ANNUAL REPORT OF THE MALAYSIAN ADVERSE DRUG REACTIONS ADVISORY COMMITTEE (MADRAC) 2012

1. Membership of MADRAC till the end of 2012

MADRAC Members*(Alternate members)*	
Mr Tan Ann Ling 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 2012, six (6) meetings were conducted with a total of 10102 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 2012 was conducted (Appendix 1).

4. MALAYSIAN ADVERSE DRUG REACTIONS ADVISORY COMMITTEE (MADRAC) SAFETY ISSUES FOR 2012

During the course of 2012, 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.

Date	Topic of Safety Issue Discussed	MADRAC Decision/ Resulting Action
16/2/2012	Rasilez® (Aliskiren): Termination Of ALTITUDE Study In High Risk Patients With Diabetes And Renal Impairment	This information was communicated to healthcare professionals via the MADRAC Bulletin.
12/4/2012	Strontium Ranelate: New Contraindications In VTE & Revised Warnings On Severe Skin Reactions	Update of package insert to include these contraindications, and close monitoring by NPCB to obtain further information on this issue.
	Simvastatin: New Restrictions To Reduce Risk Of Muscle Injury	Update of package insert to include new dose limitations and contraindications.
	Clostridium difficile- associated Diarrhoea Can Be Associated With Proton Pump Inhibitors(PPIs)	This safety information was published in the REAKSI newsletter to encourage review of the long-term use of PPIs.
	Association of Domperidone Maleate With Serious Ventricular Arrhythmias and Sudden Cardiac Death	Continued monitoring of the drug safety profile by NPCB.
24/5/2012	COX-2 Inhibitors: Appeal On Statement Regarding Limitation Of Use As Second-Line Therapy	The appeal to remove this statement from the package insert was accepted.
	Celexa® (Citalopram Hydrobromide): Drug Safety Communication: Abnormal Heart Rhythms Associated With High Doses	This information was included in package inserts for all local products in line with the innovator product.
21/7/2012	Primperan® (Metoclopramide): The French Agency For The Safety Of Healthcare Products (AFSSAPS)'s Regulatory Action To Contraindicate In Paediatric Patients Aged Less Than 18 Years	Information on the contraindication is included in the package insert for Primperan®.
20/9/2012	Reduction Of Maximum Dose From 32mg To 16 Mg With Ondansetron (Zofran®) Intravenous Due To QT Prolongation	Inclusion of additional warnings and safety information in package insert.
	Contraindication Of Volibris® (Ambrisentan) In Patients With Idiopathic Pulmonary Fibrosis (IPF)	Update of package insert with the new contraindication.
6/12/2012	Issue: Appeal On Re-Registration Of Nimesulide Tablet	Appeal was not considered as the risk of using nimesulide outweighs the benefits.
	Class Labeling Of Statins	Update of package inserts to include information on cognitive adverse events, and increased HbA1c and fasting blood glucose.

