ANNUAL REPORT OF THE MALAYSIAN ADVERSE DRUG REACTIONS ADVISORY COMMITTEE (MADRAC) 2011

1. Membership of MADRAC till the end of 2011

MADRAC Members*(Alternate members)*	
Mr Selvaraja Seerangam Director of National Pharmaceutical Control Bureau *(Dr Tajududdin Akasah)* *Acting Director of National Pharmaceutical Control Bureau*	Chairman
Ms Sameerah Shaikh Abdul Rahman Deputy Director of Centre for Post Product Registration Centre National Pharmaceutical Control Bureau	Secretary
Ms Siti Aida Abdullah Secretary, Drug Control Authority, Ministry of Health	Committee Member
Datuk Dr Jeyaindran Tan Sri Dr. Sinnadurai Head of Department and Senior Medical Consultant (Critical Care), Hospital Kuala Lumpur *(Dr Hjh Rosaida Mohd Said)*	Committee Member
Dr Hussein Imam Hj. Muhammad Ismail Head of Department and Senior Consultant Paediatrician, Hospital Kuala Lumpur *(Dr Norzila Mohd Zainudin)*	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
Dr Gun Suk Chyn Head of Department and Senior Medical Consultant (Rheumatology), Hospital Tuanku Ja'afar *(Dr Muhaini Othman)*	Committee Member
Dr Tan Chwee Choon Head of Department and Senior Medical Consultant (Nephrology), Hospital Tuanku Ampuan Rahimah *(Dr Sunita Bavanandan)*	Committee Member

Dr Rohani Jahis Senior Principal Assistant Director, Infectious Disease Branch, Disease Control Division, Ministry of Health *(Dr Nor Zahrin Hasran)*	Committee Member
Ms Wan Mohaina Wan Mohammad Senior Principal Assistant Director, Pharmaceutical Services Division, Ministry of Health *(Ms AnisTalib)*	Committee Member

2. MEETINGS

During the calendar year 2011, six (6) meetings were conducted with a total of 9385 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 2011 was conducted (Appendix 1).

4. DRUG CONTROL AUTHORITY (DCA) REGULATORY ACTION

During the course of 2011, the following regulatory actions were proposed by MADRAC and approved by the DCA. 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 data from local institutions.

No.	MADRAC Meeting	DCA Meeting	Products Involved	Description
1	120 (24/3/11) & 121 (19/5/11)	240 (26/5/11)	All antipsychotic drugs	**Class labelling updates regarding use during pregnancy & potential risk to newborns** • Neonates exposed to antipsychotic drugs during the third trimester of pregnancy are at risk for extrapyramidal and/or withdrawal symptoms following delivery. • These complications vary in severity. In some cases, neonates required intensive care unit support and prolonged hospitalisation. • Antipsychotic drugs should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus.
2	120 (24/3/11) & 122 (21/7/11)	242 (28/7/11)	All beta agonists	**Strengthened warnings against use in preterm labour** • Serious adverse reactions including death have been reported after administration of terbutaline/salbutamol to women in labour. • In the mother, these include increased heart rate, transient hyperglycaemia, hypokalaemia, cardiac arrhythmias, pulmonary oedema and myocardial ischaemia. • Increased foetal heart rate and neonatal hypoglycaemia may occur as a result of maternal administration.
3	122 (21/7/11)	242 (28/7/11)	All 5-alpha reductase inhibitors (5-ARIs)	**Class labelling updates to warn about potential risk of high grade prostate cancer** • Men aged 55 and over with a normal digital rectal examination and PSA ≤3.0 ng/mL at baseline taking finasteride 5 mg/day in the 7-year Prostate Cancer Prevention Trial (PCPT) had an increased risk of Gleason score 8-10 prostate cancer. • Similar results were observed in a 4-year placebo-controlled clinical trial with dutasteride. • However, whether the effect of 5-ARIs to reduce prostate volume, or study-related factors, impacted the results of these studies have not been established.

4	122 (21/7/11)	242 (28/7/11)	All products containing fluoroquinolones	**Class labelling updates to include warning of exacerbation of myasthenia gravis** • Fluoroquinolones have neuromuscular blocking activity and may exacerbate muscle weakness in patients with myasthenia gravis. • Post-marketing serious adverse events, including deaths and requirement for ventilator support have been been associated with fluoroquinolones use in persons with myasthenia gravis. • Avoid fluoroquinolones patients with known history of myasthenia gravis.
5	122 (21/7/11)	243 (25/8/11)	All products containing ketoconazole	**Contraindication & boxed warnings for risk of serious hepatotoxicity** • Contraindicated in patients with acute or chronic liver disease. • Very rare cases of serious hepatotoxicity, including cases with a fatal outcome or requiring liver transplantation have occurred with the use of oral ketoconazole. Some of these cases occurred within the first month of treatment, including some within the first week. • Assess liver function, prior to treatment to rule out acute or chronic liver disease, and monitor at frequent and regular intervals during treatment, and at the first signs or symptoms of possible hepatotoxicity.

