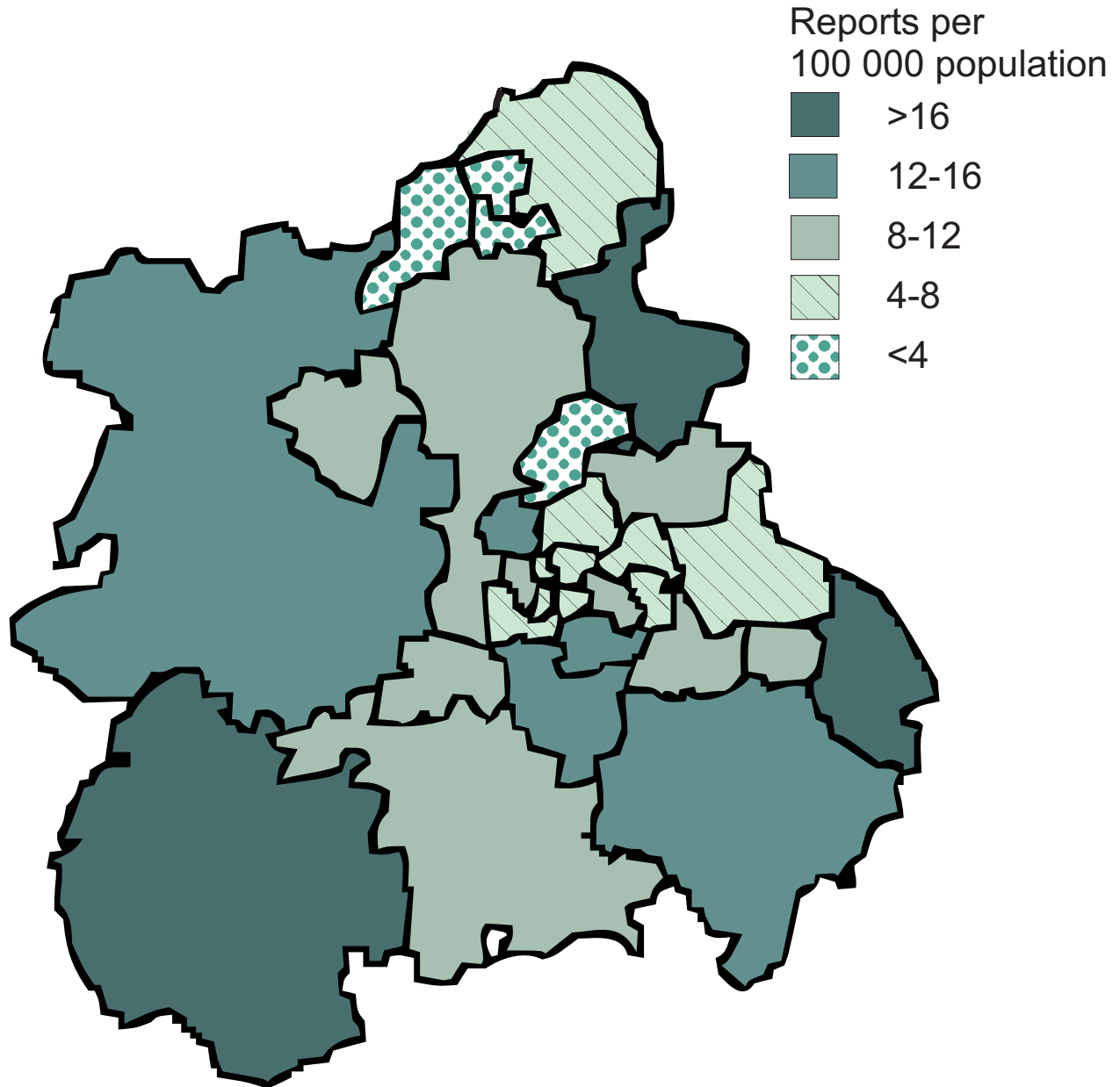




WEST MIDLANDS CENTRE FOR ADVERSE DRUG REACTION REPORTING



Annual Report 2002

ANNUAL REPORT OF REGIONAL MONITORING CENTRES,
MEDICINES CONTROL AGENCY

WEST MIDLANDS CENTRE
FOR ADVERSE DRUG REACTION REPORTING

2002

1. Centre Staff

Director - Dr R E Ferner
Specialist Registrar - Dr N J Langford
Administrative Co-ordinator - Mr C Anton
ADR Pharmacist - Mr A R Cox
Clerical Officer - Mr D Handy

