

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

Summary Minutes of third meeting held on Monday 17<sup>th</sup> July 2006

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)  
Prof. Amrit Hungin  
Prof. Paul Little  
Ms Barbara Meredith  
Dr Sarah Meredith

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

Dr Sarah Davis (Secretariat)  
Mr Stephen Fawbert (Secretariat)  
Dr Jane Moseley  
Dr Tim Williams  
Dr Tarita Murray-Thomas

Dr Robin Ferner (member for the day)

**Apologies:**

Prof Ian Harvey

**1. Welcome & Apologies**

Apologies had been received from Ian Harvey.

Robin Ferner was welcomed to the meeting as a member for the day, co-opted to join the meeting in light of his extensive experience with Yellow Card data.

The Committee was informed that Sarah Meredith had agreed to deputise for the Chairman in his absence or in the event of a conflict of interest.

**2. Minutes of the second ISAC meeting.**

The draft minutes of the meeting held on 17<sup>th</sup> May 2006 were agreed as a true record without amendment.

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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

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

The Committee was informed that the agenda for the current meeting covered all the issues arising in the minutes of the second meeting with two exceptions. Firstly, the MHRA was still taking forward action points on Yellow Card Scheme promotion and the application process and will return to the Committee at a later date. Secondly, the Regional Monitoring Centres, now known as Yellow Card Centres, had not yet submitted their further application.

## **GENERAL PAPERS**

### **4. The National Research Register**

Following a suggestion made at the first ISAC meeting, the MHRA presented proposals for the contribution of information on ISAC-approved protocols to the National Research Register (NRR), which is a register of ongoing/recently completed research projects funded by or of interest to the NHS.

Given the voluntary nature of contribution to the NRR for projects which are not funded by the NHS, it was proposed that applicants should be asked whether they were content for information on their project to be submitted to the Register at the time of approval of the protocol/application. In order to ensure that the MHRA provided to the Register descriptions considered appropriate by the researchers responsible for the project, it was proposed that investigators for approved protocols/applications should be asked to provide suitable wording for inclusion in the Register; this would also streamline the process.

The Committee endorsed the proposal for the MHRA to provide information on all ISAC-approved protocols/applications to the NRR, subject to the agreement of the investigators. Since the research proposals reviewed by ISAC are based on UK data, it was considered that all such proposals, including those conducted outside the UK, would be of potential interest to the NHS. However, the MHRA would need to clarify whether the NRR accepted details of research projects conducted outside the UK.

To complement this, a proposed list of all projects approved on MHRA website/ISAC annual report inclusion in which would be a condition of ISAC approval. While this approach was endorsed in principle as being in line with ISAC's aim of operating in a transparent manner, there was general concern that the publication of research questions may have an adverse impact on public health by inadvertently triggering safety scares. An additional concern for some researchers may be that they wish their research questions to remain confidential until their research was published. The Committee did not wish to see the premature publication of information on proposed research projects.

The Committee therefore asked the MHRA to consider these issues and to provide specific proposals on the most appropriate approach to publishing

information on ISAC-approved protocols, including timing of release of information and the amount of information to be provided.

#### **5. Publication of summary minutes**

MHRA presented a paper on different approaches that could be adopted when publishing summary minutes. It was agreed that minutes of the first meeting could be published on the MHRA website in full as they did not contain any information on applications.

The Committee considered that there could be serious commercial and public health implications of releasing information on pending applications and said it would decide on a formula for publishing minutes at the next meeting.

#### **6. Expanding membership of the Committee**

The Committee was informed of the recruitment exercise which was being set up via the NHS Appointments Commission to recruit a replacement statistician, as well as additional expertise (including a clinical pharmacologist, another epidemiologist and possibly a paediatrician) in order to expand the membership of ISAC. It was expected that the new members would be appointed in time for the November 2006 meeting.

The Committee asked whether the recruitment exercise would include appointing a second lay member. The MHRA agreed to consider this. The Committee also felt that increasing the size of the meeting attendance and preparation fees paid to members might make membership of the Committee a more attractive prospect, although it was recognised that this may not be possible as fees were paid according to standard rates set within the Agency or the Department.

### **GPRD DATA**

#### **7. GPRD protocols for consideration**

The Committee considered 4 applications. The Committee required further information from 2 applicants before a decision could be reached and would consider a revised protocol from 2 applicants.

#### ***Study on prescribing and dispensing of medicines***

ISAC had been asked to comment on the linkage of GPRD prescribing data at practice level to similar regional and national data sources. Such an undertaking was not covered by current MREC approval granted to ISAC and therefore required separate study-specific ethics approval.

Additionally, the policy of GPRD was not to release aggregated data where the cell size consisted of less than three practices. This limit was agreed with the National Vision User Group. One possibility would be to seek permission from individual contributing practices for the use of their data in this specific potential study.

## **8. Patient involvement in GPRD research**

Following on from the discussion of this issue at the May meeting, the Committee considered some examples illustrating when patient involvement in GPRD research might have been useful, at the time of protocol development and/or during the interpretation of findings.

The Committee agreed that the Instructions on GPRD Protocol Content should be updated to ask researchers whether they have considered seeking involvement of appropriate patient groups in the development of protocols and/or the interpretation of findings. A link to the 'Involve' website [www.invo.org.uk](http://www.invo.org.uk) should be included, to direct researchers to an appropriate source of information on this area if required.

## **YELLOW CARD DATA**

### **9. IT security and storage/destruction of Yellow Card data**

The MHRA introduced its draft guideline on how Yellow Card data should be destroyed by applicants once research was complete. Members agreed that these needed to be developed into a more robust document with legally binding conditions on how data would be handled and stored, as well as destroyed. The issue of how data would be shared between applicants also needed to be addressed given the relative lack of security associated with email correspondence, as some research teams were based in different countries and would want to communicate information electronically.

The Committee reminded the MHRA that some primary research data needed to be kept for 10 years and it was suggested the MHRA set up a repository of all data. The Committee also suggested that the MHRA ask the Information Commissioner how long derived data should be stored for.

The MHRA clarified that as Yellow Card data is not being sent to Committee members, members did not need to apply the same strict data storage and destruction requirements as applicants. The confidentiality undertaking that ISAC members have signed is evidence of members' willingness to comply with good information management. Once the "portal" was established any risk of data being inappropriately accessed electronically would be eliminated.

### **Items 10 and 11 Yellow Card Applications**

The Committee considered 2 applications, and both required further information from the applicant before a decision could be reached.

### **12. Any other business**

Meetings for 2007 would be agreed as soon as possible. **Action MHRA**

**13. Date of next meeting**

The next meeting would be held on Wednesday 6<sup>th</sup> September 2006 at 10.30am in Market Towers.

Post meeting note – revised date 29 November 2006

GPRD/VRMM  
July 2006