ANNUAL REPORT OF THE MALAYSIAN ADVERSE DRUG REACTIONS ADVISORY COMMITTEE (MADRAC) 2010

1. i) Membership of MADRAC for the year 2010

MADRAC Members/*(Alternate members)*	
En Selvaraja Seerangam Director of National Pharmaceutical Control Bureau.	Chairman
Cik Sameerah Shaikh Abdul Rahman Deputy Director of Centre for Post Product Registration Centre National Pharmaceutical Control Bureau	Secretary
Pn Siti Aida Abdullah Secretary, Drug Control Authority, Ministry of Health	Committee Member
Dato' Dr Jeyaindran Tan Sri Dr. Sinnadurai DSSA / *(Dr. Hjh Rosaida Mohd Said)* Head of Department and Senior Consultant (Medical), Hospital Kuala Lumpur	Committee Member
Dr. Sarfraz Manzoor Hussein / *(Dr. Siti Nor Aizah Ahmad)* Head of Department and Senior Consultant Psychiatrist, Hospital Kuala Lumpur	Committee Member
Dr G.R. Letchuman Ramanathan/*(Dr. Padmini Menon)* Head of Department and Senior Consultant Physician, Hospital Taiping.	Committee Member
Yg Bhg. Dato' Dr. Roshidah Baba/*(Dr. Rohna Ridzwan)* Head of Dermatology Services Head od Department and Consultant (Dermatology).	Committee Member
Dr. Gun Suk Chyn/*(Dr. Muhaini Othman)* Senior Consultant Physician (Rheumatology), Hospital Hospital Tuanku Ja'afar	Committee Member
Dr Hussein Imam Bin Hj. Muhammad Ismail / *(Dr. Norzila Mohamed Zainudin)* Head of Department and Consultant Paediatrician, Hospital Kuala Lumpur	Committee Member
Dr. Tan Chwee Choon / *(Dr. Sunita Bavanandan)* Head of Department and Senior Consultant Physician (Nefrology), Hospital Tuanku Ampuan Rahimah	Committee Member
Dr. Rohani Jahis / *(Dr. Nor Zahrin Hasran)* Principal Assistant Director	Committee Member
Pn. Zawiyah Mat Johor / *(Pn. Rosminah Mohd. Din)* Deputy Director, Pharmaceutical Services Division, Ministry of Health.	Committee Member

2. MEETINGS

The committee met six times over the year and a total of 5615 adverse drug reactions reports were reviewed.

3. ANALYSIS OF ADVERSE DRUG REACTIONS REPORTS

A detailed review and analysis of the adverse drug reactions (ADR) reports received during the year 2010 was conducted (Appendix 1).

4. DCA REGULATORY ACTION

These are the major directive action directed by the DCA on certain pharmaceutical products following the alerts received from other international regulatory agencies as well as from local institutions.

NO.	DCA MEETING	PRODUCTS INVOLVED	DESCRIPTION
1	224 (28/1/2010)	All products containing sibutramine	-To include SCOUT (Sibutramine Cardiovascular Outcome Trial) study summary description into package inserts. -Result of the SCOUT study suggested that sibutramine is associated with increased cardiovascular risk.
2	227 (29/4/10)	All products containing red yeast rice (monascuspurpureus)	-To limit the dose of traditional medicines containing red yeast rice to ensure content of lovastatin consumed is less than 10mg/day. -To add a warning statement regarding concurrent use of statins or fibrates to the product labels. -Concurrent use of fibrates may cause severe myositis and myoglubinuria.
3	228 (27/5/2010)	All products containing propylthiouracil	-To add a box warning regarding the incidence of “severe liver injury and acute liver failure” into package inserts.
4	228 (27/5/2010)	All products containing carbocysteine, acetylcysteine and methylcarbocysteine (Mecysteine)	-To add in the statement “contraindicated in children below 2 years of age” in the package inserts. -This is due to the findings of Afssaps (French Health Agency) showing there is risk of aggravation of respiratory symptoms following the consumption of the mentioned products.
5	234 (22/11/2010)	All products containing rosiglitazone	-To revise the indication, contraindication and warning and precaution parts of package insert. -Rosiglitazone is contraindicated in patients with NYHA Class I to IV heart failure or history of cardiac failure, ischaemic heart disease, and Acute Coronary Syndrome (unstable angina, non-ST segment elevation myocardial infarction (NSTEMI) and ST segment elevation myocardial infarction (STEMI)). -Rosiglitazone is to be prescribed to new patients only if they are unable to achieve adequate blood glucose control with all other oral antidiabetic medications.
6	235 (23/12/2010)	All products containing sibutramine	-To cancel the registration of all sibutramine products and not to register any new products containing sibutramine in Malaysia.

