ANNUAL REPORT OF
THE MALAYSIAN ADVERSE DRUG REACTIONS ADVISORY COMMITTEE 2000

ADR Reports Received by MADRAC 2000 (February)

MADRAC received a total of 875 ADR reports during 1999 which represents a 45.1% increase as compared to 1998. Fig. 1 shows the number of reports submitted by health professionals from the various states in 1999.

Graph 1 : Analysis Of ADR Reports By Health Professionals

A small increase (50%) was seen in the number of reports submitted by health professionals in the private sector (1998-44; 1999-66 reports). The number of reports submitted by pharmacists increased by 131% (1998-61; 1999-141 reports). There was also a significant increase (200%) in the number of reports submitted through the pharmaceutical industry (1998-18; 1999-54 reports).

Health Professionals	No. Of Reports
Government doctors	607
Pharmacists	141
Private practitioners	66
University	54
Industry	7
TOTAL	**875**

Graph 2 : Analysis Of ADR Reports By Health Professionals From Various States

MADRAC received a total of 875 ADR reports during 1999 which represents a 45.1% increase as compared to 1998. Fig. 1 shows the number of reports submitted by health professionals from the various states in 1999.

States	No. Of Reports
Kedah	24
Penang	33
Perak	149
Selangor	103
N. Sembilan	58
Melaka	37
Johor	82
Pahang	39
Terengganu	45
Kelantan	17
Sarawak	32
Sabah	48
Kuala Lumpur	194
Labuan	3

Graph 3 : Progress Of ADR Reporting Between 1987 - 1999

When ADR reporting was first initiated in 1987, only 10 reports were received. There has been a gradual increase in the number of reports received and in 1999, a total of 875 reports were received which was an increase of 45.1% as compared to 1998 (Fig.1).

Bukan Racun	48
Tradisional	126

1996	1997	1998	1999
531	602	714	1635
530	602	603	875
55	97	111	151

The incidence of adverse reactions:population ratio in 1999 was 44-reports/million population. The estimated incidence of ADRs by the WHO is 200-reports/million population.

Initially, the program relied on the submission of reports by clinicians, which resulted in reports being received mainly from the public sector. Initiatives have been taken to promote reporting amongst private practitioners in order to widen the scope of drugs being monitored as drugs used by the private sector vary from those used in government institutions. In 1999, only 7.5% of the total number of reports received were from doctors in the private sector.

A multidisciplinary approach towards ADR monitoring is being encouraged. Pharmacists in both the public and private sectors are beginning to realise their role in this system as they are in ideal position to provide detailed information on drugs which may have been used in patients who experience adverse reactions.

The pharmaceutical industry which has been very passive in the past has also recently started to monitor adverse reactions with marketed products. The number of reports submitted by pharmacists and through the pharmaceutical industry increased by 131% and 50% respectively in 1999 as compared to 1998 (Fig.2).

Graph 4 : Analysis Of ADR Reporting By Pharmaceutical Industry

Source of ADR Reports in 1999	No. of Reports
Government Doctor	319
Pharmacist	70
Government Specialist	68
Private Specialist	24
Pharmacuetical Company	20
General Practitioner	6
Total	**507**

Graph 5 : Analysis Of ADR Reports By Both Registered And Unregistered Drugs

A total of 4004 reports have been submitted to the national centre from 1987 to 1999. These include reports related to both registered and unregistered drugs.

Pharmacological Group

The pattern of ADR reports received for the period 1997 to 1999 showed a similar profile with the majority of ADRs being reported for antibiotics followed by cardiovascular drugs, analgesics and antiepileptic agents (Fig.3)

Pharmacological Group	No. of Reports
Antibacterials	266
Cardiovascular drugs	153
Analgesics	98
Antiepileptics	51
Antivirals	26
Contrast medias	25
Traditional drugs	23
Antipsychotics	20
Vaccines	17
Antineoplastics	13
Corticosteroids	13
Antiasthmatics	12
Antifungals	11
Antiimpotences	11
Antihistamines	10
Antiulcers	6
Others	120
TOTAL	**875**

The drugs which have been implicated with the largest number of ADR reports has remained relatively consistent. Collectively, the penicillins have been implicated in the most number of adverse reactions but the drug with the most number of ADR is cotrimoxazole and carbamazepine. An analysis of the top 10 drugs associated with the with the most ADR reports over the three year period is shown in Table 1.

Table 1: Drugs associated with the most adverse reactions 1997-1999

1997 (n=602)	1998 (n=603)	1999 (n=875)
Cotrimoxazole (33) Carbamazepine (28) Amoxycillin (22) Mefenemic acid (18) Pyrazinamide (15) Allopurinol (14) Cloxacillin (13) Erythromycin (13) Nifedipine (13) Methotrexate (12)	Cotrimoxazole (40) Carbamazepine (27) Amoxycillin (17) Phenytoin (15) cloxacillin (15) Mefenemic acid (14) Diclofenac (14) Aspirin (13) Allopurinol (12) Nifedipine (11)	Cotrimoxazole (45) Carbamazepine (29) Enalapril (29) Amoxycillin (25) Mefenemic acid (24) Phenytoin (19) Erythromycin (17) Diclofenac (17) Cloxacillin (16) Traditional medicines (16)

Traditional Medicine

In 1997, 11 (1.8%) reports were associated with the use of traditional medicines. An increasing number of reports to this group of drugs is being received with 15 (2.5%) reports in 1998 and 23 (2.6%) in 1999. This increasing trend could be attributed to the fact that practitioners are now aware that ADRs to traditional medicines should also be reported.

