

ANNUAL REPORT OF REGIONAL MONITORING CENTRES,  
MEDICINES CONTROL AGENCY

WEST MIDLANDS CENTRE  
FOR ADVERSE DRUG REACTION REPORTING

2001

1. Centre Staff

Director - Dr R E Ferner  
Senior Registrar - Dr M Landray (till June 2001)  
Administrative Co-ordinator - Mr C Anton  
ADR Pharmacist - Mr A R Cox  
Clerical Officer - Mr D Handy

2. Summary

The number of yellow cards received by CSM West Midlands in 2001 was 1317. This large apparent decrease was mainly due to the end of the meningitis C vaccination campaign. This year we received only 33 reports of reactions to meningitis C (11 as part of the primary infant vaccination course), compared with 1343 reports in 2000. If the meningitis C vaccination campaign is discounted there was an increase of 0.5% in the number of reports received. The percentage of serious reports has risen to 50% the highest that the centre has seen, and across nearly all reporting groups.

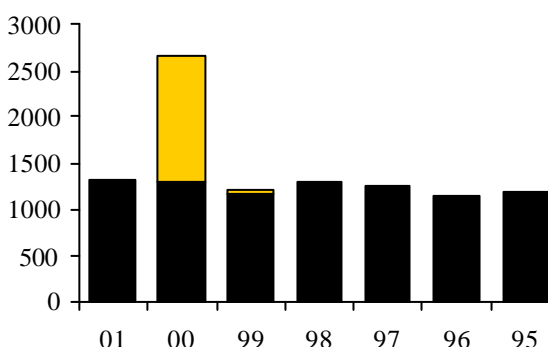
With the advent of the HIV reporting scheme and electronic reporting which report centrally the bypass rate has continued to rise. In 2001 17% of all reports emanating from West Midlands reporters bypassed the centre - 30 of these reports were GP electronic reports and 9 were HIV scheme reports. The total number of reports submitted from the West Midlands region was 1588 (7% of all yellow card reports for 2001).

3. Number of reports received

3.1 Table 1 shows the number of reports received and the previous five years for comparison. **In this and all subsequent tables data in brackets are with reports from the meningitis C vaccination campaign discounted.**

Table 1

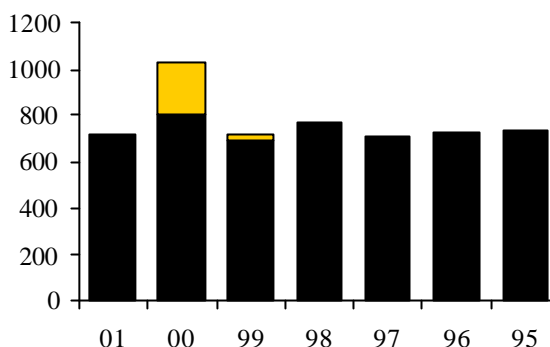
Year	Total number of reports received	Change on previous year (%)
2001	1317	-50 [+1]
2000	2654 [1311]	+103 [+12]
1999	1306 [1173]	0 [-10]
1998	1306	+6
1997	1236	+8
1996	1149	-3



3.2 Table 2 shows the number of reports received from GPs. There were 153 additional reports which bypassed the centre.

Table 2

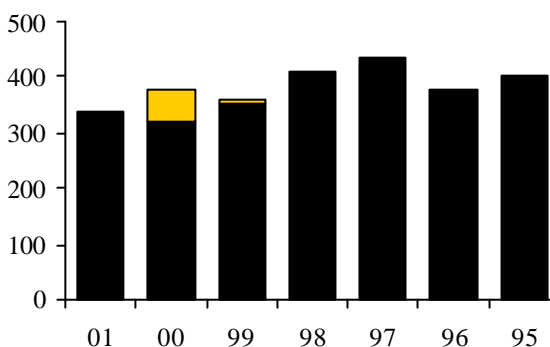
Year	Total No of reports received from GPs	Percentage of total reports	Change on previous year (%)
2001	716	54%	-31 [-11]
2000	1032 [804]	39% [61%]	+44 [+15]
1999	719 [697]	55% [59%]	-5 [-9]
1998	765	59%	+8
1997	707	57%	-3
1996	729	63%	-1