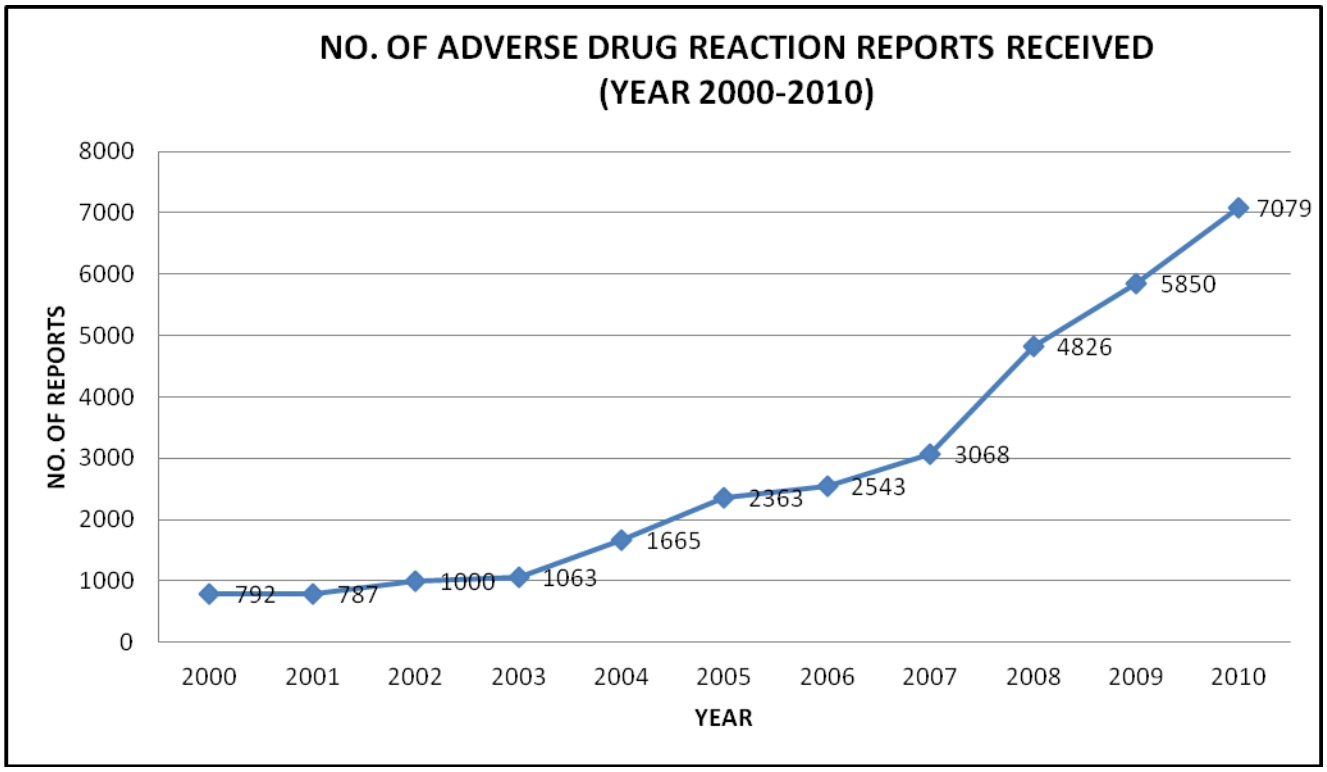
MADRAC had also proposed to add a boxed warning to the package inserts of all promethazine hydrochloride injection products. It is regarding the warning of the possibility of causing fatal respiratory depression in paediatrics patients less than 2 years of age and also severe tissue injury. On the 228th DCA meeting held on 27th May 2010, decision had been made that all of the hospitals shall be informed of this adverse drug reactionso to increase the monitoring and the ADR reporting of this drug. The proposition regarding the addition of a boxed warning is then postponed.