2. Summary

Although the number of reports received in 2002 was down to 926, the percentage of serious reports received was the highest we have recorded at 52%. An additional 209 reports were sent directly to the MCA. The total of reports originating in the West Midlands was 1135, a 29% decrease on 2001. The bypass rate has increased again to 18% — 7 of these were GP electronic reports, 1 was an HIV scheme report and 2 were internet reports. The fall in reports was mostly from GPs and reports from GPs now contribute less than half our total, although the percentage of reports to ▼ drugs by GPs reached the highest we have recorded at 45%. The fall in all other reporter groups was about 10%. We have continued to receive reports from nurses.

The number of reports to bupropion decreased from 272 to 36. Cox-2 inhibitors have taken over from SSRIs as the most commonly reported drugs.

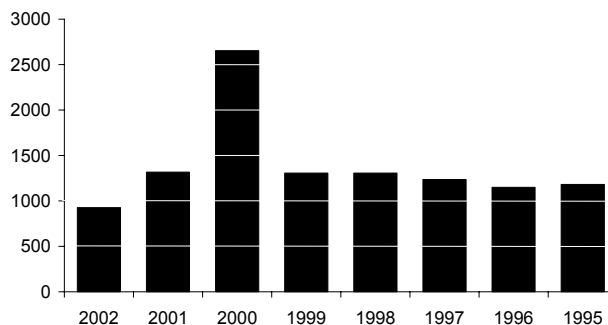
We have again made an effort to bring information to our reporters with talks to doctors, nurses and pharmacists throughout the Region and nationally. Our website continues to be popular and received over 130,000 hits in 2002.

3. Number of reports received

3.1 Table 1 shows the number of reports received and the previous five years for comparison. If the reports for bupropion are discounted there was a 12% decrease in the number of reports received.

Year	Total number of reports received	Change on previous year (%)
2002	926	-30
2001	1317	-50
2000	2654	+103
1999	1306	0
1998	1306	+6
1997	1236	+8

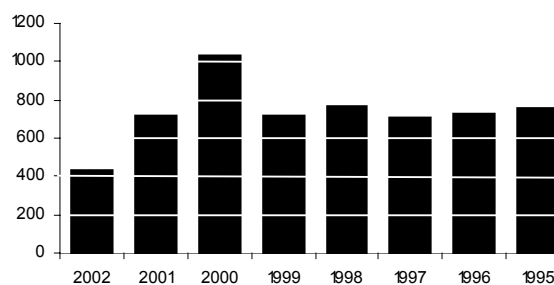
Table 1



3.2 Table 2 shows the number of reports received from GPs. There were 92 additional reports which bypassed the centre [153 in 2001].

Table 2

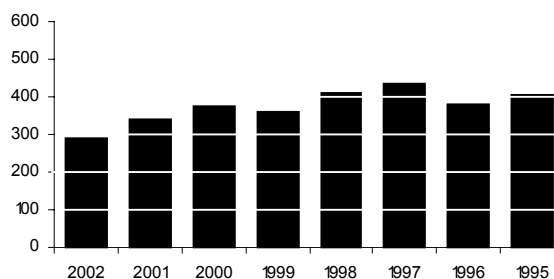
Year	Total No of reports received from GPs	Percentage of total reports	Change on previous year (%)
2002	435	47%	-39
2001	716	54%	-31
2000	1032	39%	+44
1999	719	55%	-5
1998	765	59%	+8
1997	707	57%	-3



3.3 Table 3 shows the number of reports received from hospital doctors. There were 62 additional reports which bypassed the centre [54 in 2001].

Table 3

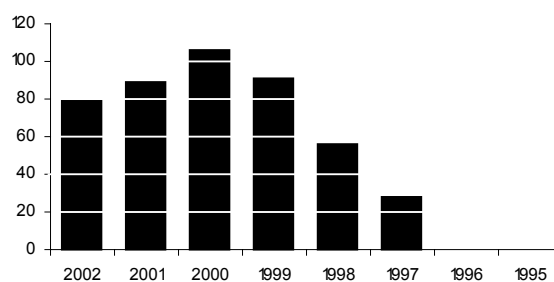
Year	Total No of reports received from hospital doctors	Percentage of total reports	Change on previous year (%)
2002	292	32%	-14
2001	341	26%	-9
2000	376	14%	+4
1999	362	28%	-9
1998	411	31%	-6
1997	436	35%	+15



3.4 Table 4 shows the number of reports received from hospital pharmacists. There were 5 additional reports which bypassed the centre [8 in 2001].

