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

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 Date	Safety Issue Discussed	MADRAC Recommendation/ Resulting Actions			
		PI Update	DHPC	Publication of article	Further review
21/2/2013	Pradaxa® (dabigatran etexilate mesylate): New Contraindication For Pradaxa In Patients With Prosthetic Valves	✓		✓	
	Mabthera® (rituximab): Association with Toxic Epidermal Necrolysis (TEN) and Stevens-Johnson Syndrome (SJS)	✓		✓	
18/4/2013	Prolia® and Xgeva® (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® (cyproterone Acetate, ethinylestradiol): Suspension of Marketing Authorisation in France	✓		✓	
	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	✓	✓		
	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 Date	Safety Issue Discussed	MADRAC Recommendation/ Resulting Actions			
		PI Update	DHPC	Publication of article	Further review
	Lovastatin-containing products: New Restrictions To Reduce Muscle Injury				✓
22/8/2013 & 24/10/2013	Hydroxyethyl Starch (HES)-containing products: Suspension of Marketing Authorisation by European Medicines Agency (EMA) Due To Increased Mortality And Risk 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: Suspension of Marketing Authorisation by European Medicines Agency (EMA) Due To Association with the Risk of Hepatotoxicity	✓	✓	✓	
12/12/2013	Protaxos® (strontium ranelate): Association With Increased Risk Of Serious Heart 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® (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

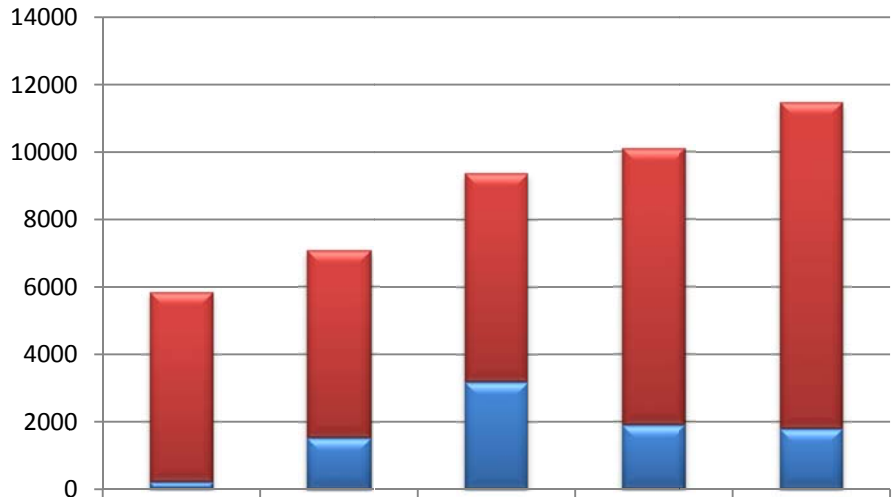
Quality Used of Medicine and Pharmacovigilance was one topic of the parallel programme in this conference. It focused more on the importance of pharmacovigilance in quality used of medicine.

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

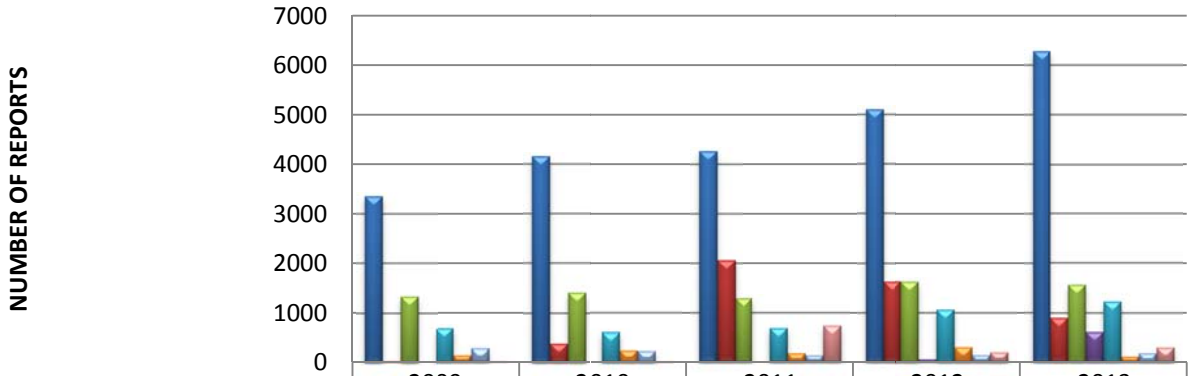
APPENDIX 1

ADR and AEFI Reports Received (2009-2013)