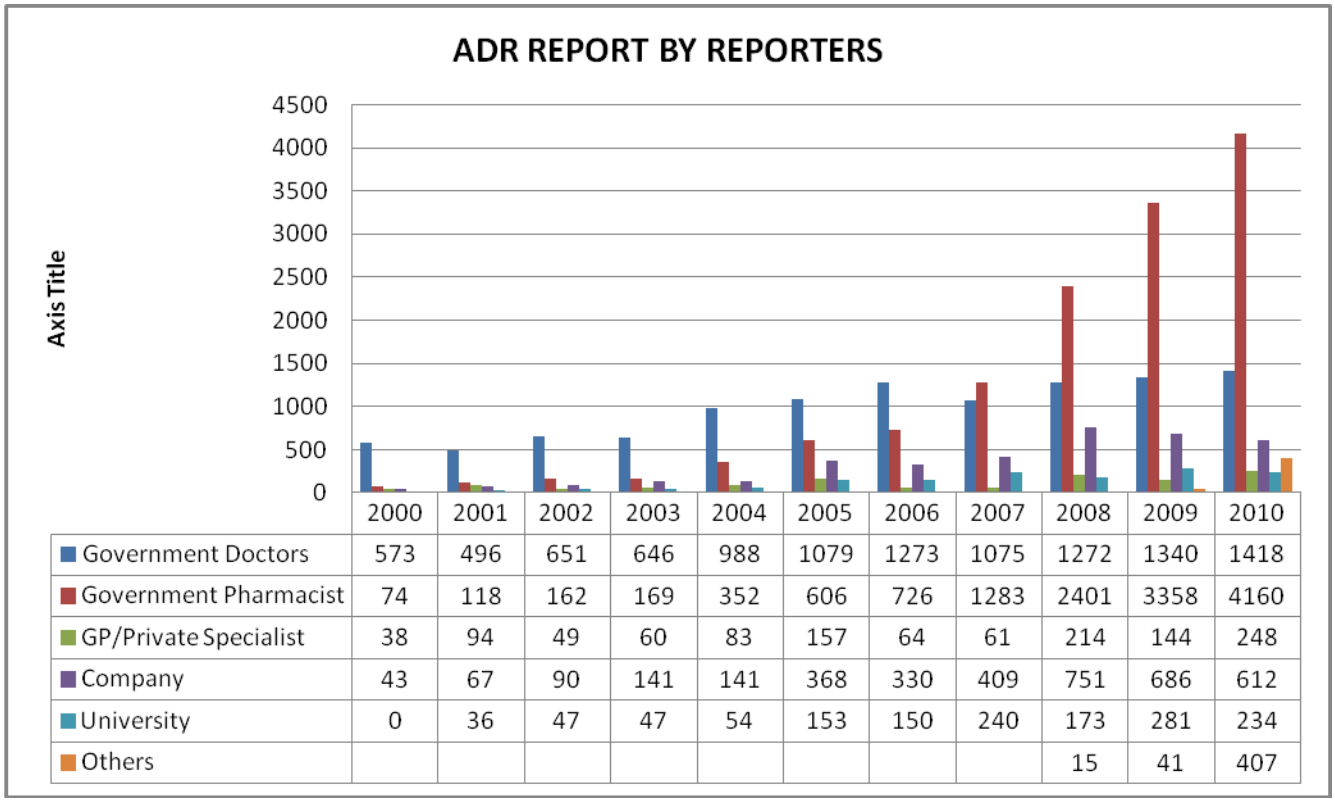
PROMOTING ADR REPORTING

Talks were conducted following invitations by some institutions and universities, as listed below. These workshops and talks were aimed at increasing awareness of the importance of reporting adverse events of drugs and vaccines, as well as improving the quality of ADR reports submitted.

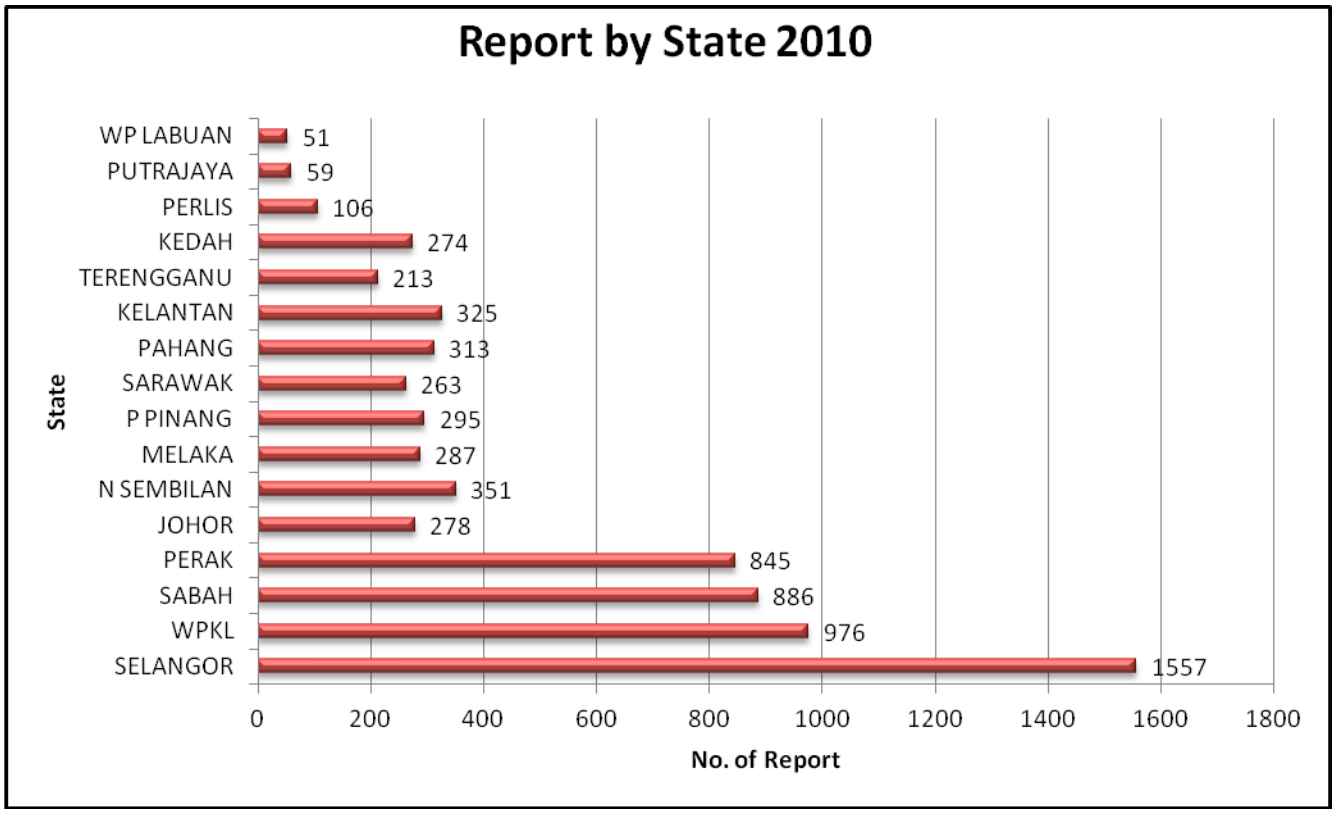
PRESENTATION TOPIC	NUMBER OF TALKS GIVEN THROUGHOUT 2010
Pharmacovigilance	3
Adverse Drug Reaction Reporting and Monitoring	8
Adverse Drug Reaction Reporting and Vaccine	2
Risk Management and Risk Assessment Plan	1
Adverse Drug Reaction Related To Skin Therapy	1
Adverse Drug Reactions And Medication Errors Associated With Cytotoxic Drugs	1
Adverse Event Following Immunisation (AEFI)	4