Table 4

Year	Total received from hospital pharmacists	Percentage of total reports	Change on previous year (%)
2002	79	9%	-11
2001	89	7%	-16
2000	106	4%	+16
1999	91	7%	+63
1998	56	4%	+100
1997	28	2%	-

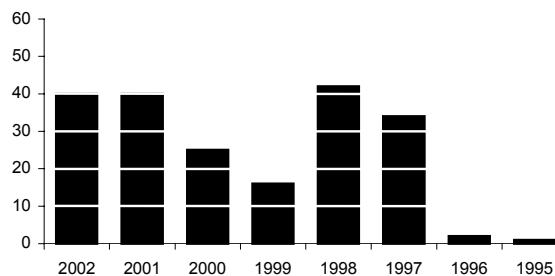


3.5 Table 5 shows the number of reports received from community pharmacists. There were 13 additional reports which bypassed the centre [7 in 2001]. This was the best year we

have had for community pharmacist reports and they represent 5% of all reports originating in the West Midlands.

Table 5

Year	Total received from community pharmacists	Percentage of total reports	Change on previous year (%)
2002	40	4%	0
2001	40	3%	+60
2000	25	1%	+56
1999	16	1%	-62
1998	42	3%	+24
1997	34	3%	-



3.6 Table 6 shows the number of reports received from other groups or reporters. There were 36 additional reports which bypassed the centre [7 in 2001].

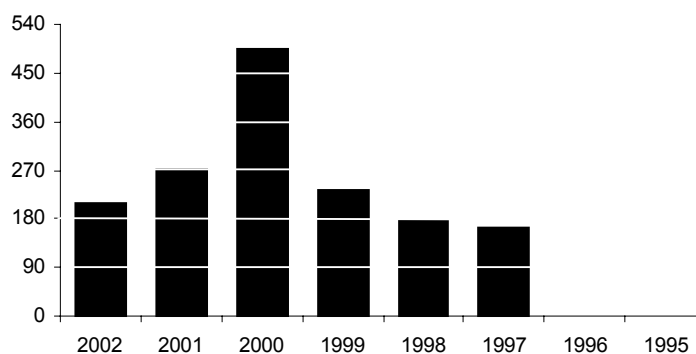
Table 6

Type or reporter	Total received	Percentage of total reports	Change on previous year (%)
Dentist	1		-50
Practice nurse	57	6%	-25
Hospital nurse	14	2%	-36
Health visitor	5	1%	-38
Coroner	0		
Other health professional	3		+200

