# ANNUAL REPORT OF THE NATIONAL CENTRE FOR ADVERSE DRUG REACTION MONITORING, NPCB 2013

## 1. Membership of Malaysian Adverse Drug Reactions Advisory Committee (MADRAC) till the end of 2013

MADRAC Members (Alternate members)	
Mr Tan Ann Ling	Chairman
Director of Pharmacy Regulatory	
National Pharmaceutical Control Bureau	
Ms Sameerah Shaikh Abdul Rahman	Secretary
Deputy Director	
Centre for Post-Registration of Products	
National Pharmaceutical Control Bureau	
Ms Noorizam Ibrahim	Committee Member
Secretary of Drug Control Authority	
National Pharmaceutical Control Bureau	
Prof. Datuk Dr. Jeyaindran Tan Sri Sinnadurai, PJ	Committee Member
Deputy Director General of Health (Medical)	
Ministry of Health	
(Dr. Hjh Rosaida Mohd. Said)	
Datuk Dr Roshidah Baba	Committee Member
Head of Dermatology Services	
Head of Department and Senior Consultant Dermatologist,	
Hospital Melaka	
(Dr Rohna Ridzwan)	
Dr Lim Chong Hum	Committee Member
Head of Department and Senior Consultant Psychiatrist,	
Hospital Ampang	
(Dr Zanariah Mat Saher)	
Dr G.R. Letchuman Ramanathan	Committee Member
Head of Department and Senior Medical Consultant (Endocrinology),	
Hospital Taiping	
(Dr. Padmini Menon)	
Dato' Dr Gun Suk Chyn	Committee Member
Head of Department and Senior Medical Consultant (Rheumatology),	
Hospital Tuanku Ja'afar	
(Dr Muhaini Othman)	
Dato' Dr Tan Chwee Choon	Committee Member
Head of Department and Senior Medical Consultant (Nephrology),	
Hospital Tuanku Ampuan Rahimah	
(Dr Sunita Bavanandan)	
Assoc. Professor Datin Dr. Zoriah binti Aziz	Committee Member
Department of Pharmacy, Faculty of Medicine	
University of Malaya	
(Prof. Dr. Mohamed Mansor Manan)	

Dr. Rohani Jahis Head Of The Vaccine Prevention Of Disease/Food&Water Borne UD54 Disease Control Division (Dr. Jamiatul Aida Md. Sani)	Committee Member
Ms. Anis Talib Deputy Director Formulary and Pharmacoeconomic Section, Pharmaceutical Services Division (Ms. Azuwana Supian)	Committee Member
Ms. Wendy Khor Hooi Chin Malaysian Pharmaceutical Society (MPS) (Mr. Lam Kai Kun)	Committee Member
Ms. Eliza Basir Association of Private Hospitals of Malaysia (APHM) (Ms. Lee Seng Dee)	Committee Member
Dr. Koh Kar Chai Malaysian Medical Association (MMA) (Dr. Azizan Binti Abdul Aziz)	Committee Member
Dr. Steven Chow Federation of Private Medical Practitioners' Association Malaysia (FPMPAM) (Dr. G.Shanmuganathan)	Committee Member

### 2. MEETINGS

During the calendar year 2013, six (6) meetings were conducted with a total of 11368 adverse drug reactions reports were reviewed by the committee

### 3. ANALYSIS OF ADVERSE DRUG REACTIONS REPORTS

A detailed review and analysis of the adverse drug reactions (ADR) reports received during the year 2013 was conducted (Appendix 1).

# 4. Drug Safety Issues Discussed by MADRAC in 2013 and Resulting Risk Minimisation Actions

During the course of 2013, the following regulatory actions were proposed by MADRAC. These are the actions on certain pharmaceutical products following the Alerts received from other international regulatory agencies as well as data from local institutions.

