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**Minutes from Advisory Group Meeting  
Wednesday 25 February 2004 at 2pm  
In Seminar Room 5, 1<sup>st</sup> floor, Chancellor's Building, NRIE**

**Present:** Professor D Webb, Professor of Clin Pharmacol, University of Edinburgh (Chair)  
Dr D Alexander, General Practitioner, Dunfermline  
Dr N Bateman, Medical Director, SPIB and CARDS, RIE  
Melinda Cuthbert, Senior Pharmacist, CARDS, RIE  
Jane Harris, Academic Team Leader for Public Health & Primary Care Nursing,  
School of Nursing & Midwifery, University of Dundee  
Dr N Lannigan, Trust Chief Pharmacist, LUHT  
Anne Lee, Principal Pharmacist, Medicines Information, Glasgow Royal  
Infirmary  
Professor T MacDonald, Deputy Director of MEMO, Ninewells Hospital, Dundee  
Dr S Maxwell, Senior Lecturer, Dept Clinical Pharmacol, University of Edinburgh  
Dr R Taylor, Senior Lecturer, Dept General Practice in Primary Care, Aberdeen

**1 Apologies for absence**

Apologies were received from Sheena Kerr, Hugh Purves and Professor S Hudson.

**2 Minutes of previous meeting**

The following errors were noted:

- a) One spelling error was noted on page 2 'aciton' should read 'action'
- b) N Bateman pointed out that the summary from future SCOP meetings would be 'verbal' not 'written'.

**3 Matters Arising**

**3.1 Letter to Prof D Lawson, Chairman of SMC, regarding BPS curriculum redesign**

Dr Maxwell reported that the letter to Prof Lawson had been sent and cc'd to Lord Patel, the chairman of NHS QIS.

In a subsequent meeting with Prof Lawson and Dr D Steel it was suggested that Dr Maxwell make contact with NES to take forward incorporating the BPS curriculum redesign recommendations into post-graduate curriculums throughout the Schools of Medicine in Scotland. Jane Harris expressed concern over the nurses BPS guidelines not being moved forward. Dr Bateman suggested that after Dr Maxwell has made his initial contact with NES and begins to prepare a proposal for implementation that maybe Jane Harris could be involved in drafting this proposal with Dr Maxwell.

**ACTION: DR MAXWELL**

### **3.2 Generic ADR PowerPoint Presentation**

Melinda Cuthbert reported that the generic ADR presentation has now been completed and is being added to the CSM Scotland web page. At present there appear to be problems within SHOW accessing this document but they are being addressed. Copies of the presentation are available on disk upon request.

Anne Lee suggested that the ADR presentation be circulated to all of the MI sites within Scotland. Jane Harris also requested 7 copies of the ADR presentation to be forwarded to her for use within the Nurse Practitioners' course.

**ACTION: M CUTHBERT**

### **3.3 Electronic reporting via G-PASS**

Dr Bateman reported that Melinda Cuthbert and himself had met with Ken Harden and David Brazier at G-PASS. The GPASS electronic yellow card is almost ready to be launched pending input from the IT department at CSM London. It is anticipated that it will be launched in June 2004 in module 5.6. Prior to CSM Scotland being able to receive these electronic yellow cards via G-PASS an NHS Net e-mail has to be set up for CSM Scotland. Dr Lannigan has been through this process of obtaining an NHS net e-mail address, and Melinda Cuthbert will liaise with him to arrange this.

**ACTION: M CUTHBERT/DR LANNIGAN**

Prof Macdonald raised the issue that currently there is still no access to the equivalent of GPASS in secondary care. He suggested that a letter be written to Charlie Knox at NHS Scotland regarding this issue and the letter should be cc'd to the CMO and the CPO.

**ACTION: PROF WEBB**

### **3.4 Feedback on CSM Scotland Launch Seminar**

Dr Bateman reported that the seminar went well and that there was good feedback both verbally and from the assessment forms. It was suggested by Dr Alexander that a breakdown of the people in attendance be done to geographical area and professional occupation for circulation to the Group.

**ACTION: M CUTHBERT**

### **3.5 Permission from J Raine to circulate CSM Scotland quarterly reports to a wider group**

Dr Bateman reported that this is currently under review within the wider context of the review of the yellow card scheme and until the outcome of that review is made public no decision will be made upon this.

### **3.6 Letter to Prof D Lawson, Chairman of SMC re CSM Scotland web page**

Dr Bateman advised that the letter had been sent to Prof Lawson saying that CSM Scotland's web site was now available, and asked him to make known to members of the SMC. Prof Webb suggested that a link between the SMC website and the CSM Scotland website might be helpful and he would try to take his forward.

**ACTION: PROF WEBB**

### **3.7 List of prescribing and clinical governance leads in LHCCs**

Melinda Cuthbert reported that she currently has a list from 2003 for both of these groups. However, due to the dissolution of trusts this list will certainly change. She will need to update this list at a later date.

**ACTION: M CUTHBERT**

### **3.8 Mechanisms for obtaining bypass reports**

Melinda Cuthbert reported that bypass reports are currently being received monthly from the CSM in London. However, from February forward weekly bypass data would be supplied.