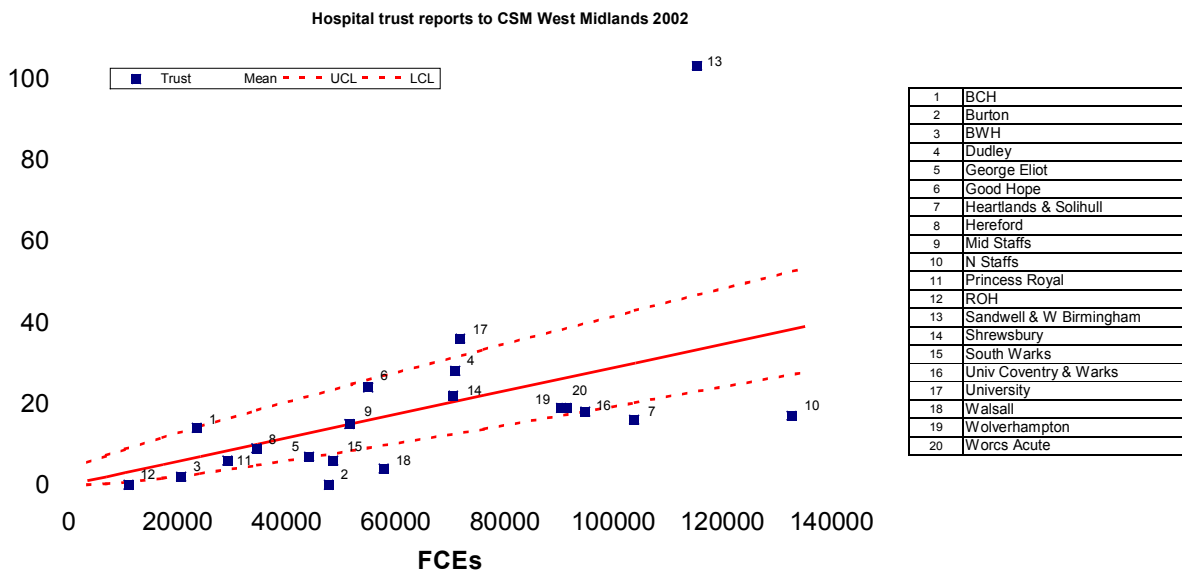
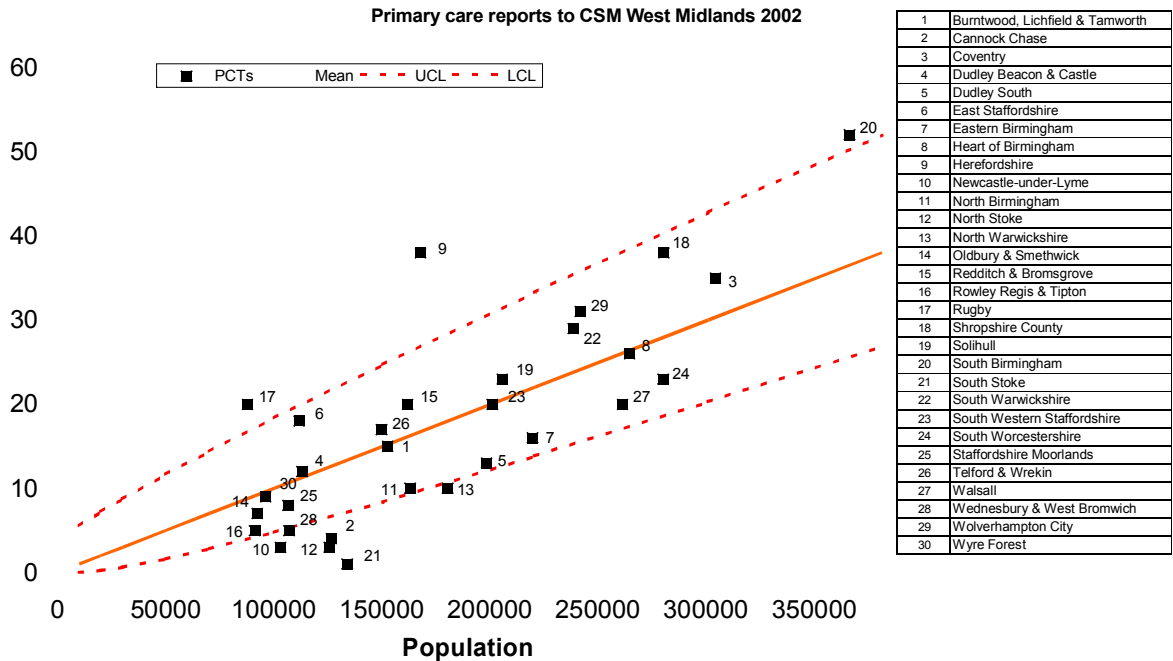
3.7 The number of valid reports sent directly to the MCA from reporters within the region is shown in Table 7.

Table 7

Year	Total bypassing centre	All WM reports
2002	209	1135
2001	271	1588
2000	495	3149
1999	232	1538
1998	178	1484
1997	163	1399



The disparity between the best and worst reporting PCTs and hospital trusts remains.



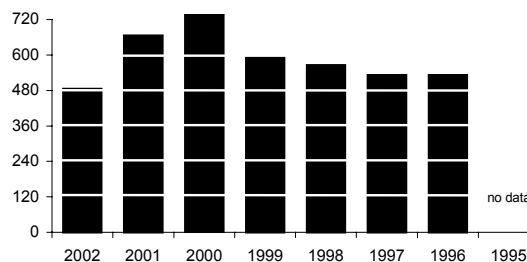
The upper (UCL) and lower control limits (LCL) approximate to the 95% confidence intervals.

4. Serious reports

4.1 We received 485 (52%) reports which were classified as serious by the ADROIT medical dictionary. The data are shown in table 8. There were 23 (3%) reports with a fatal outcome.