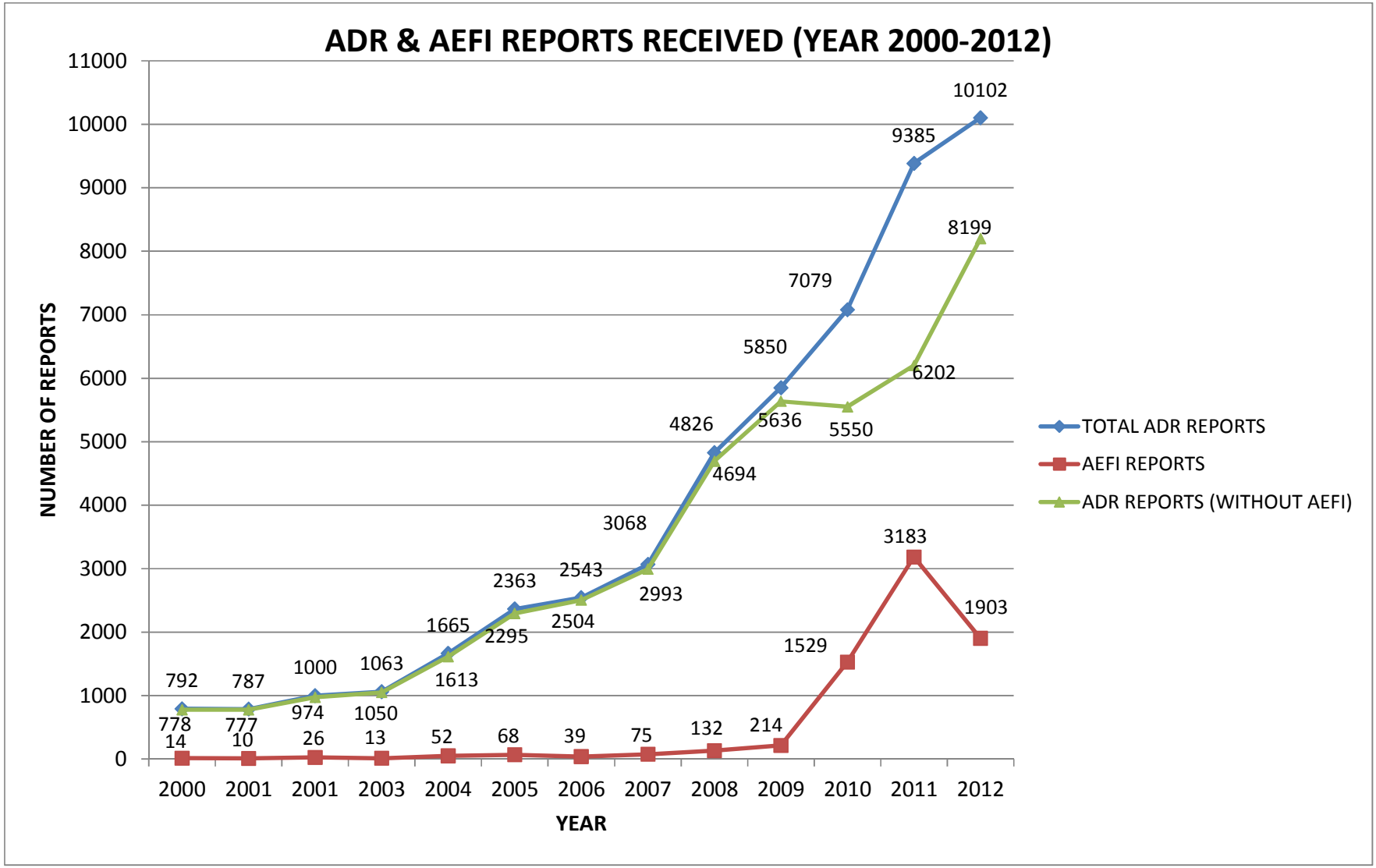
5. ACTIVITIES

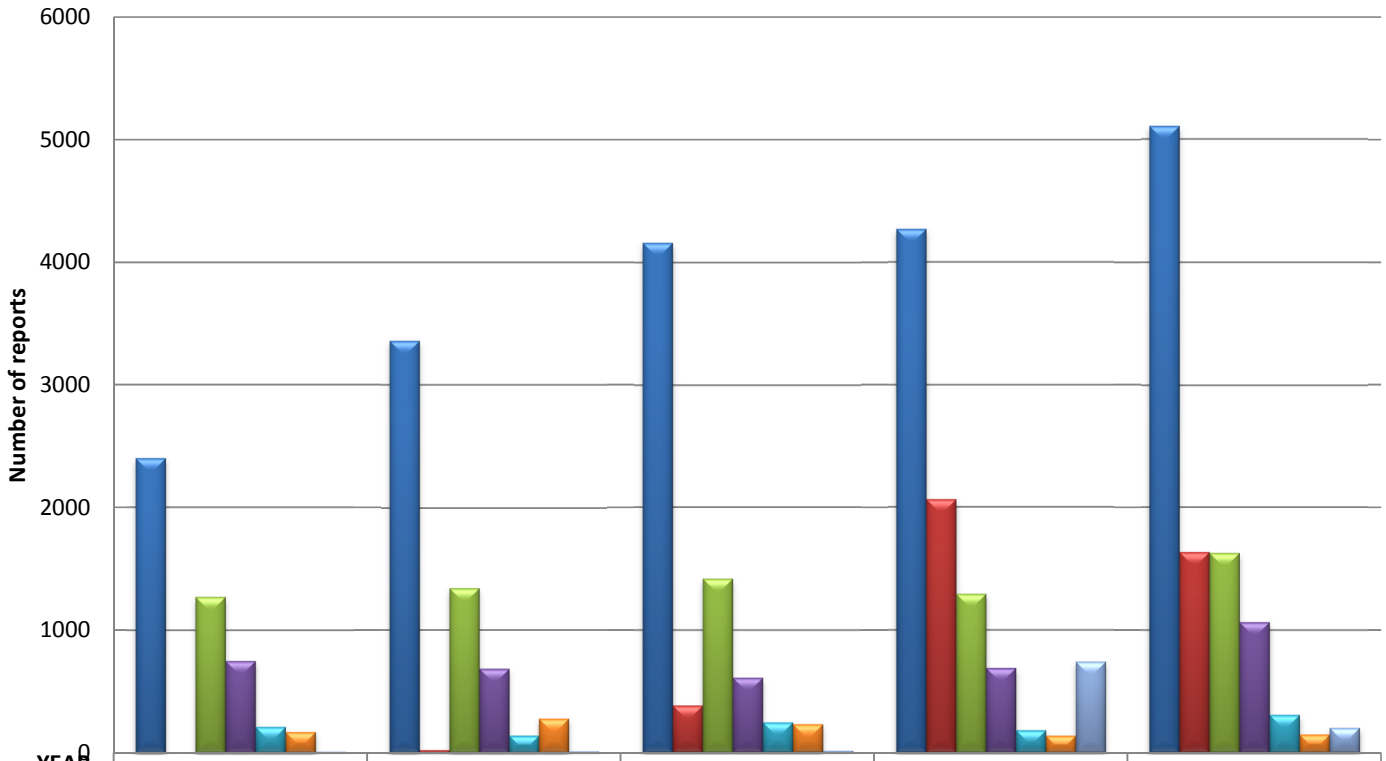
Throughout 2012 several talks in an effort to promote awareness on ADR/AEFI reporting, quality reporting as well as to update healthcare personnel on issues related to drug safety.

