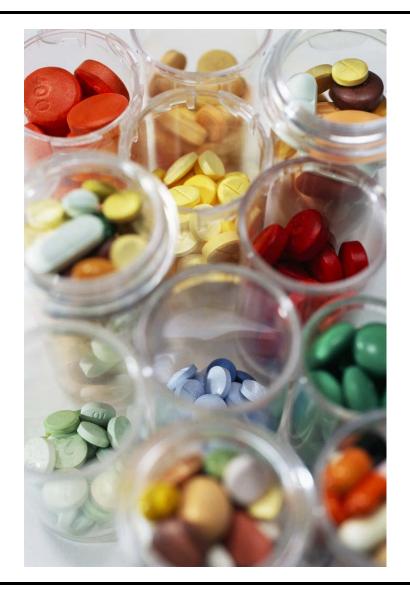


YCC Scotland



Annual Report April 2009 to March 2010

ANNUAL REPORT OF THE YELLOW CARD CENTRE SCOTLAND TO THE MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY

2009-10

1. STAFF

Professor Simon Maxwell – Professor in Clinical Pharmacology, Medical Director YCC Scotland

Professor Nick Bateman – Professor in Clinical Toxicology, Consultant Physician, Director NPIS and Ex-Medical Director YCC Scotland.

Mrs Melinda Cuthbert – Lead Pharmacist Medicines Information / YCC Scotland

Mrs Sheila C Noble – Senior Pharmacist Medicines Information / YCC Scotland

Mrs Sinéad McGhee – Information Officer Medicines Information / YCC Scotland

2. SUMMARY

2009-10 has been another busy and pro-active year for YCC Scotland. There have been two meetings of the YCC Scotland Advisory Group and four Management Board meetings.

Members of YCC Scotland have provided a number of training sessions to promote effective Yellow Card Reporting. Following appropriate training, the YCC Scotland website has been updated by one of the team and there are plans to redesign the website over the next year.

Throughout 2009-10 a total of 58 Yellow Card reports were followed up by YCC Scotland, with a response rate of 69%. The process for following up on reports was altered in 2009-10 and all follow-ups will be processed at MHRA headquarters in London in the future. Legacy Yellow Cards have continued to be forwarded appropriately to the MHRA via the YCC Scotland office.

3. YELLOW CARD DATA

	Reports in 2008-09	% of UK Total	Reports in 2009-10	% of UK Total	% Change on Previous Year
(3.1) Total UK Reports (exc MAH holders)	14292		11819		17% ↓
(3.2)Total Scottish Reports	1477	10%	1105	9%	25% ↓
	Reports in 2008-09	% of Scottish Total	Reports in 2009-10	% of Scottish Total	% Change on Previous Year
(3.3)Serious Reports Scotland	763	52%	568	51%	26% ↓
(3.4)Black Triangle Reports Scotland	632	43%	480	43%	24% ↓
(3.5)Fatal Reports Scotland	43	3%	32	3%	26% ↓

3.6. Age Banding Reports Scotland 2009-10

Age Banding	Reports in 2008-09	% 2008-09 Total	Reports in 2009-10	% 2009-10 Total	% Change on Previous Year
Child <18	318	22%	231	21%	27% ↓
18-24	48	3%	57	5%	19% ↑
25-34	113	8%	96	9%	15% ↓
35-44	191	13%	119	11%	38% ↓
45-54	201	14%	147	13%	27% ↓
55-64	228	15%	167	15%	27% ↓
65-74	166	11%	125	11%	25% ↓
75-84	98	7%	85	8%	13% ↓
>85	38	3%	22	2%	42% ↓
Age not specified	76	5%	56	5%	26% ↓
TOTAL	1477		1105		25% ↓

3.7 Age Banding Paediatric Reports Scotland 2009-10**

ICH Age Range	Paediatric Yellow Card Reports	% of Paediatric Yellow Card Reports
Preterm newborn infants	0	0
Term newborn infants (0-27 days)	0	0
Infants & toddlers (28 days – 23 months)	32	13
Children (2-11 years)	31	13
Adolescents (12-18 years)	179	74
TOTAL	242	

^{**}Please note that reports for patients aged 18 years old have been included in paediatric report numbers, these patients are part of the 18-24 year old age banding in the Age Banding Reports Scotland 2009-10 table.