Table 8

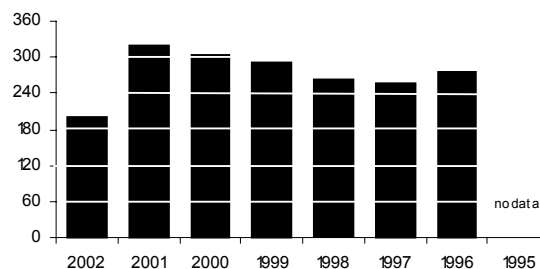
Year	Total No of serious reports received	Percentage of total reports	Change on previous year (%)
2002	485	52%	-27
2001	665	50%	-23
2000	856	32%	+44
1999	595	46%	+5
1998	565	43%	+6
1997	532	43%	0



4.2 The number of reports of serious reactions from GPs is shown in Table 9.

Table 9

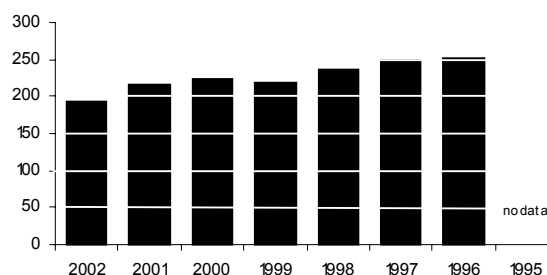
Year	Total No of serious reports received	As percentage of GP reports
2002	200	46%
2001	318	44%
2000	303	29%
1999	292	41%
1998	263	34%
1997	257	36%



4.3 The number of reports of serious reactions from hospital doctors is shown in Table 10.

Table 10

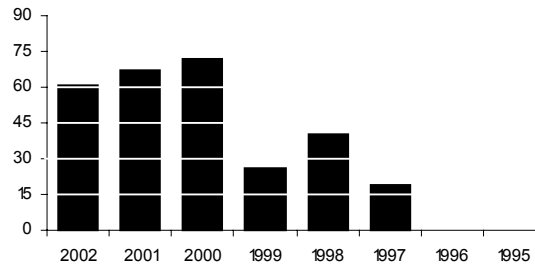
Year	Total No of serious reports received	As percentage of hospital doctor reports
2002	194	66%
2001	216	63%
2000	223	60%
1999	219	60%
1998	236	58%
1997	248	56%



4.4 The number of reports of serious reactions received from hospital pharmacists is shown in Table 11.

Year	Total No of serious reports received	As percentage of hospital pharmacist reports
2002	61	77%
2001	67	63%
2000	72	60%
1999	69	60%
1998	40	58%
1997	19	56%

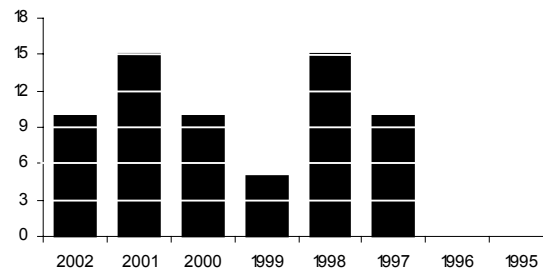
Table 11



4.5 The number of reports of serious reactions received from community pharmacists is shown in Table 12.

Year	Total No of serious reports received	As percentage of hospital pharmacist reports
2002	10	25%
2001	15	38%
2000	10	40%
1999	5	31%
1998	15	36%
1997	10	29%

Table 12



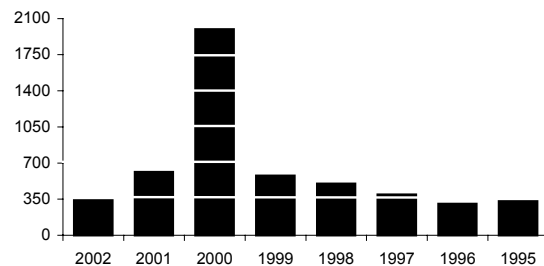
4.6 The number of reports of serious reactions reported by other reporters was 20 (25%).

