

**Independent Scientific Advisory Committee for MHRA database research (ISAC)**

**Summary Minutes of the meeting held on Thursday 10<sup>th</sup> May, 2007**

**Information regarding ongoing deliberations, or that could identify applicants and names of products is withheld under Sections 35 (Formulation of policy), 40 (Personal Information), 41 (Information Provided In Confidence) and 43 (Commercial Interests) of the Freedom of Information Act 2000 (FOIA). Further details on successful applications will be published in ISAC annual reports once research using ISAC-approved data has been published - this will also be subject to any relevant exemptions under the FOIA**

**Present:**

**ISAC Members:**

Dr Brian Gennery (Chair)  
Dr Jacqueline Cassell  
Dr Martin Gulliford  
Dr David Lovell  
Dr Richard Martin<sup>2</sup>  
Ms Marcia Saunders  
Barbara Meredith  
Prof Amrit Hungin<sup>3</sup>  
Dr Corinne de Vries  
Dr Sarah Meredith  
Prof Richard Donnelly

**MHRA<sup>1</sup>:**

Dr June Raine  
Mr Mick Foy  
Dr John Parkinson  
Mr Stephen Fawbert (Secretariat)  
Mrs Tarita Murray-Thomas (Secretariat)  
Dr Sarah Davis  
Ms Catherine King  
Dr Lesley Wise  
Dr Suzie Ekins-Daukes  
Mr David Irvine  
Miss Anna Shafe  
Tjeerd van Staa (GPRD)  
Stephan Rietbrock

**Apologies:**

Prof Paul Little

**Others:**

Prof Munir Pirmohamed<sup>4</sup>  
Prof David Hand<sup>5</sup>

**1. Welcome and apologies**

1.1. The Chairman welcomed Prof Richard Donnelly who was attending his first meeting since appointment. The Chairman welcomed Professor Munir Pirmohamed, Head of Yellow Card Centre Mersey, who was attending as guest member for the day with expertise in the Yellow Card Scheme.

1.2. Apologies had been received from Paul Little.

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<sup>1</sup> MHRA staff may be present for all or part of the meeting, or for specific items. GPRD staff are not present when Yellow Card applications are discussed and VRMM staff are not present for GPRD applications

<sup>2</sup> Left after item 13

<sup>3</sup> Arrived at Item 5

<sup>4</sup> Left after item 9

<sup>5</sup> Item 5 only

1.3. The Chairman reminded Members that the papers and proceedings were confidential and should not be disclosed. Members were also reminded to declare their personal specific, personal non-specific, non-personal specific and non-personal non-specific interests in the agenda items.

2. **Minutes of the ISAC meeting held on 16 February 2007**

The minutes (Paper 1) were agreed without amendment.

3. **Matters arising**

All items had been included on the agenda for the meeting, with the exception of the process for contacting Yellow Card patients and reporters which was still being developed.

**GENERAL ITEMS**

4. **Review of Protocol Blinding**

It was agreed that following the trial period of blinding, GPRD protocols would cease to be blinded from 1 June 2007.

5. **Data Mining in GPRD**

Prof David Hand, Professor of Statistics and Head of the Statistics Section in the Department of Mathematics, Imperial College London and President of the Royal Statistical Society (RSS) 2007 – 2009 gave a presentation on data mining methodology and introduced discussion on this topic.

**YELLOW CARD DATA**

6. **Information Paper on Yellow Card applications**

The Committee noted the information on the status of applications in Paper 2.

7. ***Application 014: Epidemiological study of Adverse Drug Reactions in Scottish hospitals using 10<sup>th</sup> International Classification of Diseases (ICD-10) discharge coding of hospitals***

The application was approved.

8. **Other applications**

The Committee was informed of an application that would come to the next meeting.

9. **Information Paper on strengthening the Yellow Card Scheme**

The Committee was informed of work the Agency was doing to increase Yellow Card reporting rates and raise awareness of the Scheme with advice from a Joint Working Group of the Patient Information and Pharmacovigilance expert advisory groups of the Commission on Human Medicines (Paper 4). [text redacted Section 35 FOIA]

## **10. Portal for accessing papers**

10.1. The Information Management Division of the MHRA demonstrated the MHRA portal, and the Committee agreed to use this for transmission of GPRD protocols to them from 1 June 2007.

10.2. Committee papers for future meetings would not be emailed as separate files but placed on the MHRA portal as a single document in PDF format. Yellow Card papers would cease to include all the guidance notes and irrelevant sections of the ISAC application form to reduce their length.

*[text redacted Section 35 FOIA]*

## **11. Proposals for 1<sup>st</sup> Annual report**

*[text redacted Section 35 FOIA]*

## **12. Statement on the National Research Register and GPRD Application Form**

The Committee endorsed the wording in Paper 6 for inclusion in the GPRD application form and publication on the MHRA website. The GPRD ISAC application form would be updated with effect from 1<sup>st</sup> July 2007.

Applicants would be requested to provide information on sample size/power calculations and the extent of user group involvement in the respective area of research. Applicants would also be encouraged to contribute data to the National Research Register (NRR).

## **13. Summary minutes of the meetings of 29 November 2006 and 16 February 2007 for publication on the MHRA website**

The Committee approved the minutes in Paper 7 for publication on the MHRA website.

## **GPRD DATA**

### **14. Information paper on GPRD applications reviewed electronically since last meeting**

The Committee noted Paper 8, the list of applications reviewed since the previous meeting.

### **15. Protocol 07- 026: Leg ulcers: the extent of the problem and their management in general practice**

This protocol was approved.

### **16. Other applications**

The Committee rejected one application, advised that one be resubmitted and that one did not need ISAC consideration.

### **17. Any other business**

None.

*Date of next meeting – Friday 6 July 2007*

**VRMM/GPRD May 2007**