COMMITTEE ON SAFETY OF MEDICINES

CSM Scotland
Centre for Adverse Reactions to Drugs (Scotland)

NHS SCOTLAND

CSM Scotland
CARDS Advisory Group Meeting
Minutes of meeting held on 30 October 2002

Present: Professor David Webb, Department of Medical Sciences, WGH (Chair)
Dr Nicholas Bateman, Medical Consultant, SPIB & CARDS
Melinda Cuthbert, Senior Pharmacist, CARDS, RIE
Sheena Kerr, Principal Pharmacist, Medicines Information, RIE
Dr Norman Lannigan, Trust Chief Pharmacist, WGH
Anne Lee, Principal Pharmacist, Medicines Information, Glasgow Royal Infirmary
Dr Simon Maxwell, Senior Lecturer in Pharmacology, WGH

Apologies: Professor Tom McDonald, Deputy Director of MEMO, Ninewells Hospital, Dundee
Professor Steve Hudson, Department of Pharmaceutical Sciences, University of Strathclyde
Dr Ross Taylor, Senior Lecturer, Department of General Practice and Primary Care, Aberdeen

1.0 INTRODUCTION

1.1 This was the first meeting for the Advisory Group. All members present gave brief introduction of themselves. Professor David Webb introduced himself as chair of the group.

2.0 NURSE REPORTING AND ELECTRONIC YELLOW CARD

2.1 Nick Bateman reported that Lord Hunt was to make a press release and formally announce on 31st October 2002 that Nurses, Midwives and Health Visitors can now complete Yellow Cards.

2.2 With this launch, the electronic Yellow Card was being launched. This would mean that reports could go directly to London, bypassing the Monitoring Centres of the CSM. This is of great concern to the Monitoring Centres that would otherwise have received the reports.

The group fully supports that reports are passed on to the Monitoring Centres where applicable. Nick Bateman to discuss with June Raine and the other directors of the monitoring centres.

Action : N Bateman

3.0 LAUNCH FOR CSM SCOTLAND, CARDS

3.1 Nick Bateman reported that the launch letter for the Centre is currently being printed, and has been co-signed by Dr Alistair Brekenridge and Bill Scott. This letter will be

posted, along with the new Yellow Card for CSM Scotland, with the next "Current Problems" due to be released in the second week of November.

3.2 The official launch seminar in Scotland is still to be confirmed. But will hopefully take place at one of the Colleges (e.g. Glasgow). Nick Bateman to liase with the Scottish Executive as to suitable dates.

Action : N Bateman

4.0 DRAFT HEADS OF AGREEMENT

4.1 The second draft of the Heads of Agreement was discussed. The funding for CSM Scotland, CARDS is approx. £35,000 per annum with half being funded by the MCA and the other half by the Pharmacy Division of the Scottish Executive. A third draft is awaited.

4.2 At present the role of the Centre for Adverse Reactions (Scotland) is to collate, process and transmit reports generated in Scotland under the Yellow Card Scheme. As well as, any subsequent work arising from the Scheme. The Centre will also provide reports to the MCA/CSM and the Scottish Executive for the whole of Scotland as appropriate.

5.0 FUNCTIONS OF THE ADVISORY GROUP

5.1 The main functions of the Advisory Group will be to advise the Management Board. After much discussion, the functions of the Advisory Group were drafted (see enclosed).

5.2 The Group will provide advice and peer review on any reports produced. It will be the decision of the Management Board if the advice will be actioned.

5.3 The Group will meet every 4 months initially, but may change to 6 months once the Centre is fully established.

6.0 MEMBERSHIP OF THE ADVISORY GROUP

6.1 It was decided that the Committee should have input from the key professional bodies within Scotland from individuals who have an expertise and/or interest in pharmacovigilance. At present, the key people that still need to be appointed are:

*Community Pharmacist — **Action : N Lannigan**
*GP outside of an Academic Centre — **Action : N Bateman**
*Clinical Risk Management Representative from within The NHS. Preferably to come from outside Edinburgh (seek nomination from the Scottish Executive) — **Action : M Cuthbert**

*Community and Hospital Nurse (D/W CSM to get suggestions for names) — **Action : M Cuthbert**

7.0 ROLE OF THE MANAGEMENT BOARD

7.1 The Management Board consists of Dr N Lannigan, Dr N Bateman, Dr S Maxwell and Sheena Kerr.

7.2 The role of the Management Board is to deliver on the Heads of Agreement contract, (once finalised) and to ensure the Yellow Card Scheme functions as per the specifics laid out in the Standard Operating Procedure from the MCA.