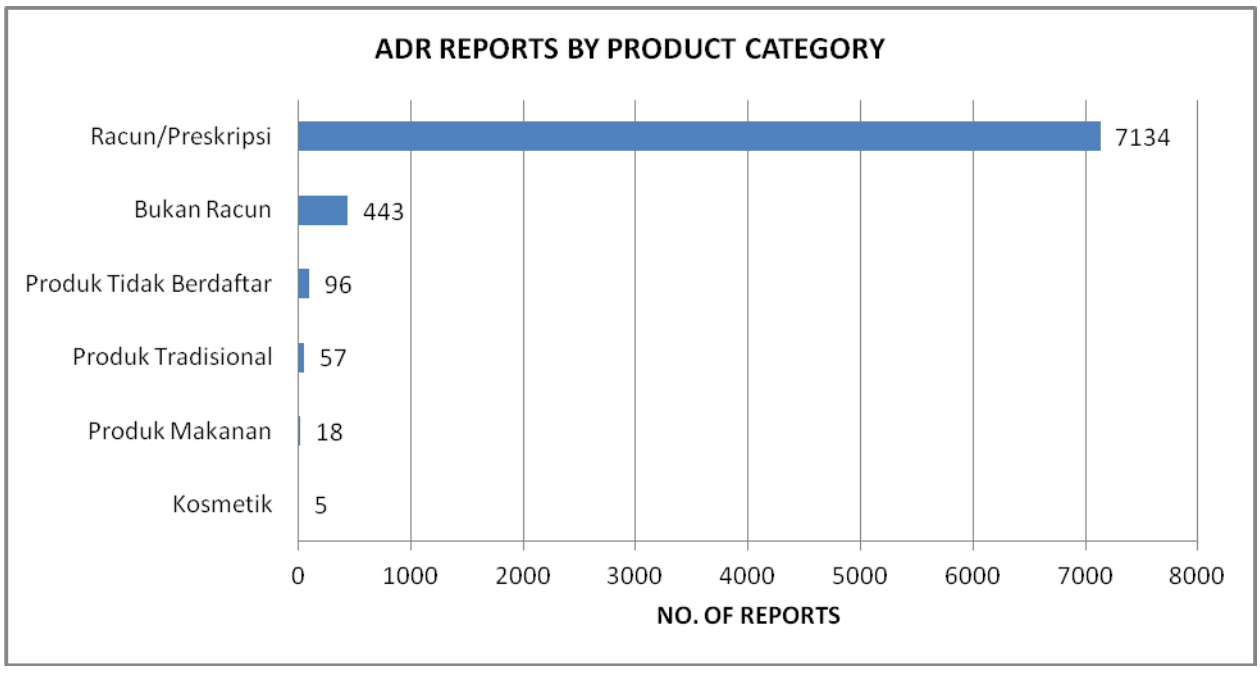
APPENDIX 1

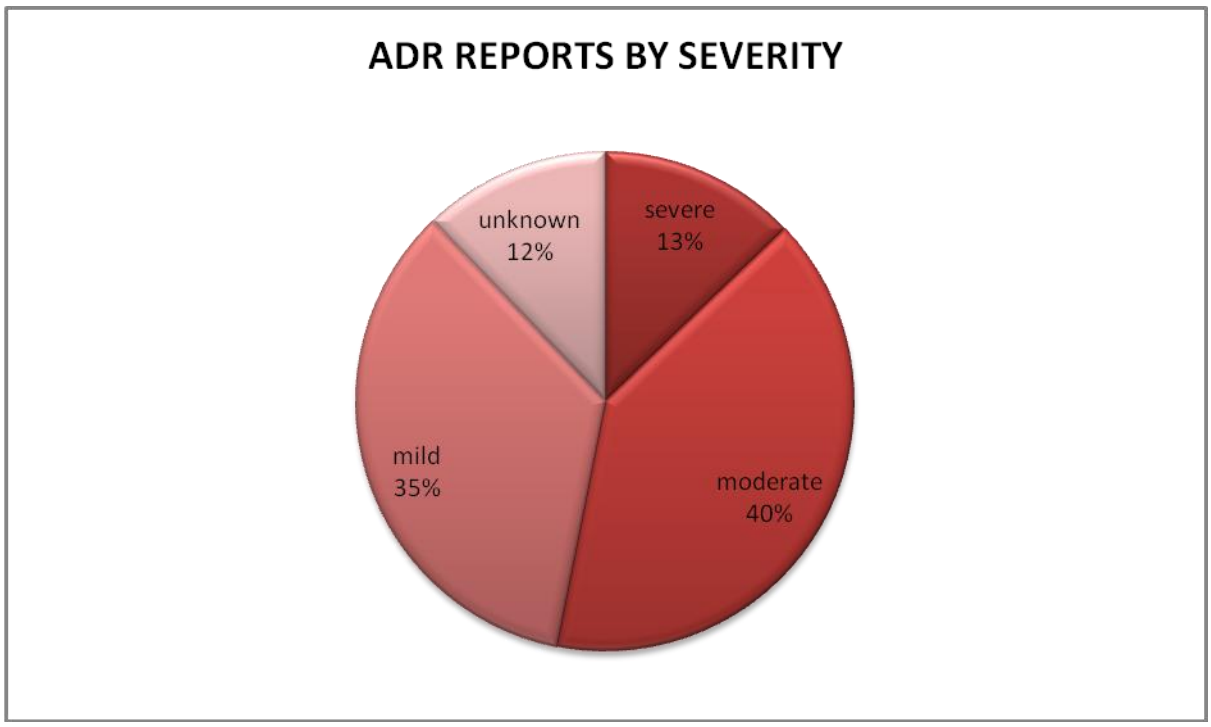


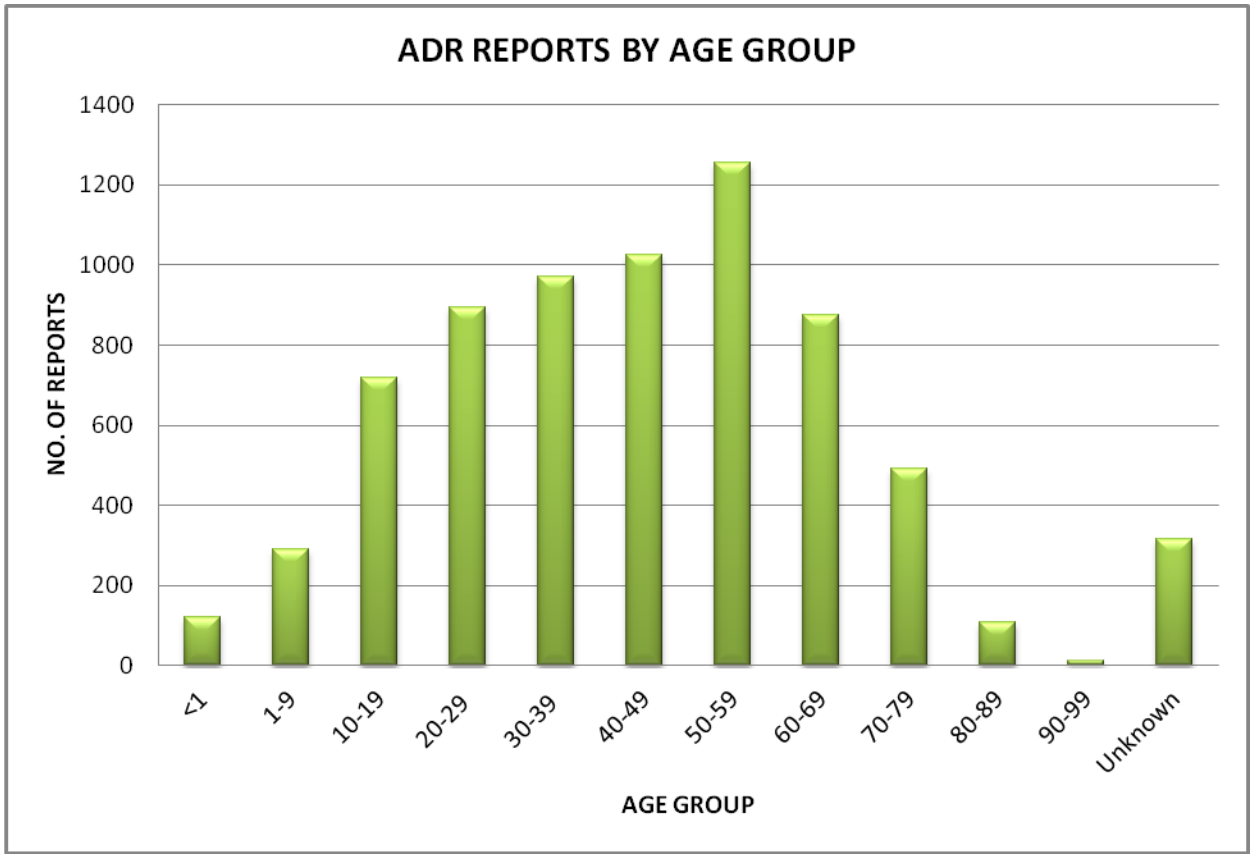


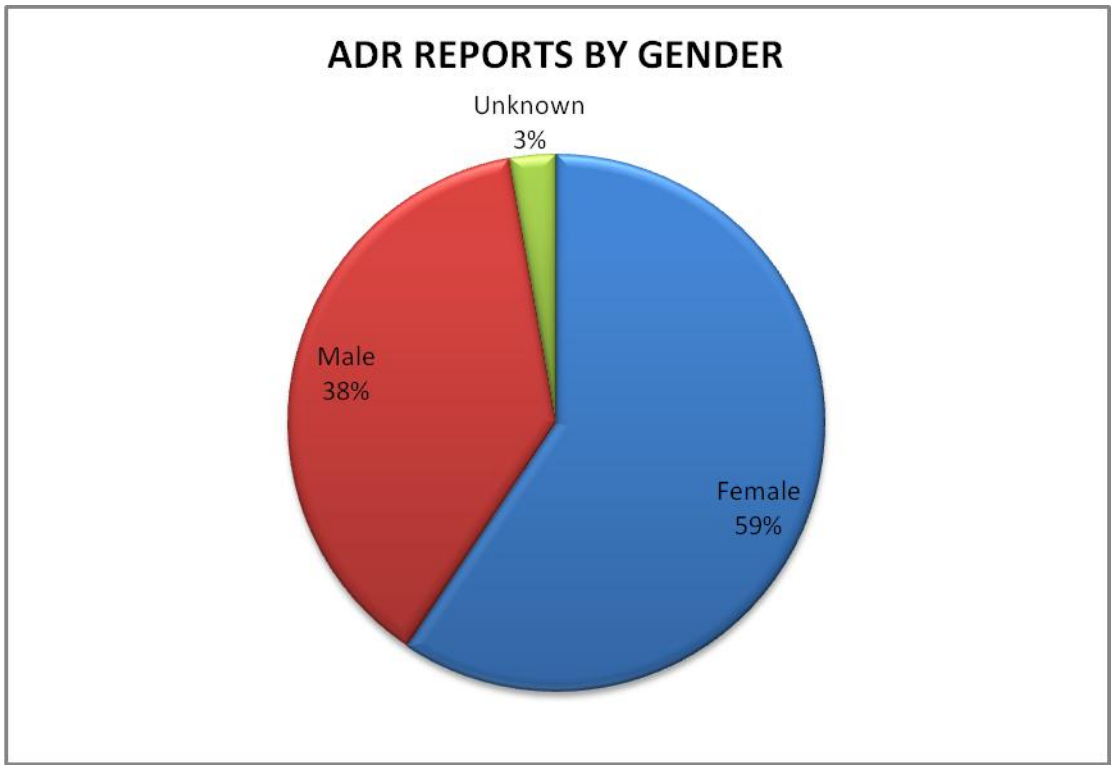
	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010
Government Doctors	573	496	651	646	988	1079	1273	1075	1272	1340	1418
