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**Management Board Meeting  
Tuesday 05 August 2003  
4pm, Pharmacy Seminar Room, RIE**

**Present:** Dr N Bateman, Medical Director, SPIB and CARDS, RIE  
Melinda Cuthbert, Senior Pharmacist, CARDS, RIE  
Dr N Lannigan, Chief Pharmacist, LUHT  
Sheena Kerr, Principal Pharmacist, Medicines Information, RIE

**1 Apologies for absence**

Apologies were received from Dr Maxwell.

**2 Minutes of previous meeting**

Minutes from the meeting held on Tuesday 3 June 2003 were accepted as a true record.

**3 Matters arising**

**3.1 Yellow Card Peer Review**

M Cuthbert reported that the next yellow card peer review meeting will be held on Monday 17 November 2003, at 12.30pm at WGH. Prior to this meeting copies of anonymised yellow card reports will be forwarded to those who will be in attendance. A distribution list has been made (appendix 1)

**3.2 Computer access**

M Cuthbert reported that Dr Maxwell advised that he still does not have access to the N:\ drive. He will make contact with Gavin Greig at WGH IT department to follow this up.

**ACTION: S MAXWELL**

**3.3 Website Launch**

M Cuthbert reported that the website is now ready to go live and should take place within the next few weeks. Dr Bateman suggested once the web page is live a letter should be drafted to the ADTCs to advise of the same.

**ACTION: N BATEMAN**

**3.4 Nomination of Scottish Executive representative**

Dr Lannigan reported that Laura McIver of the Implementation team for the Scottish Executive advised that a representative from the pharmaceutical division would be participating in the seminar on 28 November. The name of this individual is to follow.

### **3.5 Tentative meeting between N Bateman and H Purves**

Dr Bateman advised that this meeting has not yet been organised but he will contact Mr Purves to arrange

**ACTION: N BATEMAN**

### **4 Launch Seminar**

The draft programme of events for the seminar to be held on 28 November 2003 still awaits some information before a final draft can be made. The formal title of Professor Gordon Duffs and Dr Munir Pirmohamed presentations needs to be confirmed. Dr Bateman will make contact with them to confirm.

**ACTION: N BATEMAN**

The name of the representative from the Scottish Executive Pharmaceutical Division needs to be confirmed. M Cuthbert will make contact with L McIver to obtain this name.

**ACTION: M CUTHBERT**

There was some discussion about the content of the programme to ensure that material reflected the title of the seminar. As a result a few minor changes were made to the programme of events (appendix 2).

Now that the Pharmaceutical Division of the Scottish Executive has agreed to participation within this seminar, Dr Bateman will make contact with the CMO, Deputy CMO, the CNO and the Chairman of QUIS to advise of this event and to enquire as the availability to attend.

**ACTION: N BATEMAN**

M Cuthbert will forward the contact addresses and names of these individuals for the letters to be written.

**ACTION: M CUTHBERT**

Dr Bateman needs to confirm with June Raine that she is able to chair the second half of the seminar.

**ACTION; N BATEMEN**

Once the above items have been finalised the final draft of the programme will be circulated for final approval before printing. A draft registration form and letter of invitation is also required. It was suggested by Dr Bateman that in the accompanying letter of invitation should contain the statement *'if you cannot attend then please send a colleague in your place'*.

**ACTION: M CUTHBERT**

The registration form, programme and cover letter will be mailed out by the end of August.

**ACTION: M CUTHBERT**

M Cuthbert enquired about the possibility of using the Scottish Executive publicity engine for promotion of the seminar on 28 November, as suggested by Hugh Purves at the Advisory Group meeting in May. Dr Lannigan will enquire about this.

**ACTION: N LANNINGAN**

## **5 Any Other Business**

### **5.1 Electronic cards via GPASS link**

Dr Bateman advised that the CSM London is happy for CSM Scotland to proceed with an electronic card link within the GPASS system. Dr Bateman will take this forward once he has the contact name. S Kerr will obtain the name of the contact person for GPASS from Dr Crookes.

