

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

Summary Minutes of the meeting held on Tuesday 24 March 2009

**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:

Prof Jennifer Adgey (Chair)  
Prof Jacqueline Cassell<sup>2 3</sup>  
Prof Richard Donnelly  
Prof Corinne de Vries<sup>2</sup>  
Prof Pali Hungin<sup>2</sup>  
Dr David Lovell<sup>2</sup>  
Prof Richard Martin<sup>2</sup>  
Dr Sarah Meredith<sup>2</sup>  
Prof Simon Mitchell<sup>2</sup>  
Prof Barbara Pierscionek  
Ms Marcia Saunders<sup>4</sup>  
Dr Richard Stevens  
Dr Ruben Thanacoody<sup>2</sup>

#### MHRA<sup>1</sup>:

Prof Sir Alasdair Breckenridge  
Mr Mick Foy  
Dr John Parkinson  
Mrs Tarita Murray Thomas (Secretariat)  
Mr Stephen Fawbert (Secretariat)  
Ms Sharon Suri  
Ms Shahin Kauser  
Mr Philip Tregunno  
Ms Susan Frade

### Apologies:

Prof Paul Little  
Dr Umesh Kadam  
Dr Martin Gulliford

## **Part One – induction**

### **1. Introductions, apologies and announcements**

- 1.1. New members were welcomed to the Committee by the Chairman.  
The morning meeting was an induction for new members only and

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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> Present for Part 2 only

<sup>3</sup> Left during item 15.1

<sup>4</sup> Present for item 5 onwards

existing members would join after lunch. Prof Donnelly was attending as he had missed his induction.

1.2. 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. Terms of reference**

2.1. The Committee discussed the terms of reference of the Committee that had been agreed in February 2006, to which no amendments were proposed (Tabled Paper 1).

## **3. GPRD data**

3.1. The GPRD Group presented an overview of the GPRD, describing the data held within the database and the principles under which it is operated by the GPRD Group within the MHRA. The arrangements in place to control access to and use of the data were described, including Section 60 and ethical approval. The GPRD Group outlined the procedures for the review of GPRD protocols by ISAC.

## **4. Yellow Card data**

### **4.1. Introduction to the Yellow Card Scheme**

The MHRA gave a presentation on the history of the Yellow Card Scheme, reporting rates and reporting methods.

### **4.2. The Yellow Card ISAC application process and requests received to date**

The MHRA gave a presentation on the applications ISAC had reviewed so far and some case studies.

### **4.3. Tour of Pharmacovigilance Departments**

Members were given a tour of the Pharmacovigilance Group of the MHRA to see how the Yellow Card process operates and how Signal Detection is carried out. The Sentinel and Lincoln IT systems were demonstrated, as was the signal case folder.

## **5. ISAC: The lay perspective**

5.1. The MHRA Patient and Public Engagement Manager spoke about initiatives MHRA were doing to increase patient and lay involvement in decision making. There were meetings for all lay members twice a year. Lay members could contact the MHRA Patient and Public Engagement Manager at any time and in confidence about any issues relating to lay membership of committees.

5.2. Ms Marcia Saunders spoke about her role and experience as a lay member on ISAC.

## **Part Two – All members**

## **6. Welcome from MHRA Chairman Prof Sir Alasdair Breckenridge**

6.1. The Chairman formally welcomed new members to the committee.

## **7. Introductions, apologies and announcements**

7.1. Existing ISAC members joined the second part of the meeting, to discuss routine ISAC business. Apologies had been received from Umesh Kadam, Paul Little and Martin Gulliford.

7.2. 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.

## **8. Minutes of the ISAC meeting held on Thursday 30 October 2008 and summary minutes for publication on the MHRA website**

8.1. The minutes were agreed without amendment and the Chairman signed a copy as a true record. Amended minutes of the July 2008 meeting, previously reviewed by email, were also signed as a true record. Summary minutes would be published on the MHRA website.

## **9. Matters arising from the minutes**

9.1. All actions had been completed or included on the agenda.

## **YELLOW CARD DATA**

### **10. *Application***

10.1. ISAC rejected one application.

## **GPRD DATA**

### **11. Protocols reviewed electronically since the last meeting**

11.1. The Committee noted tabled paper 2.

### **12. The approach for dealing with the problem of descriptive studies**

12.1. To resolve this issue, the Committee agreed that the ISAC application checklist should be updated to explicitly request the following information from applicants: 1. whether the study was of a descriptive nature and the statistical methods to be used 2. whether hypothesis testing would be undertaken and the statistical methods applicable to the area of research; and 3. the justification for not undertaking sample size calculations for the study. The current heading on data analysis should be expanded to include statistical analysis.

### **13. Protocol Deviations**

13.1. After much discussion, the Committee agreed that protocol deviations and subsequent requests for amendment of protocol should be dealt with on a case-by-case basis. MHRA could develop a short form to be completed by applicants seeking an amendment of protocol. This information would be used to gauge whether requests constituted substantial deviations from the originally approved protocol and whether a new application or an amendment of protocol only was warranted. The ISAC Secretariat would liaise with the Chair on such issues.

#### **14. Provision of GPRD data**

14.1. The GPRD proposes to develop a short questionnaire which all applicants would be required to complete in order for the Research Team to determine whether proposals to use the database were operationally feasible. Applicants would be asked to complete and return this form at the same time as their ISAC submission. This information would be held solely by the GPRD and would not form part of the reviewing process.

#### **15. Any other business**

##### *15.1. Access to funding under the GPRD- MRC scheme*

The Committee maintained that access to funding under the scheme was based on scientific integrity as well as merit. At the next meeting the Committee would clearly define the reviewing mechanism for accessing data from the GPRD and assessing eligibility for funding under the GPRD-MRC scheme.

#### **16. Date of next meeting**

16.1. The next meeting would be on **Thursday 2 July 2009** at 10:30am.

**Close**