

Independent Scientific Advisory Committee for MHRA database research (ISAC)

Summary minutes of the meeting held on Friday 26th October, 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 David Lovell
Dr Martin Gulliford
Dr Jacqueline Cassell
Ms Marcia Saunders
Prof Amrit Hungin

MHRA¹:

Dr Tim Williams
Mr Mick Foy
Dr John Parkinson
Mr Stephen Fawbert (Secretariat)
Mrs Tarita Murray-Thomas (Secretariat)
Ms Saira Afzal
Ms Jacqueline O'Shea
Ms Susan Soanes

Apologies:

Dr Sarah Meredith
Prof Richard Donnelly
Prof Paul Little
Dr Corinne de Vries
Dr Richard Martin
Ms Barbara Meredith

1. Welcome and apologies

- 1.1. The Chairman welcomed Professor Sir Alasdair Breckenridge, MHRA Chairman, who was attending this meeting. No Yellow Card Centre Head was attending as there were no Yellow Card applications for consideration at the meeting.
- 1.2. Apologies had been received from Paul Little, Richard Martin, Richard Donnelly, Sarah Meredith, Dr Corinne de Vries and Barbara Meredith for the day.
- 1.3. The Chairman reminded Members that the papers and proceedings were confidential and should not be disclosed. Members were also

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

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 6 July 2007 and a summary for publication on the MHRA website

The minutes (Paper 1) were agreed without amendment and the summary would be published on the MHRA website.

3. Matters arising

3.1. MHRA informed the committee that the annual report had been updated to include the suggestion that there might be greater need for academic applicants to utilise the resources of GPRD to undertake preliminary protocol review/study feasibility before submission to ISAC.

GENERAL ITEMS

4. First Annual report

4.1. The first ISAC annual report had been launched by Dr June Raine at the International Society of Pharmacovigilance Conference on 22 October 2007. It was published on the MHRA website on 25 October and a copy of the report, along with a press release, was provided for members. Copies of these would be sent to members who were not present. Copies would be sent to all successful and unsuccessful applicants. The Committee asked that a copy was also sent to the ABPI and to all GPRD licence holders.

5. ISAC appraisals

5.1. Based on the practice that the Commission on Human Medicines adopted following the appointment of its members by the Appointments Commission, MHRA proposed that members have an annual one-to-one appraisal with the Chairman. The Appointments Commission had advised on the development of an appraisal form which members endorsed.

5.2. It was proposed that appraisals took place in the final quarter of each year. The period from the establishment of the Committee in February 2006 to October 2007 was agreed for the first reporting period. The Chairman would agree a suitable time to meet every Committee member.

6. Recruitment of new members and work sharing proposals

6.1. Following the July 2007 ISAC meeting, an advert for new professional members was placed in the BMJ in autumn 2007. Appointments would be made in November 2007.

6.2. The current GPRD review process with two teams was working well. Any further changes could be agreed with the new Chairman when

appointed. A notice would, however, be put on the GPRD website asking applicants to submit a 200 word lay summary with protocols.

GPRD DATA

7. Information paper on GPRD applications reviewed electronically since last meeting

7.1. The Committee noted Tabled Paper 1, the list of applications reviewed since the previous meeting.

8. GPRD protocols

The Committee advised that two protocols be resubmitted.

9. Researchers wishing to conduct future studies on the basis of blanket approval obtained under SEAG will now be required to re-submit a new proposal for consideration by ISAC. This will be made effective from 1 January 2008. All users of current GPRD and the historical extract of GPRD (EPIC) will be notified of the change.

10. Issue of Age discrimination in the use of GPRD data.

10.1. The Committee was informed by GPRD that several users have raised concerns about feedback relating to age discrimination in study design and conduct from reviewers. GPRD advised that in many cases the exclusion of certain age groups was scientifically based.

10.2. The Committee advised that it only wished to promote 'best practice' and suggested that guidance documents analogous to that in the National Health Service (NHS) be placed on the website to inform users of the framework within which the Committee operates.

Date of next meeting – January 31 2008 at 10:30am