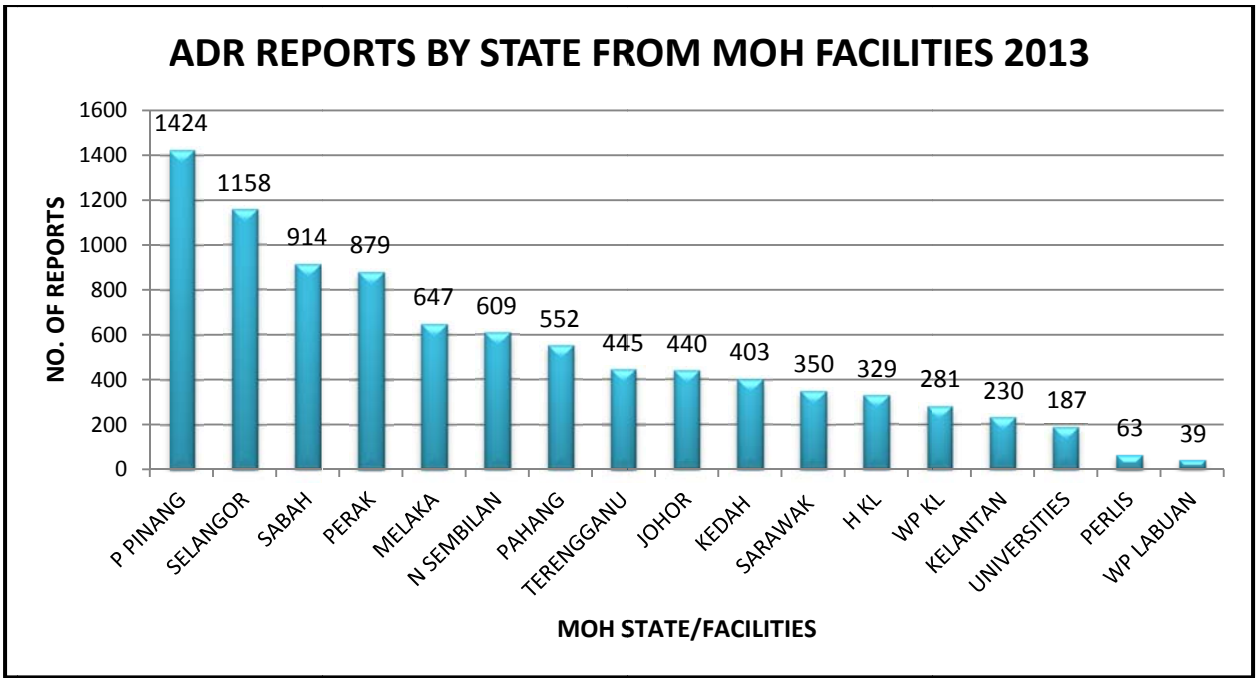


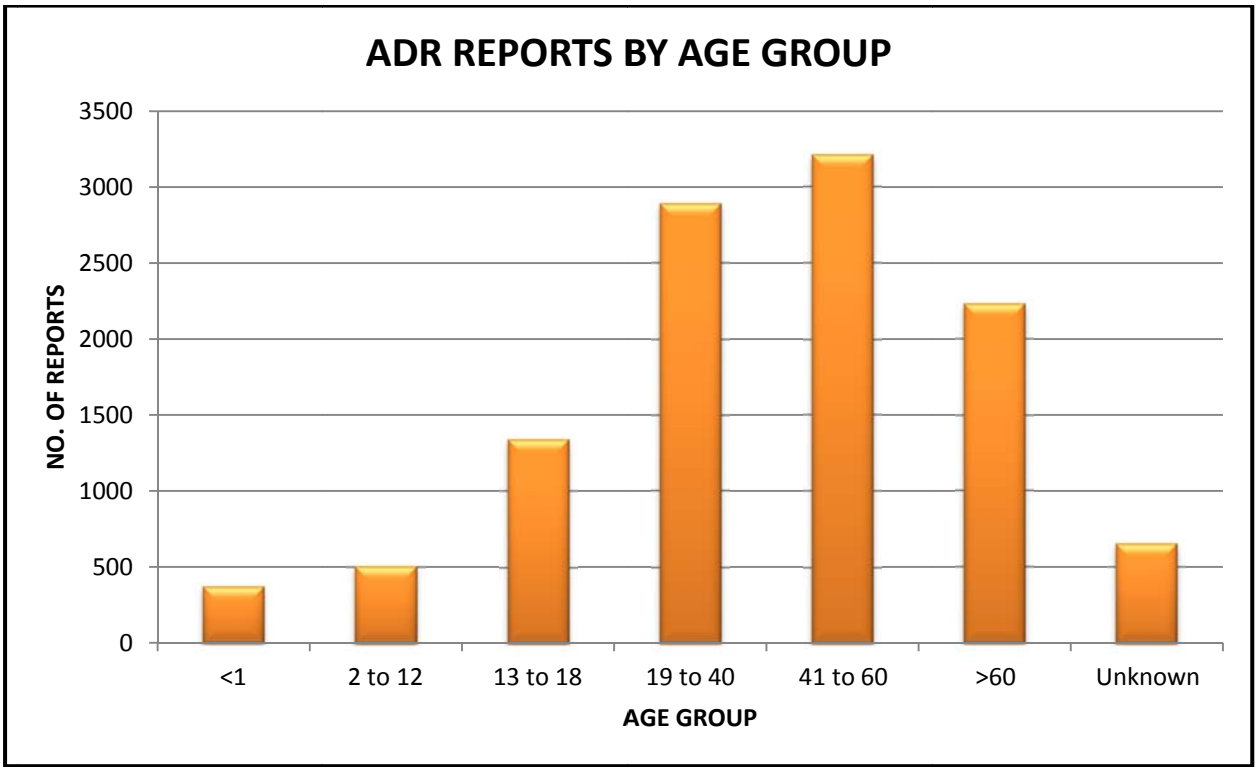
	2009	2010	2011	2012	2013
ADR Reports without AEFI	5636	5550	6202	8199	9678
AEFI Reports	214	1529	3183	1903	1795