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

Table 3

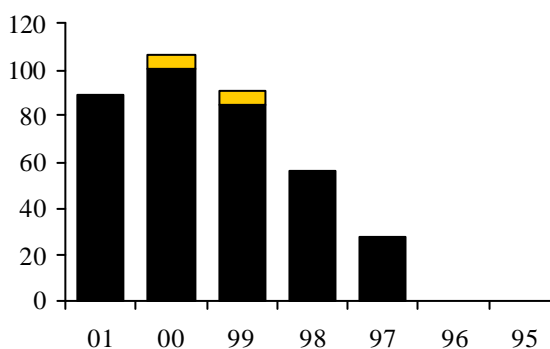
Year	Total No of reports received from hospital doctors	Percentage of total reports	Change on previous year (%)
2001	341	26%	-9 [+7]
2000	376 [320]	14% [24%]	+4 [-10]
1999	362 [355]	28% [30%]	-9 [-14]
1998	411	31%	-6
1997	436	35%	+15
1996	379	33%	-6



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

Table 4

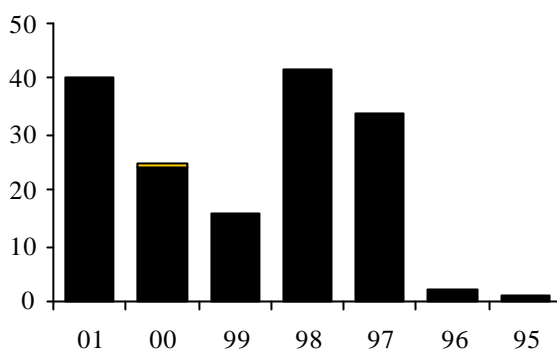
Year	Total received from hospital pharmacists	Percentage of total reports	Change on previous year (%)
2001	89	7%	-16 [-11]
2000	106 [100]	4% [8%]	+16 [+18]
1999	91 [85]	7% [7%]	+63 [+52]
1998	56	4%	+100
1997	28	2%	-



3.5 Table 5 shows the number of reports received from community pharmacists. There were 7 additional reports which bypassed the centre.

Table 5

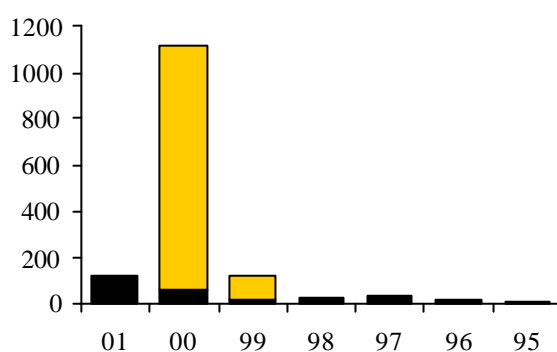
Year	Total received from community pharmacists	Percentage of total reports	Change on previous year (%)
2001	40	3%	+60 [+67]
2000	25 [24]	1% [1%]	+56 [+50]
1999	16 [16]	1% [1%]	-62 [-62]
1998	42	3%	+24
1997	34	3%	-
1996	2	-	-



3.6 There was a large number of reports submitted other types of reporter in 2001: many reports of reactions to amfebutamone were reported by smoking cessation nurses (35 reports); school nurses continue to report reactions to **all** vaccines (48); and the number of reports from specialist hospital nurses is continuing to increase (23). Reports from previous years have been reclassified and there may be some small differences in the GP and hospital doctor tables. Dentists, coroners and other health professionals continue to report very few reactions. The results are shown in Table 6. There were 49 additional reports which bypassed the centre.