Melinda Cuthbert reported that there is a difference between the levels in which the RMCs are currently breaking down their data. For example, some of the RMCs breakdown to hospitals and Trust but at the moment CSM Scotland has been requested to breakdown only to the health Board level. The review of the yellow card scheme will hopefully give guidance on this issue and make it the same for all RMCs.

### **3.9 Review of the Yellow Card Scheme**

Dr Bateman reported that a review of the yellow card scheme is currently under way with Jeremy Metters as the chair of the group. Both Dr Bateman and Prof Webb have submitted responses to the consultation on the yellow card (see enclosures 2 and 3). Dr Bateman reported that Jeremy Metters had met with the electronic reporting group on 24 February. During this meeting he had raised the concern that the data on reporting rates compiled by RMCs could be used for disciplinary purposes (which it is not meant to do), which could result in a decrease in reporting. Also it is possible that patient details could inadvertently be revealed. In his opinion, it would be acceptable for these reports to be used for internal use.

However, until the publication of the consultation on the review of the yellow card scheme we will not know what data we can release or publish. Dr Taylor commented that he thought that the risk to the yellow card system would outweigh any potential benefit that could be achieved from audit reports on reporting rates.

Prof Webb enquired as to the mechanism by which the outcome of the review would be made public. Dr Bateman reported that he thought it would go through the CSM first and then to the Minister of Health before dissemination and publication.

## **4 Initiatives for Improving Scottish ADR Reporting**

Much discussion ensued around the initiative. The majority of these initiatives were actually linked to NES collaboration (see enclosure 1). The group decided that until Dr Maxwell has made the initial contact with NES that the majority of these initiatives should be put on hold. Then one concerted effort could be made through the subsequent proposal. However, a couple of items that could be taken present at the moment were:

#### **4.1 Names of Local Trainers**

Obtaining the names of local trainers or champions for ADR presentations throughout Scotland. Dr Lannigan agreed that he would take this forward via the Association of Scottish Trust Chief Pharmacists.

**ACTION: DR LANNIGAN**

#### **4.2 EPASS Accreditation**

Dr Alexander mentioned that all accreditation for GP postgraduate learning must be EPASS approved from now on. EPASS refers to the Educational Providers Accreditation Scheme Scotland. EPASS is designed to award educational accreditation to organisations that wish to gain recognition for their commitment of the education. This would include any web-based learning. At present the ADR module that is accredited via the DSRU website for GP postgraduate learning does not have EPASS accreditation. It is unlikely that the DSRU would pursue this accreditation since it is based in England. Melinda Cuthbert will make contact with the DSRU to see if EPASS accreditation will be sought. If not, she will ascertain whether or not CSM Scotland could become an agent for this on-line ADR module in Scotland.

**ACTION: M CUTHBERT**

#### **4.3 Grand Round Talks**

Grand round talks on ADRs have been done in some areas of Scotland. However, Greater Glasgow is one area that has not been covered. Anne Lee will contact the appropriate organisers and liaise with Dr Maxwell and Dr Bateman for suitable dates.

**ACTION: A LEE**

#### **4.4 Research Topics in Pharmacovigilance**

Anne Lee suggested that the group compile a list of topics for research in pharmacovigilance. All Advisory Board members should give consideration to this prior to the next meeting.

**ACTION: ALL**

### **5 Annual Report 2003**

Dr Bateman reported that CSM Scotland had seen a 6% increase in reporting from the previous year. It was also noted that unlike other areas of the UK GP reporting had remained static in Scotland. In the rest of the UK, GP reporting continues to fall (see enclosure 5).

Melinda Cuthbert reported that clozapine was the number 1 reported medication for the whole of the UK and had appeared in the top 10 reported medicines to CSM Scotland in 2002. However, it did not appear in the top 10 this year. This is due to the fact that CSM London did not hand back any bypass data for clozapine. The reason given for this is that the clozapine monitoring did not give the postcodes or addresses, so they are unable to link them to specific geographical areas. If these reports had been passed back to CSM Scotland it would have made a difference to the total reports as well as the top ten reported medicines.

Melinda Cuthbert reported that permission from CSM London has been requested to make the annual report available to the public domain. However, until permission is received from them the report cannot be added to the CSM website.

## **6 Feedback from SCOP meeting 24 February 2004**

Dr Bateman mentioned an interesting paper that had been tabled at the meeting, on risk communication and patient information leaflets. It was suggested that this document be circulated to all members.

**ACTION: M CUTHBERT**

Some other items of interest which were raised at this meeting were:

- a) There is an increased association of risk of cerebrovascular adverse events, including CVA and TIAs, in patients receiving atypical antipsychotics, particularly in the elderly and in patients with pre-existing risk factors. To minimise the risk risperidone should not be given to patients with a past history of CVA/TIA, hypertension, AF or diabetes.
- b) SSRIs in combination with NSAIDs considerably increases the risk of GI side effects than that seen with NSAIDs alone. Therefore, the CSM will advise of the warning that concomitant use of SSRIs and non-selective NSAIDs/ aspirin should be avoided. The concomitant use of COX-2 selective inhibitor should be used with caution in those at high risk of GI adverse effects.
- c) There is concern over the use of black cohosh in patients with oestrogenic dependent tumours such as breast cancer, although this is not proven. Also there is a possible risk of hepatotoxicity with black cohosh.