No.	Date	Programme / Presentation Topic	Organiser
1	4/4/2012	Workshop on the Management of Human Papilloma Virus (HPV) Vaccination Programme	Lembaga Penduduk dan Pembangunan Keluarga Negara (LPPKN)
2	12/4/2012	Medication Safety Course: What is an ADR?	Hospital Kajang, Selangor
3	16-17/4/2012	Briefing on Adverse Drug Reaction Reporting	Pharmaceutical Services Division, JKN Perak
4	23-25/4/2012	Workshop on the Management of Adverse Events Following Immunization (AEFI)	Pharmaceutical Services Division, Ministry of Health and NPCB
5	24/4/2012	Asia-Pacific Economic Cooperation And Standards: Product Complaints and Pharmacovigilance	Asia-Pacific Economic Cooperation
6	15/5/2012	ADR Workshop: MADRAC Updates	Hospital Selayang, Selangor
7	20/5/2012	45th MPS Annual Seminar Focus on Non-Communicable Diseases: Awareness and Importance of ADR Reporting	Malaysian Pharmaceutical Society
8	29/5/2012	Causality Assessment and Quality Reporting for ADR Workshop	Pharmacovigilance Section, NPCB
9	21/6/2012	7th National Pharmacy R&D Conference 2012: The Future of Pharmacovigilance	Pharmaceutical Services Division, Ministry of Health and Malaysian Pharmaceutical Society
10	26/6/2012	Quality Reporting for ADR Workshop: Causality Assessment Of ADRs	Pharmacovigilance Section, NPCB
11	27/6/2012	Pharmacy Course Lecture: Adverse Drug Reactions	Faculty of Pharmacy, Cyberjaya University College of Medical Sciences
12	27/6/2012	Continuous Medical Education Session: Adverse Drug Reactions	National Heart Institute (IJN)
13	28/6/2012	Ward Pharmacy Documentation Workshop: ADR Reporting	JKN Selangor
14	3-5/7/2012	Workshop on the Management of Human Papilloma Virus (HPV) Vaccination Programme	Lembaga Penduduk dan Pembangunan Keluarga Negara (LPPKN)
15	26/9/2012	Continuous Medical Education Session: Quality Reporting & Causality Assessment Of ADRs	Hospital Sungai Buloh, Selangor.

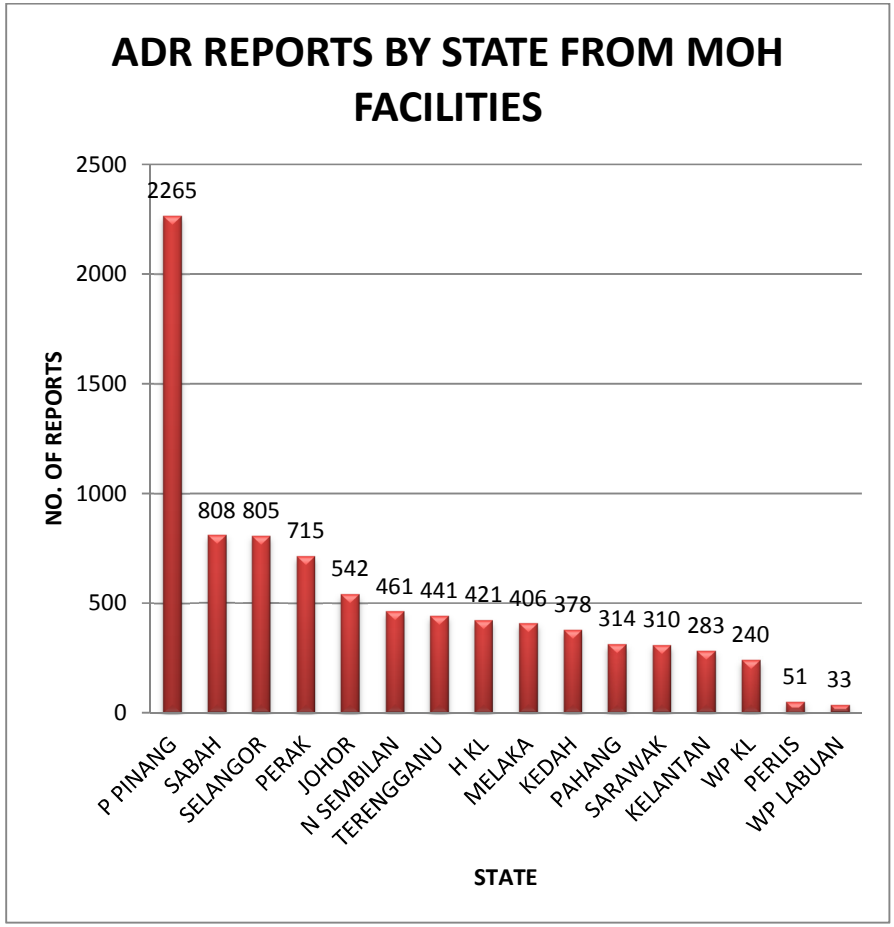
16	27/9/2012	Medication Safety Course: Quality Reporting of ADRs	Pharmacy Unit, Hospital Orang Asli Gombak, Selangor.
17	11/10/2012	Workshop on Medication Safety for Pharmacists and Assistant Pharmacists	Pharmaceutical Services Division, JKN Negeri Sembilan
18	23/10/2012	Briefing on Pharmacovigilance & Adverse Drug Reaction Reporting	JKN Melaka
19	24/10/2012	Briefing on Pharmacovigilance & Adverse Drug Reaction Reporting	JKN Melaka
20	13/12/2012	Medication Safety Course: Quality Reporting of ADRs	Pharmacy Unit, Hospital Orang Asli Gombak, Selangor.
21	14/12/2012	Continuous Medical Education Session: Pharmacovigilance in Malaysia	Hospital Tengku Ampuan Rahimah, Klang, Selangor

