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**Minutes from Advisory Group Meeting  
Thursday 11 January 2007 at 2pm  
held in Board Room 2, Royal Infirmary of Edinburgh**

Present: Professor D Webb, Professor Clin Pharmacol, University of Edinburgh (Chair)  
Professor N Bateman, Medical Director, SPIB and CARDS, RIE  
Sheena Kerr, Principal Pharmacist, YCC Scotland, RIE  
Melinda Cuthbert, Senior Pharmacist, YCC Scotland, RIE  
Sheila Noble, Senior Pharmacist, YCC Scotland, RIE  
Dr S Maxwell, Senior Lecturer, Dept Clinical Pharmacol, University of  
Edinburgh  
Dr D Alexander, General Practitioner, Dunfermline  
Professor N Lannigan, Chief Pharmacist, WGH  
Jane Harris, Teaching Dean, School of Nursing & Midwifery, University of  
Dundee  
Asgher Mohammed, Community Pharmacist, Glasgow representing RPSGB in  
Scotland  
Professor T MacDonald, Director, MEMO

### **1 Apologies for absence**

Apologies were received from Dr R Taylor, J Watt, and Professor S Hudson.

### **2 Minutes of previous meeting – 15 June 2006**

It was noted that Asgher Mohammed's name was spelt incorrectly. Apologies were offered from Melinda Cuthbert. Otherwise the minutes were accepted as a true record.

### **3 Matters Arising**

#### **3.1 Completion of DOTs ADR package**

Dr Maxwell reported that the ADR package for the on-line DOTs programme had been completed and rolled out to the FY1s. M Cuthbert further added that the module was included in the mandatory modules that must be completed by FY1 doctors (deadline for completion of the module set for 25 June 2007).

Professor Lannigan suggested that the NES regional pharmacy tutors, which have been recently appointed for the North, West and South East Scotland might be able to promote this package as a resource for evidence for the Scottish Vocational Training Programme. Therefore it would be worthwhile making them aware of this resource once they are in post.

**ACTION: M CUTHBERT**

### **3.2 Electronic yellow card reporting via EMAS IT platform**

M Cuthbert reported that she had met with Alison Strath and Derek McAllister (IT specialist) on 8 August 2006. Both were happy to collaborate in incorporating an electronic card with pre-populated fields into the system. However, since 10 different computer platforms are involved in the network they were unable to predict when they might be able to bring this to completion.

As an interim measure they were putting a link to the SHOW webpage for the new community pharmacy contract. Derek will now ask pharmacy facilitators to promote the availability of the link and would ask the FPGC to do so through their next mailing as well. Derek had suggested that YCC Scotland might wish to add a facility to tour the YCC Scotland webpage and allow users to add to their favourites. This would allow them to access via the pharmacy desktop as well as from the community pharmacy website.

### **3.3 ADR patient reporting campaign in Scottish community pharmacies under the new contract**

M Cuthbert reported that under the new Scottish community pharmacy contract one of the core areas included public health. Under this section of the contract SEHD Pharmaceutical Division are purchasing Window space from the community pharmacy for window displays and promotional campaigns on public health. Alison Strath was quite receptive to patient reporting of ADRs as one of these topics. It was thought that ADR patient reporting might best be fitted in between the three seasonal campaigns.

At present this initiative is being held back by the production of the window display apparatus that the posters would slot into. Once the dimensions for window displays area are available Alison will advise M Cuthbert and they will proceed with producing the posters.

### **3.4 Contact with Helen McKinnon regarding patient yellow card reporting**

Professor Bateman reported that he had spoken to Helen McKinnon at NES regarding this. She had suggested that Anne Wales, who is responsible for patient knowledge, might be the best person with whom to take this forward. Professor Bateman is still in discussion with Anne Wales.

### **3.5 GP registrar ADR training**

Professor Bateman reported that he and Dr Simon Maxwell, Sheena, Dr Dave Crookes, Dr Ruben Thanacoody, and Stephen Waring had carried out an ADR training session to the South East of Scotland GP Registrars (organised through Dr David Blaney). The feedback forms were positive and reflected the opinion that the session went well.

