

Independent Scientific Advisory Committee for MHRA database research (ISAC)

Summary Minutes of the meeting held on Wednesday 30 April 2008

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
Prof Richard Donnelly
Dr Martin Gulliford
Dr Umesh T Kadam
Prof Paul Little
Dr David Lovell
Dr Richard Martin
Ms Barbara Meredith
Dr Simon Mitchell
Ms Marcia Saunders
Dr Ruben Thanacoody

MHRA¹:

Dr June Raine
Dr John Parkinson
Ms Shahin Kauser
Mr Stephen Fawbert (Secretariat)
Ms Tarita Murray Thomas (Secretariat)
Mr John Watkins
Ms Kavita Chadda

Apologies:

Prof Pali Hungin
Dr Sarah Meredith
Prof Corinne de Vries

1. Introductions, apologies and announcements

- 1.1. 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.

¹ 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

1.2. Apologies had been received from Prof Pali Hungin, Dr Sarah Meredith, Prof Corinne de Vries.

2. Minutes of the ISAC meeting held on Thursday 31 January 2008 and summary minutes for publication on the MHRA website

2.1. The minutes of the meeting held on Thursday 31 January 2008 (Paper 1) were agreed as a true record.

3. Matters arising from the minutes

3.1. Members who had not completed an appraisal with Dr Gennery could do so at the next meeting on 27 June, or conduct this by telephone. Participation in the appraisal process was a condition of membership.

GENERAL ITEMS

4. Lay members on MHRA Committees

4.1. On 31 March the MHRA and Commission on Human Medicines Secretariat held a meeting for lay members on MHRA committees. This was part of its wider work on patient and public involvement. Lay members of ISAC had been invited and one had attended.

4.2. The meeting reinforced the need for lay membership on committees. They have different qualities from professional members and useful insight in areas such as governance, data protection, confidentiality and research methodologies. There might be scope for lay members to meet together regularly to advise MHRA on corporate and strategic issues.

4.3. There were some wider issues on patient engagement that ISAC applicants are expected to include on the GPRD application form in relation to patient and public involvement. This must not be seen as a box ticking exercise. Some effort would be required on the part of the applicant to ensure they had considered how their outcomes might affect patients, how results could be disseminated to them and how they could help develop the protocol. The Department of Health and Cochrane had made it clear this must always be done for health research. There was useful guidance on the Involve website www.involve.org.uk. Lay members would develop a summary of bullet points to assist GPRD applicants.

5. MHRA expenses policy

5.1. This was an information item to provide a copy of the MHRA staff expenses policy to members. Paper 2 was sent to members before the meeting. Any claims made by Committee members must be consistent with this policy. The Secretariat would check members' tax liability in relation to expenses.

6. Meeting Dates for 2009

6.1. The dates circulated previously by email were provided for members' information (Paper 3).

YELLOW CARD DATA

7. Application AYD017 Assessment of the impact of a Scottish community pharmacy campaign on Patient Yellow Card reporting

7.1. The application was approved.

8. Any other business

Patient /Users Group Involvement:

8.1. The Chairman asked the lay members of the Committee to provide a brief guidance document (bullet points) to assist users of GPRD data with the completion of the 'patient/user group involvement' section of their research protocol. Lay members questioned the need to create a separate document, iterating the fact that there were already many existing sources of information to guide users on this aspect e.g. the Involve website. It was suggested that there might be grounds for providing a reference document specifically for GPRD users, as researchers using the database were undertaking secondary research and under such circumstances was not always clear when and how patient/user group involvement might benefit a study. The lay members agreed to work together to produce a guidance document for the website.

MRC Support:

8.2. Members asked about the plans of the GPRD to continue to obtain support for the GPRD-MRC scheme as the Board that was instrumental in supporting the scheme was being disbanded. MHRA was confident that support would continue through other streams such as the Wellcome Trust.

Financial Times article on use and confidentiality of data:

8.3. There had been a recent publication in the Financial Times about data confidentiality. Members enquired about GPRD strategy to ensure confidentiality especially in light of the linkage of GPRD data to other sources. MHRA assured the Committee that appropriate measures were in place to hold the data securely and to protect against external breaches.

Date of next meeting – Friday 27 June 2008 at 10:30am

Close