**ACTION: N BATEMAN / S KERR**

### **5.2 Glasgow Prescribing Bulletin**

M Cuthbert advised that the article written by Anne Lee on the yellow card scheme within Scotland has now been published (appendix 3). M Cuthbert suggested it might be worthwhile to use an adapted version of this article within the Lothian Prescribing Bulletin upon permission from A Lee.

### **5.3 Heads of agreement**

Dr Lannigan advised that the heads of agreement has now been officially signed but a copy of the agreement has not been received yet.

### **5.4 Quality improvement Scotland – Quality Prescribing meeting**

Dr Bateman advised that he attended a meeting on quality prescribing in Glasgow. At this meeting medication errors within Scotland were discussed. Dr Bateman suggested a medication error collecting system should be established. Due to the linked role medication errors have with ADR reporting he thought that this might well come under the umbrella of CARDS as CSM Scotland. However, at present there are no resources for the establishment of such a system. Dr Bateman will liase with Mr Scott to see if there are any resources to make this a reality.

**ACTION: N BATEMAN**

### **5.5 Lothian Prescribing Bulletin**

M Cuthbert advised that an article on nurse reporting to the yellow card scheme has been written and approved by CSM London to be published in the Lothian Prescribing Bulletin and it should appear in the next issue (appendix 4).

### **5.6 CSM Scotland Quarterly report for April – June 2003**

M Cuthbert reported that during this period a total of 273 yellow card reports had been received directly by CSM Scotland. This was an increase of 30% from the previous quarter. She still awaits the by-pass figures from London to complete this report. Once the report is completed it will be distributed to members of the management board.

**ACTION: M CUTHBERT**

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

The next meeting will be held on Tuesday 7 October at 4pm in the Seminar Room, Pharmacy Department, RIE

## Appendix 1

Dr Norman Lannigan  
Trust Chief Pharmacist  
Pharmacy Department  
WGH

Miss Sheena Kerr  
Principal Pharmacist  
Medicines Information Service  
RIE

Dr Simon Maxwell  
Senior Lecturer in Pharmacology  
Clinical Pharmacology Unit  
and Research Centre  
2<sup>nd</sup> Floor Out-Patients  
WGH

Dr James Oliver  
Clinical Pharmacology Unit  
and Research Centre  
2<sup>nd</sup> Floor Out-Patients  
WGH

Professor David Webb  
Clinical Research Centre  
Dept of Medical Sciences  
The University of Edinburgh  
WGH

Dr Stephen Waring  
Clinical Pharmacology Unit  
and Research Centre  
2<sup>nd</sup> Floor Out-Patients  
WGH

Dr Bob Carlson  
Clinical Pharmacology Unit  
and Research Centre  
2<sup>nd</sup> Floor Out-Patients  
WGH

Dr Philip Rutledge  
Director of Medicines Management  
At Lothian Health  
Deaconess House  
Edinburgh

Dr Teresa Attina  
Research Fellow  
Clinical Pharmacology Unit  
and Research Centre  
2<sup>nd</sup> Floor Out-Patients  
WGH

Dr Rupert Payne  
Research Fellow  
Clinical Pharmacology Unit  
and Research Centre  
2<sup>nd</sup> Floor Out-Patients  
WGH

Dr Shani Esmail  
Research Fellow  
Clinical Pharmacology Unit  
and Research Centre  
2<sup>nd</sup> Floor Out-Patients  
WGH

Bushra Ilyas  
Research Fellow  
Clinical Pharmacology Unit  
and Research Centre  
2<sup>nd</sup> Floor Out-Patients  
WGH

Dr Nick Bateman  
Medical Director  
SPIB & CARDS  
Royal Infirmary of Edinburgh  
Edinburgh

Jill Macintyre  
Principal Pharmacist  
Pharmacy Department  
Western General Hospital  
Edinburgh

Rhoda Morgan  
Principal Pharmacist  
Pharmacy Department  
Western General Hospital  
Edinburgh

Wendy Thom  
Pharmacy Department  
Western General Hospital  
Edinburgh

Miu Wah Cheung  
Pharmacy Department  
Western General Hospital  
Edinburgh

Carole Callaghan  
Pharmacy Department  
Western General Hospital  
Edinburgh

Heather Dalrymple  
Pharmacy Department  
Western General Hospital  
Edinburgh

Claire Stein  
Pharmacy Department  
Western General Hospital  
Edinburgh

Sheila Selkirk  
Pharmacy Department  
Western General Hospital  
Edinburgh

Pharmacists from RIE may attend,  
pending availability



Appendix 2

CSM Scotland  
Centre for Adverse Reactions to Drugs  
(Scotland)