A major problem that is being encountered with monitoring ADRs to traditional medicines is due to the fact that these products often contain multiple ingredients thus making it difficult to identify the causative agent associated with reactions encountered.

Organ System

Based on organ system involvement, the majority of ADRs reported have been related to skin reactions with 371 (61.6%) reports in 1997, 313 (52%) reports in 1998 and 342 (39.1%) reports in 1999. This was followed by ADRs involving the central nervous system: 1997- 114 (18.9%); 1998 – 84 (14%); 1999-119 (13.6%).

Table 2. Drugs associated with renal and hepatic adverse reactions.

Year	Organ	No. Of Reports	Drug Implicated
1997	Renal	7 (1.1%)	Netilmicin, enalapril, captopril, nifedipine
	Hepatic	15 (2.5%)	Rifampicin, INH, dapsone, oxyphenacatin, azithromycin, chitosan, traditional
1998	Renal	6 (1.0%)	Gentamicin, enalapril, perindopril, traditional
	Hepatic	9 (1.5%)	Allopurinol, glibenclamide, carbimazole, streptokinase,INH, lisinopril, traditional
1999	Renal	24 (2.8%)	Enalapril, captopril, diclofenac, mefenemic acid, amoxycillin, perindopril, losartan, frusemide, pravastatin, alprostadil, ultravist, traditional
	Hepatic	30 (3.5%)	Paracetamol, glibenclamide, amlodipine, doneribavarin, simvastatin, chlropromazine, famotidine, INH, streptomycin, rifampicin

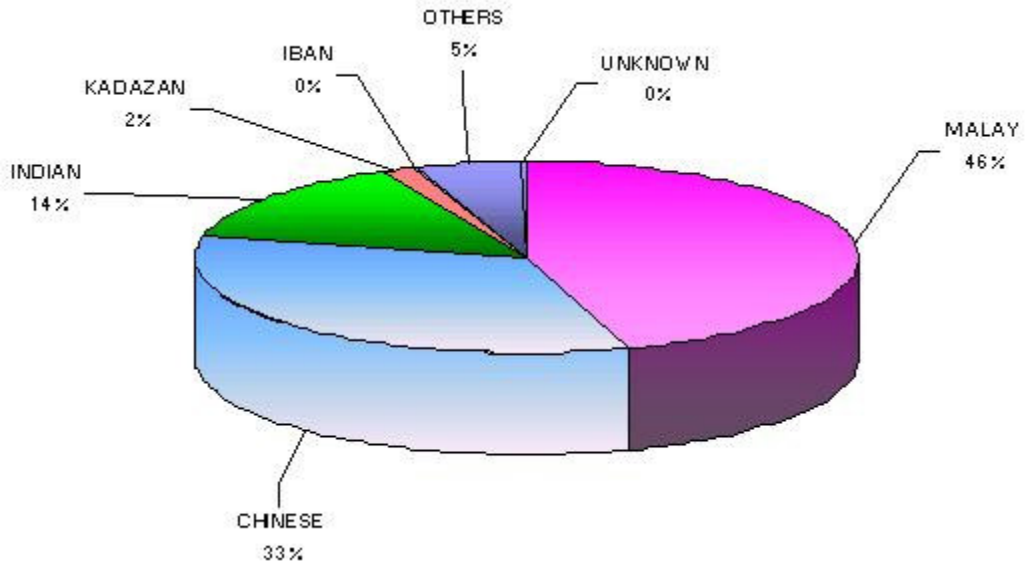
Graph 6 : Analysis Of ADR Reports By Ethicity , Gender And Age

Analysis of the ADR reports based on ethnicity reflected the racial composition of the country implying that no race was more prone to ADRs.

Ethnicity

Analysis of the ADR reports based on ethnicity in 1999 (n=409)

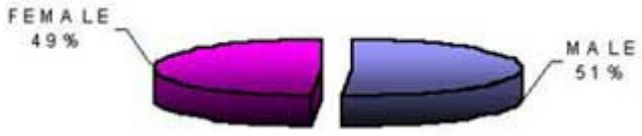
View Graph



Gender

Analysis of the ADR reports based on gender in 1999 (n=429)

View Graph



Age

Age	No. Of Reports
<1year	10
1<year<7	21
7<year<12	10
12<year<18	22
18<year<45	177
45<year<60	107
<60year	69
>80year	6
Total	**422**

Patients who were 18 years of age or more were the major groups who experienced adverse drug reactions. This probably was due to their health status which needed more medication.