

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

**1. i) Membership of MADRAC for the year 2010**

<b>MADRAC Members/(Alternate members)</b>	
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 of 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 myoglobinuria.
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 228<sup>th</sup> DCA meeting held on 27<sup>th</sup> 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.

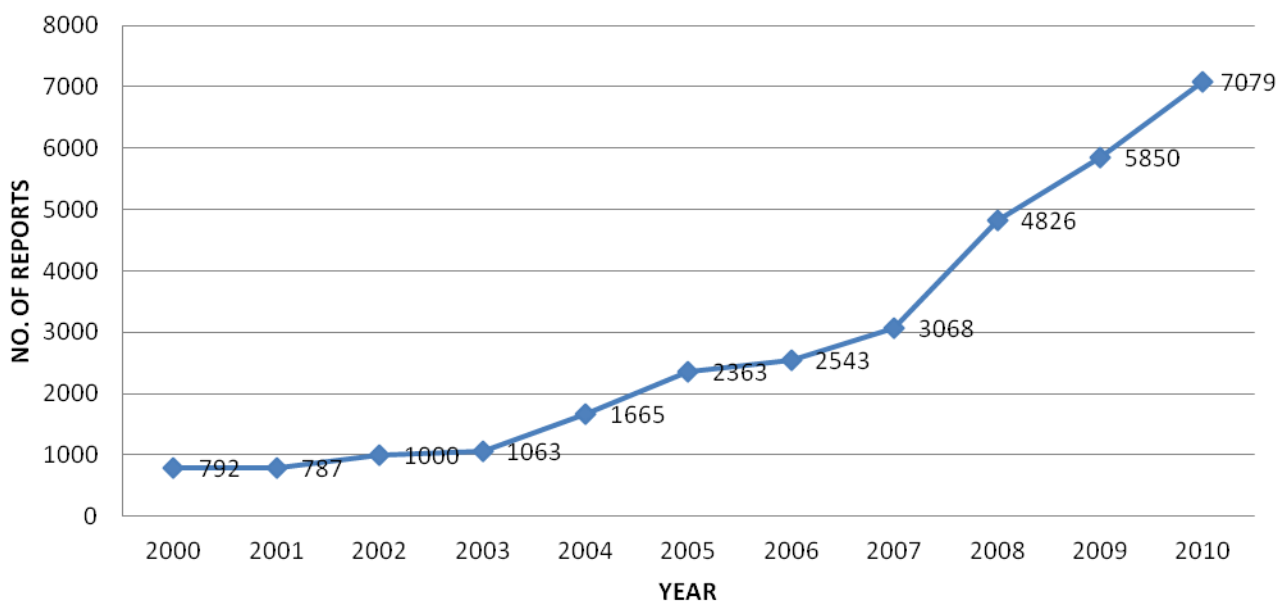
### **PROMOTING ADR REPORTING**

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.

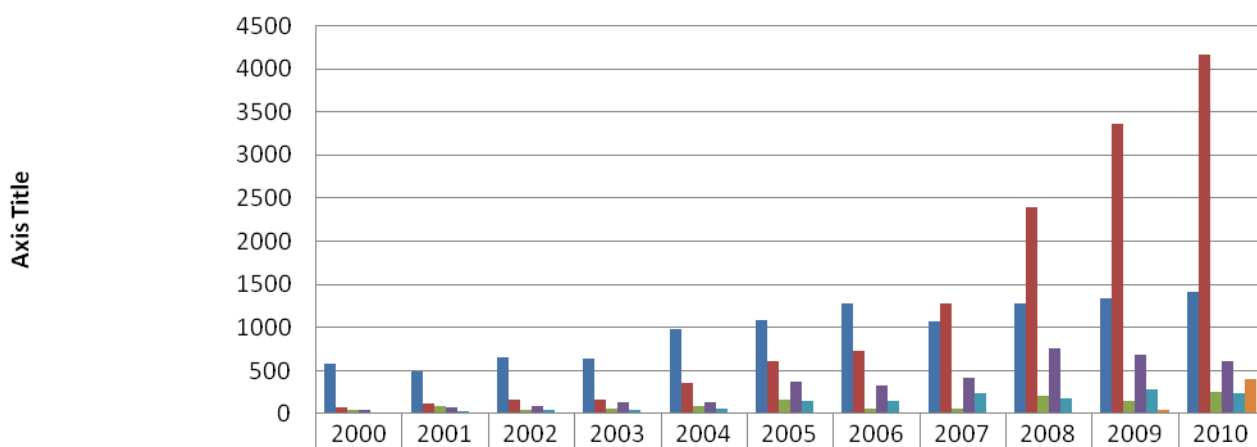
<b>PRESENTATION TOPIC</b>	<b>NUMBER OF TALKS GIVEN THROUGHOUT 2010</b>
Pharmacovigilance	3
Adverse Drug Reaction Reporting and Monitoring	8
Adverse Drug Reaction Reporting and Vaccine	2
Risk Management and Risk Assessment Plan	1
Adverse Drug Reaction Related To Skin Therapy	1
Adverse Drug Reactions And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