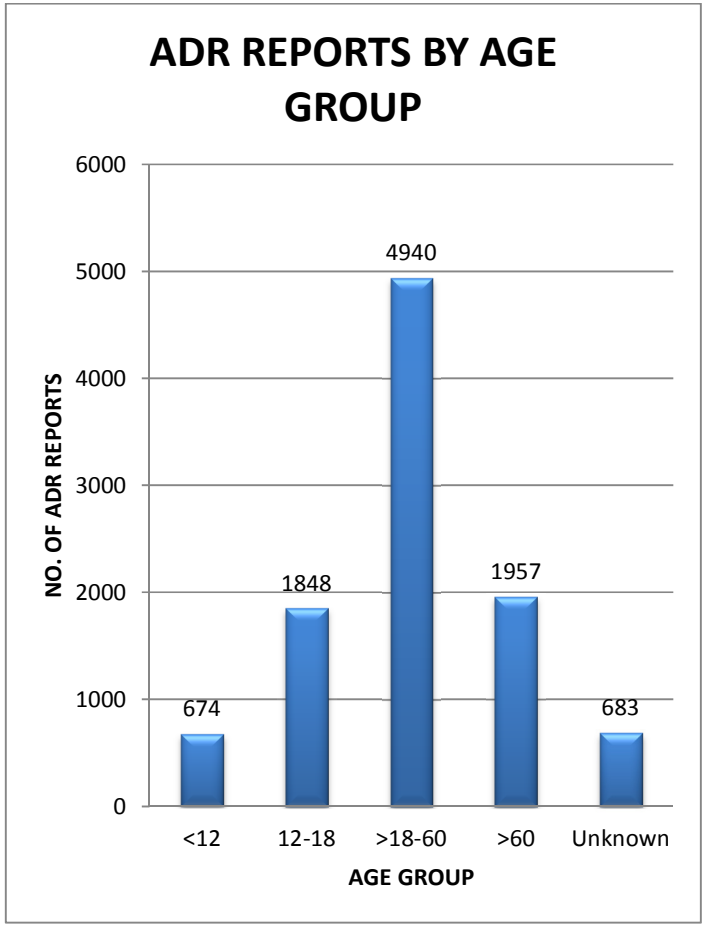
APPENDIX 1

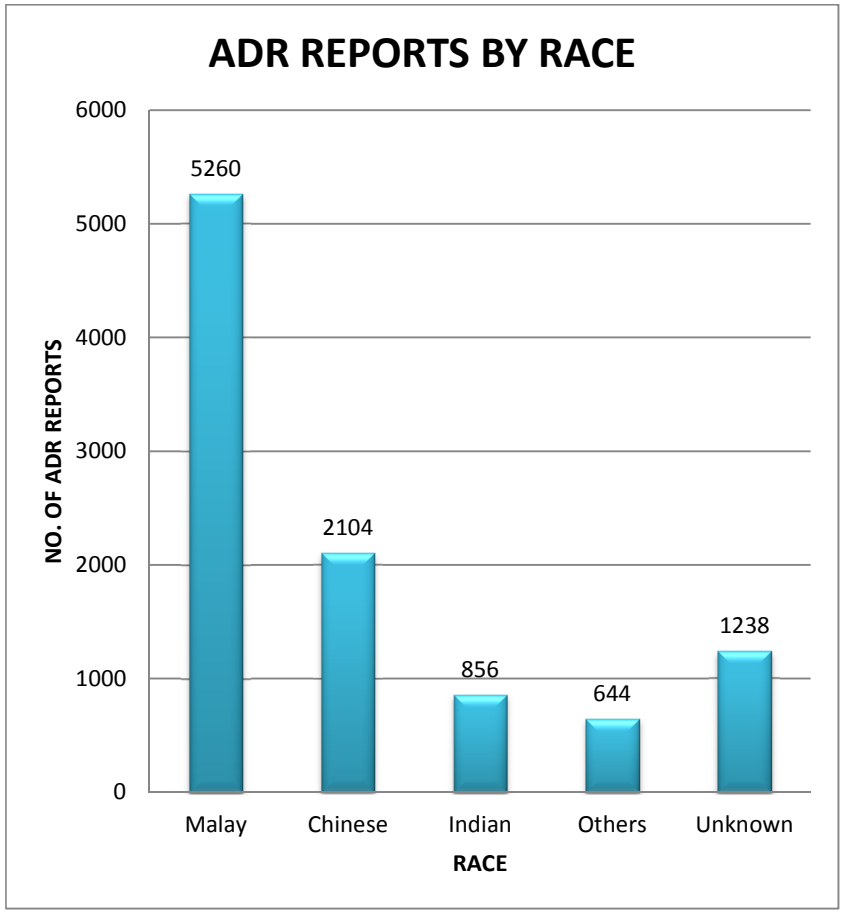

ADR & AEFI REPORTS RECEIVED (YEAR 2000-2012)
NUMBER OF REPORTS
YEAR
11000
10000
9000
8000
7000
6000
5000
4000
3000
2000
1000
0
2000
2001
2001
2003
2004
2005
2006
2007
2008
2009
2010
2011
2012
792
787
1000
1063
1665
2363
2543
3068
4826
5850
7079
9385
10102
778
777
974
1050
1613
2295
2504
2993
4694
5636
5550
6202
8199
14
10
26
13
52
68
39
75
132
214
1529
3183
1903
TOTAL ADR REPORTS
AEFI REPORTS
ADR REPORTS (WITHOUT AEFI)

