

# Health Policy

## NEWSLETTER

### Good Publication Practice: Maintaining the Integrity of Scientific Communications

Good Publication Practice (GPP) is a set of guidelines within the health care communication industry that encourages the responsible and ethical publication of scientific data. GPP has its origins in the mid-1990s when it first came to public awareness that involvement of unacknowledged, industry-funded medical writers could compromise the integrity of scientific articles. While medical writers were initially regarded skeptically by medical journal editors, their valuable contribution to the accuracy and currency of scientific communications is now fully acknowledged and a more balanced view of the relationship between author, sponsor and medical writer is gradually emerging. In fact, a 2007 article in the *British Medical Journal* commented that: “medical writers are not a fifth column but are working in a fast-moving modern environment to help disseminate scientific information. . . . and their work needs to be embraced and acknowledged. . . .”<sup>1</sup> Furthermore, the World Association of Medical Editors (WAME) urges editors to make it clear in their instructions to authors that medical writers can be legitimate contributors.<sup>2</sup>

However, a recent editorial in the *Financial Times* makes it clear that, “Using professional writers to improve the standard of manuscripts submitted to medical journals is acceptable, and even desirable. Ghost-writing, which conceals the underlying influence and authorship, is wrong.”<sup>3</sup> Since it is in the interest of all parties involved in disseminating scientific data to eliminate such questionable practices, various national and international guidelines have been developed to ensure that manuscripts are not only of a high quality, but that the preparation process is beyond reproach.

The Good Publication Practice for the Pharmaceutical Companies<sup>4</sup> (GPPPC) guidelines were first published in 2003 and updated in 2009. These guidelines are aimed to increase transparency and to encourage the ethical

dissemination of data. Numerous guidelines produced by associations representing medical writers, medical editors and the pharmaceutical industry have followed and continue to evolve.

Authorship is key to the integrity of any written communication, and the definition of an author given by the International Committee of Medical Journal Editors<sup>5</sup> (ICMJE) is widely accepted. According to this definition, an author must make a substantial contribution to the conception and design, acquisition of data or analysis and interpretation of data, as well as writing the first draft of the article (or revising it critically) and giving final approval. The ICMJE also stipulates that all authors must take public responsibility for their work. If authors do use the services of medical writers, they must always agree with the content and outline with the writer before the first draft is written and the two parties must maintain contact throughout development of the manuscript.<sup>4</sup>

Given the ICMJE criteria, it is clear that medical writers will not usually qualify to be authors, perhaps with the exception of review articles in which the writer performed the literature search, identified articles and evaluated the data. However, there is universal agreement that a medical writer’s contribution should be clearly acknowledged in the article and any funding disclosed.<sup>2,4,6</sup> WAME goes further and considers all parties involved in concealing medical writer involvement to be responsible (including marketing, communications and medical education companies) and suggests the ‘naming and shaming’ of culprits.<sup>7</sup>

Of course, the scope of GPP guidelines goes beyond the single issue of medical writers and covers other areas crucial to the unbiased communication of biomedical literature. The ICMJE and the GPPPC discourage duplicate publications of data. Exceptions

include symposium proceedings, alternative analyses, data grouping with other studies and publication for different audiences.<sup>4,5</sup> Furthermore, WAME requires that authors disclose details of related papers they have authored, even if they are in a different language, in press or submitted to another journal.<sup>3</sup> The ICMJE and the GPPPC consortium are also among the organizations seeking to persuade pharmaceutical companies to publish all trial results, negative as well as positive.<sup>4,5</sup> To this end, the ICMJE, the GPPPC and WAME strongly support the registration of clinical methodology,<sup>4,5,7</sup> while the 2007 FDA Amendment Act goes a step further and requires that researchers also register all trial results. This policy should go a long way to identifying unpublished—and therefore probably negative—data which will help to avoid a potentially misleading weighting of results.

Conflict of interest disclosure is another area taken very seriously by medical journal editors; the Journal of the American Medical Association investigates all allegations of undisclosed conflicts, emphasizing that reporting the best available biomedical science is of prime importance and should not be jeopardized by such misrepresentation.<sup>8</sup>

GPP guidelines are continuing to develop and are gaining wide acceptance by all parties involved in the communication and dissemination of biomedical information. The principles of clear, unbiased and ethical reporting of results, opinions and ideas can only be of benefit to the medical community in particular and society as a whole. ■

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