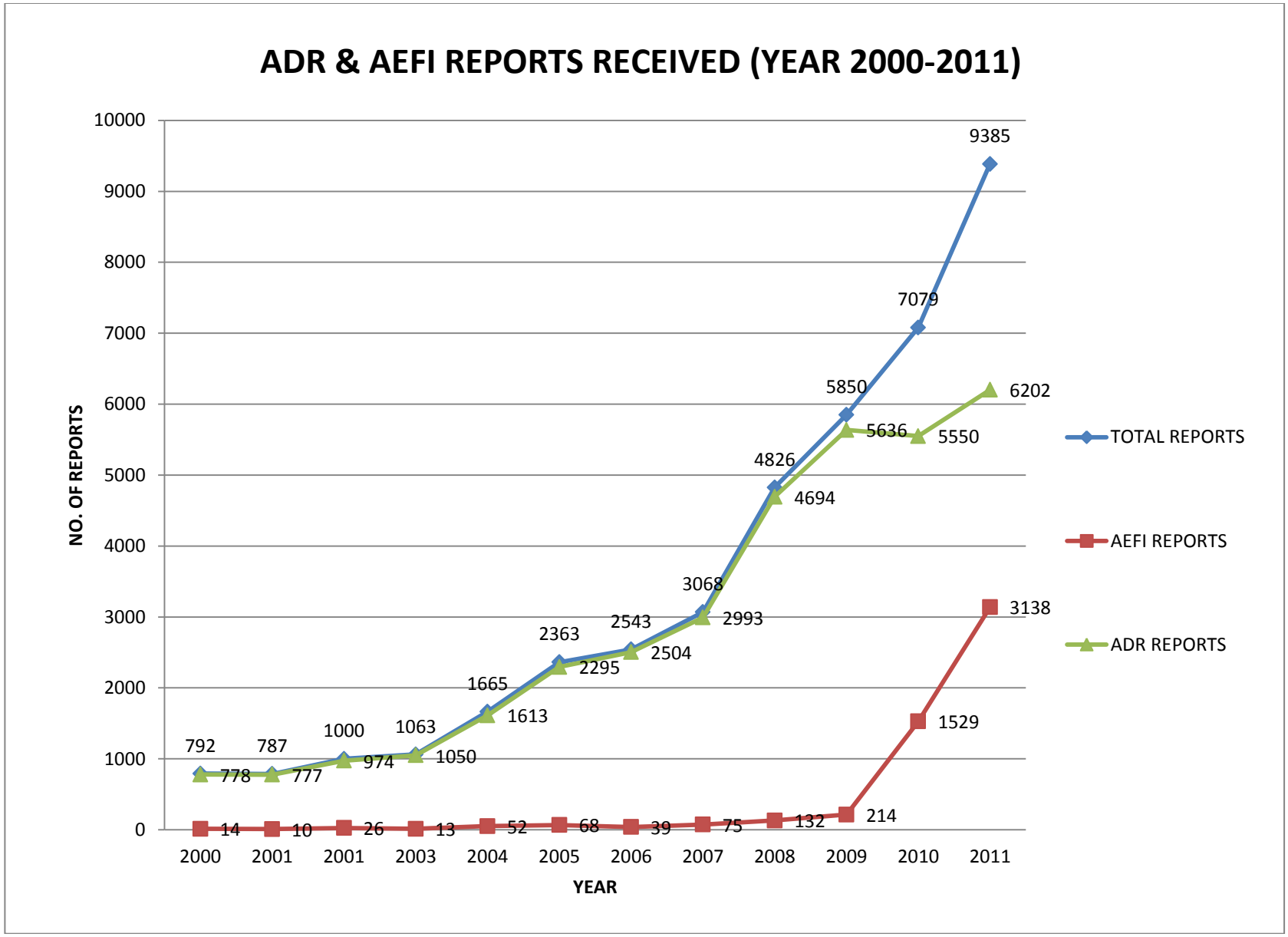
5. ACTIVITIES

Throughout 2011 several talks in an effort to promote awareness on ADR/AEFI reporting, quality reporting as well as to update healthcare personnel on issues related to drug safety.