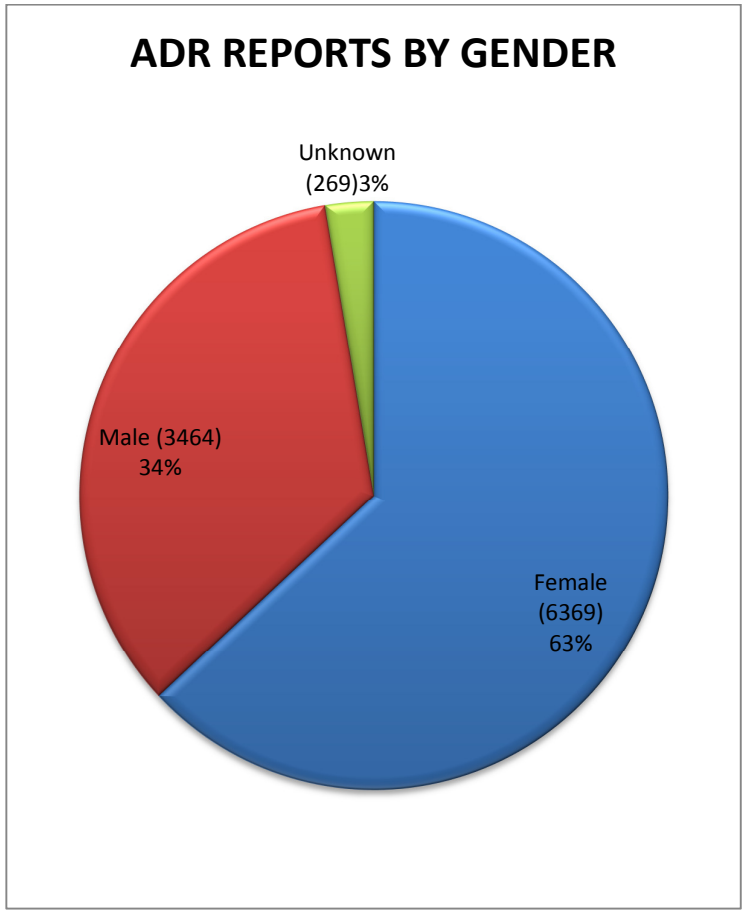


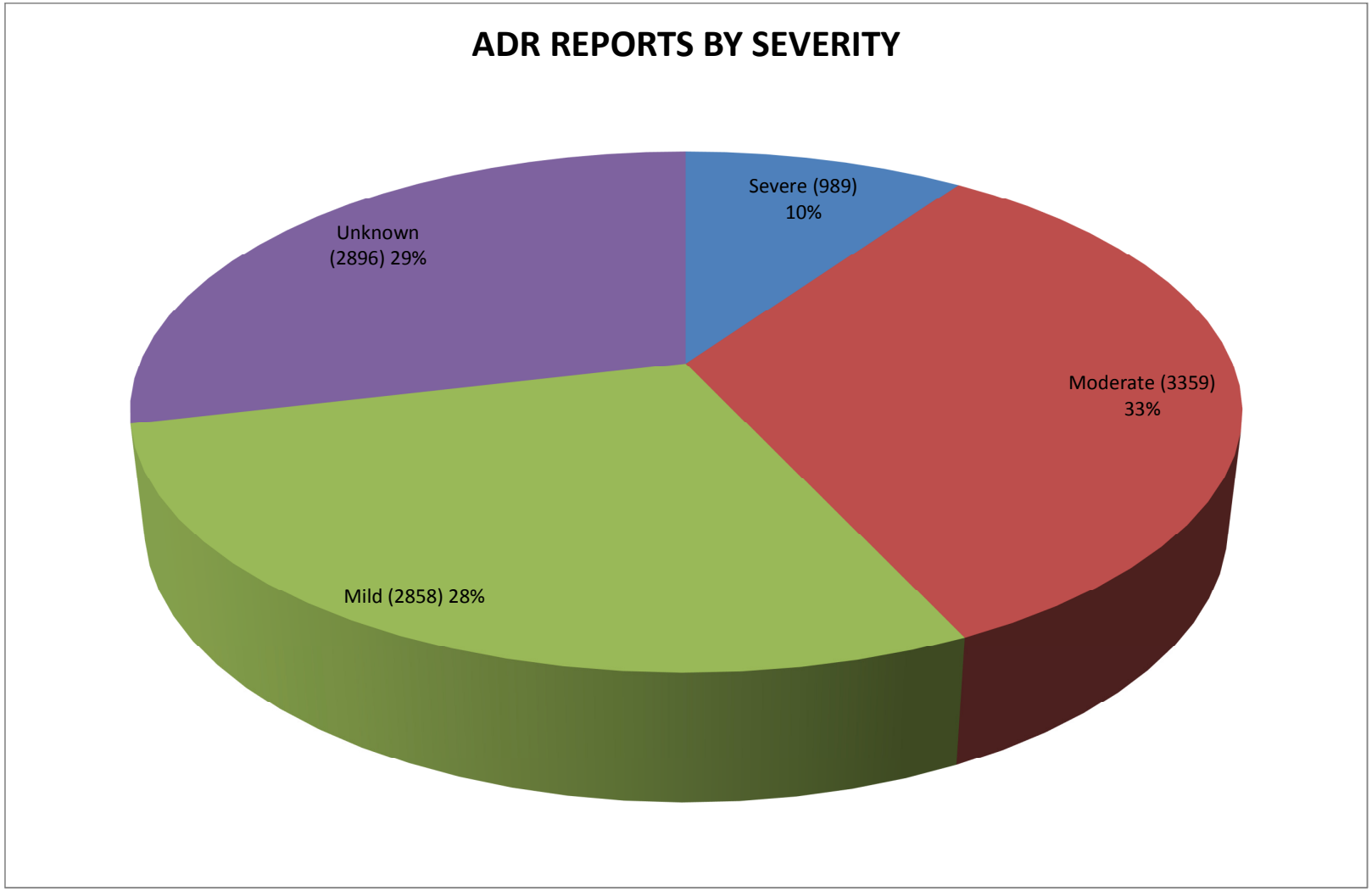
	2008	2009	2010	2011	2012
MOH Pharmacists	2401	3358	4160	4267	5106
MOH nurses	3	25	388	2063	1636
MOH doctors	1272	1340	1418	1295	1627
Product Registration Holders	751	686	612	691	1066
Private Specialists / GPs	214	144	248	185	310
Universities	173	281	234	142	151
Others	12	16	19	742	206

