

Unit of the secretariat of the Committee on Safety of Medicines before implementation.

(10) Any postmarketing surveillance study which gives cause for concern because it seems to be a sales promotion may also be reported to the Code of Practice Committee of the ABPI for adjudication regarding a possible breach of the code of practice.

(11) The medicines used in company sponsored postmarketing surveillance studies shall be prescribed and supplied to patients by prescription in the normal way—for example, in National Health Service practice by an FP10 form written by the general practitioner or by the usual hospital methods.

(12) The company must not indicate that a study has been “approved” or “requested” by the Committee on Safety of Medicines in any literature or communication which is not confidential to the Committee on Safety of Medicines or the DHSS or both.

(13) Responsibility for the design, conduct, and analysis of the study shall be vested in a company’s medical department under the supervision of a medical practitioner registered in the United Kingdom, and whose name will be recorded in the documents.

(14) Company representatives should not be involved in such a way that the study can be seen as a promotional exercise.

(15) Interim and final reports should be made available without undue delay to participating doctors and lodged with the Committee

on Safety of Medicines. A final report should be made available for publication.

(16) Doctors must be reminded of their commitment to notify adverse drug reactions to the Committee on Safety of Medicines. Any reporting requirements of adverse drug reactions imposed by the Committee on Safety of Medicines, the Medicines Division, DHSS, or the industry must be observed. Participating companies should ensure that doctors taking part in sponsored postmarketing surveillance studies notify the company’s medical department immediately of any serious suspected adverse drug reaction which occurs during the course of the study.

(17) Normal standards of professional confidentiality must be exercised.

Remuneration

(18) No inducement to undertake a study shall be offered to, requested by, or given to a doctor participating in a company sponsored postmarketing surveillance study.

(19) Subject to compatibility with NHS guidance and terms of service reasonable payment may be offered to the doctor as a recompense for completing record forms and expenses incurred in the work involved in a company sponsored postmarketing surveillance study. A scale of fees appropriate for this purpose shall be drawn up between the ABPI and the BMA.

For Debate . . .

Retraction of research findings

International Committee of Medical Journal Editors

The following statement was agreed by the International Committee of Medical Journal Editors at its 1987 meeting in Helsinki. The committee would welcome debate and comment about the statement, not only from editors but also from researchers and those responsible for funding and organising research, and may revise it in the light of comments received.

Editors must assume initially that authors are reporting work based on honest observations. Nevertheless, two types of difficulty may arise.

First, errors may be noted in published articles that require the publication of a correction or erratum of a part of the work. It is conceivable that an error could be so serious as to vitiate the entire body of the work, but this is unlikely and should be handled by editors and authors on an individual basis. Such an error should not be confused with inadequacies exposed by the emergence of new scientific information in the normal course of research. The latter require no corrections or withdrawals.

The second type of difficulty is scientific fraud. If substantial doubts arise about the honesty of a work, either submitted or published, it is the editor’s responsibility to ensure that the question is appropriately pursued (including possible consultation with the authors). However, it is not the task of editors to conduct a full investigation or to make a determination; that responsibility lies with the institution where the work has been done or with the

funding agency. The editor should be promptly informed of the final decision, and, if a fraudulent paper has been published, the journal must print a retraction.

The retraction, so labelled, should appear in a prominent section of the journal, be listed in the contents page, and include in its heading the title of the original article. It should not simply be a letter to the editor. Ideally, the first author should be the same in the retraction as in the article, although under certain circumstances the editor may accept retractions by other responsible persons. The text of the retraction should explain why the article is being retracted and include a bibliographic reference to it.

The validity of previous work by the author of a fraudulent paper cannot be assumed. Editors may ask the author’s institution to assure them of the validity of earlier work published in their journals or to retract it. If this is not done they may choose to publish an announcement to the effect that the validity of previously published work is not assured.

Inquiries and comments should be sent to Dr Edward J Huth, Annals of Internal Medicine, 4200 Pine Street, Philadelphia, PA 19104, USA, or Dr Stephen Lock, British Medical Journal, BMA House, Tavistock Square, London WC1H 9JR.

The members of the International Committee of Medical Journal Editors are given on page 401.