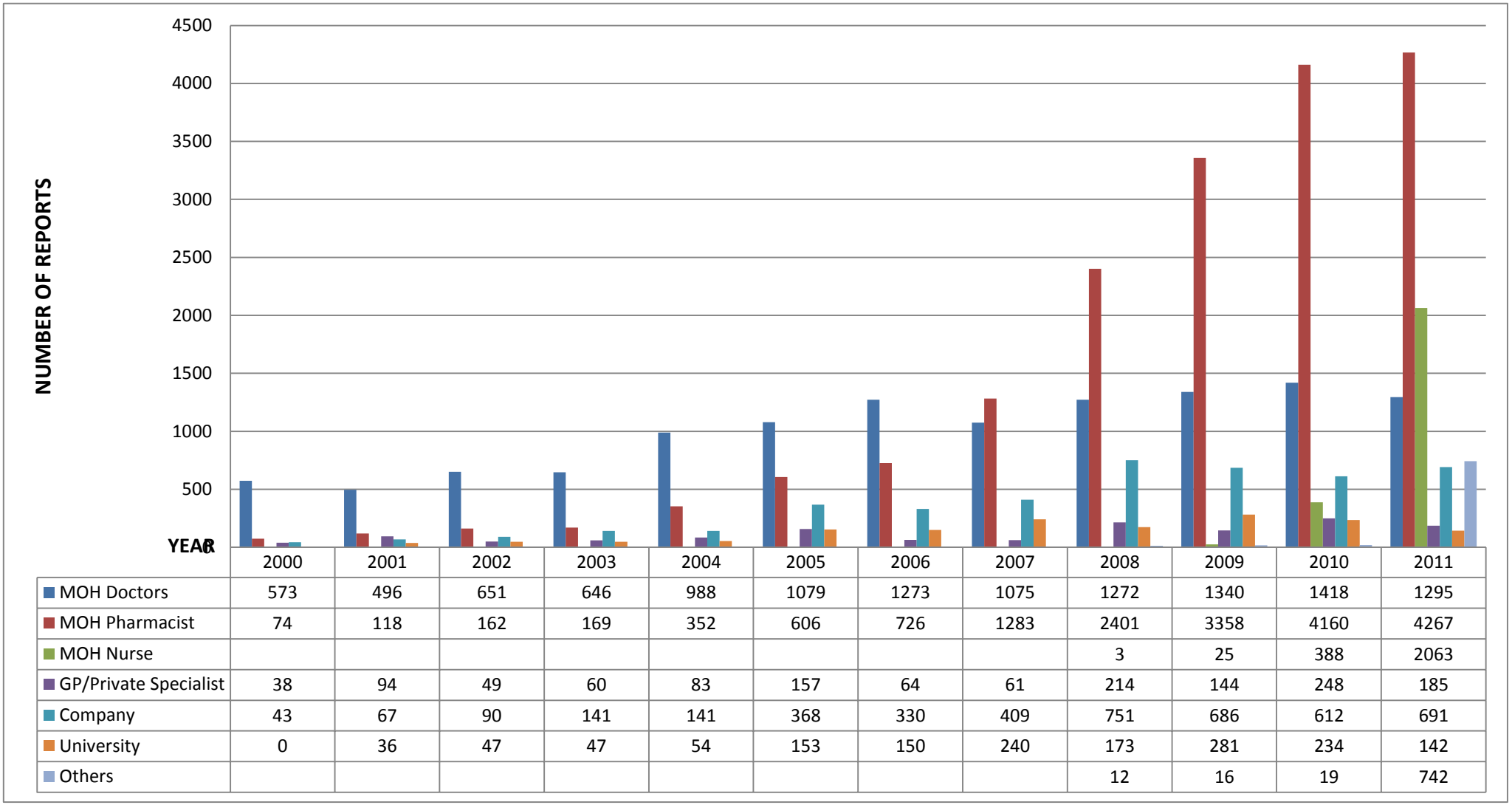
NO.	PROGRAMME	PLACE	TITLE OF PRESENTATION
1	Program “Kenali Ubat Anda”	Hospital Jelebu	ADR Reporting
2	Bengkel Pengurusan Laporan Adverse Drug Reaction & Medication Error	Senawang Health Clinic, Negeri Sembilan	Reporting system for Adverse Drug Reaction
			Adverse Events Following Immunization (AEFI)
3	Bengkel Pengurusan AEFI dan Sistem Rangkaian Sejuk	Insitut Keselamatandan Kesihatan Pekerjaan Negara (NIOSH), Bangi, Selangor	Pengenalan kepada Kesan Advers Selepas Pelalian
			Pengendalian Kesan Advers Selepas Pelalian
4	Sesi Kelab Jurnal Bil 06/2011	National Pharmaceutical Control Bureau	Human Papillomavirus (HPV)
5	Sesi Pembentangan Latihan Dalaman Pusat Pasca Pendaftaran Produk	National Pharmaceutical Control Bureau	Vaccination Program in Malaysia
6	Kursus Medication Safety	Hospital Tuanku Jaafar, Seremban, Negeri Sembilan	Adverse Drug Reaction Reporting
7	Bengkel Meningkatkan Kualiti Pelaporan Kesan Advers Ubat dan Vaksin	National Pharmaceutical Control Bureau	Overview to Pharmacovigilance Activity
			Drug Safety Monitoring and Role of Pharmacist
			Adverse Event Following Immunization (AEFI)
			Quality Reporting
			Causality Assessment of Suspected Drug/Vaccines
			Local Case Studies - The Value of Reports
8	Kursus “Hospital Pharmacy” (PHR528)	Faculty of Pharmacy, Universiti Teknologi MARA (UiTM), Puncak Alam, Selangor	Adverse Drug Reactions and ADR Reporting
9	Kursus “Pharmacy Practice” (PHAR4563)	Faculty of Pharmacy, Cyberjaya	“Pharmacovigilance”

		University College of Medical Sciences	
10	Bengkel Pelaporan Kesan Advers Ubat	Hospital Putrajaya	Overview Of Pharmacovigilance In Malaysia
11	Traditional and Complementary Medicine Seminar	Hotel Istana	Traditional And Complementary Medicine For Pharmacist