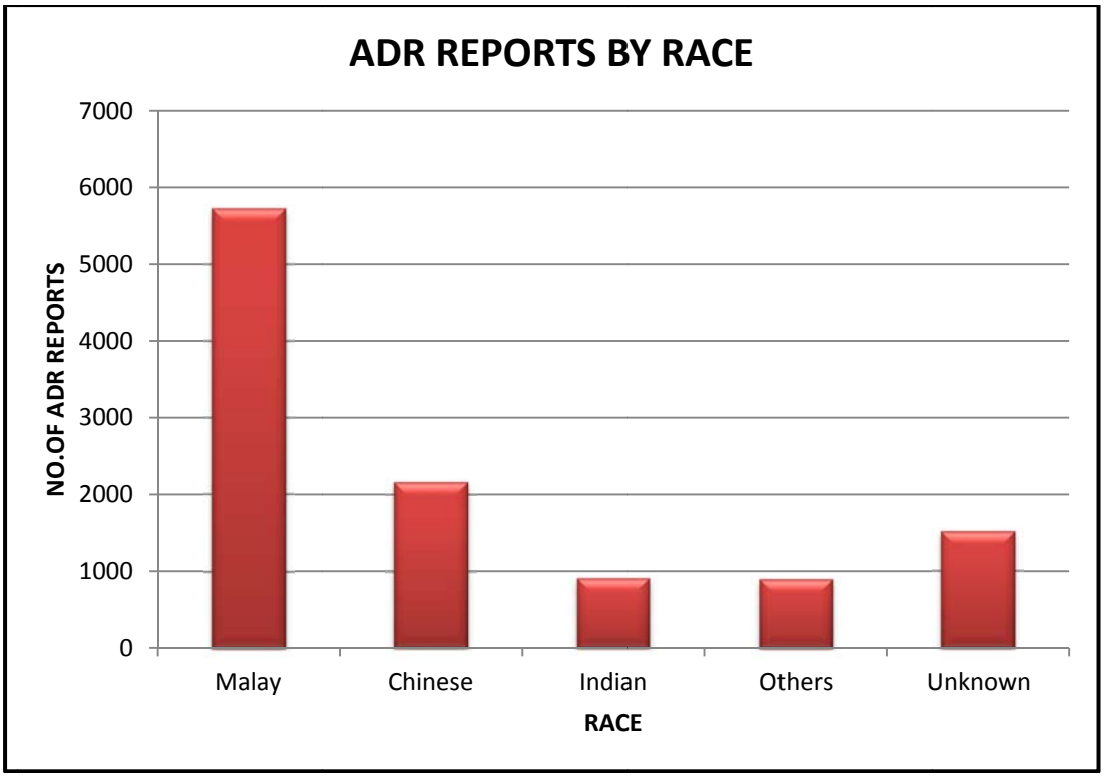
ADR REPORTS BY REPORTERS

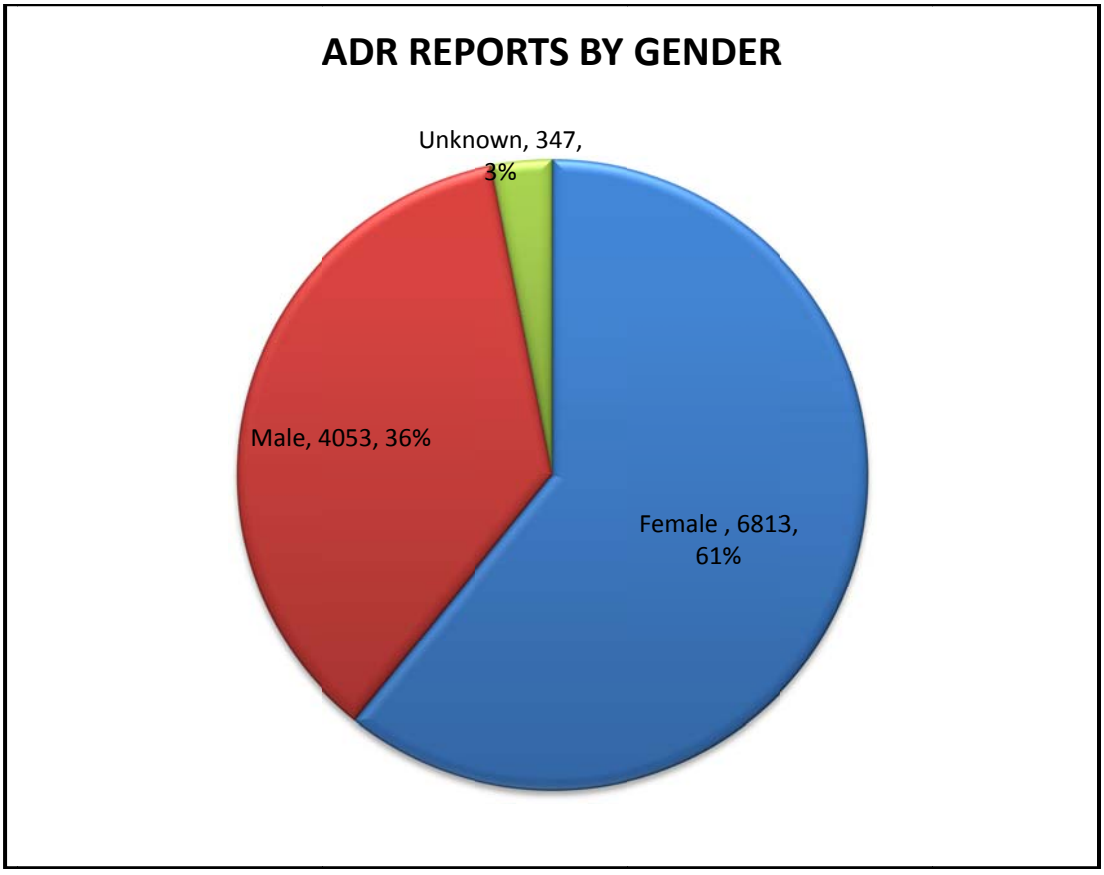


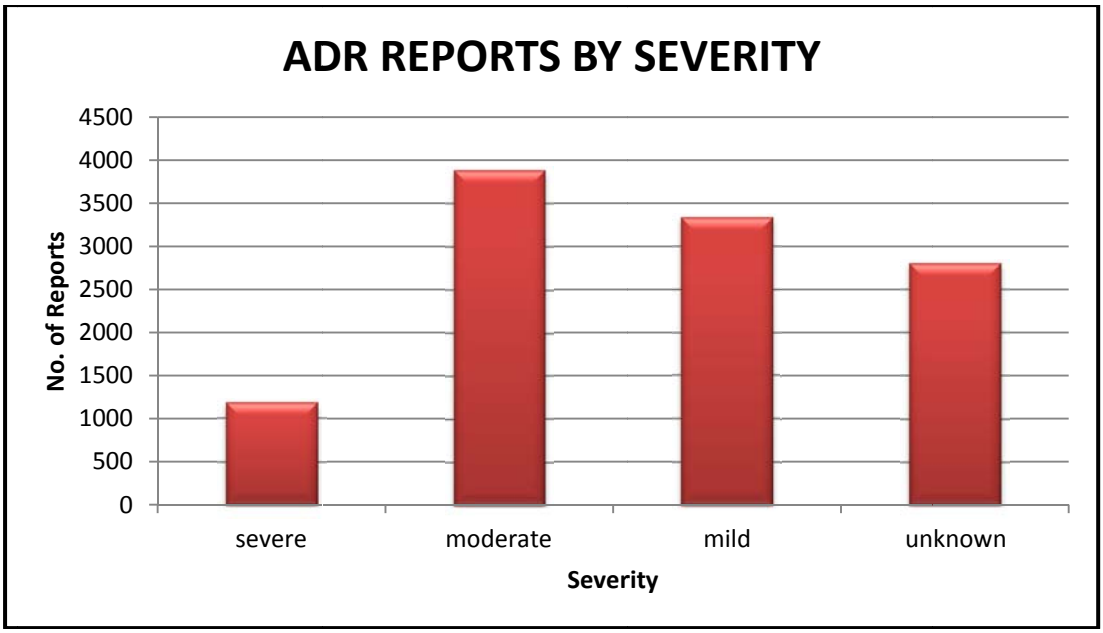
	2009	2010	2011	2012	2013
MOH Pharmacist	3358	4160	4267	5106	6283
MOH Nurse	25	388	2063	1636	905
MOH Doctors	1340	1418	1295	1627	1560
Other Govt Agency	0	0	0	67	621
Product Registration Holder	686	612	691	1066	1235
GP/Private Specialist	144	248	185	310	119
University	281	234	142	151	187
Others	16	19	742	206	303