5. Reports to black triangle drugs

5.1 A total of 338 (37%) reports to black triangle drugs were received. The data are shown in Table 13.

Table 13

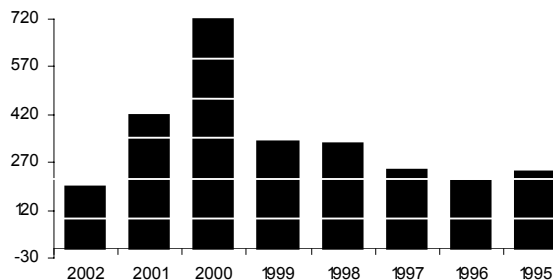
Year	Total No of ▼ reports received	Percentage of total reports	Change on previous year (%)
2002	338	37%	-45
2001	613	47%	-70
2000	1996	75%	+246
1999	577	44%	+16
1998	498	38%	+26
1997	394	32%	+30
1996	302	26%	-9



5.2 The number of reports of reactions to ▼ drugs from GPs is shown in Table 14.

Year	Total No of ▼ reports received	As percentage of GP reports
2002	195	45%
2001	419	44%
2000	721	29%
1999	336	41%
1998	330	34%
1997	245	36%

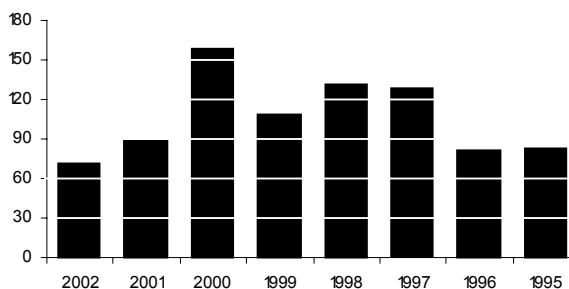
Table 14



5.3 The number of reports of reactions to ▼ drugs from hospital doctors is shown in Table 15.

Year	Total No of ▼ reports received	As percentage of hospital doctor reports
2002	71	24%
2001	88	26%
2000	158	42%
1999	108	30%
1998	132	32%
1997	129	29%

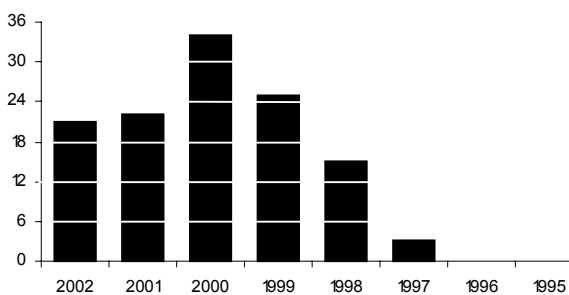
Table 15



5.4 The number of reports of reactions to ▼ drugs from hospital pharmacists is shown in Table 16.

Year	Total No of ▼ reports received	As percentage of hospital pharmacist reports
2002	21	27%
2001	22	25%
2000	34	32%
1999	25	27%
1998	15	27%
1997	3	11%

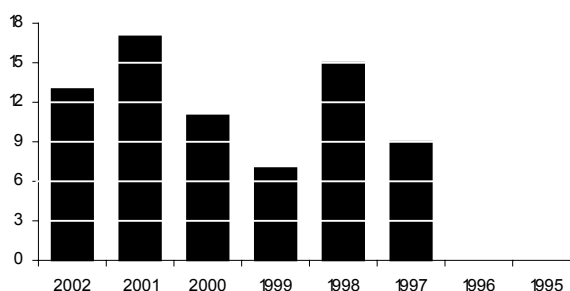
Table 16



5.5 The number of reports of reactions to ▼ drugs from community pharmacists is shown in Table 17.

Year	Total No of ▼ reports received	As percentage of community pharmacist reports
2002	13	33%
2001	17	43%
2000	11	44%
1999	7	44%
1998	15	38%
1997	9	26%

Table 17



5.6 The number of reports of reactions to ▼ drugs from other reporters was 38 (48%).

6. Most commonly reported drugs

The 10 drugs most often mentioned in reports are listed in Table 18

Table 18

Suspected drug substance	No of reports in 2002	No of reports in 2001
rofecoxib ▼	39	46
bupropion ▼	36	272
celecoxib ▼	30	32
meningitis C vaccine ▼	28	33
diphtheria, tetanus and pertussis vaccine*	27	6
sibutramine	27	4
haemophilus influenzae type b vaccine*	21	4
citalopram	20	8
venlafaxine	14	15
simvastatin	14	12

* 19 of these reports were with the combined ACT-HIB® DTP dc.