**Adverse Drug Reaction Reporting in Scotland  
Protecting Patients and Improving Therapy – the First Year and Beyond**

**Stirling Management Centre  
Friday, 28 November 2003**

**Draft Program of Events**

13:00 Registration / Tea Coffee

13:20 Welcome and Introduction

Pharmaceutical Division,  
Scottish Executive  
Rep ~~TBA (? Scottish Exec  
member)~~

***PROTECTING PATIENTS***

**Chair: Pharmaceutical Division, Scottish Executive Representative ~~Scottish  
Exec Representative~~**

13:30 History and global perspective of ADRs

Professor Gordon Duff,  
Chairman CSM

14:00 ADR reporting in Scotland

Sheena Kerr, CSM  
Scotland

14:30 Improving ADR reporting in Scotland  
– why, how and who?

Dr Simon Maxwell,  
University of Edinburgh

15:00 Tea/Coffee

***IMPROVING THERAPY***

**Chair: Dr June Raine, MHRA**

15.20 The mechanisms of ADRs

Dr Munir Pirmohamed,  
CSM Mersey

15:55 ~~Adverse Drug reaction~~ ADR reporting - the  
Nick Bateman, CSM  
Future of pharmacovigilance in Scotland

Dr  
Scotland

16:15 Discussion

16:30 Close of conference



## Appendix 3

### Yellow card scheme moves into the 21<sup>st</sup> century

**"An adverse drug reaction (ADR) is an unwanted or harmful reaction experienced following the administration of a medicine or combination of medicines under normal conditions of use and is suspected to be related to the medicine."<sup>1</sup>**

**Pharmacovigilance is the process** of (a) monitoring the use of medicines to identify previously unrecognised, or changes in the pattern of, adverse effects; (b) assessing the risks and benefits of medicines; (c) providing information to optimise safe and effective use of medicines; (d) monitoring the impact of any action taken. The Committee on Safety of Medicines (CSM) yellow card scheme is regarded as one of the best spontaneous reporting schemes for suspected adverse drug reactions (ADRs) in the world. The scheme acts as an early warning system for the identification of previously unrecognised reactions. It has helped to identify many safety issues including renal failure due to aristolochia in Chinese herbs, severe oesophageal reactions with alendronate and serious cardiovascular reactions with cisapride. About 20,000 reports are submitted each year by doctors, dentists, pharmacists, coroners and the pharmaceutical industry. About half that number represent serious ADRs, but it is generally accepted that there is under-reporting to CSM by a factor of 10. That would mean that about 100,000 people in the UK suffer a serious ADR every year.

The establishment of a CSM monitoring centre – CSM Scotland, Centre for Adverse Reactions to Drugs (Scotland) - in October 2002 provides a welcome opportunity to improve ADR reporting and monitoring in Scotland. Based at the Royal Infirmary of Edinburgh, the centre will administer the yellow card scheme in Scotland and promote pharmacovigilance in collaboration with the CSM/MCA. The Medical Director, Dr Nick Bateman, hopes that the centre will develop education and training initiatives in collaboration with multidisciplinary bodies to facilitate the increased quality and quantity of reporting by health professionals across Scotland. The centre will also provide regular feedback on reports submitted and undertake specific research projects in

pharmacovigilance. During the period October 2002 to March 2003 the centre has received 368 reports directly from health professionals across Scotland; 35% of these originated from NHS Lothian and 18% from NHS Greater Glasgow.