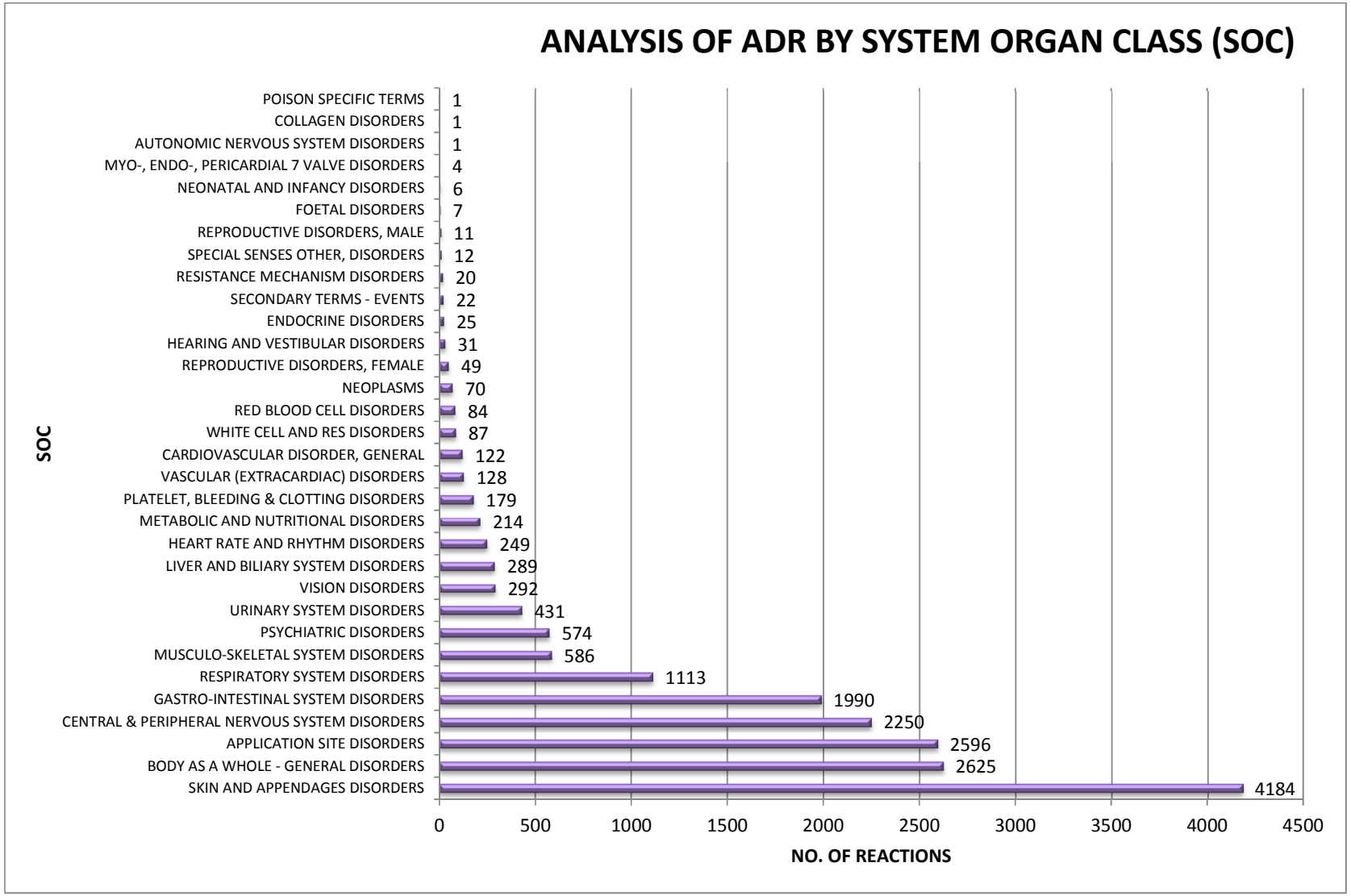

ADR REPORTS BY STATE FROM MOH FACILITIES
NO. OF REPORTS
2500
2000
1500
1000
500
0
2265
808
805
715
542
461
441
421
406
378
314
310
283
240
51
33
P PINANG
SABAH
SELANGOR
PERAK
JOHOR
N SEMBILAN
TERENGGANU
H KL
MELAKA
KEDAH
PAHANG
SARAWAK
KELANTAN
WP KL
PERLIS
WP LABUAN
STATE

