant tests/ laboratory data with dates

13. Other relevant history, including pre-existing medical conditions (e.g., allergies, race, pregnancy, smoking, alcohol use, hepatic/ renal dysfunction, etc.):

14. Seriousness of the reaction
☐ Death (dd/mm/yy)_____ ☐ Congenital anomaly
☐ Life threatening ☐ Required intervention to prevent permanent impairment/ damage
☐ Hospitalization-initial or prolonged
☐ Disability
☐ Other (specify)_____

15. Outcomes
☐ Fatal ☐ Recovering ☐ Unknown
☐ Continuing ☐ Recovered ☐ Other (specify)_____

C. Suspected medication(s)

Sl. No.	8. Name (brand and / or generic name)	Manufacturer (if known)	Batch No. / Lot No. (if known)	Exp. Date (if known)	Dose used	Route used	Frequency	Therapy dates (if unknown, give duration)		Reason for Use or prescribed for
								Date started	Date stopped	
i										
ii										
iii										
iv										

Sl. No. As per C	9. Reaction abated after drug stopped or dose reduced					10. Reaction reappeared after reintroduction				
	Yes	No	Unknown	NA	Reduced dose	Yes	No	Unknown	NA	If reintroduced, dose
i										
ii										
iii										
iv										

11. Concomitant medical products including self medication and herbal remedies with therapy dates (exclude those used to treat reaction)

D. Reporter (see confidentiality section in first page)

16. Name and Professional Address: _____

Pin code: _____ E-mail: _____
Tel. No. (with STD Code): _____
Occupation: _____ Signature:

17. Causality Assessment:

18. Date of this report (dd/mm/yy):