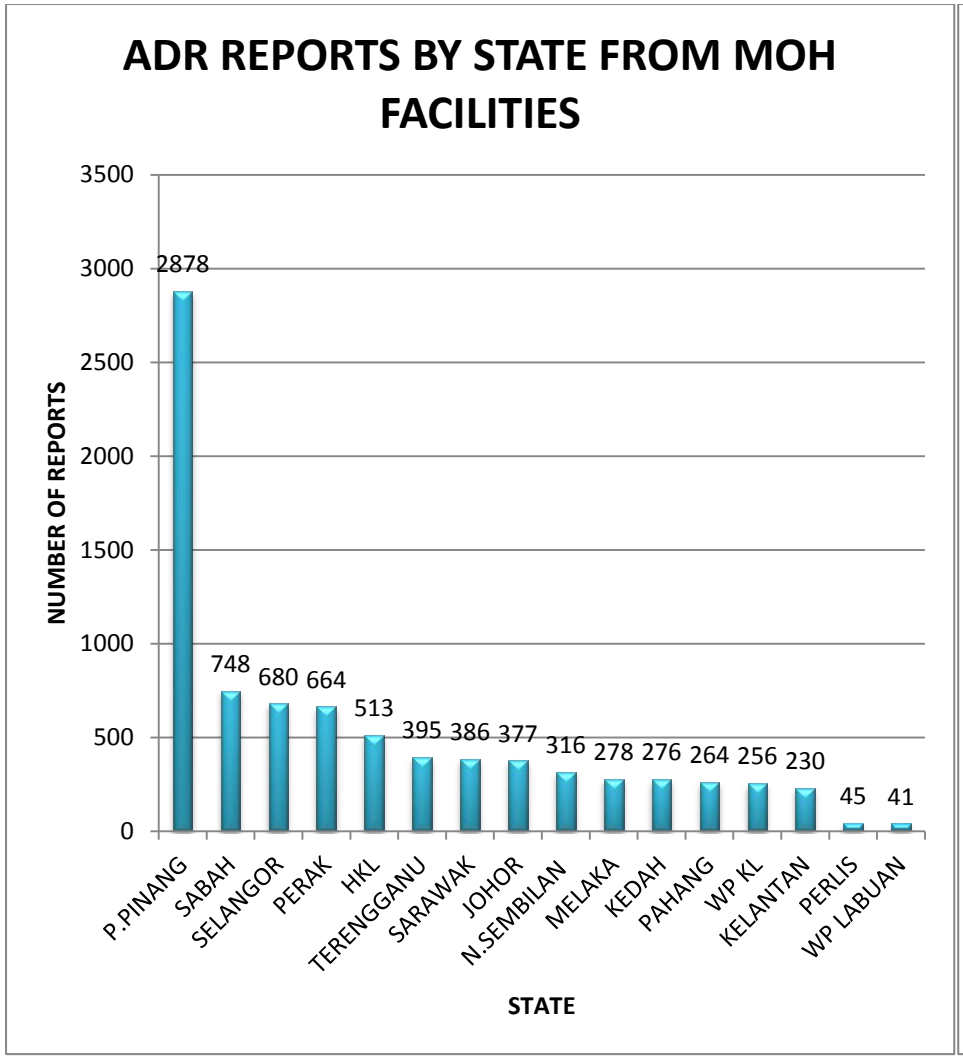
APPENDIX 1

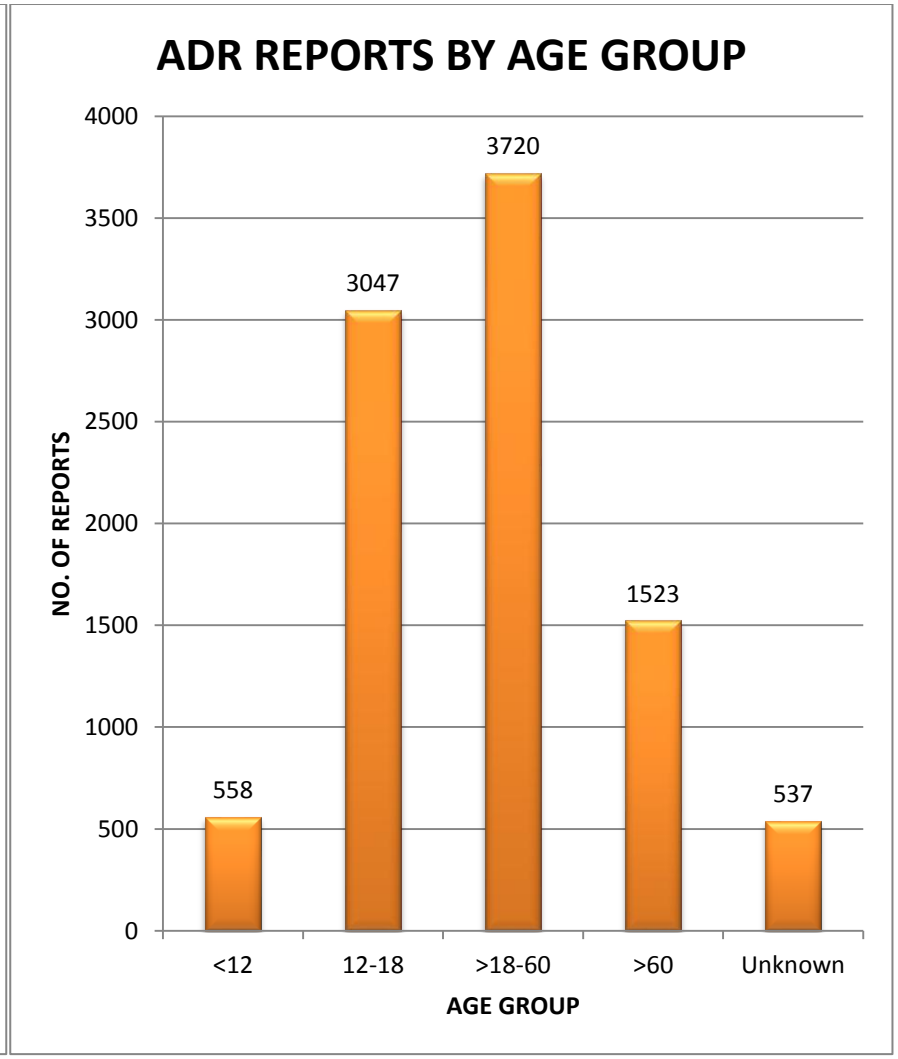

ADR & AEFI REPORTS RECEIVED (YEAR 2000-2011)
NO. OF REPORTS
YEAR
10000
9000
8000
7000
6000
5000
4000
3000
2000
1000
0
2000
2001
2001
2003
2004
2005
2006
2007
2008
2009
2010
2011
792
787
1000
1063
1665
2363
2543
3068
4826
5850
7079
9385
778
777
974
1050
1613
2295
2504
2993
4694
5636
5550
6202
14
10
26
13
52
68
39
75
132
214
1529
3138
TOTAL REPORTS
AEFI REPORTS
ADR REPORTS

