Staying ahead of the game in the changing arena of ethical medical communications – Viewpoint of a freelance medical writer

Sharon Smalley
Precision Medical Writing, Macclesfield, UK

Correspondence to:
Sharon Smalley
Precision Medical Writing Ltd
Redshank Drive
Tytherington
Macclesfield
SK10 2SN
UK
+ 44 (0)7547 120552
sharon@precisionmedicalwriting.co.uk

Abstract
Laws, regulations, pharmaceutical industry codes of practice, and other guidelines play an important role in ethical medical communications. When working on medical education programmes and materials, a professional medical writer must not only consider audience, timelines, and potential content to fulfil client briefs, but also ensure alignment with the appropriate regulations. For medical writers who are freelance, staying informed of evolving laws/codes of practice is essential but may feel like a challenge. However, in an era where information is accessible 24/7, staying ahead of the game is not an impossible task.

Laws, regulations, and guidelines in med comms – A daunting prospect?
Laws and regulations that guide interactions between the pharmaceutical industry and healthcare professionals (HCPs) play a significant role in medical communications. On the surface, these wordy, complex documents and lists of 'rules' may appear somewhat daunting to a professional medical writer or, for that matter, any medical communications specialist. However, their importance in this field cannot be understated – one minor deviation or slip from ethical guidance could result in significant ramifications for the pharmaceutical company and the HCP concerned, potentially damaging reputations and, in

turn, public confidence in the healthcare industry.

This article will examine the landscape of ethical medical communications from the personal perspective of an independent (freelance) professional medical writer. In particular, this piece will provide a general overview of typical regulations and guidelines available, and examine which of these may be considered when developing medical education materials, such as items for meetings, publications, and so forth. Finally, the question of how to stay informed of evolving laws and regulations will be addressed.

Healthcare compliance – Where to start?

Numerous laws, regulations, and codes of practice are in place that help to govern ethical, transparent, and appropriate interactions between the pharmaceutical industry and HCPs (Box 1). These include international, regional, and national association codes of practice relating to the promotion and marketing of medicines, such as those from the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) and the European Federation of Pharmaceutical Industries and Associations (EFPIA).[1,2] These codes of practice encompass all methods of medicine promotion, including oral and written promotional activities, journal advertising, use of internet/electronic communications, and video recordings. Ultimately, their aim is to ensure that any information available to HCPs is accurate, fair, and objective, thus helping support prescribing independence and in turn benefiting patient care. Furthermore, pharmaceutical codes of practice extend beyond the realm of regulating promotion of medicines to guide interactions with HCPs/medical institutions, covering items such as fees for services and disclosure of fees/transfers of value, entertainment, hospitality, and gifts.[1–5] As well as industry codes, there are laws that embrace the pharmaceutical sector to prevent bribery, such as the UK Bribery Act 2010 and the US Foreign Corrupt Practices Act (2012),[6,7] both of which have a global reach (Box 1).[8] Pharmaceutical companies may also have their own internal standard operating procedures and codes of conduct that enforce international/regional/national codes of practice and applicable laws/regulations.

Box 1. Key pharmaceutical laws and regulations on promotion of medicines and HCP interactions*

- International Federation of Pharmaceutical Manufacturers and Associations Code of Pharmaceutical Marketing Practices[1] (http://www.ifpma.org)
- European Federation of Pharmaceutical Industries and Associations Codes of Practice on the Promotion of Medicines[2] (http://transparency.efpia.eu)
- Pharmaceutical Research and Manufacturers of America (PhRMA) Code on Interaction with Healthcare Professionals[4] (http://www.phrma.org)
- Association of the British Pharmaceutical Industry (ABPI) Code of Practice for the Pharmaceutical Industry[5] (http://www.abpi.org.uk)
- Other European country-specific codes of practice (available from: http://transparency.efpia.eu/codes-of-conduct/countries)
- UK Bribery Act 2010[6] (http://www.legislation.gov.uk/ukpga/2010/23/contents)
- US Foreign Corrupt Practices Act[7] (http://www.justice.gov/criminal-fraud/foreign-corrupt-practices-act)

*This is not an exhaustive list and serves to provide examples only.