Table 6

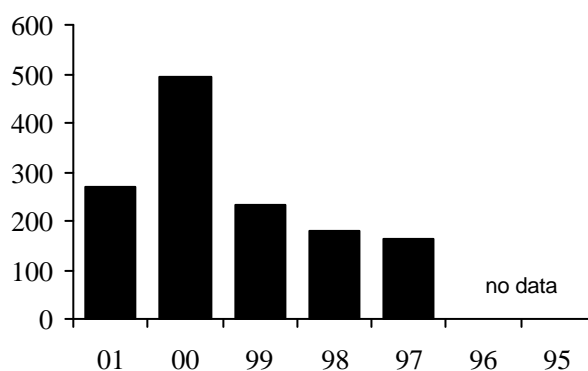
Year	Total received from other reporters	Percentage of total reports	Change on previous year (%)
2001	122	9%	-89
2000	1110	42%	+833
1999	119	9%	+341
1998	27	2%	-10
1997	30	2%	+76
1996	17	1%	



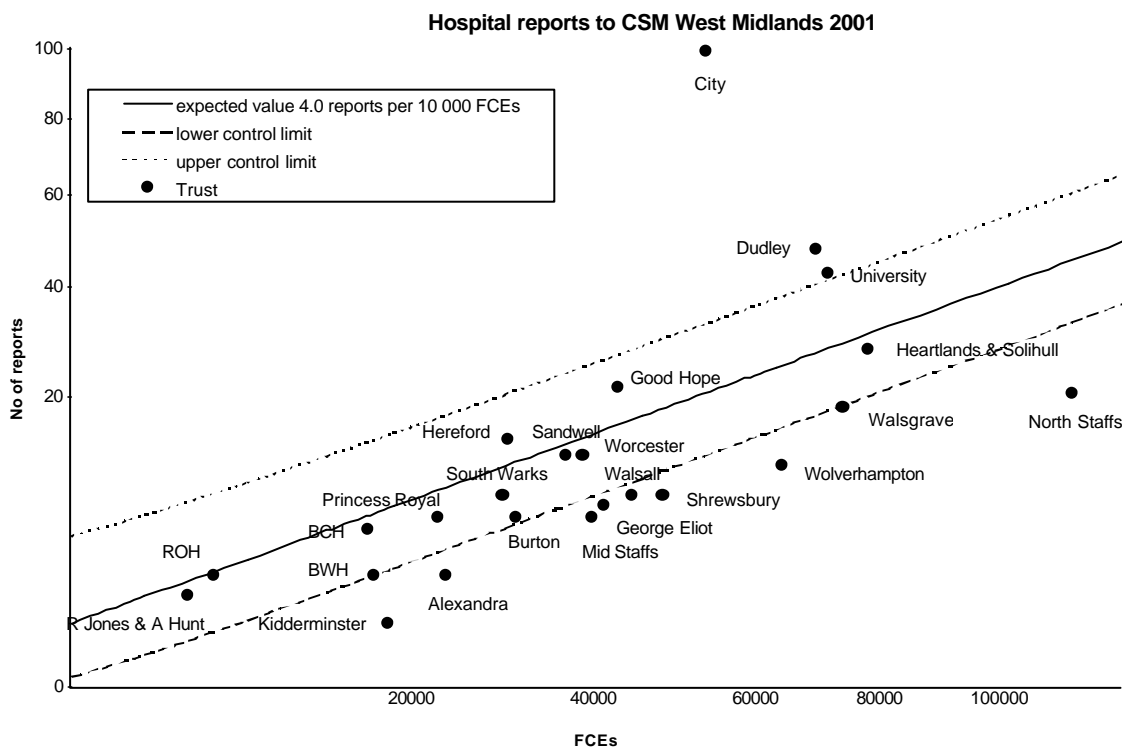
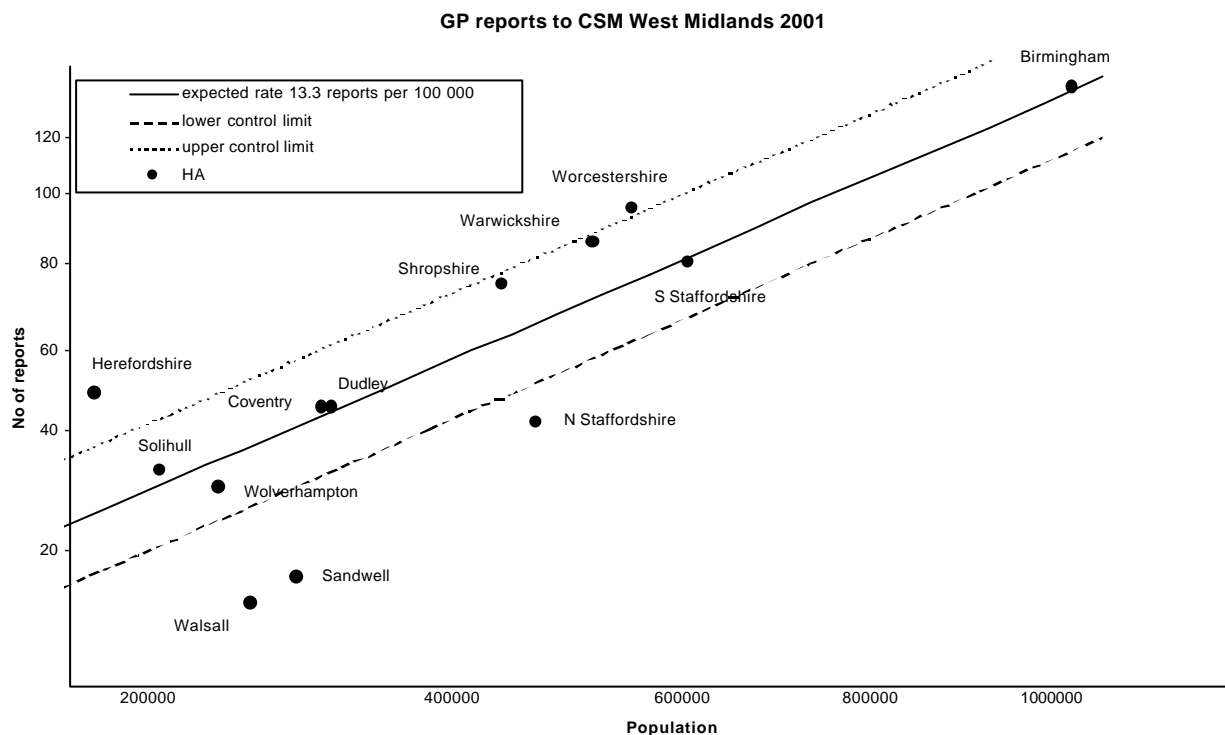
3.7 The number of valid reports sent directly to the MCA from reporters within the region is shown in Table 7.