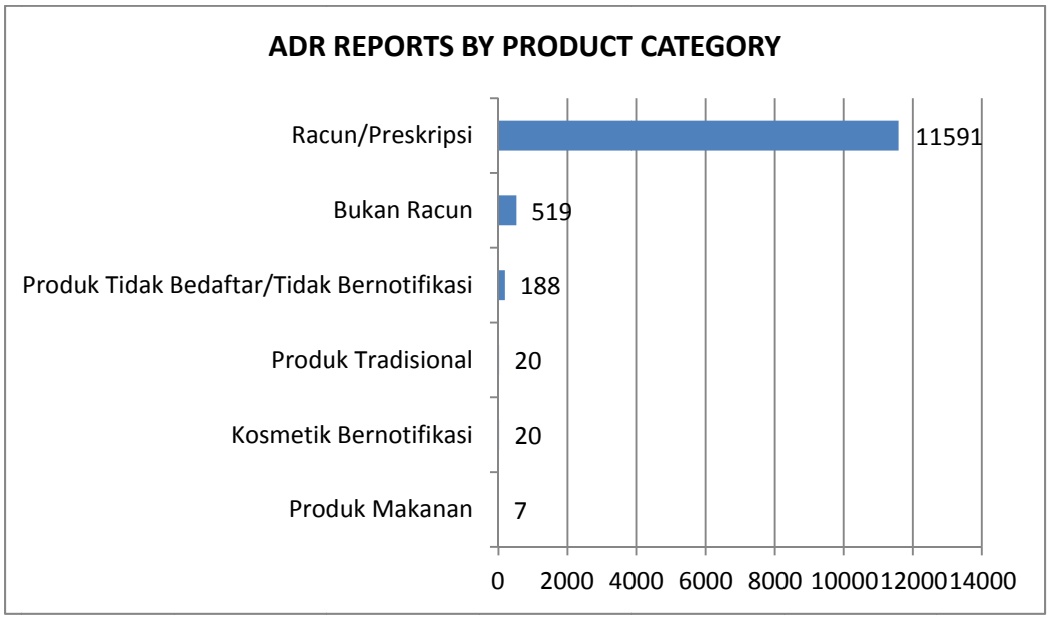

ADR REPORTS BY STATE FROM MOH FACILITIES 2013
NO. OF REPORTS
1600
1400
1200
1000
800
600
400
200
0
1424
1158
914
879
647
609
552
445
440
403
350
329
281
230
187
63
39
P PINANG
SELANGOR
SABAH
PERAK
MELAKA
N SEMBILAN
PAHANG
TERENGGANU
JOHOR
KEDAH
SARAWAK
H KL
WP KL
KELANTAN
UNIVERSITIES
PERLIS
WP LABUAN
MOH STATE/FACILITIES