3.8 Sources of Yellow Card Reports

Source of Reports Scotland	Reports in 2008-09	% of 2008-09 total	Reports in 2009-10	% of 2009-10 total	% Change on Previous Year
Carer	10	<1%	7	1%	30% ↓
Community Pharmacist	49	3%	37	3%	24% ↓
Consumer	0	0%	2	<1%	200% ↑
Dentist	5	<1%	3	<1%	40%↓
GP	373	25%	230	21%	38%↓
Hospital Doctor	213	14%	176	16%	17% ↓
Hospital HCP	102	7%	69	6%	32% ↓
Hospital Nurse	51	4%	61	6%	20% ↑
Hospital Pharmacist	116	8%	98	9%	16% ↓
Nurse	240	16%	162	15%	33% ↓
Optometrist	1	<1%	3	<1%	200% ↑
Other HCP	114	8%	94	9%	18% ↓
Parent	15	1%	8	1%	47% ↓
Patient	138	9%	104	9%	25% ↓
Pharmacist	25	2%	27	2%	8% ↑
Physician	25	2%	23	2%	8% ↓
TOTAL	1477		1104		25% ↓

HCP = Health Care Professional

3.9 Top Ten Medicines reported 2009-10

Ranking	Scotland Medicine Name	Number of reports (Direct only)	UK Medicine Name	Number of reports (Direct and Indirect)
1	HPV vaccines	157	clozapine	2552
2	varenicline	151	HPV vaccines	2324
3	diphtheria-containing vaccines	24	varenicline	1246
4	pneumococcal vaccines	17	infliximab	426
4	exenatide	17	adalimumab	346
6	quetiapine	16	simvastatin	323
7	etanercept	14	etonogestrel	280
8	simvastatin	13	risperidone	265
8	ciprofloxacin	13	etanercept	246
10	omeprazole	12	exenatide	223

3.10 Top Five Medicines reported in Paediatric Reports 2009-10

Paediatric Ranking	Medicine Name		
1	HPV vaccines		
2	diphtheria-containing vaccines		
3	pneumococcal vaccines		
4	measles, mumps and rubella (MMR) vaccines		
5	meningococcal vaccines		

3.11 Top Five Black Triangle Medicines (Scotland) 2009-10

Brand Name (Generic Medicine Name)	Yellow Card Reports
Cervarix (HPV vaccines)*	156
Champix (varenicline)	151
Byetta (exenatide)	17
Enbrel (etanercept)	14
Cymbalta (duloxetine)	7
Humira (adalimumab)	7

^{*} Reports that listed an unspecified HPV vaccine were included in this count as the brand Cervarix was contracted to supply NHS Scotland.

4. INTERPRETATION

4.1 Total UK Reports (excluding Market Authorisation Holders reports)

The total number of Yellow Card reports for the UK decreased by 2473 in 2009-10 compared with 2008-09 i.e. a 17% decrease. 11% of reports came from patient groups while the remaining 89% of reports came from Healthcare Professionals. 48% of reports submitted by Healthcare Professionals recorded a reaction classified as serious, close to the Scottish average of 52% serious ADR reporting. 82% of reports submitted by patient groups recorded a reaction classified as serious, this is much higher than the overall average for Scotland.

4.2 Total Scottish Reports (excluding Market Authorisation Holders reports)

The total number of Scottish Yellow Card reports submitted in 2009-10 decreased by 372 compared with 2008-09 i.e. a 25% decrease. Scottish reports represented 9% of all UK Yellow Card reports. This fell slightly from 10% in the previous year and considerably above what would be expected with the Scottish population comprising 8.4% of the total UK population (based on statistics from mid 2009 obtained via the Office of National Statistics). Despite the decrease in reporting Scottish reporters are continuing to submit more Yellow Card reports per head of population than the UK average.

4.3 Serious Reports (Scotland)

In 2009-10 the total number of serious ADRs reported in Scotland decreased by 26% from 763 in 2008-09 to 568 in 2009-10. The proportion of serious reports as a percentage of all Scottish reports remained largely stable decreasing from 52% in 2008-09 to 51% in 2009-10.

The introduction of the HPV vaccine during 2008 resulted in a large number of non-serious ADR reports for this Black Triangle product of which only 38 of 157 reports (24%) were classed as serious.