# APPENDIX 1

### NO. OF ADVERSE DRUG REACTION REPORTS RECEIVED (YEAR 2000-2010)

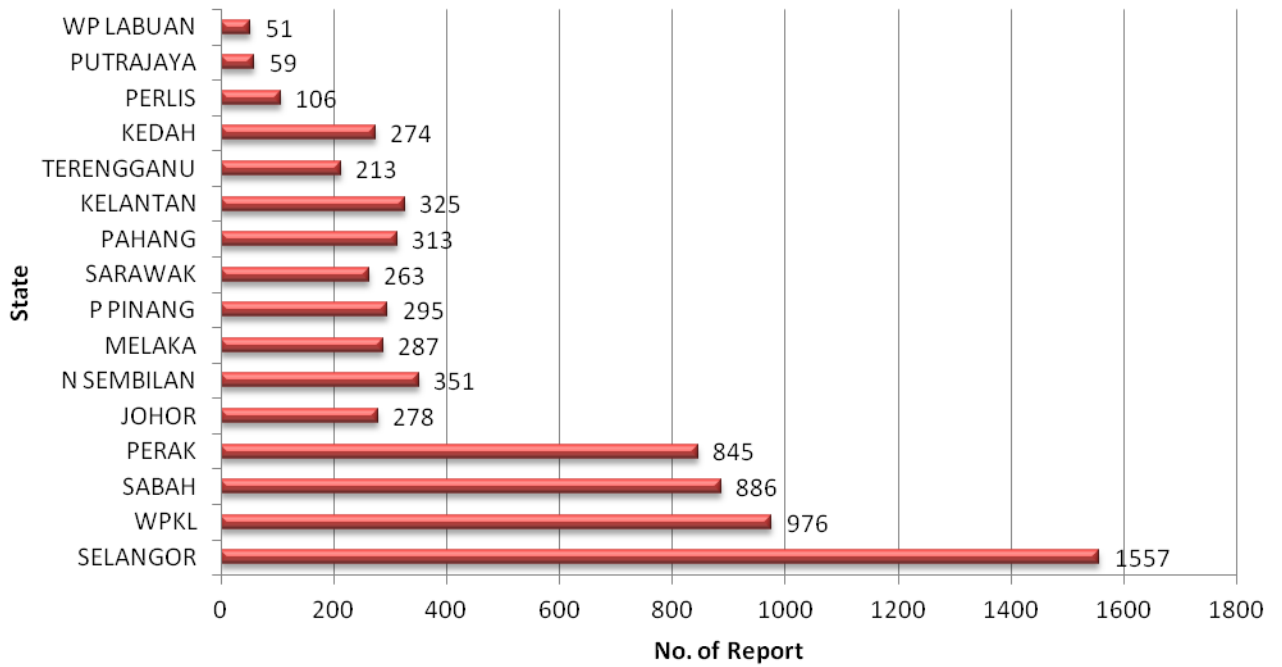


### ADR REPORT BY REPORTERS

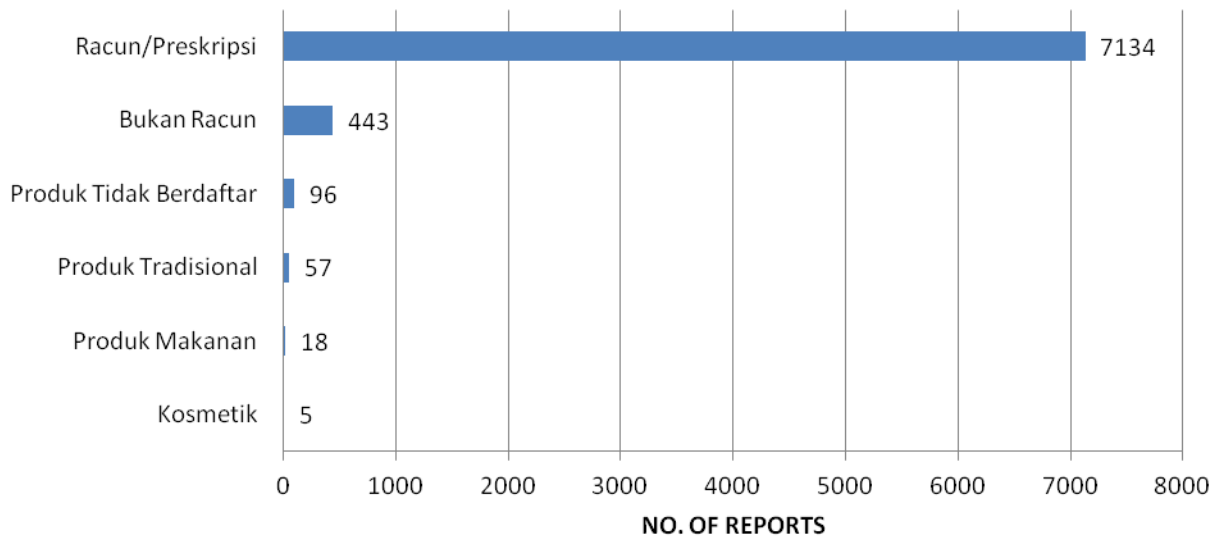


Year	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010
Government Doctors	573	496	651	646	988	1079	1273	1075	1272	1340	1418
Government Pharmacist	74	118	162	169	352	606	726	1283	2401	3358	4160
GP/Private Specialist	38	94	49	60	83	157	64	61	214	144	248
Company	43	67	90	141	141	368	330	409	751	686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