Table 7

Year	Total bypassing centre	% of all WM reports
2001	271	17%
2000	495	16%
1999	232	15%
1998	178	12%
1997	163	12%



The disparity between the best and worst reporting districts remains, and that amongst GPs has grown larger.

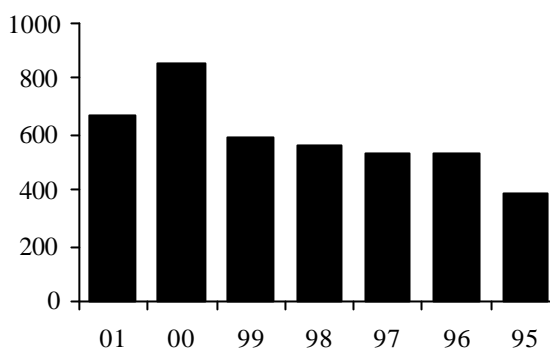


#### 4. Serious reports

4.1 We received 665 (50%) reports which were classified as serious by the ADROIT medical dictionary. The data are shown in table 8. There were 35 reports with a fatal outcome.

Table 8

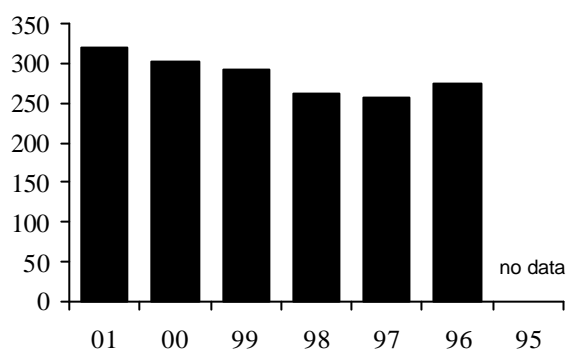
Year	Total No of serious reports received	Percentage of total reports	Change on previous year (%)
2001	665	50%	-23
2000	856	32%	+44
1999	595	46%	+5
1998	565	43%	+6
1997	532	43%	0
1996	532	46%	+49



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

Table 9

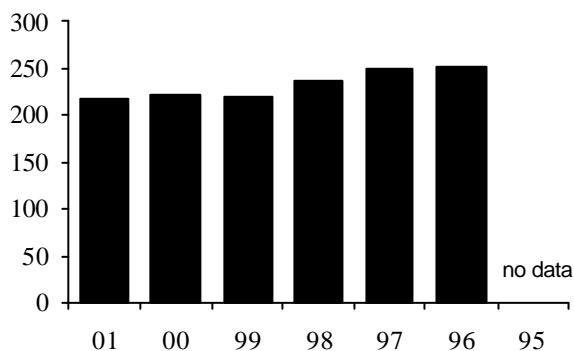
Year	Total No of serious reports received	As percentage of GP reports
2001	318	44%
2000	303	29%
1999	292	41%
1998	263	34%
1997	257	36%
1996	274	37%



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

Table 10

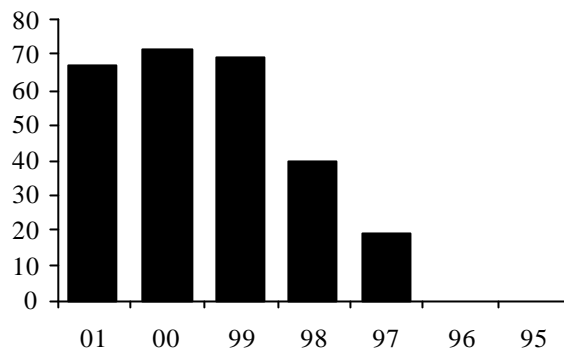
Year	Total No of serious reports received	As percentage of hospital doctor reports
2001	216	63%
2000	223	60%
1999	219	60%
1998	236	58%
1997	248	56%
1996	252	65%



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
2001	67	63%
2000	72	60%
1999	69	60%
1998	40	58%
1997	19	56%

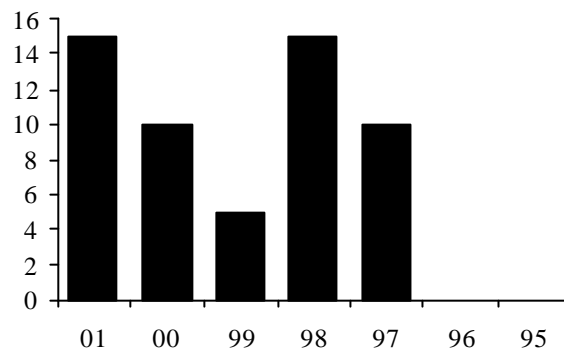
Table 11



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
2001	15	38%
2000	10	40%
1999	5	31%
1998	15	36%
1997	10	29%

Table 12



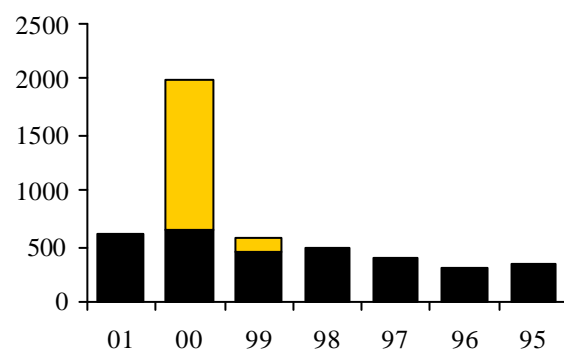
4.6 The number of reports of serious reactions reported by other reporters was 47 (39%).