Professor Webb requested that copies of the feedback forms be made available to him.

**ACTION: N BATEMAN/M CUTHBERT**

Professor Webb enquired as to whether or not the sessions would be repeated or if it would be expanded to other GP training programmes within Scotland. Professor Bateman said that it would depend on Dr David Blaney and he would pursue this with him.

**ACTION: N BATEMAN**

### **3.6 Coverage of ADRs in undergraduate programmes and supplementary prescribers course**

S Noble reported that letters had been sent out on 4 January 2007 to the teaching heads of all of the healthcare professional programmes within Scotland. Professor Webb requested that a copy of this letter be made available to the Advisory Group.

**ACTION: S NOBLE/M CUTHBERT**

Professor MacDonald reported that Professor Allan Struthers at the University of Dundee had received the letter. Professor Struthers had nominated Professor MacDonald to deliver these lectures there.

### **3.7 Coverage of ADRs in pre-registration training manuals**

M Cuthbert reported that there are 2 training manuals which cover ADR reporting for pre-registration pharmacists:

1. The RPSGB training manual - as one of the core competencies pre-regs are required to recognise possible ADRs, evaluate risk and action accordingly. The action might include advising or informing the patient or representatives, discussion with colleagues and reporting to the MHRA.
2. The Scottish Vocational training folder - one of the core competencies is that pre-regs are expected to recognise possible ADRs, evaluate the risk and take action accordingly, with the evidence being examples and reports. This manual also has written sections on different topics. However it is incomplete at present, and there is no section on ADR reporting at present.

M Cuthbert reported that she had contacted Stephen Peddie (responsible for the development of the Scottish NHS Pre-registration pharmacists scheme that will be nationally co-ordinated by NES). Melinda had enquired whether ADRs were covered nationally at all pre-reg study days Scotland wide. Stephen had replied that there were 3 regional programmes currently (i.e. Lothian, Glasgow and Tayside). ADR reporting is covered by the pharmacy staff at YCC Scotland in the form of either a presentation or presentation and a workshop to Glasgow and Lothian respectively.

NES are moving towards a situation where the structure of pre-reg programme and the topics to be covered by Study days will be standardised by them. Stephen envisaged that NES would be commissioning core study day sessions to be delivered on a regional basis and he was very supportive of ADR reporting being covered. M Cuthbert had offered the services of YCC Scotland to deliver these tutorials to pre-regs Scotland-wide. Stephen Peddie had been very receptive to this and would be in touch in the future regarding this. Also there is currently a review of the manual being undertaken and he would be grateful for any help YCC Scotland could give in developing the materials for training on ADR reporting.

### **3.8 Grand round talks in major Scottish centres**

M Cuthbert reported that no progress has been made in this area at present. It is anticipated that the ADR champions from the health boards within Scotland would assist in taking this forward. However ADR champions have not been appointed for all health boards. M Cuthbert will pursue obtaining ADR champions for the remaining Health Boards.

**ACTION: M CUTHBERT**

### **3.9 ADR talk at national nurses prescribing conference**

J Harris reported that the conference would be going ahead on 3 May 2007. She had put forward M Cuthbert's name to speak at the conference.

Dr Maxwell reported as well that the British Pharmacological society (BPS) would be having a meeting to discuss prescribing at which there would be an ADR component. Dr Maxwell will pass on the details of this to M Cuthbert for circulation to the group.

**ACTION: DR MAXWELL/ M CUTHBERT**

### **3.10 Invitation to Sonya Lam to join Advisory Group**

Professor Bateman reported that no action has been taken on this to date, however he would do so in the near future.

**ACTION: N BATEMAN**

### **3.11 Scottish datasets usage in UK pharmacovigilance strategy & MHRA**

Professor Bateman summarised to the group the changes to ways of working for YCC Scotland and the MHRA effective 31 May 2006. He also highlighted some of the difficulties that have been encountered during this process, including the lack of availability of yellow card reports for the area of Scotland. There is an application pending with IASC at the MHRA. However, the outcome of this application is unknown. Professor Bateman suggested the way around this problem would be to pursue access to data for educational initiatives or measurement of success of educational initiatives within Scotland. A research programme would need to be written around this and we could then request data prior to initiating a programme for teaching and education initiatives.