Government Pharmacist	74	118	162	169	352	606	726	1283	2401	3358	4160
GP/Private Specialist	38	94	49	60	83	157	64	61	214	144	248
Company	43	67	90	141	141	368	330	409	751	686	612
University	0	36	47	47	54	153	150	240	173	281	234
Others									15	41	407

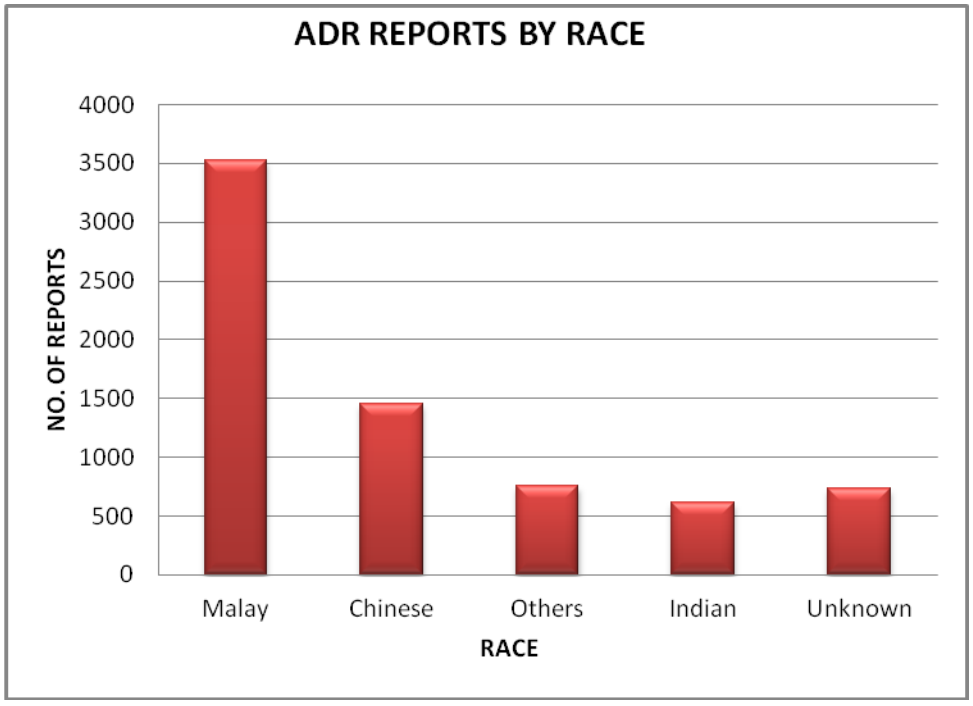

Report by State 2010
WP LABUAN
PUTRAJAYA
PERLIS
KEDAH
TERENGGANU
KELANTAN
PAHANG
SARAWAK
P PINANG
MELAKA
N SEMBILAN
JOHOR
PERAK
SABAH
WPKL
SELANGOR
51
59
106
274
213
325
313
263
295
287
351
278
845
886
976
1557
State
0
200
400
600
800
1000
1200
1400
1600
1800
No. of Report