## 5. Reports to black triangle drugs

5.1 A total of 1996 (75%) reports to black triangle drugs were received. The data are shown in Table 13.

Year	Total No of – reports received	Percentage of total reports	Change on previous year (%)
2001	613	47%	-70
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

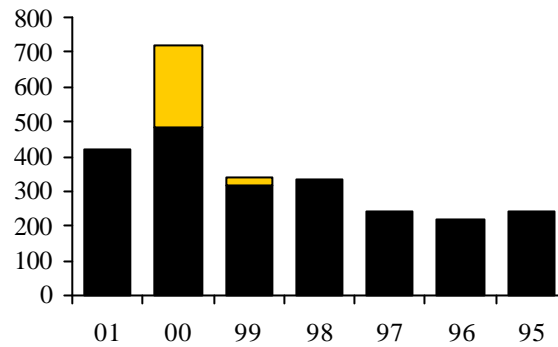
Table 13



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
2001	419	44%
2000	721 [483]	29%
1999	336 [315]	41%
1998	330	34%
1997	245	36%
1996	215	37%

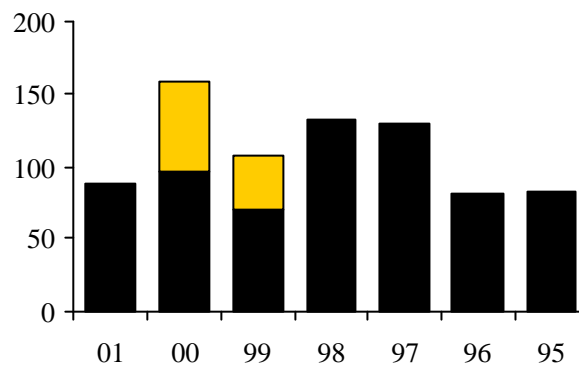
Table 14



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
2001	88	26%
2000	158 [96]	42% [30%]
1999	108 [69]	30% [19%]
1998	132	32%
1997	129	29%
1996	82	21%

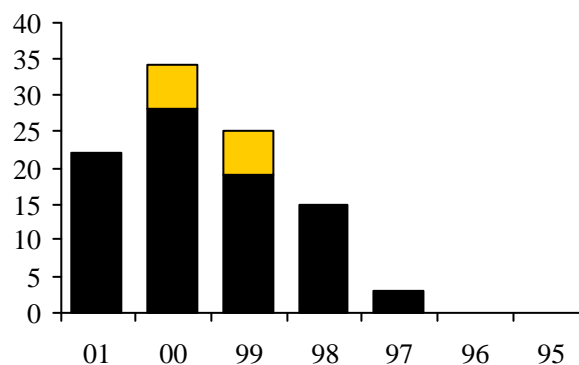
Table 15



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

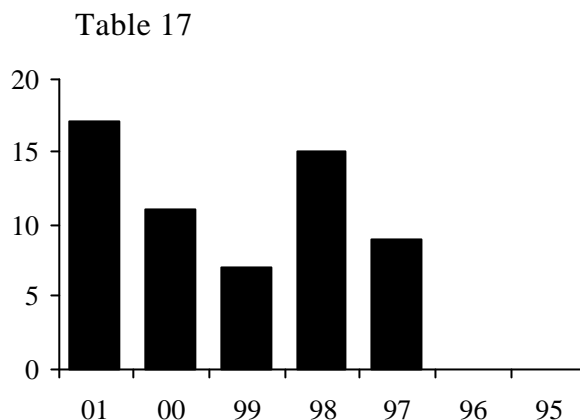
Year	Total No of – reports received	As percentage of hospital pharmacist reports
2001	22	25%
2000	34 [28]	32% [28%]
1999	25 [19]	27% [22%]
1998	15	27%
1997	3	11%

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
2001	17	43%
2000	11	44%
1999	7	44%
1998	15	38%
1997	9	26%



5.6 The number of reports of reactions to – drugs from other reporters was 68 (56%).

## 6. Most commonly reported drugs

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

Table 18

Suspected drug	Number of reports in 2001	Number of reports in 2000
amfebutamone (bupropion) –	272	218
rofecoxib–	46	93
meningitis C vaccine–	33	1351
celecoxib–	32	22
rosiglitazone–	21	8
influenza vaccine	21	16
paroxetine	21	18
diclofenac	19	16
levonorgestrel	18	16
hepatitis B vaccine	16	18
levetiracetam–	16	0

These top 10 drugs accounted for 39% of all reports for 2001 (67% in 2000, 29% in 1999, 21% in 1998, 26% in 1997, 28% in 1996, 29% in 1995).