In addition, the majority of reports for varenicline (Champix), another Black Triangle product, were considered not to be serious with only 38 out of 151 varenicline Yellow Cards reports (25%) being classified as serious.

4.4 Black Triangle Reports (Scotland)

The number of Scottish Black Triangle reports in 2009-10 was down 152 on the previous year, resulting in an overall decrease in reporting of 24% in Black Triangle reporting in Scotland. The proportion of Black Triangle reports as a percentage of total Scottish reports remains unchanged (43%). The vast majority of Black Triangle reports were for Cervarix (HPV vaccine) and Champix (varenicline). Of the other drugs in the Top Five Black Triangle Medicines there were 19 Byetta (exenatide) reports, up from 8 in 2008-09; Enbrel (etanercept) reports continued to come in, with 14 reports in both 2009-10 and in 2008-09; 7 reports were submitted for Cymbalta (duloxetine) and 7 reports were submitted for Humira (adalimumab).

4.5 Fatal Reports (Scotland)

The number of fatal reports has decreased from 43 in 2008-09 to 32 in 2009-10 showing a reduction of 26%. The proportion of fatal reports as a percentage of total Scottish reports remains unchanged (3%). As we do not currently have access to details of the medicines associated with fatalities, it is not possible to comment further upon this.

4.6 Age Banding (Scotland)

There was a decrease in ADR reports for paediatric reports in children under 18 years with 231 reports in 2009-10, 87 fewer than in the previous year. Although this is a 27% reduction in report numbers on the previous year the percentage of reports as a proportion of total Scottish reports has fallen only slightly from 21% in 2009-10 to 22% in 2008-09. Looking more closely at paediatric reports the majority of reports are for adolescents (12-18 age range). There were 179 reports for this age group, 74% of all paediatric reports. Children under 18 years continue to be the patient group for which the highest volume of Yellow Card reports are submitted. This can largely be explained by the 157 reports for the new HPV (Cervarix) vaccine which is generally given to girls who are under 18 years of age. There were slight variations in levels of reporting for other age groups however the general trend was very similar to that seen in previous years.

4.7 Sources of Yellow Card Reports (Scotland)

Healthcare Professionals submitted 89% of all Yellow Cards in 2009-10 while **Patient Groups** submitted the remaining 11% of reports. 48% of reports submitted by Healthcare Professionals recorded a reaction classified as serious, close to the Scottish average of 52% serious ADR reporting.

GPs continue to be the group who submit the highest volume of Yellow Cards providing 21% of all reports submitted in 2009-10. Report numbers fell considerably from 373 (25%) in 2008-09 to 230 (21%) in 2009-10. This was a 38% decrease in the number of Yellow Cards submitted by GPs compared with the previous year. 46% of GP reports were classed as serious.

The percentage of reports as a proportion of total Scottish reports provided by **Hospital Doctors** has increased from 14% in 2008-09 to 16% in 2009-10. Hospital Doctors provided 176 Yellow Card reports, down 37 reports on the previous year. 126 of the 176 (72%) Hospital Doctor reports were for serious ADRs.

Nurses (unspecified) submitted 15% of all Yellow Cards in Scotland. This was similar to the percentage reported the previous year (16%). More nurses continue to receive formal training on ADR reporting at the University of Dundee and Queen Margaret University as undergraduates and as postgraduates training to be independent or supplementary prescribers. Those involved with Patient Group Directions will also have raised awareness of ADR reporting. Unspecified Nurses were the highest reporters of ADRs to the HPV vaccine of the 157 reports submitted during 2009-10 with 97 reports (62%) being submitted by this group and a further 13 reports (8%) being submitted by Hospital Nurses. 19% of all Unspecified Nurse reports were classed as serious with only 17 of the 157 HPV vaccine reports being serious ADRs (11%).

Patients and consumer reporting provided 10% of all Scottish reports. The total number of patient and consumer reports decreased from 138 in 2008-09 to 104 in 2009-10 showing an overall 25% decrease. Parent reporting fell from 15 in 2008-09 to 8 in 2009-10 and Carer reporting also fell from 10 reports in 2008-09 to 7 reports in 2009-10. There was a slight overall decrease in reports from the general public from 163 in 2008-09 (11%) to 121 in 2009-10 (10%). The patient reporting publicity campaign ran in community pharmacy outlets across Scotland finished until April 2008; the reduction in patient reporting in 2009-10 may relate to the end of the campaign. 82% of reports submitted by patient groups recorded a reaction classified as serious, this is much higher than the overall average for Scotland of 52% serious ADR reporting.