The laws and codes of practice touched upon here serve as a brief snapshot of the types of guidelines that exist, and highlight how tightly pharmaceutical-HCP relationships are regulated, as well as the scrutiny under which the industry operates. As stipulated in codes of practice,[1,2] pharmaceutical companies must ensure that agencies/other parties operating on their behalf are aware of and comply with industry regulations. For their part, medical communication companies have compliance divisions/compliance programmes aimed at equipping all accountable personnel with the knowledge and tools required to make sure that HCP-directed activities are implemented in accordance with professional and ethical standards.

Which guidelines sit at the top of a professional writer's list?

While anti-bribery laws, disclosure codes, and similar such guidelines are important in the context of pharmaceutical-HCP interactions, the most *relevant* regulations for a writer to consider will depend on the area of medical communications in which the materials to be developed sit. There are, broadly speaking, three key areas of medical communications:

- Promotional activities and materials, e.g. sales aids, product launch meetings, advertisements/advertorials
- Educational/scientific, e.g. scientific meeting content and materials, slide decks, disease area websites, associated literature
- Scientific/clinical publications, e.g. posters, abstracts, clinical trial publications, review articles

As a general rule, typical medical writing projects 'fit' into one of these categories, although compartmentalising some projects is not always an easy task and a degree of overlap may exist.

By and large, when starting out on a writing assignment, certain questions immediately spring to mind such as 'What is the project?', 'Who is the intended audience?', 'What will the content focus on?', and 'What are the timelines/When is the first draft required?' (Figure 1). However, as medical writers, regardless of the number of years' experience accumulated, do we immediately turn to pharmaceutical-HCP interaction codes of practice and relevant laws? Whatever the answer, it

is always worth reminding ourselves of key guidance because codes of practice and other regulations are constantly evolving and, ultimately, they help determine permissible content and dictate other requirements, such as authorship criteria and inclusion of disclaimers or abbreviated prescribing information.

The following is a brief discussion of guidelines with respect to promotional communications, medical meetings, and publications. In no way is this meant to be an in-depth discussion of the do's and don'ts stipulated in the various laws, guidelines, and codes of practice. For additional information and clarification on guideline requirements and ethical communications, the reader is advised to consult the appropriate websites and documentation, as cited below.

Promotional communications

In the context of the pharmaceutical industry, promotion is any activity that a pharma company has involvement in to help encourage the sale/supply of its products.[2] In this regard, a medical writer may work on a variety of medical communications deemed promotional, including journal advertorials, website content, and exhibition booth panels/materials. For these types of activity, it is appropriate for pharma to follow national industry association codes of practice for the promotion of medicines (see Box 1), not only for the country in which the company is located, but also those of the country where the promotional activity is planned to take place.[2] The EFPIA website (http://transparency.efpia.eu/codes-of-conduct) contains links to national codes of practice for member associations based in Europe. A key element of all promotional materials is that content should be accurate, fair, balanced, objective, complete, up-to-date, capable of substantiation by approved labelling or scientific evidence, and consistent with the product licence.[1,2,4,5]

Medical meetings and associated content/materials

Meetings are often a core component of medical communications and therefore may be central to a medical writer's daily responsibilities. Medical writers become involved in many different types of meetings (promotional, scientific, professional) supported by pharmaceutical companies, including but not limited to standalone meetings, product launch meetings, advisory boards, satellite symposia/congresses, and speaker training forums. Since most meetings will involve interactions with HCPs, complying with the appropriate national/regional guidance is necessary as there is potential for breaching rules that apply not only to meeting content/distribution of materials and associated activities, but also to speaker selection, meeting venue, speaker honoraria, and hospitality.[2] The industry association codes of practice include sections (clauses/articles) that focus on pharma-supported meetings, associated activities, and hospitality.[1,2,4,5] As stated in the IFPMA Code of Practice, the purpose of any meeting organised by a pharmaceutical company and directed towards HCPs should be to provide scientific or educational information with content that is relevant to the audience.[1]