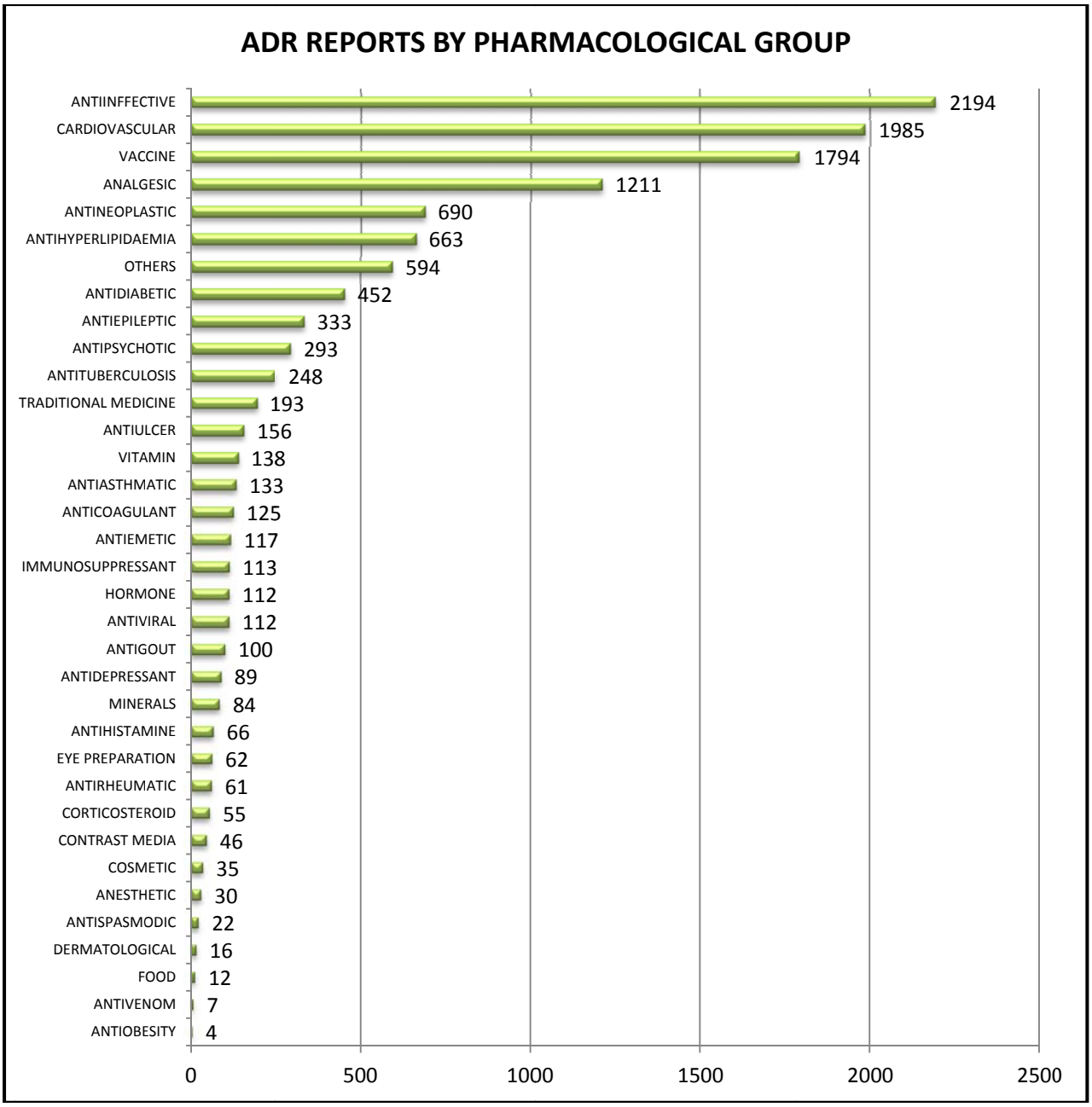

ADR REPORTS BY AGE GROUP
NO. OF REPORTS
3500
3000
2500
2000
1500
1000
500
0
<1
2 to 12
13 to 18
19 to 40
41 to 60
>60
Unknown