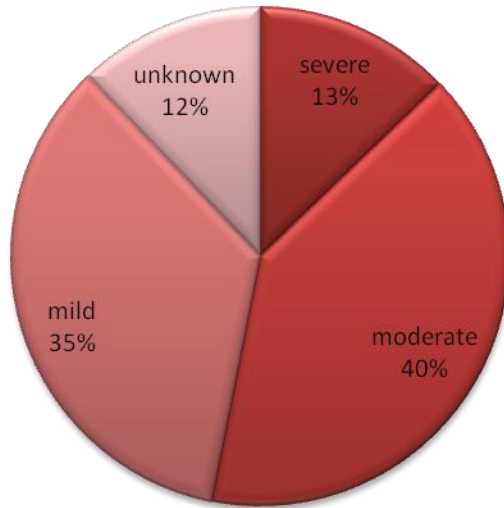
### Report by State 2010



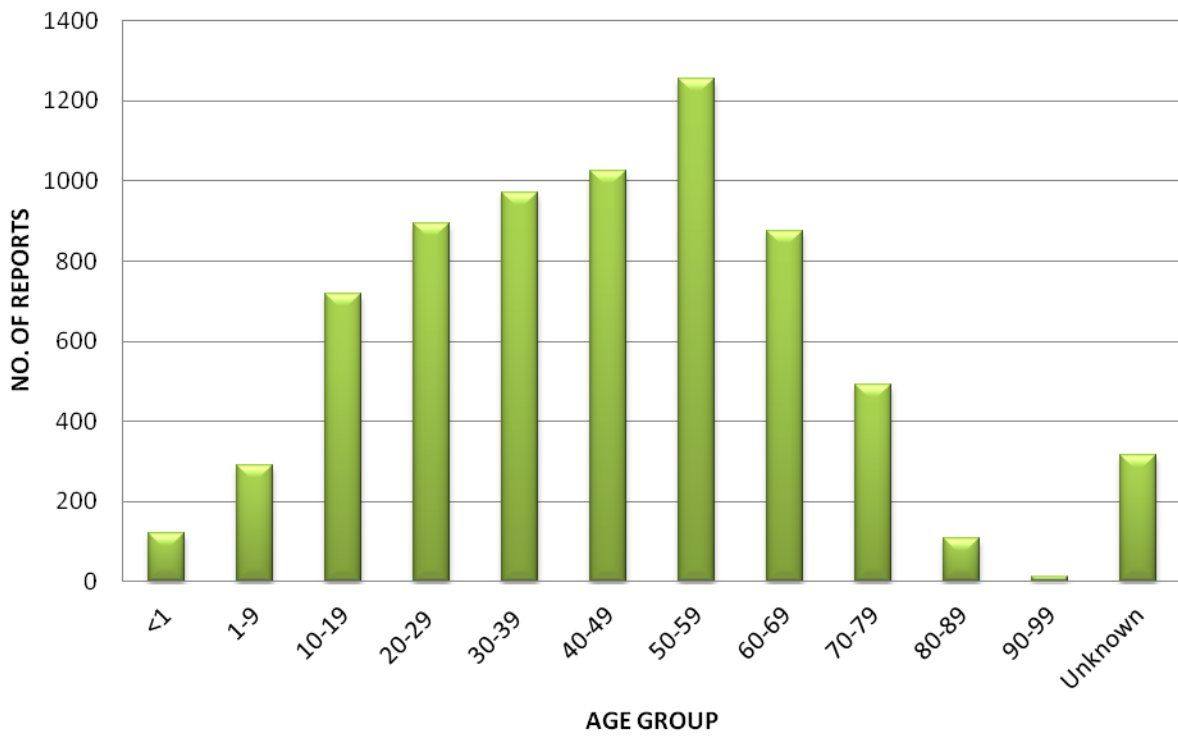
### ADR REPORTS BY PRODUCT CATEGORY



### ADR REPORTS