

ANNUAL REPORT OF REGIONAL MONITORING CENTRES,
MEDICINES CONTROL AGENCY

WEST MIDLANDS CENTRE
FOR ADVERSE DRUG REACTION REPORTING

2000

1. Director - Dr R E Ferner
Senior Registrar - Dr M Landray, Dr N Langford
Administrative Co-ordinator - Mr C Anton
ADR Pharmacist - Mr A R Cox
Clerical Officer - Mr D Handy
2. The number of yellow cards received by CSM West Midlands in 1999 was 2654 - an increase of 103% on 1998. This large increase was mainly due to the impact of the meningitis C vaccination campaign. In 1999, 133 reports to meningitis C vaccine were received and in 2000, 1351 reports were received. If these reports are discounted there was an increase in the number of reports received from 1173 in 1999 to 1303 in 2000, an increase of 11%.
3. **Number of reports received**
- 3.1 Table 1 shows the number of reports received and the previous five years for comparison. **In this table and all subsequent ones data in brackets are with meningitis C reports discounted.**

Table 1

Year	Total number of reports received	Change on previous year (%)
2000	2654 [1311]	+103 [+12]
1999	1306 [1173]	0 [-10]
1998	1306	+6
1997	1236	+8
1996	1149	-3
1995	1181	+7

- 3.2 Table 2 shows the number of reports received from GPs.

Table 2

Year	Total number of reports received from GPs	Percentage of total reports	Change on previous year (%)
2000	1034 [794]	39% [61%]	+43 [+14]
1999	719 [697]	55% [59%]	-7 [-10]
1998	772	59%	+8
1997	713	58%	-4
1996	744	65%	-1
1995	753	64%	+1

3.3 Table 3 shows the number of reports received from hospital doctors

Table 3

Year	Total number of reports received from hospital doctors	Percentage of total reports	Change on previous year (%)
2000	374 [316]	14% [24%]	+3 [-11]
1999	362 [355]	28% [30%]	-11 [-13]
1998	408	31%	-9
1997	446	36%	+16
1996	386	33%	-6
1995	407	34%	+21

3.4 Table 4 shows the number of reports received from hospital pharmacists

Table 4

Year	Total number of reports received from hospital pharmacists	Percentage of total reports	Change on previous year (%)
2000	106 [100]	4% [8%]	+16 [+18]
1999	91[85]	7% [7%]	+63 [+52]
1998	56	4%	+100
1997	28	2%	

3.5 Table 5 shows the number of reports received from community pharmacists

Table 5

Year	Total number of reports received from community pharmacists	Percentage of total reports	Change on previous year (%)
2000	25 [24]	1% [1%]	+56 [+50]
1999	16 [16]	1% [1%]	-62 [-62]

1998	42	3%	+24
1997	34	3%	

- 3.6 There was a large number of reports submitted by health visitors and practice and school nurses in 1999. This was as a result of the meningitis C vaccination campaign. The breakdown of these other reports is shown in Table 6.

Table 6

Type of reporter	Total number of reports received	Percentage of total reports
Dentist	2	
Health Visitor	9	
Hospital nurse	7	
Optician	1	
Practice/school nurse	918	35%
Specialist clinic	50	2%
Vaccine co-ordinator	122	5%

- 3.7 The number of valid reports sent directly to the MCA from reporters within the region was 495 (232 in 1999, 178 in 1998). This probably arises from the greater number of reports this year as well as a large number of cards distributing in the region with the London address when the scheme was relaunched in September.

4. Serious reports

4.1 We received 594 (46%) reports which were classified as serious by the ADROIT medical dictionary. The data are shown in table 7. There were 21 reports with a fatal outcome.

Table 7

Year	Total number of serious reports received	Percentage of total reports	Change on previous year (%)
2000	856	32%	+44
1999	595	46%	+5
1998	565	43%	+6
1997	532	43%	0
1996	532	46%	+49
1995	358	30%	

4.2 The number of reports of serious reactions from GPs is shown in Table 8. Data for years before 1996 are not available.