Professor MacDonald suggested that a randomised trial of teaching in Scotland was another possibility that could be pursued.

Professor Bateman reported that a letter from John Parkinson of GPRD had been received regarding risk management plans methodology data streams from all GP systems. Professor MacDonald said that 9 practices had switched over to Vamp Vision within Tayside. He suggested that Professor Bateman might wish to speak to Professor Andrew Morris to discuss this further.

**ACTION: N BATEMAN**

## **4 Large simplified safety study**

Professor MacDonald explained the background to large simplified studies. He said that there are 2 sections to their study.

### **Section A – large simplified safety study**

This first study is a commercial one funded by Pfizer through the University of Dundee. The only thing that Pfizer gets at the end is a report though.

### **Section B – consented database for community pharmacists**

Professor MacDonald initially proposed that a consented dispensing database through community pharmacies could be an initial stage. Initially would write to all community pharmacies to ascertain their willingness to consent to participate in giving out consent forms to patients on access to prescribing and medical records for the purpose of detecting and quantifying ADRs and effectiveness.

Numerous issues surrounding this proposal were discussed by the group including the following:

- Attitude of general public to give this data and to who.
- Weakness in ISD coding and ISD data
- Drop out rates
- How long would the consent last once given by the patient
- Better to pursue through Scottish Executive instead of community pharmacy
- Would GPs be willing to co-operate or participate
- The wording of the consent form should make it explicit enough that patients would understand the full picture of what they did and what it would be used for and who would have access to it.

Professor MacDonald envisioned after stage 1 consent survey had been completed then a pilot would be done in a couple of pharmacies. Professor Webb stated that before YCC Scotland Advisory Group could give consent to proceed with this or assume ownership that it would be desirable for Professor MacDonald to submit a draft to the committee for review and comment.

**ACTION: PROFESSOR MACDONALD**

Professor Webb thought it would be best to seek at 2 levels for community pharmacy record access and for patient consent for medical records.

Once the drafts have been received from Professor MacDonald the group will review and discuss at the next meeting. If it is agreed to proceed, then an application to MREC would be sought.

## **5 Education & Training strategy**

It was thought by the group that the majority of the items covered under the education and training strategy had been previously discussed. The only other item discussed was publicity. Dr Maxwell said that the centre required a higher profile and publicity would be required to achieve this. Professor Bateman stated that, from experience, the media is only interested in information that is of topical interest to the public or if a concern for public safety has been raised. S Noble suggested that if we did decide to proceed with Professor MacDonald's study it might be an opportunity to have publicity for this under the aegis of the YCC Scotland.

Professor Lannigan suggested that it would be beneficial to send out a copy of the education and training strategy for YCC Scotland to major stakeholders to obtain their input into how we might improve ADR reporting (e.g. BMA, NES, Scottish College of Physicians, Post-graduate Deans, etc). Professor Bateman suggested we could send it out with the annual report.

**ACTION: M CUTHBERT/S NOBLE**

## **6 Pharmacovigilance Seminar**

Professor MacDonald reported that BSPE had funding to support initiatives, and since BSPE dealt with both pharmacovigilance and epidemiology then they would be receptive to sponsoring a seminar on pharmacovigilance. A suggested title for the day could be "Opportunities for Pharmacovigilance in Scotland". A high profile, keynote speaker would be essential. It was suggested that maybe Professor Jerry Avorn could be one such keynote speaker.

Dr Alexander said that we would have to decide upon what audience we were trying to target and what the objectives of the day would be. He also noted that it may be difficult to cater to education and research and clinical practice interests. He suggested that if we were trying to target the attendance of GPs, we might consider having an item which was clinically relevant and topical (e.g. highlight on NSAIDS or Polypharmacy in the elderly). EPASS accreditation would be an incentive as well.