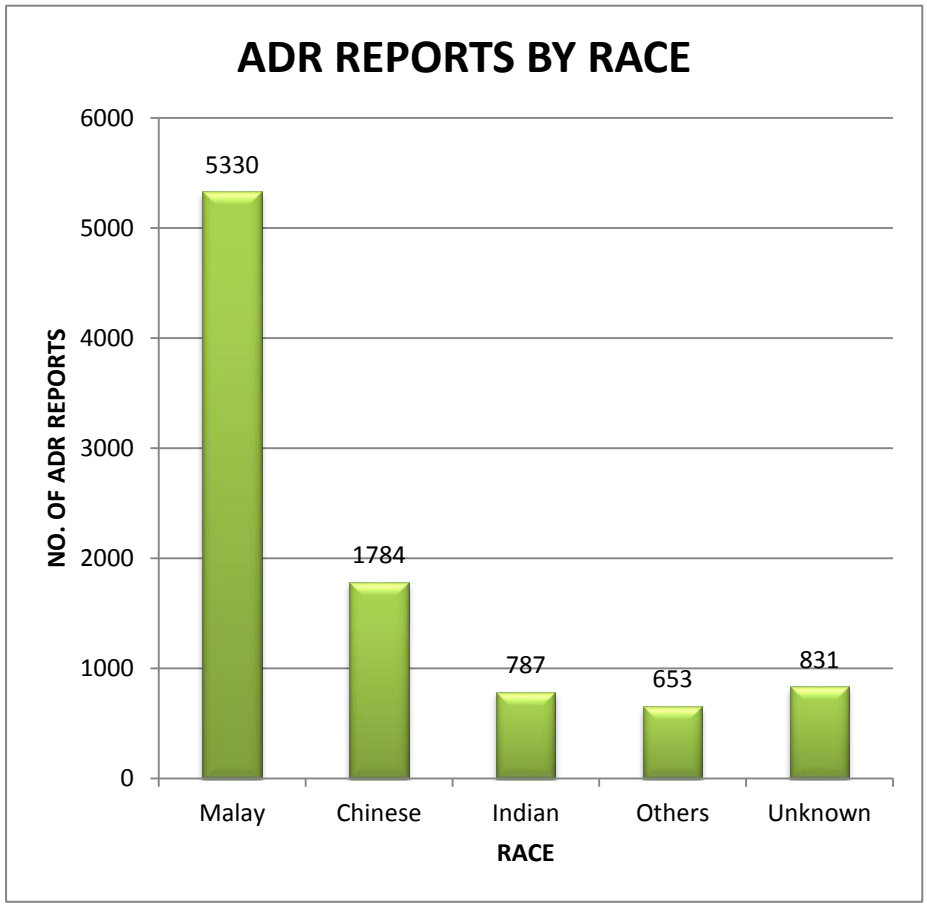
ADR REPORTS BY REPORTERS

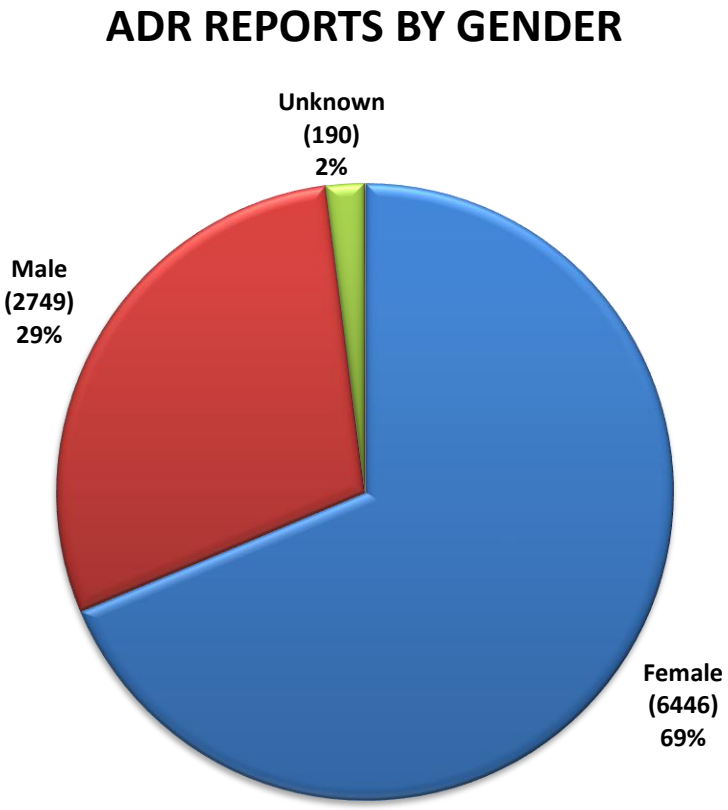


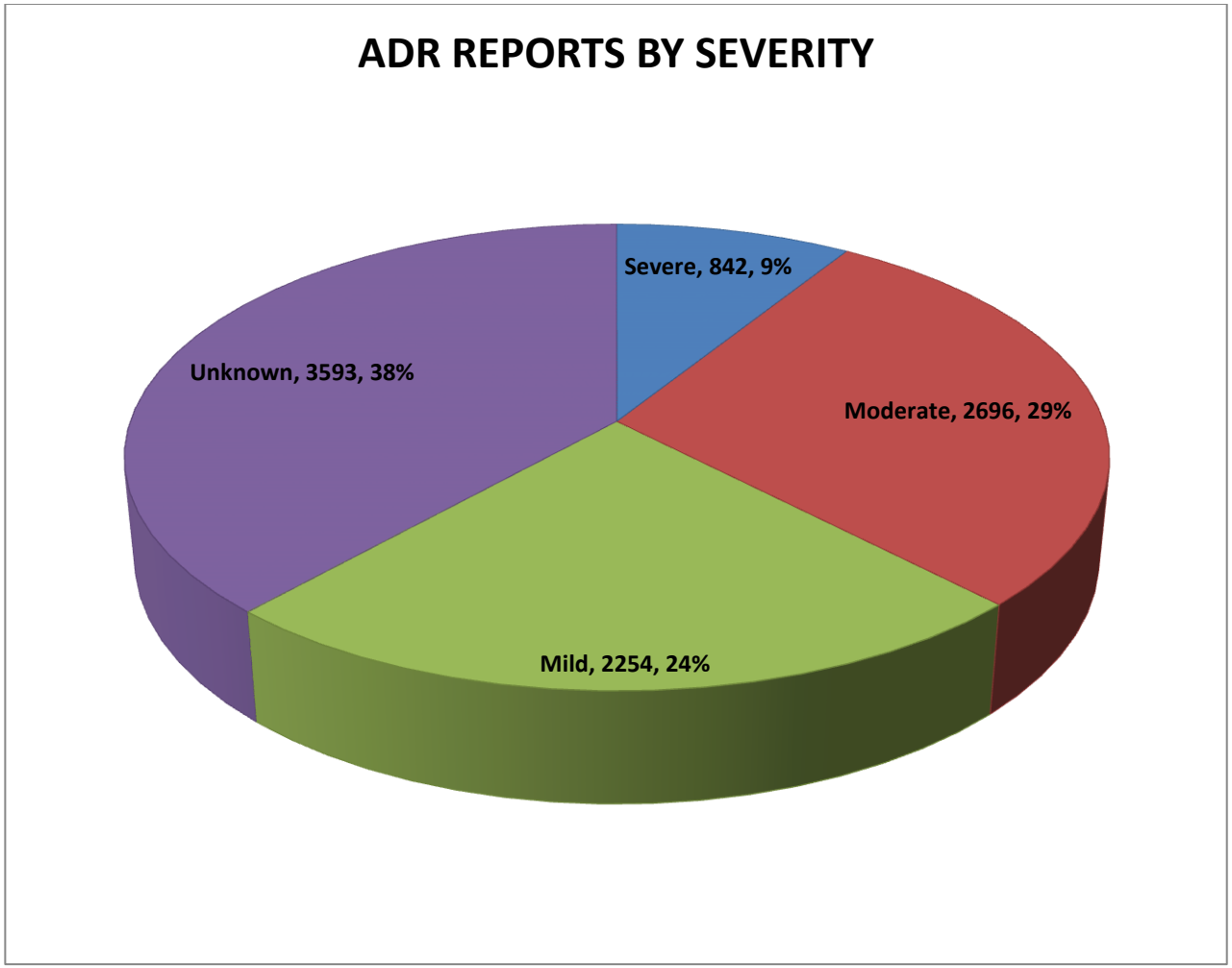
	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011
MOH Doctors	573	496	651	646	988	1079	1273	1075	1272	1340	1418	1295
MOH Pharmacist	74	118	162	169	352	606	726	1283	2401	3358	4160	4267
MOH Nurse									3	25	388	2063
GP/Private Specialist	38	94	49	60	83	157	64	61	214	144	248	185
Company	43	67	90	141	141	368	330	409	751	686	612	691
University	0	36	47	47	54	153	150	240	173	281	234	142
Others									12	16	19	742