BY SEVERITY

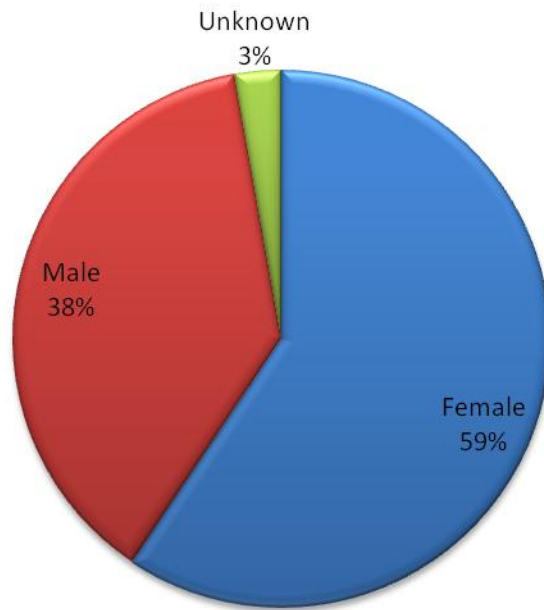


### ADR REPORTS BY AGE GROUP

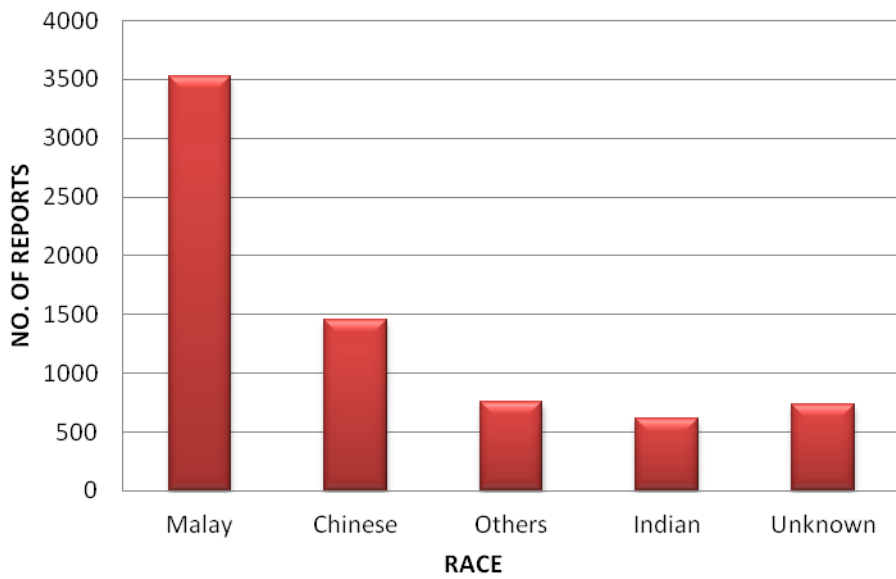




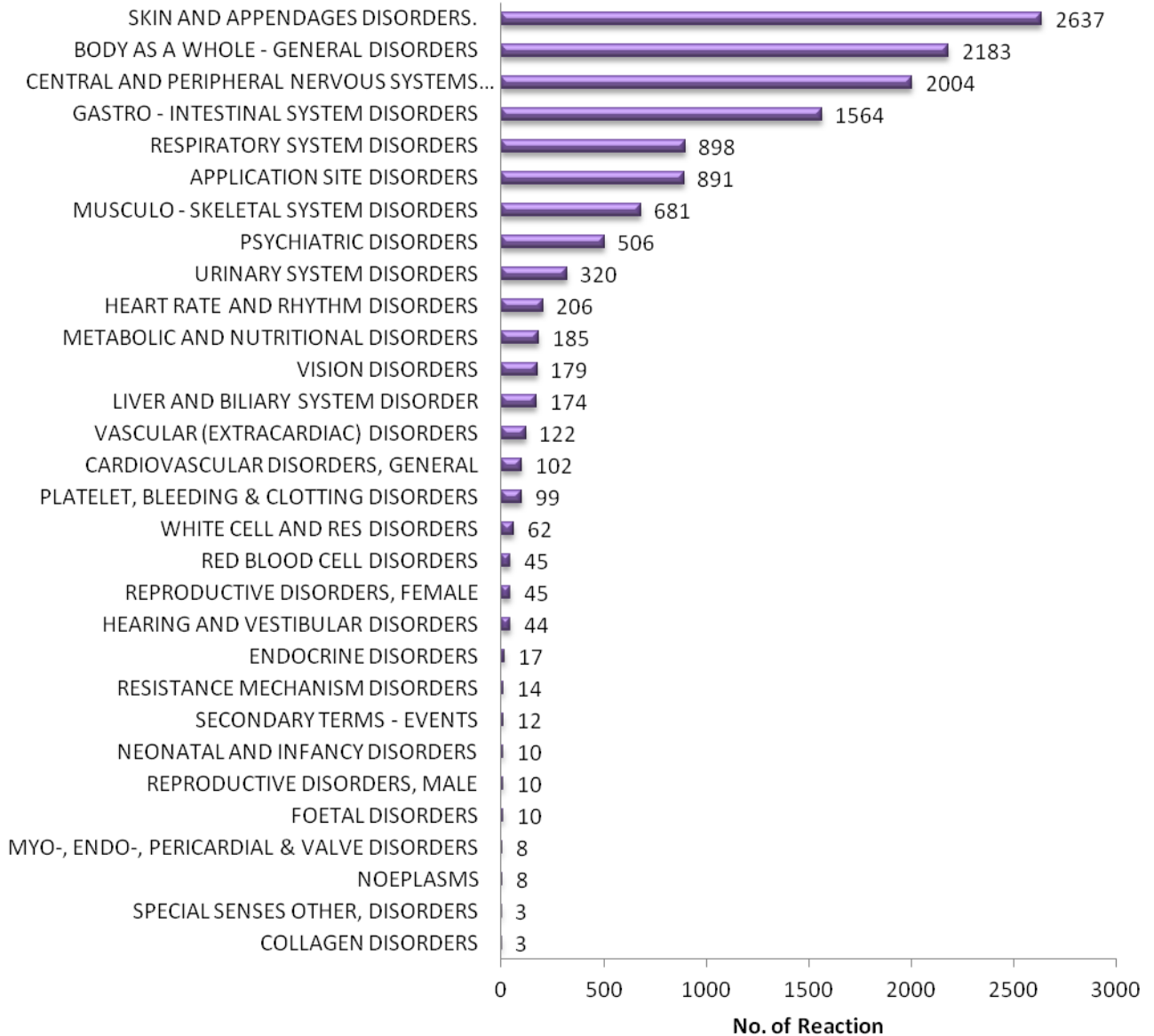
### ADR REPORTS BY GENDER



### ADR REPORTS BY RACE



## ANALYSIS OF ADR REPORTS BY SYSTEM ORGAN CLASS (SOC)



## ADR REPORTS BY PHARMACOLOGICAL GROUP