AGE GROUP

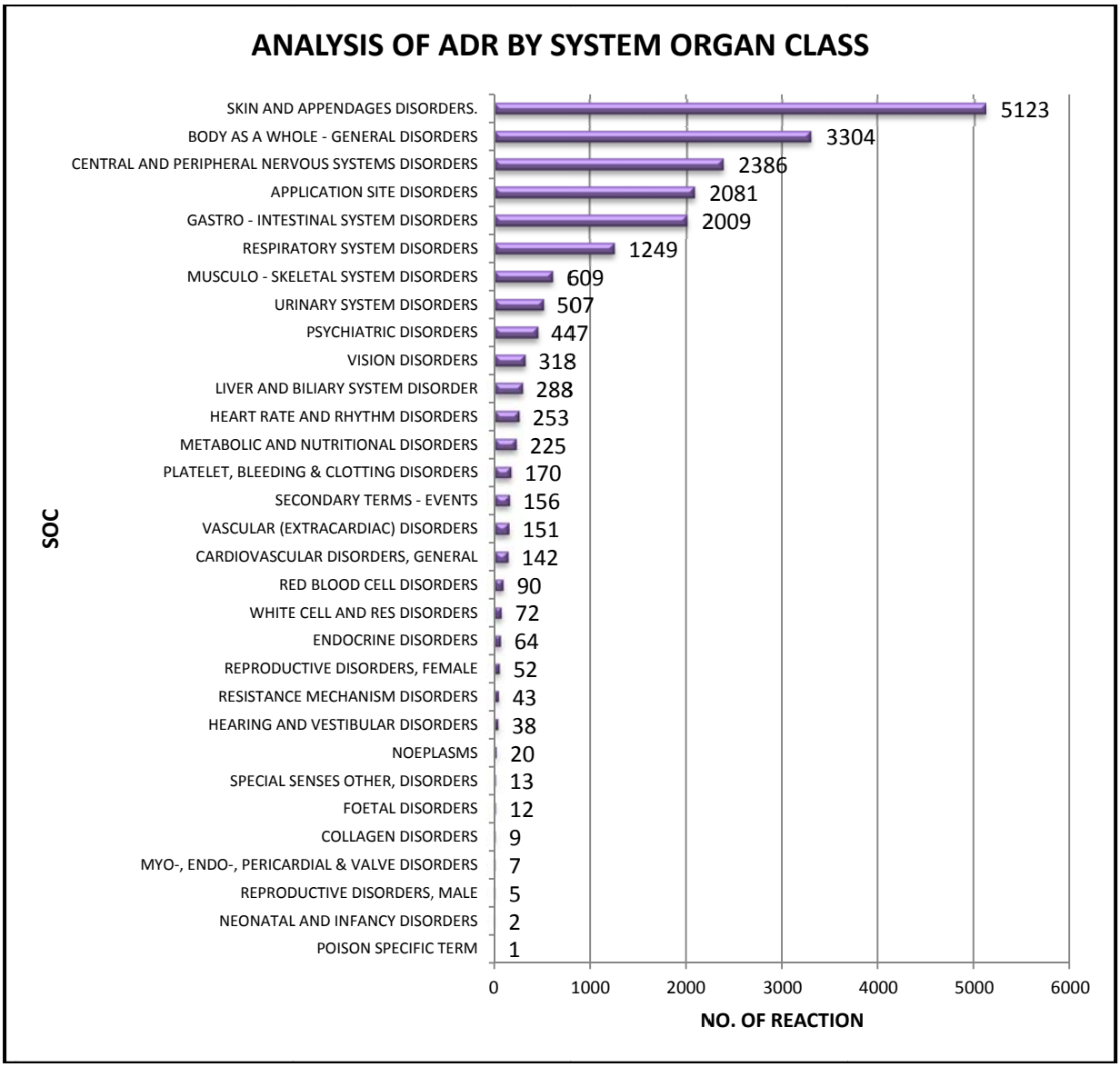

ADR REPORTS BY RACE
NO.OF ADR REPORTS
7000
6000
5000
4000
3000
2000
1000
0
Malay
Chinese
Indian
Others
Unknown
RACE