7.3 Also, responsible for increasing the profile for pharmacovigilance in Scotland, and fostering research in pharmacovigilance.

8.0 PRE-LAUNCH REPORT FOR 2000/2001

8,1 The pre-launch report which was circulated with the Agenda was presented by Melinda Cuthbert. (See attached summary of report).

8.2 Two errors in the original report were noted. These errors were:

1. In Table 3 the number for Nurse for 2000 should be "504" not "6".
2. In Table 27, the population for Mersey is 2.28 million. Hence, changing the percentages for this area from 8.5 and 5.6 to 5.1 and 3.4 respectively. An amended page for this table was circulated.

8.3 Two reporting trends which were noted, and will require further looking at in the future, was the high % of reports coming from Community Pharmacists in Tayside, and the % of reports coming from GPs in Strathclyde.

8.4 The percentage of reports coming from Lothian based on reporting rates per population is lower than all of the other areas of Scotland. The preliminary analysis is not able to account for the reasons for any of the reporting trends. Professor Webb suggested that the Lothian Joint Formulary and low prescribing of new drugs maybe a reason contributing to this. It was therefore decided that prescribing data from ISD would be sought for the Top 10 reported medications for 2000 and 2001. This data would be analysed to see if the prescribing or lack of prescribing has an impact.

Action : M Cuthbert

8.5 It was suggested that this data should be written and published in a journal, and the Scottish Health Bulletin. It is thought that this might encourage a positive, competitive aspect between the areas of Scotland that might help to increase Yellow Card Reporting. Simon Maxwell offered to assist Melinda Cuthbert in producing this paper.

Action : M Cuthbert / S Maxwell

9.0 IMPROVING PHARMACOVIGILANCE

9.1 It is essential to improving Pharmacovigilance in Scotland that the Centre establish links with:

MEMO
ISD
New Drugs Committee of the SMC
Scottish Education Board

Further discussion on the topic will ensue at a later date.

9.2 With regard to under-graduate education of medical staff and pharmacists, the Advisory Group need to encourage the incorporation of training in the area of Yellow Cards (if not already included) in the core curriculum. There are 4 Schools of Medicine in Scotland (i.e. Edinburgh, Glasgow, Dundee and Aberdeen), and there are 2 Schools of Pharmacy (i.e. Strathclyde University and Robert Gordon University). At present, it is known that it is included in the curriculum at Strathclyde and is taught by Anne Boyter.

Action : M Cuthbert / S Kerr

9.3 Post-graduate medical training will also have to be assessed to see if the current programme offers any teaching within this area.

Action : M Cuthbert / S kerr

9.4 The post-graduate training for Adverse Drug Reactions in pharmacy is presently covered by SCPPE.

Action : All

9.5 The Group will seek to find out from representative groups what initiatives CSM Scotland can undertake to best support them in promoting the reporting of ADRs. At the next meeting, it was suggested that each group represented on the Advisory Group would offer ideas from their perspective on this topic.

9.6 Contacts with the Scottish Medicines Information Pharmacists will be made to aid in the dissemination of information and promotion of ADR reporting. A letter will be drafted within the next week to advise of the official launch of the Centre. This letter will also be sent to all the Scottish Chief Pharmacists.

Action : M Cuthbert/S Kerr

9.7 Research will be one area that will be enthusiastically sought and supported by the Advisory Group. The areas of research which were suggested included:

New drugs
Areas with traditional under-reporting such as paediatrics and cancer

Simon Maxwell and David Webb are very interested in Education and Research and will be very happy to become involved with this work. The group as a whole will provide methodological support, as well as, review any work that is produced.

9.8 Melinda Cuthbert will be undertaking a M.Phil in Research based around Pharmacovigilance. She is very eager to begin but a topic has yet to be decided upon.

