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# EMWA

## Position statement and guidelines on the role of medical writers in developing peer-reviewed publications


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[www.MedCommsNetworking.com](http://www.MedCommsNetworking.com)



EUROPEAN MEDICAL WRITERS ASSOCIATION





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### **Disclosures**

Jo Whelan has been a member of EMWA for 16 years. She was a member of the EMWA Executive Committee from 2011 to 2014 (an unpaid role), served on the EMWA Professional Development Committee, and receives travel and accommodation expenses from EMWA to teach workshops at EMWA conferences.

COMMENTARY

European Medical Writers  
Association (EMWA) guidelines  
on the role of medical writers  
in developing peer-reviewed  
publications

Adam Jacobs<sup>a</sup> and Elizabeth Wager<sup>b</sup>



# The EMWA guidelines and position statement

## Guidelines

Jacobs A and Wager L, *Current Medical Research and Opinion* 2005, 21:317-321 (open access)

## Position statement

[www.emwa.org](http://www.emwa.org) (About us menu)

# Background

- These guidelines are intended for medical writers who develop papers for publication in biomedical journals or presentations for scientific conferences, on behalf of named authors.
- The guidelines may also apply to authors' editors and others who perform substantive editing in preparing publications for submission.

# Guideline development and context

Delphi process among EMWA task force



Consultation: journal editors, academic investigators, medical writers (pharma, medcomms)

GPP3

CONSORT etc

ICMJE

Journal requirements



# Role of medical writers

- **Medical writers have a legitimate role** in assisting named authors in developing manuscripts for peer-reviewed journals and material for presentation at peer-reviewed scientific meetings.
- Properly trained writers bring expertise in:
  - The requirements and conventions of biomedical publishing, including reporting guidelines
  - Language, communication and data presentation
- **Medical writers can raise the standard of publications and accelerate the publication process.**

# Should medical writers be listed authors?

- Medical writers do not normally qualify as authors under ICMJE requirements:
  - No substantive role in conception, data acquisition, analysis or interpretation
  - No final approval over manuscript
  - No responsibility for the research
- They should not therefore be listed as authors (unless they meet ICMJE requirements)



# Acknowledging medical writers

To ensure transparency and make readers aware of any potential conflicts of interest:

The contribution of medical writers should be acknowledged, along with their source of funding



# Acknowledging medical writers

- Acknowledgement should be explicit:
  - Avoid vague phrases such as ‘editorial assistance’
- Suggested wording such as:

‘We thank Dr Jane Doe, who provided medical writing services on behalf of XYZ Pharmaceuticals Ltd’

‘Assistance with drafting the manuscript was provided by ABC Communications and was funded by XYZ Pharmaceuticals Ltd’

- Writer retains the right to withdraw his/her name, e.g. if contributed material is replaced

# Relationship with named authors

- The medical writer is a facilitator; the named authors take responsibility for the content.
- The medical writer should:
  - ensure authors are involved at the earliest possible stage
  - discuss and agree the content with the authors before preparing a detailed draft, usually via the authors approving an outline
  - resist attempts to do detailed work before the authors have been confirmed and the content discussed with them
  - endeavour to ensure that all authors review drafts and approve the final version

# Access to data

- Both the medical writer and the named authors must have access to the relevant study data, e.g. clinical study report or statistical tables.
- Writer should also have access to the protocol.

# Professional and ethical responsibilities

All medical writers, whether employed by the sponsor, working for an agency, or working as a freelancer, should:

- Endeavour to ensure that publications are produced in a responsible and ethical manner and that relevant guidelines are met.
- Be aware of relevant guidelines (e.g. GPP, ICMJE, CONSORT) and advise clients, colleagues or authors if these are not being followed.
- Strive to ensure that publications are accurate and scientifically valid.

# Professional and ethical responsibilities

- Ensure that results are presented in a responsible and balanced fashion.
- Ensure that conclusions are fully supported by the data and that publications do not contain unjustified claims.
- Secondary publications and post-hoc analyses must be clearly identified as such.
- Medical writers should refuse requests to develop publications in an unethical or irresponsible manner.

# Review articles

When preparing review articles (whether systematic or non-systematic):

- Ensure that the search criteria are stated.
- Even in non-systematic reviews, all relevant major studies should be included, and not only those that support the key message of the review.
- If a writer is aware of good quality evidence that contradicts a point being made in a review, or in the discussion section of a primary publication, the writer should attempt to ensure that this research is cited.

# Role of pharmaceutical companies

- Research sponsors (whether commercial companies, charities, or public bodies) have a legitimate interest in the publication of the research they fund.
- EMWA encourages pharmaceutical companies to follow the Good Publication Practice for Communicating Company-Sponsored Research (GPP3) guidelines.<sup>1</sup>
- The issues about involving medical writers and the appropriate role of sponsors are separate but sometimes overlap:
  - involvement of medical writers should not be equated with attempting to exert undue influence over publications

1. Ann Int Med 2015;163(6):461-4



# 'Ghostwriting'

- The term 'ghostwriting' implies an invisible or concealed contribution.
- EMWA believes that the contribution of medical writers and their funding should be openly acknowledged.
- The involvement of a professional medical writer whose role and funding are acknowledged is not 'ghostwriting'.

# EMWA

Find EMWA at [www.emwa.org](http://www.emwa.org) or see the EMWA LinkedIn group, Twitter or Facebook page

