



Medical Writing Forum at the VII Meeting of Pharmaceutical Medicine (AMIFE) in Spain

by Vicente Alfaro

A forum on 'Medical Writing in Spain' was held on 16 November 2006 in Madrid during the VII Meeting of the Spanish Association of Pharmaceutical Medicine (AMIFE). This forum formed part of a more global discussion on 'Outsourcing in the Spanish Pharmaceutical Industry', which was moderated by José Javier García, president of the Spanish Association of Contract Research Organizations (AECIC). During his initial speech, José Javier García explained why it was time to discuss medical writing at a meeting of relevance in Spain such as AMIFE. Medical writing is today the third top niche clinical research organization (CRO) service (requested by 41% of the respondents in a CenterWatch survey) [1]. In fact, the greatest increase in CRO fees (more than 16%) was invested in the preparation of manuscripts for peer-reviewed journals. Data on benchmarking for CROs in Spain [2] have shown that the services of medical writing most offered in 2006 have been protocol writing (89%), final study reports (75%), manuscripts for peer-review journals (75%), and posters for scientific meetings (69%). These data agree with previous findings by EMWA freelance and small business surveys and with American Medical Writers Association (AMWA) surveys, and suggest that documentation related to clinical testing/further drug approval and peer-reviewed manuscripts constitute the most valuable services of medical writing worldwide.

The scheme for the forum was first, a presentation by a person from a pharmaceutical company (myself, Head of Medical Writing at PharmaMar); second, a presentation by a person from a CRO (Roser de Castellar, Medical Director at Trial Form Support Spain), and third, an open discussion. Before starting the presentations, three questions were asked to the audience to promote discussion. The first question was: do you prefer a medical writer (i.e. physician) or a writer of medical texts (including other academic background)? The most common response was that people prefer expert professionals, regardless of their background. Medical writing was defined as the activity of writing scientific documentation by someone who is a specialized writer (the medical writer) and who generally is not one of the investigators involved in the research. Thus, the medical writer is anyone engaged in communication in the medical or allied professions and sciences. The purpose of medical writing is to have a writing specialist working together with the people who produce the scientific data to create documents that effectively and clearly express the messages the data have to tell. The medical writer also

serves to make sure that the documents comply with regulatory, journal or other guidelines in terms of content, format and structure. Therefore, the medical writer was defined not only as a writer but also as an advisor in scientific communication.

The second question focused on authorship in scientific articles: ghostwriter or star writer? In other words, is the medical writer a person contracted to format results, without any further implications? Or perhaps the medical writer is an expert who fosters the spreading of results and, therefore, should sign as an author? The most frequent response was that medical writing tasks in peer-reviewed manuscripts should be openly acknowledged in a way agreed between the medical writer and the contractor. Apart from signing as an author in the byline, other possibilities discussed were an acknowledgment placed at the end of the article in a particular section, or in a footnote in the first page of the article. At this point, the EMWA guidelines and statements on the role of medical writers in developing peer-reviewed publications [3] were presented, and it was suggested that medical writers should be listed as authors only if they fulfill the criteria of the target journal [usually according to International Committee of medical Journal Editors (ICMJE) criteria] but bearing in mind that, as an author, the medical writer takes on public responsibility for the research.

The third and last question was: quality control or disaster prevention? In other words, does the medical writer, as an expert professional, assure the quality of the communication of results, or perhaps the function of the medical writer is to improve the presentation of results to make them understandable and communicable? In this third question, and contrary to what happened with the two previous questions, the audience showed a divided response, with almost equal percentages. This revealed a perception of the medical writer as an expert who improves the quality of texts, figures and tables, but also as a key professional who increases the success rate in document revision and approval. The difference between poor-quality and high-quality medical writing may mean the difference between a speedy and a delayed submission and approval of a regulatory dossier or of a manuscript in a peer-reviewed journal.

In the past, medical writing has been an underappreciated field by the Spanish pharmaceutical industry, but more recently it has gained attention as an important task in drug development by sponsor companies looking for faster, more efficient ways to bring new drugs to the market.

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Moreover, since 2004 the current national legislation in Spain states that the sponsor is obliged to publish the results from clinical trials, both positive and negative, in scientific journals [4]. This new legislation will surely result in an increase in the publication rate and, therefore, in an increasing demand for medical writers helping in manuscript writing and/or editing.

Contrary to the information reflected in the EMWA [5] and AMWA salary surveys [6], most medical writers working in Spain are freelance or are based in CROs rather than in pharmaceutical companies. The reason for this is that medical writing departments are usually located in the headquarters of pharmaceutical companies and, therefore, they are in countries other than Spain, such as the United Kingdom, Switzerland, or the U.S.A. Most medical writers in Spain are not physicians, and scant information on medical writing is available at a national level. During the forum, the role of associations such as EMWA or the recently created Spanish Medical Writer Association (AERTeM, www.redactoresmedicos.com) in the training of medical writers was emphasised.

The overall opinion at the end of the forum was that medical writing is gaining a position in the Spanish pharmaceutical industry, although training programmes for new professionals (in English, such as the EMWA Professional Development Programme, but also in Spanish) are required.

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