



## **Submission regarding the Transparency Model and the update to the Medicines Australia Code of Conduct**

**To:** The Medicines Australia Code of Conduct Committee and the Transparency Working Group

**From:** ProScribe Medical Communications

**Date:** 19 September 2013

**Issue:** Section 5.3 Exclusion of clinical research payments, including those for medical writing services

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Thank you for the opportunity to provide comment on the Transparency Model Consultation and Discussion Paper. Consistent with our area of expertise, we are limiting our comments to Section 5.3.

### ***Section 5.3, Page 10***

5.3 Payments made under a product research or development agreement where there is a written agreement, a research protocol, or both between the company making the payment and the healthcare professional.

**Clinical research**

The transparency model suggests that payments associated with clinical research would not be required to be reported.

Does Section 5.3 adequately describe and define clinical research activities?

We request that the updated Code confirm that payments for medical writing services associated with research activities be excluded from financial reporting requirements. The main reasons for this request are outlined below:



## **1. Results reporting is part of the research process**

Results reporting (eg, via a peer-reviewed publication, results database submission, conference presentation, summary for clinical trial participants) is a critical step in the research process. Research reporting services and their associated costs should be clearly and legitimately included within the research exclusion (ie, 5.3).

## **2. Medical writers can help ensure timely, accurate, and complete reporting of clinical research results.**

Researchers have an ethical and scientific responsibility to report research results to patients and the broader healthcare community (including regulators, payers, prescribers). Recent studies, however, show that results reporting is shamefully low and slow. Notably, results reporting rates are worse for non-industry-sponsored research compared with industry-sponsored research (see Prayle et al., BMJ 2012; Ross et al., BMJ 2012). Researchers need support, particularly as the main reasons for not reporting results relate to lack of time or resources (see Scherer et al., Peer Review Congress, 2013). Manuscripts prepared with medical writing support are published more quickly, are more compliant with quality reporting guidelines, and are less likely to be retracted for misconduct (see Woolley et al., CMRO 2012; Woolley et al., Annals Pharmacotherapy 2013). Payments for medical writing support to help disseminate research results should not be inappropriately attributed to a single healthcare professional. If authors decline medical writing support, an already unacceptable situation of low and slow reporting could be made even worse.

**Many journal editors recognize that help from a professional writer can raise reporting standards, improve compliance with guidelines, and elevate overall editorial quality. The World Association of Medical Editors (WAME) therefore states, "Editors should make clear in their journal's information for authors that medical writers can be legitimate contributors."**

<http://www.ncbi.nlm.nih.gov/pubmed/20569069>

### **3. Medical writing support is already required to be disclosed**

In terms of transparency, guidelines from editors, industry associations, and academic organisations already require full and complete disclosure of medical writing support and funding sources. The current Code of Conduct (Section 11) indicates that ghostwriting is unacceptable, but we have requested that this section be updated to provide stronger and more specific guidance (see ProScribe Submission 23 August 2013). Actions taken to enhance transparency and reduce ghostwriting appear to be having a meaningful effect. Recent studies have shown that ghostwriting is declining (see Wislar et al., BMJ 2011; Woolley et al., Am J Med 2012). There is a risk, however, that some authors may stop disclosing medical writing support in the belief that this would lead to an inappropriate attribution of payment. This risk means we could encounter the ironic situation of a misguided transparency requirement leading to a lack of transparency.

### **4. Payments for authorship are not recommended**

Industry guidelines (eg, Good Publication Practice 2) already recommend that payments NOT be made to healthcare professionals for authorship duties. Providing researchers with research support (eg, use of research nurses, lab technicians, statistical support, medical writing support) to help ensure research is conducted and reported appropriately should be encouraged and not expose healthcare professionals to an inappropriate attribution of payment.

### **5. Difficulty in providing fair, accurate, and consistent reporting for medical writing services**

As evident from the confusion surrounding the Sunshine Act and how medical writing payments or transfers of value may or may not be reportable, there's much "devil in the detail". Complex algorithms have been proposed for how to report payments (if necessary) and little agreement has been reached on the best way forward. We do not



believe that medical writing services should be included in financial reports for individual healthcare professionals.

However, if the Transparency Working Group believes these research-related services should be included (and is aware of the risks that such reporting could have on hindering the timely dissemination of research results), then clear guidelines would be required to facilitate fair, accurate, and consistent reporting. Some of the issues that would need to be addressed - should medical writing services be deemed reportable - include:

- a. How much of the medical writing support paid should be allocated to each healthcare professional when such support also covers the research sponsor's requirements (eg, preparation and project management of publication agreements; organising legal reviews; providing status updates; ensuring authors meet their authorship requirements, updating publication tracking software re. timelines, compliance)?
- b. How much of the medical writing support should be allocated to each healthcare professional when working with co-authors? Should the payment be divided based on the number of the authors, the order of the authors, the extent of work done by each author at each section of the research project (eg, protocol development, study conduct, manuscript writing)? What effects might payments have on international co-authorship, company employee authorship etc...?
- c. How would "Fair Market Value" for medical writing services be calculated?
- d. Should payments differ based on the type and complexity of each results reporting document?
- e. When is the "transfer of value" deemed to have occurred – at the time of writing support, at the time of submission, at the time of publication?
- f. If a paper is never published (ie, no value gained by the healthcare community, patients, prescribers, payers etc...), is the transfer of value still valid? How would retractions or corrections be made?



## **Summary**

We request that the updated Code confirm that payments for medical writing services associated with research activities be excluded from financial reporting requirements. Medical writing is an essential part of the research process and there are mechanisms in place that require full transparency regarding the use of and funding for writing services. Unnecessary and inappropriate reporting requirements could make it even harder for researchers to meet their ethical and scientific responsibilities to share results with patients and the broader healthcare community.

## **Expertise**

*ProScribe Medical Communications (est. 2000; Australia, China, Japan) is internationally recognised for conducting and publishing research on ethical publication practices.*

*ProScribe's PhD- and MD-qualified medical writers are active members of international associations that advocate for ethical medical writing practices and condemn ghostwriting.*

*ProScribe staff developed and published the anti-ghostwriting checklist, published the first paper differentiating ghost writers from professional medical writers, and conducted the first systematic review on the prevalence of ghostwriting in the medical literature. ProScribe was the first medical communications company in the Asia-Pacific region to employ Certified Medical Publication Professionals (ie, staff who have passed an international exam on ethical medical writing practices).*