Good Publication Practice for Pharmaceutical Companies: why we need another set of guidelines

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Peer-reviewed publication is an integral part of biomedical research; yet, although the conduct of trials sponsored by pharmaceutical companies is closely regulated by Good Clinical Practice (GCP), their reporting had, until now, no such framework. Journal editors have highlighted the problems that can arise if the relationship between sponsor companies and academic investigators is abused. In particular, they have drawn attention to the issues of non-publication of findings that do not support the sponsor's marketing aims, and the need for investigators to have full access to the data [1] They have also raised concerns about the role played by professional medical writers working for pharmaceutical companies [2].

Although the International Committee of Medical Journal Editors (ICMJE) has reinforced and enlarged its guidance about investigator:sponsor relations and conflict of interest, until now there was no single document describing responsible publication behaviour for pharmaceutical companies and, in particular, no published guidance about the roles and responsibilities of medical writers.

We are publishing guidelines on Good Publication Practice for Pharmaceutical Companies (GPP) in the hope of stimulating further discussion, because we believe that standards will rise only on the basis of dialogue between all the parties involved and, because, until now, the views published have been largely those of journal editors.

Although the development of the GPP guidelines predates the most recent statement from the ICMJE [1], we hope they will contribute usefully to the current discussion. They have been developed after extensive consultation with many pharmaceutical companies, some of which felt sufficiently strongly to publicly endorse them (see 'companies').

The original idea for the guidelines arose from a retreat organized jointly by the Council of Biology Editors and members of the pharmaceutical industry in 1998. This meeting allowed journal editors, academic investigators and pharmaceutical company employees closely involved with their companies' publication policies and strategies to exchange information and air their concerns. From that meeting, a working group was set up from within the industry and we have been working, since then, on developing and promoting GPP.

We recognize that we are a self-appointed group and cannot speak for the entire industry, and we are therefore publishing these guidelines in our individual capacities, but we are encouraged that other organizations such as the Pharmaceutical Research & Manufacturers Association in the United States (PhRMA) and the Association of the British Pharmaceutical Industry (ABPI) are

now addressing similar topics, partly as a result of the discussions we have initiated [3, 4].

We also realize that the best guidelines emerge from an iterative process, and we hope that Good Publication Practice will evolve as a result of future discussions. We hope that publishing these guidelines will represent a first step in establishing a common standard for the publication of industry-sponsored studies, and that future review and discussion will lead to continually rising standards.

References

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