ADR REPORTS BY STATE FROM MOH FACILITIES
NUMBER OF REPORTS
3500
3000
2500
2000
1500
1000
500
0
2878
748
680
664
513
395
386
377
316
278
276
264
256
230
45
41
P.PINANG
SABAH
SELANGOR
PERAK
HKL
TERENGGANU
SARAWAK
JOHOR
N.SEMBILAN
MELAKA
KEDAH
PAHANG
WP KL
KELANTAN
PERLIS
WP LABUAN
STATE

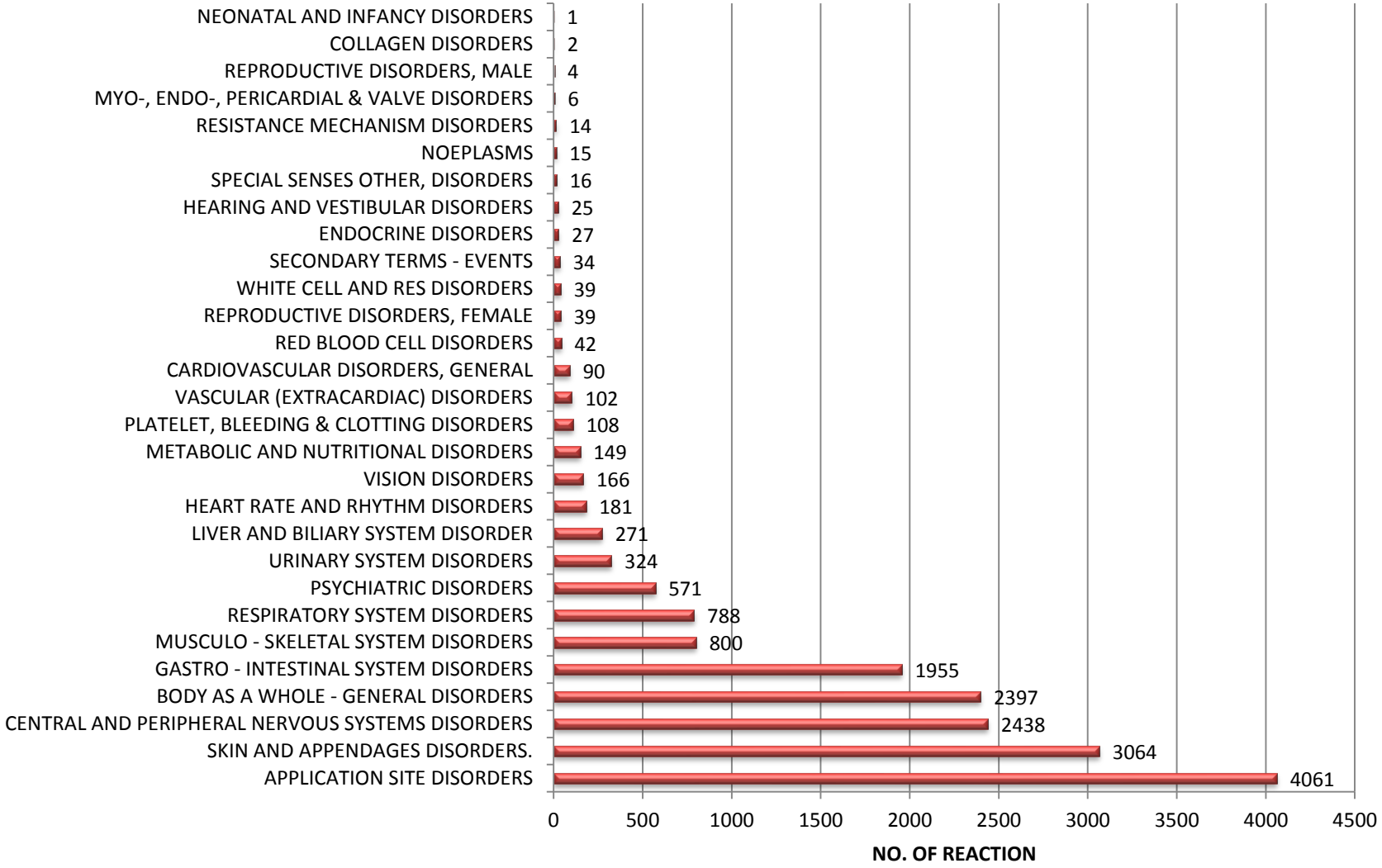

ADR REPORTS BY AGE GROUP
NO. OF REPORTS
4000
3500
3000
2500
2000
1500
1000
500
0
558
3047
3720
1523
537
<12
12-18
>18-60
>60
Unknown
AGE GROUP