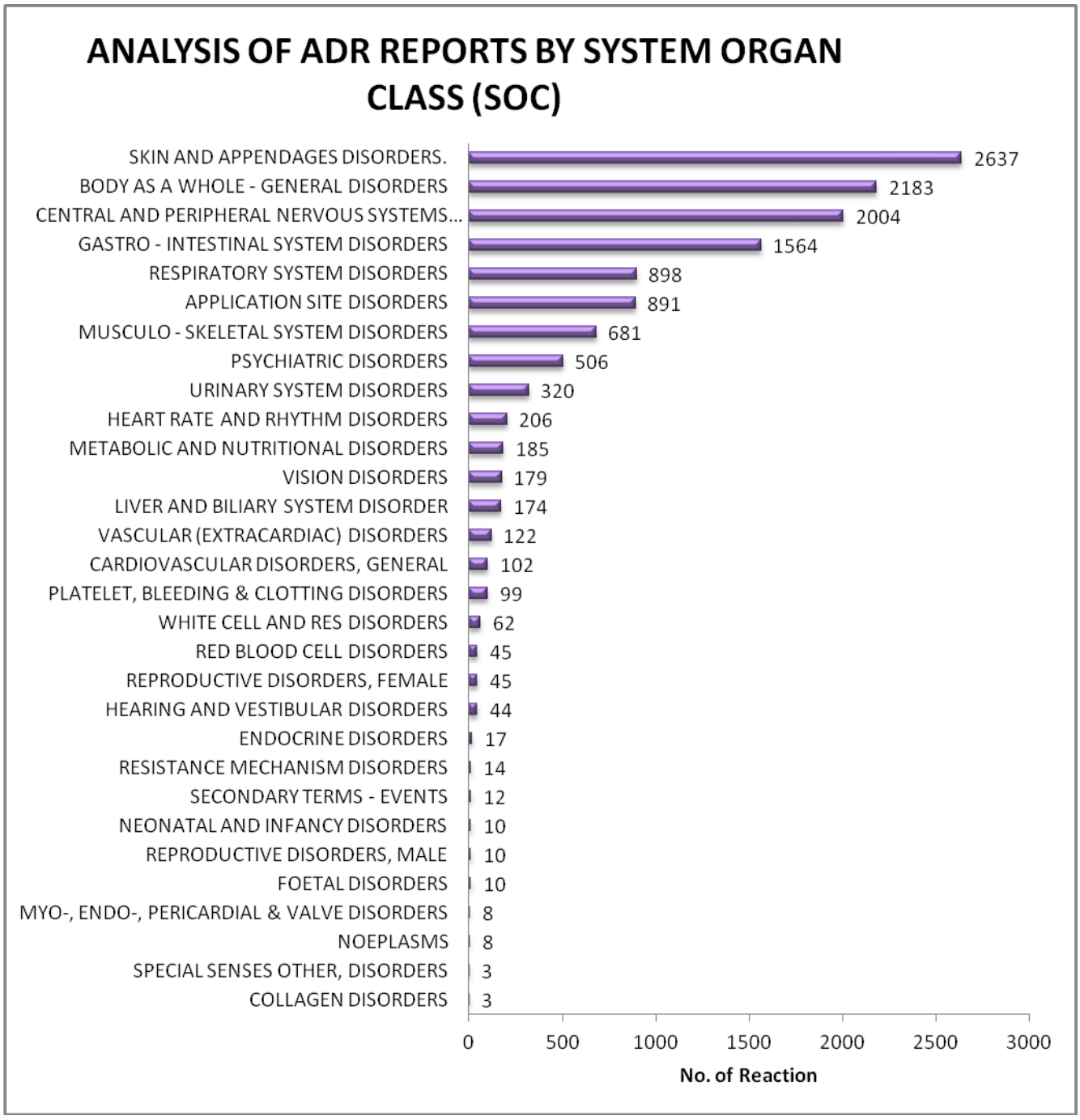

ADR REPORTS BY PRODUCT CATEGORY
Racun/Preskripsi
Bukan Racun
Produk Tidak Berdaftar
Produk Tradisional
Produk Makanan
Kosmetik
7134
443
96
57
18
5
0
1000
2000
3000
4000
5000
6000
7000
8000
NO. OF REPORTS