Hospital Pharmacists submitted 98 reports (9%) of all Yellow Cards. Although this is a 16% reduction in report numbers on the previous year the percentage of reports as a proportion of total Scottish reports has actually increased from 8% in 2008-09 to 9% in 2009-10. It is of note that 83 of the 98 Yellow Cards (85%) submitted by hospital Pharmacists were for serious ADRs compared to the Scottish rate of 52% serious ADRs.

Other Healthcare Professionals (unspecified) also submitted 9% of Yellow Cards. Although there were 20 fewer reports submitted by this group in 2009-10 than in the previous year the percentage of reports as a proportion of total Scottish reports have increased from 8% in 2008-09 to 9% in 2009-10. 18% of reports from this reporter group recorded a reaction classified as serious.

Hospital Healthcare Professional reports fell from 102 in 2008-09 to 69 in 2009-10, a 32% decrease. The percentage of reports as a proportion of total Scottish reports has also decreased slightly from 7% in 2008-09 to 6% in 2009-10. The number of reports from this group may have been affected by more accurate recording of speciality on reports. Serious ADRs comprised 62% of all Hospital HCP reports.

Hospital Nurse reporting provided 61 Yellow Card reports, an overall increase of 10 Hospital Nurse Yellow Cards, showing a 20% increase on the previous year. The percentage of reports as a proportion of total Scottish reports has increased from 4% in 2008-09 to 6% in 2009-10. It can be proposed that ADR training for supplementary and independent nurse prescribers at Queen Margaret University, the University of Abertay and the University of Dundee by YCC Scotland may have helped with this improvement in reporting. The percentage of serious reports from this group was 38%.

Community Pharmacists provided 3% of all Scottish Yellow Card reports, unchanged from 2008-09. This group submitted 12 fewer reports in 2009-10

than in the previous year. 32% of Community Pharmacist reports were classed as serious.

Unspecified Pharmacists provided 2% of all Scottish Yellow Card reports. This group provided an additional 2 reports in 2009-10 compared to 2008-09. 48% of Pharmacists (unspecified) reports recorded reactions classified as serious.

Physicians submitted 23 Yellow Cards, 2% of all Scottish reports. Although 2 fewer reports were submitted in 2009-10 than in 2008-09 the percentage of reports as a proportion of total Scottish reports remains unchanged from 2008-09. Serious ADRs comprised 57% of all Physician reports.

Optometrist and **Dentist** reporting continues to be very low. There were 3 reports from Dentists, 2 fewer than the previous year, and 2 of these reports were concerning a serious ADR. There were 3 reports from Optometrists, 2 more than the previous year, and 1 of these reports concerned a serious ADR. Neither of these groups has had any formal training on ADR reporting from YCC Scotland. Despite a number of attempts to liaise with the Scottish Dental Schools we have not been able to arrange any teaching sessions with them and this requires to be pursued further.

4.8 Top Ten Medicines Reported (Scotland)

HPV vaccines are the most frequently reported products in 2009-10 in Scotland with 157 reports. HPV vaccines are also the most frequently reported medicine in **paediatric reports** in 2009-10. The HPV vaccine was introduced for vaccination of school-age girls during the early autumn of 2008 and the nurses involved have clearly been very vigilant in reporting both serious and minor ADRs in line with the recommendations for a new Black Triangle product. 70% of all HPV vaccine reports come from Nurses, both hospital and unspecified.

Varenicline is the second most frequently reported drug in Scotland. There were 151 reports in 2009-10, down from 237 reports in 2008-09, a 36% reduction. As with 2008-09 varenicline has continued to have a high media profile. Scottish varenicline reports provide 12% of all UK reports. This is slightly higher than the expected 8.4% based upon population.

Diphtheria-containing vaccines were the third most reported product in Scotland for the second year running although they did not reach the Top Ten nationwide. With 24 reports this was a decrease on the 35 reports for the same range of products in the previous year. Diphtheria-containing vaccines are the second most reported medicine in paediatric reports.