In a separate development, in October 2002 the Medicines Control Agency (MCA) extended the yellow card scheme to include reporting by all nurses, midwives and health visitors. The CSM/MCA recognise that nurses are now more individually responsible for patient care and are involved in the prescribing of medicines together with supply and administration under Patient Group Directions. Patients will benefit from this development because more health professionals involved in their care now have the opportunity to report suspected adverse reactions. All yellow card reporting is being further supported and enhanced by the introduction of an electronic yellow card. This will enable quicker and easier submission of reports by all health professionals. The card can be seen at <http://www.mca.gov.uk/ourwork/monitorsafeequalmed/yellowcard/submitc/yreporter.htm>

All paper yellow card reports from Scotland should now be sent to CSM Scotland (CARDS). The address is included on yellow cards in the BNF from edition 44 (September 2002). Reports submitted electronically will be fed back to CARDS by the MCA in London. The CSM/MCA ask for reports to be submitted on all serious suspected reactions to established drugs and all suspected reactions to new medicines (indicated by the black triangle symbol 6 in prescribing information). Further details on what to report can be found in the BNF or on the CSM website <http://www.mca.gov.uk/aboutagency/regframework/csm/csmhome.htm>

### PostScript - Primary Care

For many years, GPs in Glasgow have benefited from a monthly newsletter, *Glasgow Prescriber*, from the Medicines Management Team in the Primary Care Trust. Many topics in *PostScript* and *Glasgow Prescriber* are of relevance to both primary and secondary care, and we have been fortunate to have strong input from the PCT Medicines Management Team to *PostScript*.

In recognition of the increasingly common ground, *Glasgow Prescriber* has changed. It is now *PostScript – Primary Care* and uses the same logo and colours as *PostScript*.

Secondary care readers should take a regular look at <http://www.show.scot.nhs.uk/ggnhsb/adtc/> to get a quick idea of some of the prescribing issues affecting primary care colleagues.

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## Appendix 4

### Yellow Card Scheme - Nurse Reporting and CSM Scotland

The Committee on Safety of Medicines (CSM) and The Medicines and Healthcare Products Regulatory Agency (MHRA) extended the Yellow Card Scheme **to nurses, midwives and health visitors** on 31st October 2002. This was accompanied by the launch of an electronic Yellow Card.

~~The Yellow Card Scheme is the system by which suspected adverse reactions to medicines may be voluntarily reported to the CSM/MHRA. Over the past 30 years, Yellow Cards have been critically important in monitoring drug safety in normal clinical practice, increasing knowledge about the known adverse drug reactions (ADRs) and acting as an early warning system for the identification of previously unrecognised safety hazards.~~ The CSM/MHRA are always striving to maximise the effectiveness of the Scheme and are aware that the role and responsibilities of nurses are changing. Nurses are becoming more individually responsible for patient care and may observe suspected adverse drug reactions experienced by their patients. Appropriate training in recognising adverse drug reactions is important. Guidance notes are available to provide nurses with the information they need in order to understand why and how they should report suspected adverse drug reactions using the Yellow Card Scheme. This information is available free of charge on the CSM website, [www.mhra.gov.uk](http://www.mhra.gov.uk).

The MHRA ~~would like to~~ encourage nurses to help test and evaluate the usefulness of the electronic Yellow Card by using this method when reporting suspected ADRs. The electronic Yellow Card, together with instructions on how to use it are available on the CSM website. However, for those unable to access the Internet, copies of the Yellow Card can be found in the BNF, ~~NPF-ABPI~~ and MIMS companion. CSM Scotland, the Centre for Adverse Reactions to Drugs (Scotland), is the monitoring centre for Scotland and yellow cards can also be obtained by contacting them. There contact details are as follows:

CSM Scotland, Freepost NAT3271, Edinburgh, EH16 4BR.  
0131 242 2919  
[cardsCSMScotland@luht.scot.nhs.uk](mailto:cardsCSMScotland@luht.scot.nhs.uk)

In 2002 the CSM/MHRA received a total of 258 reports from Lothian Health Board. This accounted for 18.8% of the 1369 reports received from Scotland for this period. Table 1 shows the breakdown of reports by reporter origin for the Lothian Health Board. General practitioners, hospitals doctors and hospital pharmacists were the 3 top reporting groups. Only 2.3 % of the reports from within Lothian in 2002 came from the nursing profession. CSM Scotland looks forward to increased reporting from the nursing profession in the future.

(general information extracted from MCA webpage; Scotland & Lothian reporting statistics obtained from CSM Scotland Annual Report 2002 )

Table 1\_– Comparison of yellow card reports in 2002 from Lothian by reporter group