Table 8

Year	Number of serious reports	As percentage of GP reports
2000	303	29%
1999	292	41%
1998	263	34%
1997	257	36%
1996	274	37%

4.3 The number of reports of serious reactions from hospital doctors is shown in Table 9

Table 9

Year	Number of serious reports	As percentage of hospital doctor reports
2000	223	60%
1999	219	60%
1998	236	58%
1997	248	56%

1996	252	65%
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4.4 The number of reports of serious reactions received from hospital pharmacists is shown in Table 10.

Table 10

Year	Number of serious reports	As percentage of hospital pharmacist reports
2000	72	68%
1999	69	76%
1998	40	71%
1997	19	68%

4.5 The number of reports of serious reactions received from community pharmacists is shown in Table 11.

Table 11

Year	Number of serious reports	As percentage of community pharmacist reports
2000	10	40%
1999	5	31%
1998	15	36%
1997	10	29%

4.6 The number of reports of serious reaction reported by school and practice nurses, health visitors and vaccine co-ordinators was 237.

5. Reports to – drugs

5.1 A total of 1996 (75%) reports of black triangle drugs were received. The data are shown in Table 12.

Table 12

Year	Total number of – reports received	Percentage of total reports	Change on previous year (%)
2000	1996 [653]	75% [50%]	+246 [+47]
1999	577[444]	44% [38%]	+16 [-11]
1998	498	38%	+26
1997	394	32%	+30
1996	302	26%	-9
1995	331	28%	+19

5.2 The number of reports of – reactions from GPs is shown in Table 13.

Table 13

Year	Number of – reports	As percentage of GP reports
2000	721 [483]	70% [61%]
1999	336 [315]	47% [45%]
1998	332	43%
1997	247	35%
1996	218	29%
1995	244	32%

5.3 The number of reports of reactions to – drugs from hospital doctors is shown in Table 14.

Table 14

Year	Number of – reports	As percentage of hospital doctor reports
2000	158 [96]	42% [30%]
1999	108 [69]	30% [19%]
1998	132	32%
1997	129	29%
1996	82	21%
1995	83	20%

5.4 The number of reports of reactions to – drugs from hospital pharmacists is shown in Table 15.

Table 15

Year	Number of – reports	As percentage of hospital pharmacist reports
2000	34 [28]	32% [28%]

1999	25 [19]	27% [22%]
1998	15	27%
1997	3	11%

5.5 The number of reports of reactions to — drugs from community pharmacists is shown in Table 16.

Table 16

Year	Number of — reports	As percentage of community pharmacist reports
2000	11 [11]	44% [46%]
1999	7 [7]	44% [44%]
1998	15	38%
1997	9	26%

6. The 10 drugs most often mentioned in reports are listed in Table 17

Table 17

	Suspected drug	Number of reports in 2000	Number of reports in 1999
1	meningitis C conjugate vaccine —	1351	133
2	bupropion — (amfebutamone)	218	0
3	rofecoxib —	93	42
4	fluoxetine	23	18
5	celecoxib —	22	0
5	citalopram	22	24
5	lamotrigine	22	10
8	venlafaxine	20	25
9	gabapentin —	19	10
10	hepatitis B vaccine	18	33
10	paroxetine	18	28
10	atorvastatin	18	17
10	lansoprazole	18	25

These top 13 drugs accounted for 67% of all reports for 1998 (29% in 1999, 21% in 1998, 26% in 1997, 28% in 1996, 29% in 1995). Changes from last year are the inclusion of bupropion, fluoxetine, celecoxib, lamotrigine, gabapentin and atorvastatin which have displaced montelukast (9 reports in 2000), sildenafil (13) and DTP vaccine (16).