9.9 A website is one area which will need to be addressed shortly. It was suggested that Debs Hamilton who is currently employed with Dr Anna Gregor be sought to aid in this venture. The webpage should appear in show. Another ideal was that recommended references on pharmacovigilance should be kept updated within the website. At present, references that were compiled by Anne Lee will be forwarded to any Advisory Group members interested.

Action : M Cuthbert

9.10 Funding for research projects should be sought. It was suggested that both the Education Board and the Pharmaceutical Division of the Scottish Executive could be possible sources. An application for funds will be done to the Education Board for small project grants.

Action : S Kerr

10 **ANY OTHER AREAS OF BUSINESS**

10.1 It was suggested that at the next meeting plans for the launch seminars and means of increasing profile of the Centre and education should be discussed.

10.2 CSM Scotland will be assigned one seat on SCOP, but no representative on the CSM. The representative on SCOP will be the Medical Advisor of CSM scotland.

11. **DATE AND TIME OF NEXT MEETING**

11.1 The next meeting will be arranged for the end of January 2003 or beginning of February 2003 depending upon member's diary.

Action : M Cuthbert

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Summary notes on "Preliminary Analysis of ADR reporting in Scotland for 2000 and 2001" - As presented to CSM Advisory Group 30 October 2002

1 Introduction

The aim of the preliminary analysis of ADR reporting data for Scotland in 2000 and 2001 is to establish a baseline for spontaneous reporting via yellow cards in Scotland. This information will aid in identifying current reporting trends, and developing a plan for the promotion of adverse drug reaction reporting in Scotland. Also, it will be used as a baseline marker for the success of the Centre.

Data for this report was supplied by CSM London and includes all reports made to the CSM from Scotland for 2000 and 2001. In this analysis, I have looked at the total reports for each year, total black triangle drug reports for each year and the total number of serious drug reactions for both of these. The reports are further analysed by geographical area and the source of the reports.

2 Number of reports

As you can see from Table 1 the total number of reports for 2000 and 2001 were 2513 and 1455 respectively.

As table 2 shows, there was an inflated number of reactions in 2000 due to the meningococcal group C campaign (i.e. 43% of the years total reports). This increase in reporting was also the same for the rest of the UK, including the 4 regional monitoring centre.

If we were to exclude the reports for the meningococcal group C vaccine for 2000, and compare it to the total reports for 2001 you will see a 2.4% increase in reporting from 2000 in Scotland. When the CSM did the same comparison for the whole of the UK it showed a 2% decrease in reporting from 2000 to 2001.

3 Reporter origin

If you look at table 3, it will show you a breakdown of the reports by the reporter origin.

In 2000, 47% of the reports came from GPs to make them the number 1 reported. Nurses accounted for 20% of the reports which can be linked to the huge number of reports which came from the meningococcal group C vaccine. This is reinforced by the fact that in 2001,

only 2.1% of the reports came from nurses. The reports from community pharmacists and hospital pharmacists are quite low (i.e. 2% and 4.3% respectively).

In 2001, GPs once again were the number one reporter. They accounted for 55% of the total reports. Overall, there was a slight increase in reporting by GPs, hospital doctors and both hospital and community pharmacists.

4 Geographical Area

In table 4, you will see the reports by geographical area in Scotland. It is obvious to see that the area of Strathclyde lead in reporting by quite a wide margin to the other areas.

In table 12, you can see that if with removing the meningococcal group C vaccine and bupropion, Strathclyde still has a much higher reporting rate than the other areas.

5 Table 5 and 6

In tables 5 and 6, you can see the reports for 2000 and 2001 broken down by both geographical area and origin of reporter.

In 2000 and 2001 the biggest reporting area was Strathclyde and Tayside was second. Approximately 45% of these reports for Strathclyde came from GPs in both 2000 and 2001.

In 2000, with regard to hospital doctors, again a great number of reports (i.e. 45%) for this reporter origin came from Strathclyde. The same is true with 2001 with 58% for this origin group coming from Strathclyde.

With regard to hospital pharmacist reporting, in 2000 the greatest percentage of reports came from Strathclyde. But in 2001, Lothian was the leader by a light margin (i.e. 6%).