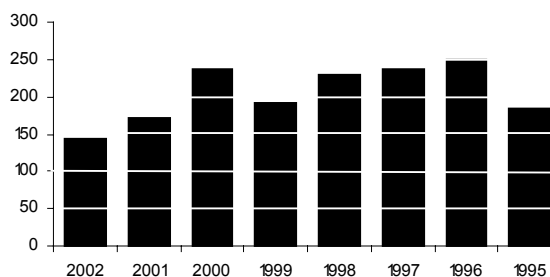
These top 10 drugs accounted for 26% of all reports for 2002 (39% in 2001, 67% in 2000, 29% in 1999, 21% in 1998, 26% in 1997). Rosiglitazone (13 reports), influenza vaccine (7), paroxetine (12), diclofenac (13), levonorgestrel (7), hepatitis B vaccine (8) and levetiracetam (11) have dropped from the top 10 in 2002.

7. Follow-up of reports

7.1 We requested follow-up information from 143 reporters and the data are given in Table 19.

Table 19

Year	Total No of reports followed-up	As percentage of reports	Follow-up response rate
2002	143	15%	62%
2001	171	13%	69%
2000	237	9%	27%
1999	191	15%	40%
1998	230	18%	73%
1997	238	19%	65%



- 7.2 To date, we have received further information on 88 reports out of the 143 (62%) where we have requested more information.
8. A total of 249 (27%) reporters requested further information from us and the data are given in Table 19. This compares with 32% in 2001, 25% in 2000, 29% in 1999, 32% in 1998, 35% in 1997. 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 19

Type of reporter	Number of reports	As percentage of reports
GPs	85	20%
Hospital doctors	97	33%
Community pharmacists	13	33%
Hospital pharmacists	29	37%
Others	25	34%
Total	249	27%

9. Information on the type of card received is shown in Table 20

Table 20

	Number of reports	percent age	Change on previous year (%)
BNF (or copy)	649	70%	-31
AR20 (or copy)	246	27%	-30
FP10	1		
DSC	7		
MIMS	6		
Other	17	2%	

10. We have published 3 editions of *re:Action* (issues 24–26), our occasional bulletin, since the last annual RMC meeting covering:

metformin and radiography
ingrowing toenails with indinavir and ritonavir
urinary retention with fentanyl
warfarin and Cox-2s interaction
suicide with beta-blockers
fluticasone and adrenal crisis
drug-induced QT interval prolongation
selegiline and paraphilia
Cox-2 inhibitors and bone fractures
adulteration of herbal and traditional medicines
changes to the Yellow Card scheme
Cox-2s and renal failure
SSRI withdrawal reactions
warfarin interaction with etoricoxib
additions to black triangle drugs list

We have produced six editions of the *Adverse Drug Reaction Bulletin*.

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

Anton C. Statins as the new aspirin. National Institute for Clinical Excellence should assess statins. *British Medical Journal* 2002; **324**: 789.

Anton C. Adverse effects of laxatives. *Adverse Drug Reaction Bulletin* 2002; 212: 811-14.

Anton C. ADRs in children. *Prescriber* 2002; **13**(9): 23.

Anton C, Cox AR, Ferner RE. Using trade names: sometimes it helps. *Archives of Internal Medicine* 2002; **162**: 2636-7.

Cox AR. Systemic effects of ocular drugs *Adverse Drug Reaction Bulletin* 2002; **215**: 823-6.

Cox AR. Embracing ADR reporting could improve pharmacists' standing. *The Pharmaceutical Journal* 2002; **269**: 14.

Cox A. Childhood vaccination, a social responsibility. *The Pharmaceutical Journal* 2002; **268**: 570.

Cox A. Book Review - Martindale 33rd edition. *The Pharmaceutical Journal* 2002; **268**: 505.

Cox A. Overwhelming evidence for safety of MMR. *The Pharmaceutical Journal* 2002; **268**: 398.

Cox A, Jenkins A. A case of carboplatin hypersensitivity. *Pharmacy in Practice* 2002; **12**: 187.

Cox A, Millane T. An adverse drug reaction as a consequence of error. *Pharmacy in Practice* 2002; **12**: 84-6.

Cox AR, Marriott JF. Take a spoonful of sugar with salt. *The Hospital Pharmacist* 2002; **9**: 90.

Cox AR, Marriott JF. Safety First. Drugs with similar sounding names have lead to deaths. What can be done to prevent any more mishaps? *Pharmaceutical Marketing Feb 2002*: 48-50.

Cox AR, Marriott JF, Wilson KA, Ferner RE. Adverse drug reaction teaching in UK undergraduate medical and pharmacy programs. *Pharmacoepidemiology and Drug Safety* 2002; **11**: s157.