Dr Maxwell suggested it might be best to divide the day up (i.e. the morning could cover items which would be of interest to those in education and research and the afternoon would be for those in clinical practice). It was suggested that the seminar would best take place in late 2007 or early 2008. It was decided that Professor Bateman, Professor MacDonald and Professor Webb would meet to take this forward.

**ACTION: PROFESSORS BATEMAN, MACDONALD and WEBB**

M Cuthbert reported that Dr Taylor had also expressed to her an interest in helping to take forward the planning of the pharmacovigilance seminar since he his now retired and has time to dedicate to this.

## **7 Updated version of ADR presentation**

It was requested that all members of the Advisory Group review the ADR presentation and provide any comments to Sheila at their earliest convenience.

**ACTION: ALL**

Once the ADR presentation has been finalised it will be added to the YCC Scotland web page. Professor MacDonald suggested that it might be advisable to add some pictures to the presentation. He offered to provide some pictures that he had used in the past. S Noble will take this forward with him. Professor Webb requested that the 'notes' section of the slides be used to help presenters.

**ACTION: S NOBLE/PROFESSOR MACDONALD**

## **8 AOCB**

### **8.1 Scottish School of Physicians)**

Professor MacDonald had suggested that the 50<sup>th</sup> anniversary of the Scottish Society of Physicians that would take place the last week of September 2008 might be a platform where Scottish pharmacovigilance could be highlighted and discussed. A presentation by someone such as Professor Sir Alasdair Breckenridge of the MHRA might be a good idea.

### **8.2 Invitation to speak at Grand Round in Carlisle**

Dr Maxwell reported that an invitation had been received from Carlisle to speak on a Wednesday at Grand Rounds on ADRs. Carlisle would fall under the YCC Northern and Yorkshire. Therefore YCC Scotland could do but we would advise Dr Simon Thomas in Newcastle that we would be delivering this Grand Round presentation. Dr Maxwell to e-mail details to Sheena for contact.

**ACTION: DR MAXWELL/S KERR**

**9 Date and time of next meeting**

M Cuthbert will circulate dates for a Thursday in about 6 months time to obtain consensus date from the group.

**ACTION: M CUTHBERT**

**Summary Action List**

<b>Item No</b>	<b>Item for Action</b>	<b>Responsible Individual</b>
<b>3.1</b>	Make NES regional tutors aware of ADR DOTS package	<b>M Cuthbert</b>
<b>3.5</b>	Provide Professor Webb with copies of feedback forms on GP Registrar training carried out by Prof Bateman et al.	<b>Professor Bateman/ M Cuthbert</b>
<b>3.5</b>	Pursue Dr Blaney regarding future GP Registrar training sessions within Scotland	<b>Professor Bateman</b>
<b>3.6</b>	Make copy of letter sent to educational institutions available to Advisory Group	<b>S Noble</b>
<b>3.8</b>	Pursue ADR champions and arranging dates for Grand Round Talks	<b>M Cuthbert</b>
<b>3.9</b>	Pass details of BPC meeting on prescribing issues including ADRs to Advisory Group	<b>S Maxwell/ M Cuthbert</b>
<b>3.10</b>	Invite Sonya Lam to join Advisory Group	<b>Professor Bateman</b>
<b>3.11</b>	Liase with Andrew Morris to discuss switch to new system (?VampVision)	<b>Professor Bateman</b>
<b>4</b>	Draft proposal for large simplified safety study to be written and circulated to Advisory Group	<b>Professor MacDonald</b>
<b>5</b>	Circulate YCC Scotland education and training strategy to major stakeholders for comments/feedback (with annual report)	<b>M Cuthbert/ S Noble</b>
<b>6</b>	Take forward planning of pharmacovigilance seminar in Scotland	<b>Professors Bateman, Macdonald &amp; Webb</b>
<b>7</b>	Provide comments/feedback on ADR presentation to S Noble	<b>All</b>
<b>7</b>	Liase to obtain photos for to be added to ADR generic presentation	<b>S Noble/Professor MacDonald</b>
<b>8</b>	Take forward Grand Round presentation in Carlisle	<b>S Kerr/ Dr Maxwell</b>
<b>9</b>	Arrange date for next meeting	<b>M Cuthbert</b>