MADRAC Meeting	Safety Issue Discussed	MADRAC Recommendation/ Resulting Actions			
Date		PI Update	DHPC	Publication of article	Further review
21/2/2013	Pradaxa® (dabigatran etexilate mesylate): New Contraindication For Pradaxa In Patients With Prosthetic Valves	~		<b>√</b>	
	Mabthera® (rituximab): Association with Toxic Epidermal Necrolysis (TEN) and Stevens-Johnson Syndrome (SJS)	✓		✓	
18/4/2013	Prolia <sup>®</sup> and Xgeva <sup>®</sup> (denosumab): Association With Risk of Anaphylactic Reactions and Atypical Femoral Fracture	✓		✓	
	Trimetazidine-containing Products: New Recommendations On The Restriction Of Use	✓			
	Miacalcic® (calcitonin salmon): European Medicines Agency (EMA) Suspends The Intranasal Formulations And Recommends New Restrictions For All Injectable Formulations				✓
	Non-Steroidal Anti-Inflammatory Drugs (NSAIDS): Association With Cardiovascular Risks				~
13/6/2013	Avastin® (bevacizumab): Association With Necrotising Fasciitis	✓			
	Champix® (varenicline): Association With Risks of Cardiovascular Adverse Events: A Review Update				✓
	Diane 35 <sup>®</sup> (cyproterone Acetate, ethinylestradiol): Suspension of Marketing Authorisation in France	<b>√</b>		<b>√</b>	
	Codeine-containing products: Adverse Drug Reactions Associated with Children (21 months-9 years) Undergoing Adenotonsillectomy and/or Tonsillectomy			✓	
22/8/2013	Trobalt® (retigabine): Restriction Of Indication Resulting From Observed Pigment Changes (Discolouration) of Ocular Tissue (Including Retina), Nails, Lips, and/or Skin	<b>~</b>	<b>√</b>		
	Votrient® (pazopanib)- Important Change in Frequency for Serum Liver Enzymes Monitoring	✓	✓		
	Mabthera® (rituximab): New Risk Management of Hepatitis B Reactivation in Patients Prior to Initiation of Therapy	✓	✓	✓	
	Paracetamol-containing products: Association with Serious Skin Adverse Drug Reactions				✓

MADRAC Meeting	Safety Issue Discussed	MADRAC Recommendation/ Resulting Actions			
Date		PI	DHPC	Publication	Further
		Update		of article	review
	Lovastatin-containing products: New				✓
	Restrictions To Reduce Muscle Injury				
22/8/2013	Hydroxyethyl Starch (HES)-containing	✓		✓	
&	products: Suspension of Marketing				
24/10/2013	Authorisation by European Medicines Agency				
	(EMA) Due To Increased Mortality And Risk				
0.4/4.0/0.4.0	Of Kidney Injury Requiring Dialysis				
24/10/2013	Erythropoetin Stimulating Agents: Adverse				✓
	Drug Reaction Reports Associated with Pure				
	Red Cell Aplasia (PRCA) Received by				
	National Pharmaceutical Control Bureau	,			
	Lariam® (mefloquine): Association with Visual Disturbance Including Optic Neuropathy	✓		✓	
	Oral Ketoconazole-containing products:	<b>√</b>	<b>√</b>	•/	
	Suspension of Marketing Authorisation by	Y	•	•	
	European Medicines Agency (EMA) Due To				
	Association with the Risk of Hepatotoxicity				
12/12/2013	Protaxos® (strontium ranelate): Association	✓	<b>√</b>	<b>√</b>	
12/12/2010	With Increased Risk Of Serious Heart	•	٧	•	
	Problems				
	Tygacil® (tygecycline): Association With			✓	
	Increased Risk of Death			•	
	Erythropoetin Stimulating Agents -Associated				✓
	Pure Red Cell Aplasia (PRCA) Adverse Drug				
	Reaction Reports in Malaysia: An Update				
	Following Contraindication of the				
	Subcutaneous Route for Eprex in Singapore				
	Xeloda® (capecitabine): Association with	✓	✓		
	Toxic Epidermal Necrolysis (TEN) and Steven				
	Johnson Syndrome (SJS)				
	Jevtana <sup>®</sup> (cabazitaxel): Potential For	✓	✓		
	Medication Error During Preparation				
	Frisium® (clobazam): Association with Toxic	✓	✓		
	Epidermal Necrolysis (TEN) and Steven				
	Johnson Syndrome (SJS)				

### 5. ACTIVITIES

During the year of 2013, we continue to enhance our ADR report rate and the quality of report received through various activities such as training and awareness programme.

### i) Training/short course/workshop

a) Training on ADR reports analysis and causality assessment

Pharmacists various hospital in Selangor, Malacca and Negeri Sembilan gathered in NPCB for this short training. This training is focusing on assessment of ADR reports, critical question that need to ask the prescriber and how to do a causality assessment based on criteria set by World Health Organization (WHO).

b) Kursus Amalan Farmasi kepada Ketua Pegawai Farmasi dan Pegawai Farmasi Kesihatan Awam

Chief Pharmacists and pharmacists from public health from all over Malaysia attended this short course held in Port Dickson, Negeri Sembilan. Adverse Drug Reactions reporting is one of the topics that had been discussed together with in group activity of ADR case study.

c) 1st National Conference on Quality Use of Medicines Conference

Quality Used of Medicine and Pharmacovigilance was one topic of the parallel programme in this conference. It focused more on the importance of pharmacovigilance in quality used of medicine.

#### ii) Awareness programme

- 1. Post Marketing Activities at the Generic Medicine Awareness Programme 8 programme
- 2. Pharmacovigilance, Adverse Drug Reaction, AEFI Handling and Reporting General Talk 11 programme
- 3. Consumer Awareness Programme 1 programme

### **APPENDIX 1**



