With Community pharmacists, in 2000 Strathclyde was the region with the greatest number of reports for this group (i.e. 38%), However in 2001, Tayside was responsible for 48.7% of the reports, with Strathclyde dropping quite a bit to only 14% of the reports for this group.

It would be interesting to know what factors were involved in this increase in reporting by community pharmacists in Tayside; and if this could be transferred to other areas to help increase reporting by community pharmacists, who on the whole have low reporting rates.

6 Serious Reactions

With regard to serious reactions, table 7 shows that 30.4% and 42.7% of the reports for 2000 and 2001 respectively were for serious reactions. This only goes to show that the quantity of reports for 2000 did not increase the quality of the reports.

Once again the number one reporter origin for serious reaction reports was GPs for both 2000 and 2001; hospital doctors were the number 2 reporter for both years. In 2000, 10.9% of the serious reports came from nurses which only goes to strengthen the case for nurse reporting on yellow cards. This initiative which will be launched shortly by the CSM/MCA. Hospital pharmacists were the third highest reporting group for serious reactions in 2001.

Table 9 shows that Strathclyde's reports were also of quality by being the number one geographical area for reporting. We will need to look closely at this geographical area to see what there is that can be learnt to help increase quality reports in other areas.

7 Black Triangles

Table 13 shows that over four fifths of the total reports received came from black triangle drugs. However, only a quarter to one third of these reactions in both years were for serious reactions.

GPs once again account for over half of the reports for black triangle drugs and almost half of these reports for black triangle drugs come from Strathclyde in both years.

Tables 18 and 19 show the number of reports for black triangles that were for serious reactions. These numbers once again reflect the high quality of reports coming from GPs, and the area of Strathclyde.

8 Top 10 drugs

Tables 20 through 25 show the top 10 reported drugs for each of the 3 categories looked at.

The major point of note is that the top 3 reported drugs overall for Scotland are the same as for the whole of the UK, i.e.

2000	2001
meningococcal group C vaccine	bupropion
bupropion	rofecoxib
rofecoxib	celecoxib

The top 3 reported overall are also the same top 3 for serious reactions and black triangles.

9 Population Comparisons

If an attempt to put the reporting into perspective with population, it is then surprising to see the top 3 areas to emerge:

2000	2001
1 Tayside	1 Western Isles
2 Borders	2 Tayside
3 Dumfries & Galloway	3 Dumfries & Galloway

Lothian however, is the area with the lowest reporting rate per 10,000 population.

It will be interesting to look at the prescribing data for these areas, as well as

- gender
- age
- socioeconomic make up

of the geographical areas to see if this has had any impact upon the reporting data as well.

10 Comparison with RMCs

If you lastly look at table 27, I would like to point out a change in this table,
i.e. population Mersey 2.28 million instead of 1.36 million

In this comparison, it is easy to see that Scotland is currently performing below the UK average. However, when you compare our reporting rate to West Midlands that has the same approximate population, we are already matching these reporting rates.

11 Conclusion

Hence, there is still a lot of work to be done but hopefully with the guidance of this Advisory Group and the centre's medical and pharmaceutical advisors, we will achieve the goals of this centre and the pharmaceutical plan for Scotland. In the process, we hope this will result in decreased morbidity and mortality for the population of Scotland.

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Functions of the Advisory Group

1 Advise center on issues relating to medicines safety in Scotland

2 Advise center on practical initiatives in which the quality and quantity of spontaneous adverse drug reactions can be improved in Scotland, including raising the profile of adverse drug reactions reporting through initiatives in undergraduate and postgraduate education in Scotland.

3 Promote research in pharmacoepidemiology through the Centre for Adverse Drug Reactions (Scotland).

4 Increase the profile of pharmacovigilance in Scotland

5 Provide peer review on any reports generated by CARDS.

6 Foster multidisciplinary approaches to adverse drug reactions within Scotland.

7 Specifically foster collaboration between pharmacy and clinical pharmacology.

8 Share good practice from other areas for avoidance of adverse drug reactions.

9 Work with the SMC in gathering information on the safety and efficacy of new medications; and provide advice where appropriate.

10 Create National ownership of CSM Scotland scheme via the groups and disciplines.