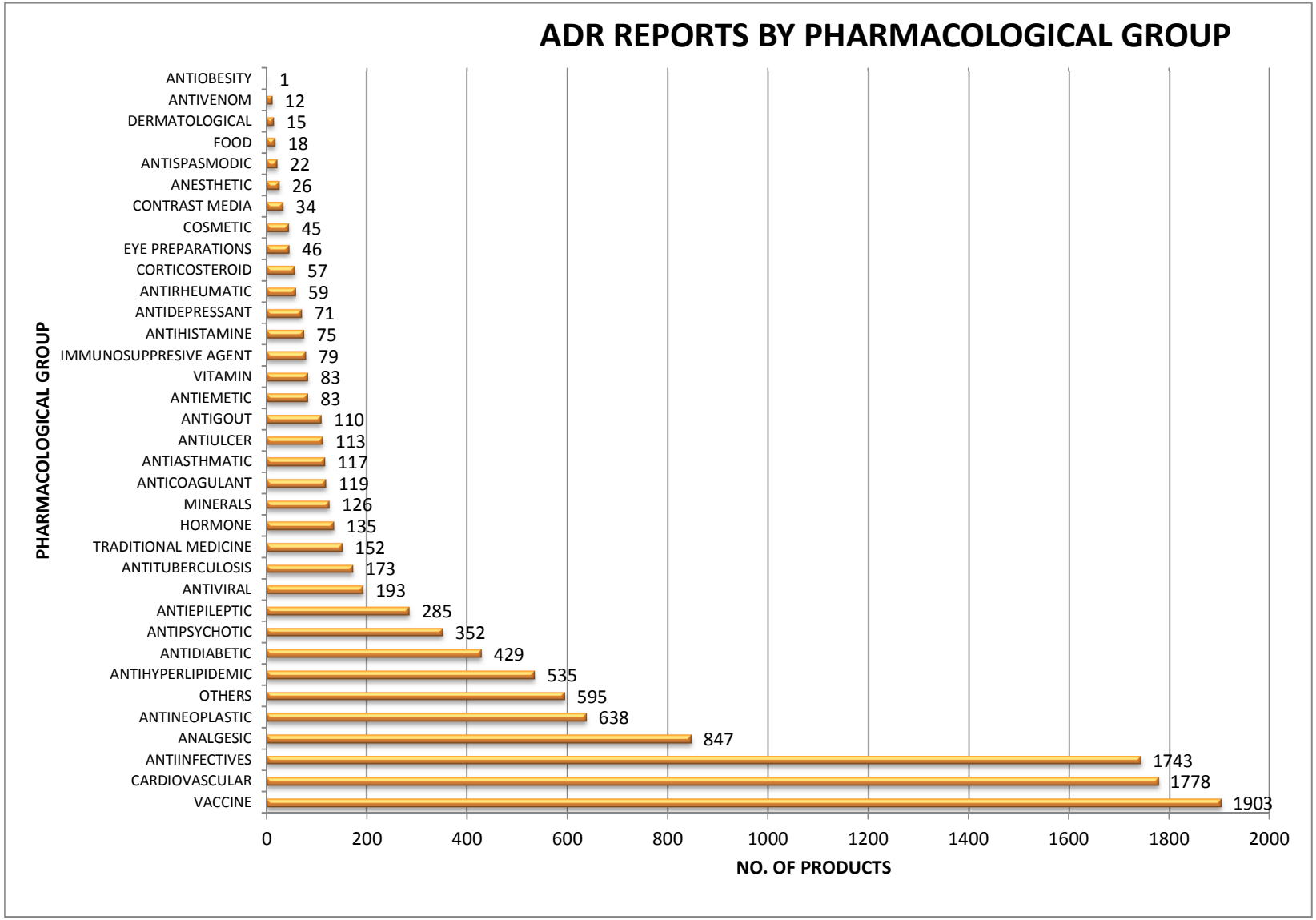

ADR REPORTS BY AGE GROUP
NO. OF ADR REPORTS
6000
5000
4000
3000
2000
1000
0
674
1848
4940
1957
683
<12
12-18
>18-60
>60
Unknown
AGE GROUP


ADR REPORTS BY RACE
NO. OF ADR REPORTS
6000
5000
4000
3000
2000
1000
0
5260
2104
856
644
1238
Malay
Chinese
Indian
Others
Unknown
RACE


ADR REPORTS BY GENDER
Unknown
(269)3%
Male (3464)
34%
Female
(6369)
63%


ADR REPORTS BY SEVERITY
Severe (989)
10%
Moderate (3359)
33%
Mild (2858) 28%
Unknown
(2896) 29%


ANALYSIS OF ADR BY SYSTEM ORGAN CLASS (SOC)
SOC
POISON SPECIFIC TERMS 1
COLLAGEN DISORDERS 1
AUTONOMIC NERVOUS SYSTEM DISORDERS 1
MYO-, ENDO-, PERICARDIAL 7 VALVE DISORDERS 4
NEONATAL AND INFANCY DISORDERS 6
FOETAL DISORDERS 7
REPRODUCTIVE DISORDERS, MALE 11
SPECIAL SENSES OTHER, DISORDERS 12
RESISTANCE MECHANISM DISORDERS 20
SECONDARY TERMS - EVENTS 22
ENDOCRINE DISORDERS 25
HEARING AND VESTIBULAR DISORDERS 31
REPRODUCTIVE DISORDERS, FEMALE 49
NEOPLASMS 70
RED BLOOD CELL DISORDERS 84
WHITE CELL AND RES DISORDERS 87
CARDIOVASCULAR DISORDER, GENERAL 122
VASCULAR (EXTRACARDIAC) DISORDERS 128
PLATELET, BLEEDING & CLOTTING DISORDERS 179
METABOLIC AND NUTRITIONAL DISORDERS 214