Pneumococcal Vaccines were ranked as the fourth most frequently reported products in Scotland in 2009-10 with 17 reports received. These vaccines were not included in the Top Ten nationwide. Scotlish reports for Pneumococcal vaccines decreased from 28 in 2008-09 to 17 in 2009-10. Pneumococcal vaccines are the third most reported medicine in paediatric reports.

Exenatide was ranked as the fourth most frequently reported product in Scotland and the tenth most frequently reported product UK-wide. There were 17 reports for this product in 2009-10, up from 10 reports in 2008-09.

Quetiapine was the sixth most frequently reported product in Scotland although the product did not reach the Top Ten nationwide. There were 16 reports for this product in 2009-10, up from 7 in 2008-09.

Etanercept was the seventh most frequently reported product in Scotland and the ninth most frequently reported product UK-wide. There were 14 reports from Scotland for etanercept in both 2009-10 and 2008-09.

Simvastatin was ranked as the eighth most frequently reported product for Scotland and the sixth most frequently reported product UK-wide. There were 13 reports from Scotland for simvastatin in 2009-10, down from 23 in 2008-09.

Ciprofloxacin was ranked as the eighth most frequently reported product for Scotland although the product did not reach the Top Ten nationwide. There were 13 reports for ciprofloxacin, up 6 on the previous year.

Omeprazole was ranked as the tenth most frequently reported medicine in Scotland although the product did not reach the Top Ten nationwide. There were 12 reports in 2009-10 for omeprazole, down from 16 in 2008-09.

Four out of the five most frequently reported medicines in **paediatric reports** are vaccines. Three of these vaccines appear on the Scottish Top Ten Medicines list; meningococcal vaccines and atomoxetine are amongst the top five paediatric medicines reported but are not on the Scottish Top Ten Medicines List. HPV vaccines are the only vaccines to appear on both the Scottish and UK Top Ten Medicines list.

In summary, the two most frequently reported drugs, HPV vaccines and varenicline dominated reports from Scotland. These comprise two of the top three most reported drugs UK-wide. There were slight variations in levels of reporting of other drugs however the general trend was very similar. There were 338 different drugs reported over 1104 Scottish Yellow Card reports in 2009-10.

5. Follow up of reports

Number of reports followed up	58
Responses received	40
Null returns	18
Response still active	0
Response rate	69%

Throughout 2009-10 a total of 58 Yellow Card reports were followed up by YCC Scotland, a 21% decrease on the previous year. The response rate was 69%, also lower than the 86% response rate the previous year.

A pilot scheme was initiated by the MHRA part way through the 2009-10 year to streamline the processing of follow-ups at their headquarters in London. As a result of the pilot scheme the MHRA decided that all follow-ups would be processed centrally at MHRA headquarters in future. Legacy Yellow Cards have continued to be forwarded appropriately to the MHRA via the YCC Scotland office.

6. Promotional Activities

Detail talks given and audience

Noble S. Side Effects of Biopharmaceuticals. NHS Education for Scotland Pharmacy, Biopharmaceuticals and their Impact in Pharmacy Practice, Roxburghe Hotel, Edinburgh (24 September 2009).

Maxwell S. Adverse Drug Reactions. Paediatric Seminar, Royal Hospital for Sick Children, Edinburgh (February 2010).

Maxwell S. Adverse Drug Reactions: When Your Medicine Does More Harm Than Good. Voluntary sector event aimed at members of the public and carers. The Gathering 2010, Edinburgh International Conference Centre (19 February 2010).

Maxwell S. A Scottish Community Pharmacy Campaign to Boost Patient Reporting. Yellow Card Centre Annual General Meeting, MHRA Headquarters, London (14 April 2010).

Maxwell S. Proposal to Build an Online Simulator to Support Yellow Card Reporting. Yellow Card Centre Annual General Meeting, MHRA Headquarters, London (14 April 2010).

Detail training and audience

Maxwell S. Adverse Drug Reactions Lecture. 4th Year Medical Students, University of Edinburgh (2 June 2009).

Maxwell S. Adverse Drug Reactions Lecture. 3rd Year Medical Students, University of Edinburgh (23 September 2009).

Cuthbert M. Adverse Drug Reactions Lecture. Non-medical Prescribers Course, University of Dundee (29 September 2009).

Bateman N. The Role of Medicines Regulation in Prevention of Serious Poisoning Lecture. Medical Toxicology Course, University of Wales, Cardiff (2 November 2009).