Amfebutamone was the most reported drug each month apart from November (influenza vaccine).

## 7. Follow-up of reports

7.1 Follow-up information was requested by us from 170 (13%) reporters [9% in 2000, 15% in 1999, 18% in 1998, 19% in 1997, 22% in 1996]. Fifty-one reporters were followed up for second time because they did not sent further information as requested, and 18 of these responded.

7.2 To date, we have received further information on 116 (68%) reports out of the 170 where we have requested more information. We are now using our enhanced follow-up letters and have seen a great improvement (mean response 1996-99 was 38%).



8. A total of 416 (32%) reporters requested further information from us and the data are given in Table 19. This compares with 25% in 2000, 29% in 1999, 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 19

Type of reporter	Number of reports	As percentage of reports
GPs	163	23%
Hospital doctors	155	46%
Community pharmacists	16	40%
Hospital pharmacists	23	26%
Others	59	48%

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)	949	72%	-33
AR20 (or copy)	351	27%	-71
FP10	2		
DSC	6		
MIMS	3		
Other	4		

10. We have published 2 editions of *re:Action* (issues 22–23), our occasional bulletin, since the last annual RMC meeting covering:

dry eyes  
sildenafil and incorrect administration  
NSAIDs and heart failure  
excipients  
influenza vaccine and warfarin interaction  
celecoxib and hepatic toxicity  
hepatitis B vaccine, arthritis, and sex differences  
spironolactone and hyperkalaemia  
thalidomide, old drug, old risks  
clopidogrel and haematological disturbances

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, Cox A.** Adverse drug reactions. *British Journal of General Practice* 2001; 51: 582-3.

**Anton C, Cox AR, Ferner RE.** What are the perceptions of the seriousness of adverse drugs reactions by reporters? Poster presented at the 1<sup>st</sup> International Society of Pharmacovigilance conference, Tunis 2001.

**Beevers DG, Ferner RE.** Why are thiazide diuretics declining in popularity? *Journal of Human Hypertension.* 2001; **15**: 287-9.

**Cox A, Anton C, Ferner R.** Take care with Zyban. *Pharmaceutical Journal* 2001; 266: 721.

**Cox A, Anton C.** Safety profile of bupropion for chronic obstructive pulmonary disease. *Lancet.* 2001; 358: 1010.

**Cox AR, Anton C, Goh CH, Easter M, Langford NJ, Ferner RE.** Adverse drug reactions in patients admitted to hospital identified by discharge ICD-10 codes and by spontaneous reports. *British Journal of Clinical Pharmacology.* 2001; 52: 337-9.

**Cox AR, Marriott J.** Is self-checking (by anyone) a risk too far? *Pharmaceutical Journal* 2001; **266**: 814.

**Cox AR,** Syncope as a possible adverse drug reaction. *Pharmacy in Practice* 2001; **11**: 286.

**Cox AR.** Hyperkalaemia associated with the use of spironolactone in heart failure. *Pharmacy in Practice* 2001; **11**: 187-9.

**Cox AR, Barnett AL.** Reporting reactions to newly marketed drugs. *Pharmacy in Practice* 2001; **11**: 121-2.

**Cox AR.** What can hospital pharmacy do to increase adverse drug reaction reporting. *Pharmacy in Practice* 2001; **11**: 84.

**Cox AR.** Haematoma associated with tirofiban and enoxaparin in an unstable angina patient. *Pharmacy in Practice* 2001; **11**: 87-8.