HEART RATE AND RHYTHM DISORDERS 249
LIVER AND BILIARY SYSTEM DISORDERS 289
VISION DISORDERS 292
URINARY SYSTEM DISORDERS 431
PSYCHIATRIC DISORDERS 574
MUSCULO-SKELETAL SYSTEM DISORDERS 586
RESPIRATORY SYSTEM DISORDERS 1113
GASTRO-INTESTINAL SYSTEM DISORDERS 1990
CENTRAL & PERIPHERAL NERVOUS SYSTEM DISORDERS 2250
APPLICATION SITE DISORDERS 2596
BODY AS A WHOLE - GENERAL DISORDERS 2625
SKIN AND APPENDAGES DISORDERS 4184
0 500 1000 1500 2000 2500 3000 3500 4000 4500
NO. OF REACTIONS


ADR REPORTS BY PHARMACOLOGICAL GROUP
PHARMACOLOGICAL GROUP
ANTIOBESITY 1
ANTIVENOM 12
DERMATOLOGICAL 15
FOOD 18
ANTISPASMODIC 22
ANESTHETIC 26
CONTRAST MEDIA 34
COSMETIC 45
EYE PREPARATIONS 46
CORTICOSTEROID 57
ANTIRHEUMATIC 59
ANTIDEPRESSANT 71
ANTIHISTAMINE 75
IMMUNOSUPPRESIVE AGENT 79
VITAMIN 83
ANTIEMETIC 83
ANTIGOUT 110
ANTIULCER 113
ANTIASTHMATIC 117
ANTICOAGULANT 119
MINERALS 126
HORMONE 135
TRADITIONAL MEDICINE 152
ANTITUBERCULOSIS 173
ANTIVIRAL 193
ANTIEPILEPTIC 285
ANTIPSYCHOTIC 352
ANTIDIABETIC 429
ANTIHYPERLIPIDEMIC 535
OTHERS 595
ANTINEOPLASTIC 638
ANALGESIC 847
ANTIINFECTIVES 1743
CARDIOVASCULAR 1778
VACCINE 1903
0 200 400 600 800 1000 1200 1400 1600 1800 2000
NO. OF PRODUCTS