Dent SN, **Cox** AR, Marriott JF, Langley CA, Wilson KA. Warfarin toxicity: do discharge ICD-codes and yellow cards accurately identify serious adverse drug reactions? *The International Journal of Pharmacy Practice* 2002; **10(suppl)**: R40.

Ferner RE. Medicines management: a sour taste. *Quarterly Journal of Medicine* 2002; **95**: 181-4.

Ferner RE, Whittington RM. Medical Errors and Lessons from Drug-Related Deaths. In: Mann RD, Andrews EB, eds. *Pharmacovigilance*. Chichester: John Wiley and Son, 2002: 509-514.

Ferner RE, Thomas M. Emergency Medicine. In: van Boxtel CJ, Santoso B, Edwards IR, eds. *Drug benefits and risks: International textbook of clinical pharmacology. 1st ed.* Chichester: John Wiley & Sons, Ltd, 2001: 442-57.

Ferner RE, Kendall MJ. Drug therapy: special considerations in diabetes. In: Pickup J, Williams G, eds. *Textbook of Diabetes, 3rd ed.* Oxford: Blackwell Science, 2002: 39.1-39.

Gittoes NJL, Ayuk J, **Ferner** RE. Drug-induced diabetes. In: Pickup J, Williams G, eds. *Textbook of Diabetes, 3rd ed.* Oxford: Blackwell Science, 2002: 26.1-26.

Jenkins A, **Cox** A. Influenza vaccine and warfarin. *Pharmacy in Practice* 2002; **12**: 140.

Langford NJ. Aspirin and Reye's syndrome: is the response appropriate? *Journal of Clinical Pharmacology and Therapeutics* 2002; **27**: 157-60.

Langford NJ. Serotonin syndrome. *Adverse Drug Reaction Bulletin*. 2002; **217**: 831-4.

Langford NJ, Martin U, Ruprah M, **Ferner** RE. Alternative venlafaxine kinetics in overdose. *Journal of Clinical Pharmacy and Therapeutics* 2002; **27**: 465-7.

Langford NJ, Kendall MJ. Rhabdomyolysis with HMG CoA reductase inhibitors: a class effect? *Journal of Clinical Pharmacy & Therapeutics* 2002; **26**: 391-5.

Langford NJ, **Ferner** RE. Episodes of environmental poisoning worldwide. *Occupational and Environmental Medicine* 2002; **59**: 855-60.

Langford NJ, **Cox** AR. Medication errors: Over reliance on any safety system is not ideal *The Pharmaceutical Journal* 2002; **269**: 248.

Maxwell S, Walley T, **Ferner** RE. Using drugs safely. *British Medical Journal* 2002; **324**: 930-1.

Rippengill KL, Higham C, **Cox** AR, Situnayake RD. Methotrexate - patient awareness and safety issues. *Pharmacy World & Science* 2002; **24**: A21.

We continue to educate reporters throughout the region about the Yellow Card Scheme and the importance of reporting adverse drug reactions. Lectures and talks were given to:

Practice nurses at Coventry, Wyre Forest, Dudley South, Dudley Beacon and Castle, Newcastle-under-Lyme, and Wolverhampton PCTs.

Hospital nurses at Good Hope and Royal Orthopaedic Hospitals.

GPs in North Stoke, South Stoke, Newcastle-under-Lyme, Staffordshire Moorlands, and Wolverhampton PCTs.

Community pharmacists in Herefordshire, Birmingham and South Staffordshire branches of the RPSGB.

Junior doctors at New Cross, Alexandra and City Hospitals.

National Paediatric Pharmacists Group: Keynote lecture, "ADRs in Children".

Royal College of Physician conferences in Advanced Medicine, "Heroin and Other Villains" and Risk Management, "Dangers of Drug Therapy."

British National Formulary Conference: Prescribing Excellence 2002, "What we should teach medical students about therapeutics."

King Edward Memorial Hospital Mumbai 2002, "Detection of adverse drug reactions".

Home Office – Coroners' Continuing Education, Gloucester 2002, "Prescribing and giving drugs".

We also regularly update the Medicines Information pharmacists of the West Midlands and Trent regions on trends in reporting.

Our website at <http://csmwm.org> received over 130,000 hits during 2002 (a 70% increase from 2001) and was praised as "super" in the November 2001 edition of the NHS Magazine.

11. We received a visit from the Chief Pharmacist of the Flinders Medical Centre, New South Wales in September 2002.
12. We continue, as a Centre, to take an interest in errors in the use of medicines.

CA
REF

January 2003