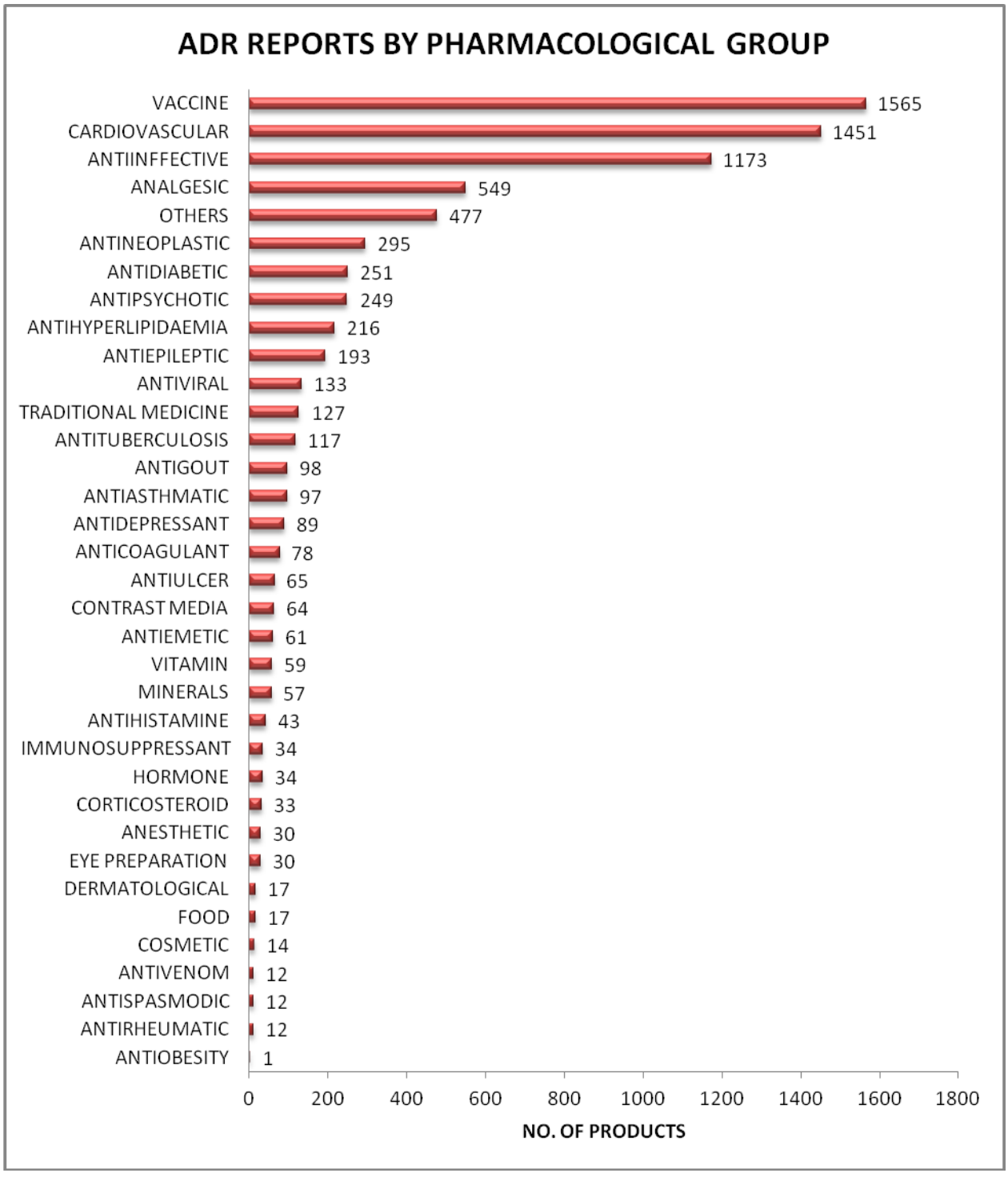

ADR REPORTS BY SEVERITY
unknown
12%
severe
13%
mild
35%
moderate
40%


ADR REPORTS BY AGE GROUP
NO. OF REPORTS
1400
1200
1000
800
600
400
200
0
<1
1-9
10-19
20-29
30-39
40-49
50-59
60-69
70-79
80-89
90-99
Unknown
AGE GROUP


ADR REPORTS BY GENDER
Unknown
3%
Male
38%
Female
59%


ADR REPORTS BY RACE
4000
3500
3000
2500
2000
1500
1000
500
0
NO. OF REPORTS
Malay
Chinese
Others
Indian
Unknown
RACE


ANALYSIS OF ADR REPORTS BY SYSTEM ORGAN CLASS (SOC)
SKIN AND APPENDAGES DISORDERS. 2637
BODY AS A WHOLE - GENERAL DISORDERS 2183
CENTRAL AND PERIPHERAL NERVOUS SYSTEMS... 2004
GASTRO - INTESTINAL SYSTEM DISORDERS 1564
RESPIRATORY SYSTEM DISORDERS 898
APPLICATION SITE DISORDERS 891
MUSCULO - SKELETAL SYSTEM DISORDERS 681
PSYCHIATRIC DISORDERS 506
URINARY SYSTEM DISORDERS 320
HEART RATE AND RHYTHM DISORDERS 206
METABOLIC AND NUTRITIONAL DISORDERS 185
VISION DISORDERS 179
LIVER AND BILIARY SYSTEM DISORDER 174
VASCULAR (EXTRACARDIAC) DISORDERS 122
CARDIOVASCULAR DISORDERS, GENERAL 102
PLATELET, BLEEDING & CLOTTING DISORDERS 99
WHITE CELL AND RES DISORDERS 62
RED BLOOD CELL DISORDERS 45
REPRODUCTIVE DISORDERS, FEMALE 45
HEARING AND VESTIBULAR DISORDERS 44
ENDOCRINE DISORDERS 17
RESISTANCE MECHANISM DISORDERS 14
SECONDARY TERMS - EVENTS 12
NEONATAL AND INFANCY DISORDERS 10
REPRODUCTIVE DISORDERS, MALE 10
FOETAL DISORDERS 10
MYO-, ENDO-, PERICARDIAL & VALVE DISORDERS 8
NOEPLASMS 8
SPECIAL SENSES OTHER, DISORDERS 3
COLLAGEN DISORDERS 3
0 500 1000 1500 2000 2500 3000
No. of Reaction


ADR REPORTS BY PHARMACOLOGICAL GROUP
VACCINE 1565
CARDIOVASCULAR 1451
ANTIINFFECTIVE 1173
ANALGESIC 549
OTHERS 477
ANTINEOPLASTIC 295
ANTIDIABETIC 251
ANTIPSYCHOTIC 249
ANTIHYPERLIPIDAEMIA 216
ANTIEPILEPTIC 193
ANTIVIRAL 133
TRADITIONAL MEDICINE 127
ANTITUBERCULOSIS 117
ANTIGOUT 98
ANTIASTHMATIC 97
ANTIDEPRESSANT 89
ANTICOAGULANT 78
ANTIULCER 65
CONTRAST MEDIA 64
ANTIEMETIC 61
VITAMIN 59
MINERALS 57
ANTIHISTAMINE 43
IMMUNOSUPPRESSANT 34
HORMONE 34
CORTICOSTEROID 33
ANESTHETIC 30
EYE PREPARATION 30
DERMATOLOGICAL 17
FOOD 17
COSMETIC 14
ANTIVENOM 12
ANTISPASMODIC 12
ANTIRHEUMATIC 12
ANTIOBESITY 1
0 200 400 600 800 1000 1200 1400 1600 1800
NO. OF PRODUCTS