ADR REPORTS BY GENDER
Unknown, 347, 3%
Male, 4053, 36%
Female , 6813, 61%


ADR REPORTS BY SEVERITY
No. of Reports
4500
4000
3500
3000
2500
2000
1500
1000
500
0
severe
moderate
mild
unknown
Severity


ADR REPORTS BY PRODUCT CATEGORY
Racun/Preskripsi
11591
Bukan Racun
519
Produk Tidak Bedaftar/Tidak Bernotifikasi
188
Produk Tradisional
20
Kosmetik Bernotifikasi
20
Produk Makanan
7
0
2000
4000
6000
8000
10000
12000
14000


ADR REPORTS BY PHARMACOLOGICAL GROUP
ANTIINFFECTIVE 2194
CARDIOVASCULAR 1985
VACCINE 1794
ANALGESIC 1211
ANTINEOPLASTIC 690
ANTIHYPERLIPIDAEMIA 663
OTHERS 594
ANTIDIABETIC 452
ANTIEPILEPTIC 333
ANTIPSYCHOTIC 293
ANTITUBERCULOSIS 248
TRADITIONAL MEDICINE 193
ANTIULCER 156
VITAMIN 138
ANTIASTHMATIC 133
ANTICOAGULANT 125
ANTIEMETIC 117
IMMUNOSUPPRESSANT 113
HORMONE 112
ANTIVIRAL 112
ANTIGOUT 100
ANTIDEPRESSANT 89
MINERALS 84
ANTIHISTAMINE 66
EYE PREPARATION 62
ANTIRHEUMATIC 61
CORTICOSTEROID 55
CONTRAST MEDIA 46
COSMETIC 35
ANESTHETIC 30
ANTISPASMODIC 22
DERMATOLOGICAL 16
FOOD 12
ANTIVENOM 7
ANTIOBESITY 4
0
500
1000
1500
2000
2500


ANALYSIS OF ADR BY SYSTEM ORGAN CLASS
SOC
SKIN AND APPENDAGES DISORDERS. 5123
BODY AS A WHOLE - GENERAL DISORDERS 3304
CENTRAL AND PERIPHERAL NERVOUS SYSTEMS DISORDERS 2386
APPLICATION SITE DISORDERS 2081
GASTRO - INTESTINAL SYSTEM DISORDERS 2009
RESPIRATORY SYSTEM DISORDERS 1249
MUSCULO - SKELETAL SYSTEM DISORDERS 609
URINARY SYSTEM DISORDERS 507
PSYCHIATRIC DISORDERS 447
VISION DISORDERS 318
LIVER AND BILIARY SYSTEM DISORDER 288
HEART RATE AND RHYTHM DISORDERS 253
METABOLIC AND NUTRITIONAL DISORDERS 225
PLATELET, BLEEDING & CLOTTING DISORDERS 170
SECONDARY TERMS - EVENTS 156
VASCULAR (EXTRACARDIAC) DISORDERS 151
CARDIOVASCULAR DISORDERS, GENERAL 142
RED BLOOD CELL DISORDERS 90
WHITE CELL AND RES DISORDERS 72
ENDOCRINE DISORDERS 64
REPRODUCTIVE DISORDERS, FEMALE 52
RESISTANCE MECHANISM DISORDERS 43
HEARING AND VESTIBULAR DISORDERS 38
NOEPLASMS 20
SPECIAL SENSES OTHER, DISORDERS 13
FOETAL DISORDERS 12
COLLAGEN DISORDERS 9
MYO-, ENDO-, PERICARDIAL & VALVE DISORDERS 7
REPRODUCTIVE DISORDERS, MALE 5
NEONATAL AND INFANCY DISORDERS 2
POISON SPECIFIC TERM 1
0
1000
2000
3000
4000
5000
6000
NO. OF REACTION