## **7 Any Other Business**

### **7.1 Representation from community pharmacy on the Advisory Group**

It was suggested by Prof Macdonald that another representative from another area, such as the chair of an area pharmaceutical committee or community pharmacist in practice from another area of Scotland might be worthwhile including in the group. Melinda Cuthbert advised that financial considerations would need to be considered here before any commitment to this could be made. She will discuss with Sheena Kerr.

**ACTION: M CUTHBERT**

## **8 Date and time of next meeting**

The next meeting will be held on 3 June 2004 at 2:30pm in Seminar Room 5, first floor, Chancellor's Building, NRIE. Lunch will be provided from 2:00 pm. Prof MacDonald intimated his apologies for this meeting.

## Summary Action List

Item No	Item for Action	Responsible Individual
3.1	Make Contact with NES to take forward incorporating the BPS curriculum redesign recommendations into post-graduate curriculum	Dr Maxwell
3.2	Circulate ADR presentation to all MI sites within Scotland, and 7 copies to Jane Harris for Nurse Practitioners' course	M Cuthbert
3.3	Obtain NHS Net e-mail for CSM Scotland	M Cuthbert / Dr Lannigan
3.3	Letter to Charlie Knox at NHS Scotland regarding no access to the equivalent of GPASS in secondary care. Letter to be copied to CMO and CPO.	Prof Webb
3.4	Prepare summary list of those in attendance at launch seminar by geographical area and professional occupation.	M Cuthbert
3.6	Try to arrange for a link to be made from the SMC website to CSM Scotland website.	Prof Webb
3.7	Update list of prescribing and clinical governance leads in LHCCs after dissolution of trusts.	M Cuthbert
4.1	Obtain names of local trainers for ADR presentations throughout Scotland via the ASTCP.	Dr Lannigan
4.2	Discuss with the DSRU if EPASS accreditation will be sought for the GP postgraduate ADR module, or if CSM Scotland could become an agent for this in Scotland.	M Cuthbert
4.3	Arrange for Grand Round talks on ADRs in Greater Glasgow. Liaise with Dr Maxwell and Dr Bateman for suitable dates.	A Lee
4.4	Compile a list of topics for research in Pharmacovigilance.	All
6	Disseminate paper on 'Risk communication and patient information leaflets' to all members of Advisory Group.	M Cuthbert
7.1	Pursue possibility of adding another representative to the group from an area pharmaceutical committee or a community pharmacist.	M Cuthbert

**Objectives for CSM Scotland & Priority Assignment**

<b>Objective</b>	<b>Assigned Priority</b>	<b>Outcome</b>
Initial launch letter & yellow card mailing	Short term	<b>Sent out Nov 2002</b>
Launch Meeting	Short term	<b>Achieved 28 November 2003</b>
Website Design	Short term	<b>Achieved July 2003</b>
Standard Operating Procedures (SOP) for CARDS	Short term	<b>Partially completed</b>
Generic template SOP on how/what to report for ADRs for circulation	Medium term/ Long term	
Training on ADRs for the following areas:	Long term	<b>Establish link with NHS Education Board Scotland (NES) to take this forward as a concerted effort</b>
- Undergraduate		<b>Initial contact made with Heads of schools</b>
- Postgraduate		<b>Lothian GP Postgraduate education to incorporate into registrar training scheme in 2004/2005. Talk done in Highlands to GPs.</b>
- Grand rounds talks		<b>Done at RIE, WGH, Borders so far. To be done in Tayside March 2004</b>
- Distance learning / web-based learning		<b>? promotion of DSRU electronic Medication Safety Module for GPs, if get EPASS approved</b>
- Academic detailing to lead prescribing advisers, clinical governance representatives		<b>Undecided at present (intensive manpower required to achieve). Support of NES and QUIS would be required to achieve.</b>
Training the trainers	Medium term/ Long term	<b>Contact with ASTCP to be made to obtain a list of individuals that would be interesting in championing this cause locally throughout Scotland.</b>

Use networks to promote ADRs (e.g. Paediatric pharmacist network, Oncology pharmacists, RCGP, PCTP, etc)	Medium term / Long term	<b>ASMIPG pharmacists, SCAN Oncology Pharmacists already involved</b>
Power point presentation packages for training	Short term	<b>Achieved</b>
Development of Bulletin	Long term	
Opinions on reporting from the multidisciplinary group of reporters	Long term	<b>Addressed via Advisory Group Members</b>
Demonstrate benefit of Yellow Card Scheme in Scotland	Medium term/ Long term	
Promotion of research on pharmacovigilance	Long term	<b>Advisory group members to compile a list of ideals/ needs for research projects that could be taken forward in this area.</b>