**Cox AR.** Adverse reactions to intra-vascular radiological contrast media. *Pharmacy in Practice* 2001; **11**: 54-5.

**Cox AR, McCarthy J.** Hepatic adverse drug reactions. *Pharmacy in Practice* 2001; **11**: 18-19.

**Cox AR.** New drugs must be prescribed judiciously. *Pharmaceutical Journal* 2001; **267**: 646-7.

**Cox AR.** What about side effects and contraindications? *Pharmaceutical Journal* 2001; **267**: 425.

**Cox AR.** Access to reports of the statutory committee. *Pharmaceutical Journal* 2001; **267**: 321-4.

**Edmunds E, Landray MJ, Li-Saw-Hee FL, Hughes BA, Beevers DG, Lip GYH.** Dyslipidaemia in patients with malignant-phase hypertension. *Quarterly Journal of Medicine* 2001; **94**: 327-32.

**Ferner RE, Chambers J.** Alcohol intake: measure for measure *BMJ* 2001; **323**: 1439-40.

**Ferner RE.** The primrose path - Errors in prescribing and giving medicines. *Drug Information Journal* 2001; **35**: 633-8.

**Ferner RE, Langford NJ, Anton C, Hutchings A, Bateman DN, Routledge PA.** Random and systematic medication errors in routine clinical practice: a

multicentre study of infusions, using acetylcysteine as an example. *British Journal of Clinical Pharmacology*. 2001; 52: 573-7. Also presented at the 1<sup>st</sup> International Society of Pharmacovigilance conference, Tunis 2001.

**Ferner RE**. Our poisoned patients. *Quarterly Journal of Medicine*. 2001; **94**: 117-20.

**Ferner RE**, Aronson JK. Retrospective case record analysis has been superseded. *BMJ* 2001; **322**: 1425.

**Ferner RE**. Reducing medication errors. *JAMA* 2001; **286**: 2091-2.

**Ferner RE**. Red Bull: more misinformation for the young. *Alcoholism* 2001; 20: 3.

**Ferner RE**, Mann RD. Drug Safety and Pharmacovigilance. In: *Integrated Pharmacology*. (2<sup>nd</sup> edn). (ed. M. Walker). Harcourt Health Sciences, 2001.

**Ferner RE**, Whittington RM. Deaths due to adverse drug events: information from Coroner's Inquests - Birmingham 1986-2000. In *Pharmacovigilance*. (1<sup>st</sup> edn).

Mann RD, Andrews E (eds). John Wiley and Sons Ltd, 2001.

**Ferner RE**, Thomas M. Emergency Medicine. In: *Drug benefits and risks: International textbook of clinical pharmacology*. (1<sup>st</sup> edn). van Boxtel CJ, Santoso B, Edwards IR (eds). John Wiley & Sons Ltd, 2001; 442-457.

Kamath S, **Landray MJ**, Lip GYH. Folic acid for all - Is the time right yet? *British Journal of Cardiology* 2001; **8**: 9-11.

**Landray MJ**. Sudden death: ACE inhibitors and beta-blockers. *Basic Research in Cardiology, Supplement* 2001; **95**: I/37-I/40.

Langford NJ, Martin U, Kendall MJ, **Ferner RE**. Medical schools can teach safe drug prescribing and administration. *BMJ* 2001; 322: 1424.

Rippengill KL, Higham CL, **Cox AR**, Situnayake RD. Methotrexate-patient awareness. Presented at UK Clinical Pharmacy Association symposium, Blackpool 2001.

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

Our website at <http://csmwm.org> received over 80,000 hits during 2001.

11. Anthony Cox was appointed a half-time teaching fellow at the School of Pharmacy, Aston University in December 2001, and submitted his first year research report - *Adverse drug reaction reporting by hospital pharmacists: development and evaluation of an educational intervention to increase reporting*. He was also appointed to the editorial board of the *Pharmaceutical Journal*
12. We continue, as a Centre, to take an interest in errors in the use of medicines. Mr Cox and Dr Ferner served as members of the MCA's Working Group on the Labelling and Packaging of Medicines in June and July 2001. Mr Cox collaborated in the production of a workshop — *Risky Business – minimizing medication errors* — for the CPPE. This will be run in July 2002.

CA  
REF

January 2002