UKM MEDICAL CENTRE

Pharmacy Bulletin

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PHARMACOVIGILENCE: The value of reporting

by Ms Michelle Tan

Before a drug is marketed, drug safety and efficacy data are limited to experiences in clinical trials. Certain adverse reactions may not be detected until a larger population is exposed during postmarketing use.

Your reports = ↑Pharmacovigilence in Malaysia

Adverse Drug Reactions are always under reported. It accounts for approximately 10% of hospital admissions and 15-20% of hospital budget could have been saved by tackling the various drug complications. In this article I would like to promote and improve the quality of ADR reporting in PPUKM.

Please report : *ADRs from new or old drugs, ADRs for generics not seen with innovator products, ADRs for traditional medicines, suspected drug-drug, drug-food, drug-food supplement interactions, ADRs associated with drug withdrawals, ADRs due to medication errors, ADRs due to lack of efficacy or suspected pharmaceutical defects.*

In reality, when a patient encounters an adverse reaction or dissatisfaction with a product, he should inform his doctor/pharmacist so they may report it to the Drug Control Authority (DCA). Therefore proper action can be taken.

LOCAL CASE REPORTS

Drug	Indications	ADR Reports	Review	Actions Taken
Kisan Injection (Vitamin K1)	For hypoprothrombinaemia, treatment & prophylaxis of haemorrhage in newborns/ antidote to coumarin anticoagulants	Oct 2007—Feb 2008: 3 reports of anaphylaxis	Cremophor EL (polyethoxylated castor oil) which is used as stabiliser was associated with severe anaphylactic reactions	**Product holder requested to state in package Insert: IV route should be reserved for situations where other routes are not feasible.Very slow IV injection may be given at < 1mg/min**
Cardiamed Injection (Noradreline)	For treatment of shock which persist after adequate fluid volume replacement	Nov 2007—Feb 2008 : 7 reports of gangrene and peripheral cyanosis		**Product holder did a voluntary recall on the 3 batches involved**
Gamat Products	Traditional Supplement for General health	Mar 2007—July 2008: 22 reports of renal failure	Suspected products: Traditional product registered with DCA, Traditional product with expired registration, Food product, Products not registered as food/ medicinal products	**All reports reviewed with nephrologists. Lab test showed products were free from adulteration. Raw material, manufacturing site and process investigated. DCA suspended a few of the implicated gamat products. Currently NPCB working with IMR to conduct toxicology study on gamat.**
Goji Yumberry	Mens' health	Patient developed numbness and cramped legs after 3 days of consumption	Sample sent for lab testing. Found adulterated with thiodimethylsildenafil, analogue for sildenafil.	**Unregistered product– forwarded to Enforcement for further action**

Role of Healthcare Professionals:

- Detect ADR from patients history
- Educate patients on possibilities of ADR
- Advise patients to inform healthcare professionals if they suspect/experience ADR
- Interview patients to obtain accurate and complete information about incident.
- If you feel ADR is related to drug/product : **REPORT TO MADRAC !** (MALAYSIAN ADVERSE DRUG REACTION ADVISORY COMMITTEE)

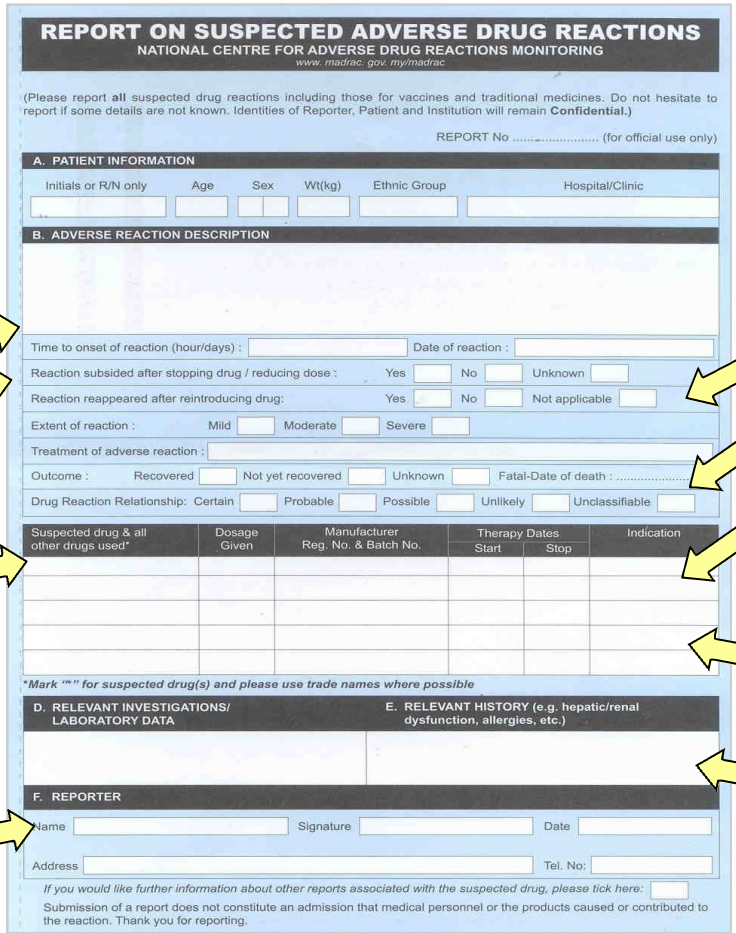
Ensure Traceability in case they call back:

Time of reaction on-set **from time of drug administration.**

Rechallenge

injection form, pls state rate of infusion, given IV/IM/SC, duration of injection. If dose planned for tds but actually patient only given once?

Contactable handphone and email address for BPFK to contact for further details or for re verting their replies after investigation.



REPORT ON SUSPECTED ADVERSE DRUG REACTIONS
NATIONAL CENTRE FOR ADVERSE DRUG REACTIONS MONITORING
www. madrac. gov. my/madrac

(Please report **all** suspected drug reactions including those for vaccines and traditional medicines. Do not hesitate to report if some details are not known. Identities of Reporter, Patient and Institution will remain **Confidential.**)

REPORT No ..... (for official use only)

A. PATIENT INFORMATION

Initials or R/N only | Age | Sex | Wt(kg) | Ethnic Group | Hospital/Clinic

B. ADVERSE REACTION DESCRIPTION

Time to onset of reaction (hour/days) : Date of reaction :
Reaction subsided after stopping drug / reducing dose : Yes No Unknown
Reaction reappeared after reintroducing drug: Yes No Not applicable
Extent of reaction : Mild Moderate Severe
Treatment of adverse reaction :
Outcome : Recovered Not yet recovered Unknown Fatal-Date of death : .....
Drug Reaction Relationship: Certain Probable Possible Unlikely Unclassifiable

Suspected drug & all other drugs used*	Dosage Given	Manufacturer Reg. No. & Batch No.	Therapy Dates Start	Therapy Dates Stop	Indication

Mark '" for suspected drug(s) and please use trade names where possible*

D. RELEVANT INVESTIGATIONS/ LABORATORY DATA | **E. RELEVANT HISTORY (e.g. hepatic/renal dysfunction, allergies, etc.)**

F. REPORTER

Name Signature Date
Address Tel. No:

If you would like further information about other reports associated with the suspected drug, please tick here:
Submission of a report does not constitute an admission that medical personnel or the products caused or contributed to the reaction. Thank you for reporting.

Dechallenge

Use the Naranjo's ADR Probability Scale (Can be obtained from google)

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Write 'No concomitant drug' or specify concomitant drugs. Do not leave blank.

No known drug allergies, smoker, underlying disease, history allergy to...,

Important questions to ask:

Oral antihistamine/paracetamol: colouring agent, flavouring agent if ADR related to allergic reaction
Allopurinol: Indication: symptomatic or asymptomatic hyperuricaemia
Antineoplastic : concomitant drugs
Serious skin reaction : diagnosed by?
Vancomycin: rate of infusion
Statin related to skin reaction: related to photosensitivity?

SLOW MOVING & SHORT EXPIRY ITEMS

Dear Professors/Dato'/Datin/Specialists/Doctors;
The following items are slow moving and will be expiring soon. Kindly prescribe these items for indicated patients under your care. Thank

- **Aprepitant Cap 80mg (2's) + 125mg (1's) Tripack**
- EXP : 06/2011
- Non-formulary (RM245/per tripack), 22 boxes
- Indication : In combination with other antiemetic agents for prevention of acute & delated nausea & vomiting associated with initial & repeated courses of highly emetogenic cancer chemotherapy including high dose cisplatin.

- **Ziprasidone 60 mg Cap (Zeldox)**
- EXP : 08/2011
- Non Formulary (RM5.60/cap)
- 1 box
- Management of schizophrenia & other psychotic disorders & for maintenance of clinical improvement.
- 40mg BD initially, max 80mg BD

- **Netilmicin 150mg Inj** • EXP : 05/2011

- **Cefaclor 187mg/5ml suspension,30ml** • 07/2011
- Category B (all doctors) • 4 bottles

- **Hyoscine butylbromide 1mg/ml syrup (Buscopan) , 100 ml**
- EXP : 10/2011 • category B (all doctors)
- 10 bottles • Dose > 6 years : 10 ml tds