7. **Follow-up of reports**

- 7.1 Follow-up information was requested by us from 191 (15%) reporters [18% in 1998, 19% in 1997, 22% in 1996, 16% in 1995, 12% in 1994, 15% in 1993]. 132 reporters were followed up for second time because they did not sent further information as requested.
- 7.2 To date, we have received further information on 67 (35%) reports out of the 191 where we have requested more information.
- 7.3 Additionally the MCA have asked us to follow-up a further 17 reports. To date we have received information on 9 of these reports.
8. A total of 375 (29%) reporters requested further information from us and the data are given in Table 18 . This compares with 32% in 1998, 35% in 1997, 34% in 1996, 35% in 1995. All these reporters were sent a DAP. Several reporters have requested more complex data and these, including ADROIT data in tabular or graphical form and RAPs, were supplied to them.

Table 18

Type of reporter	Number of reports	As percentage of reports
GPs	172	24%
Hospital doctors	135	37%
Community pharmacists	7	44%
Hospital pharmacists	38	42%
Others	23	18%

9. Information on the type of card received is shown in Table 19

Table 19

	Number of reports	percentage	Change on previous year (%)
BNF (or copy)	1422	54%	+73
AR20 (or copy)	1216	46%	+180
FP10	1		-95
DSC	7		-30
MIMS	2		-
Other	6		-

10. We have published 3 editions of re:Action (issues 19-21), our occasional bulletin, since the last annual RMC meeting covering:

The Black triangle (—) - what does it mean?
Keeping an eye on interactions: warfarin and celecoxib
Warfarin – still a bleeding nuisance
Aspirin, double edged sword?
Assessing serious reactions
Trent paediatric reporting scheme
Bother with bruxism. Methylphenidate and valproic acid interact
How many paediatric reactions?
Seizure from anaesthesia: remifentanyl
Suspected reactions to vaccines
Paediatric reports
Hypericum hyperbole
Renal failure with COX-2, too
Orlistat and hypertension
No smoke... Bupropion

A number of publications of adverse reactions and related issues have appeared during the year:

- Edmunds E, Landray M, Lip GY. Hormone replacement therapy and intima-media thickness of the common carotid artery: the Rotterdam study. *Stroke (Online)* 2000; **31**: 2266-78.
- Edmunds E, Landray M, Lip GY. Association between elevated plasma fibrinogen and the small, dense low-density lipoprotein phenotype among postmenopausal women. *American Journal of Cardiology* 2000; **86**: 126.
- Ferner RE. Commentary: Reporting of adverse events is worth the effort. *BMJ* 2000; **320**: 1186-7.
- Ferner RE, Aronson JK. Medication errors, worse than a crime. *Lancet* 2000; **355**: 947-8.
- Langford NJ, Kendall MJ. Pulmonary heart disease--the need for evidence-based management. *Journal of Clinical Pharmacy & Therapeutics* 2000; **25**: 157-9.
- Nuttall SL, Langford NJ, Kendall MJ. Frequent paracetamol use linked to asthma. *Lancet* 2000; **355**: 1648-9.
- Renwick AC, Renwick AG, Flanagan RJ, Ferner RE. Monitoring of clozapine and norclozapine plasma concentration-time curves in acute overdose. *Journal of Toxicology - Clinical Toxicology* 2000; **38**: 325-8.
- Thambyrajah J, Landray MJ, McGlynn FJ, Jones HJ, Wheeler DC, Townend JN. Does folic acid decrease plasma homocysteine and improve endothelial function in patients with predialysis renal failure? *Circulation* 2000; **102**: 871-5.
- Woolhouse I, Collinson H, Honeybourne D, Ferner RE. Pleural effusion and fever in a middle-aged Asian man. *Postgraduate Medical Journal* 1999; **75**: 687-8.

We have relaunched our website at <http://csmwm.org>

11. We appointed Mr Anthony Cox as an ADR pharmacist in April.
12. We continue, as a Centre, to take an interest in errors in the use of medicines.

January 2001