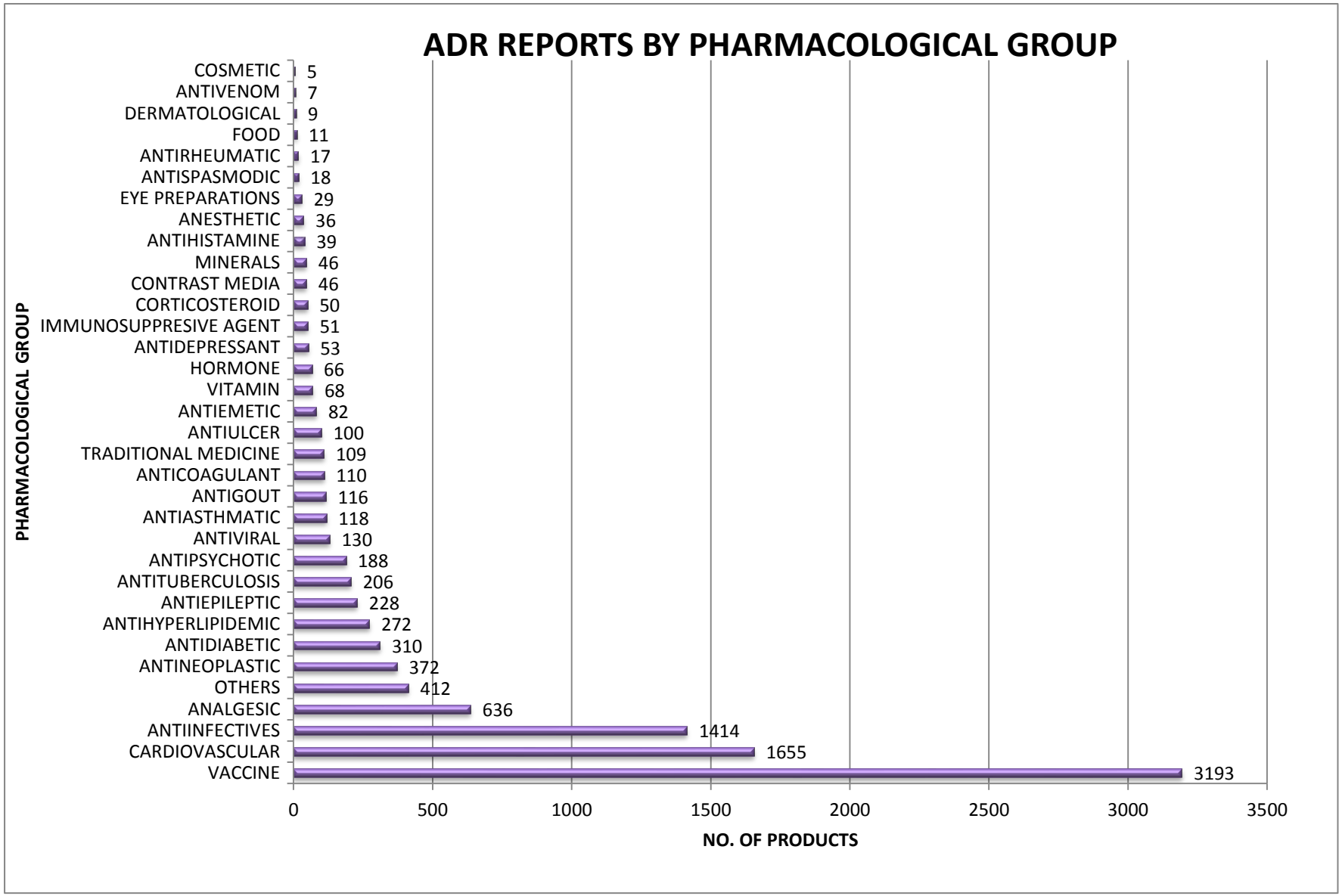

ADR REPORTS BY RACE
NO. OF ADR REPORTS
6000
5000
4000
3000
2000
1000
0
5330
1784
787
653
831
Malay
Chinese
Indian
Others
Unknown
RACE


ADR REPORTS BY GENDER
Unknown
(190)
2%
Male
(2749)
29%
Female
(6446)
69%


ADR REPORTS BY SEVERITY
Severe, 842, 9%
Moderate, 2696, 29%
Mild, 2254, 24%
Unknown, 3593, 38%

ANALYSIS OF ADR REPORTS BY SYTEM ORGAN CLASS (SOC)




ADR REPORTS BY PHARMACOLOGICAL GROUP
PHARMACOLOGICAL GROUP
COSMETIC 5
ANTIVENOM 7
DERMATOLOGICAL 9
FOOD 11
ANTIRHEUMATIC 17
ANTISPASMODIC 18
EYE PREPARATIONS 29
ANESTHETIC 36
ANTIHISTAMINE 39
MINERALS 46
CONTRAST MEDIA 46
CORTICOSTEROID 50
IMMUNOSUPPRESIVE AGENT 51
ANTIDEPRESSANT 53
HORMONE 66
VITAMIN 68
ANTIEMETIC 82
ANTIULCER 100
TRADITIONAL MEDICINE 109
ANTICOAGULANT 110
ANTIGOUT 116
ANTIASTHMATIC 118
ANTIVIRAL 130
ANTIPSYCHOTIC 188
ANTITUBERCULOSIS 206
ANTIEPILEPTIC 228
ANTIHYPERLIPIDEMIC 272
ANTIDIABETIC 310
ANTINEOPLASTIC 372
OTHERS 412
ANALGESIC 636
ANTIINFECTIVES 1414
CARDIOVASCULAR 1655
VACCINE 3193
0
500
1000
1500
2000
2500
3000
3500
NO. OF PRODUCTS