Noble S. Adverse Drug Reactions Lecture and Workshop. Non-medical Prescribers. Borders General Hospital Education Centre (25 November 2009).

Noble S. Adverse Drug Reactions Lecture and Workshop. Supplementary Prescribers Course, Queen Margaret University, Edinburgh (16 December 2009).

Noble S. Adverse Drug Reactions Lecture and Workshop. Undergraduate Podiatry, Queen Margaret University, Edinburgh (12 January 2010).

Noble S. Adverse Drug Reactions Lecture and Workshop. Community and Independent Prescribers Course, Queen Margaret University, Edinburgh (13 January 2009).

Noble S. Adverse Drug Reactions Lecture and Workshop. MSc Podiatry, Queen Margaret University, Edinburgh (15 January 2010).

Cuthbert M. Adverse Drug Reactions Lecture. BSc (Honours) Biomedical Science Course, University of Edinburgh (23 February 2010).

Noble S. Adverse Drug Reactions Lecture. Undergraduate Pharmacy programme, University of Strathclyde (1 March 2010).

Cuthbert M. Adverse Drug Reactions Lecture. Non-medical Prescribers Course, University of Dundee (11 March 2010).

Noble S. Pharmacovigilance Lecture. Fourth Year Pharmacy Undergraduate Programme, Robert Gordon University, Aberdeen (22 March 2010).

Maxwell S. Adverse Drug Reactions Lecture. 5th Year Medical Students, University of Edinburgh (25 May 2010).

Detail materials developed to promote YCS

Promotional lanyards, pen-pots and pens were purchased for promoting YCC Scotland.

Detail development of YCC website

All required updates were completed (as per MHRA contract). The website will be redesigned in 2010-11 to allow for a weekly news feed and updated links to pages pending purchase of required software to underpin.

Anything else applicable to promotion within your region

7. Publications

Adams RD, Lupton D, Good AM, Bateman DN. Comparison of poisoning severity grades allocated by enquirers and poisons information staff in pesticide exposures. Clinical Toxicology 2009; 47: 487-488.

Afshari R, Maxwell SR, Webb DJ, Bateman DN. Morphine is an arteriolar vasodilator in man. British Journal of Clinical Pharmacology 2009;67:386-93.

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Bateman DN, Sandilands E. Poisoning in special patient groups: the elderly. Clinical Toxicology 2009; 47: 436-437.

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Good AM, Bateman DN. Cases of quinine poisoning referred to a poisons information service for specialist advice. Clinical Toxicology 2009; 47: 448-449.

Jessop V, Maxwell S. Preserving objectivity in medical education. Lancet 2009;373:2196-7.

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Maxwell SR. Rational prescribing: the principles of drug selection. Clinical Medicine 2009;9:481–5

McQueen DS, Begg MJ, Maxwell SRJ. eDrugCalc: an on-line self-assessment package to enhance medical students' drug dose calculation skills. Br J Clin Pharmacol. 2010;70: in press

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O'Shaughnessy L, Haq I, Maxwell S, Llewelyn M. Teaching of clinical pharmacology and therapeutics in UK medical schools: current status in 2009. Br J Clin Pharmacol. 2010;70:143-8.

Payne RA, Maxwell SR. Deprivation-based risk scores: the re-emergence of postcode prescribing in the UK? Journal of Cardiovascular Medicine 2009;10:157-60. Payne RA, Webb DJ, Maxwell SR. Assessing cardiovascular risk. Correction and transparency of BNF risk charts. British Medical Journal 2009;338:2330.

Raine C, Webb DJ, Maxwell SR. The availability of prescription-only analgesics purchased from the internet in the UK. British Journal of Clinical Pharmacology 2009;67:250-4.

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8. Research

Brown, N. HNC Pharmacy Services Development and Management, Telford College, Edinburgh. Evaluation of the Community Pharmacy Patient Yellow Card Reporting Campaign by the Yellow Card Centre Scotland (ongoing).

Cuthbert, M. Master of Philosophy, University of Strathclyde, Glasgow. Title: Improving Standards of Pharmacovigilance Practice in Oncology (Date of submission October 2009).

Davidson, K. MSc Clinical Pharmacy, University of Strathclyde, Glasgow. Title: Acute Renal Adverse Drug Reactions (ongoing).