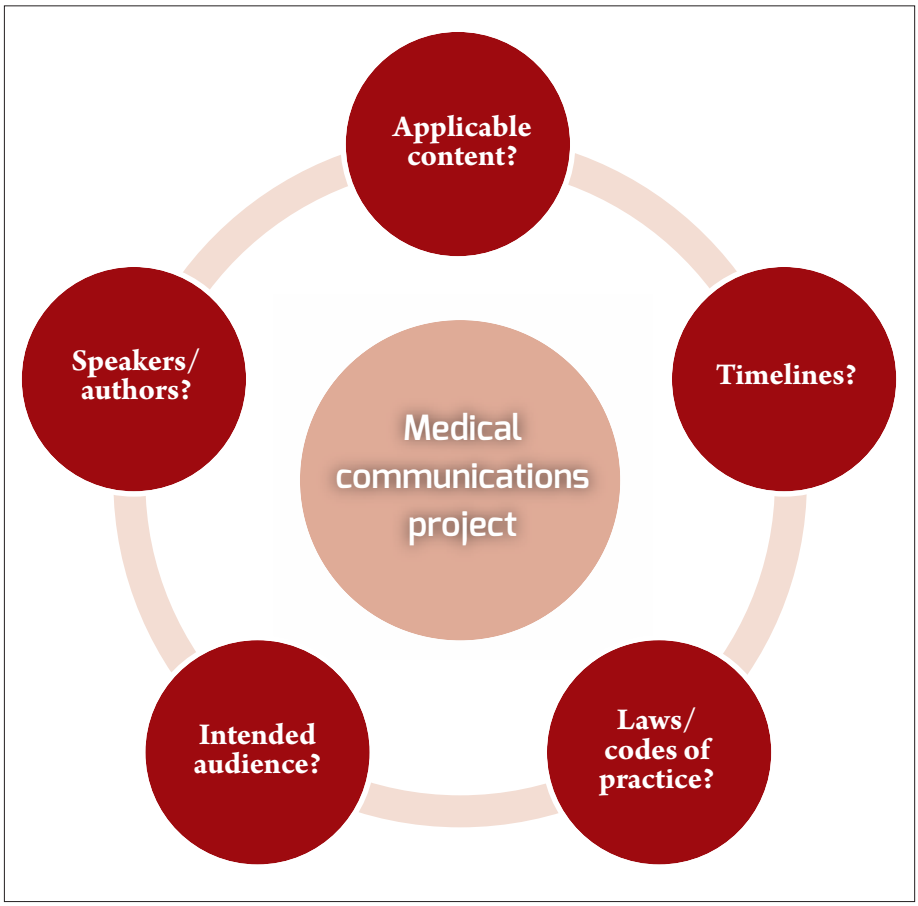

Figure 1. Questions for consideration when starting a medical communications project: Perspectives of a professional medical writer.

Publications

Publications and publication planning is likely to be another key aspect of a professional medical writer's role. There are numerous publication-specific guidelines on best publication practices and ethical standards, including the International Committee of Medical Journal Editors (ICMJE) Recommendations, which represent a cornerstone of authorship criteria,[9] and the Good Publication Practice 3 (GPP3) guidelines on communicating research results sponsored/supported by the pharmaceutical industry.[10] Additionally, various reporting guidelines exist for different study types, such as CONSORT for randomised studies,[11] STROBE for observational studies,[12] and PRISMA for systematic reviews/meta-analyses.[13]

Publication ethics is a hot topic at

present, particularly in light of publication of the GPP3 guidelines, sponsored by the International Society for Medical Publication Professionals (ISMPP), in 2015.[10] Key aspects that were updated in GPP3 include (but are not limited to) guidance on authorship; author payment and reimbursement; the role of the professional medical writer; and data sharing. Interestingly, the benefits surrounding use of professional medical writers in assisting authors to prepare publications has received further attention,[14,15] most recently following publication of a cross-sectional study that demonstrated improved clinical trial reporting and higher quality of written English in those publications with declared medical writing support.[15]

As stated in the IFPMA Code of Practice, the purpose of any meeting organised by a pharmaceutical company and directed towards HCPs should be to provide scientific or educational information with content that is relevant to the audience.

Guidelines and staying informed

It is usual when working in medical communications to be guided by the pharmaceutical company's internal standard operating procedures and recommendations from 'client' contacts. Furthermore, as freelance medical writers are often tasked to work on specific aspects of materials – sometimes mid-project – it may not always be necessary to consult guidelines. Nevertheless, there remains an obligation for professional medical writers to stay up-to-date with changing pharmaceutical-HCP codes of practice and relevant laws/regulations. When one considers the additional responsibilities of an independent writer in terms of business ownership it can be difficult to stay informed on such matters, but keeping abreast of evolving guidelines need not be challenging:

- During quiet times (which may be few and far between), check out websites such as the IFPMA and EFPIA.[1,2] It is normally easy to see at a glance if there are updates. Naturally, you can also refer to these websites when working on specific projects at the start of a task/as needed.
- Consult the EQUATOR (Enhancing the Quality and Transparency of health Research) network website (www.equator-network.org) for information related to publication ethics.
- Refer to medical writing/publication association websites such as EMWA (http://www.emwa.org/) and ISMPP (http://www.ismpp.org/). Additionally, these and similar associations offer webinars, publications, bulletins, and annual meetings that support ongoing education initiatives in areas covering ethical medical communications, thereby keeping their members up-to-date on relevant laws/regulations.
- LinkedIn is a valuable source of up-to-the-minute information. Being a member of relevant LinkedIn groups, such as EMWA, ISMPP, The Publication Plan, and MedComms Networking, makes it easy to stay informed of what's new in the field of medical communications and the pharmaceutical industry.

There are likely to be other ways in which freelance medical writers stay informed of current laws, regulations, and guidelines on pharmaceutical-HCP interactions, ethical medical communications, and publications. For example, it may be necessary when working with some clients to undertake informal 'on-the-job' compliance training before an assignment commences, particularly if the freelance writer has been contracted to assist throughout the life of a project. While this is likely atypical, inclusion of compliance training as part of a project can be a valuable exercise. It would be interesting to conduct a survey among freelancers to ascertain (1) how important it is to remain informed of codes of practice/regulations and (2) what other sources of information are of value in this regard.

Conclusion

Good publication practice as well as guidelines, regulations, and codes of practice governing pharmaceutical-HCP interactions and promotion of medicines are central to professional and ethical medical communications. Such is their importance that it is essential for all those working in the medical communications sector to stay informed of evolving guidance. For the freelance/independent professional medical writer, a number of routes are available for keeping up-to-date, including membership of professional writing/publication associations and LinkedIn professional groups.

Conflicts of Interest and Disclaimers

The views expressed in this article are those of the author and should not be construed as anything more than personal opinion. The latest available codes of practice and other guidelines cited herein have been consulted. While this article discusses some codes of practice and guidelines, the reader is advised to consult relevant websites for further understanding, information, and clarification.

References

1. International Federation of Pharmaceutical Manufacturers & Associations. IFPMA Code of Practice. 2012 [cited 2016 Feb]. Available from: http://www.ifpma.org/wp-content/uploads/2016/01/IFPMA_Code_of_Practice_2012_new_logo.pdf.
2. European Federation of Pharmaceutical Industries and Associations. EFPIA Code on the Promotion of Prescription-only Medicines to, and Interactions with, Healthcare Professionals. 2014 Jun 06 [cited 2016 Feb]. Available from: http://transparency.efpia.eu/uploads/Modules/Documents/efpia-hcp-code-2014.pdf.
3. European Federation of Pharmaceutical Industries and Associations. EFPIA HCP/HCO Disclosure Code. Consolidated Version 2014. 2014 Jun 6

[cited 2016 Feb]. Available from: http:// transparency.efpia.eu/uploads/Modules/Documents/efpia-disclosure-code-2014.pdf.
4. Pharmaceutical Research and Manufacturers of America (PhRMA). Code on Interactions with Healthcare Professionals. Updated 2009 Jan [cited 2016 Feb]. Available from: http://www.phrma.org/sites/default/files/pdf/phrma_marketing_code_2008.pdf.
5. Association of the British Pharmaceutical Industry: Code of Practice for the Pharmaceutical Industry 2016 together with the Prescription Medicines Code of Practice Authority. 2016 Jan 01 [cited 2016 Feb]. Available from: http://transparency.efpia.eu/countries/download/27/document/code-of-practice-2016.pdf.
6. UK Bribery Act 2010. 2010 Apr 08 [cited 2016 Feb]. Available from: http://www.legislation.gov.uk/ukpga/2010/23/contents.
7. Foreign Corrupt Practices Act. Updated November 2012 [cited 2016 Feb]. Available from: http://www.justice.gov/sites/default/files/criminal-fraud/legacy/2015/01/16/guide.pdf.
8. Francer J, Izquierdo JZ, Music T, Narsai K, Nikidis C, Simmonds H, *et al.* Ethical pharmaceutical promotion and communications worldwide: codes and regulations. Philos Ethics Humanit Med. 2014;9:7.
9. International Committee of Medical Journal Editors (ICMJE). Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals. Updated 2015 Dec [cited 2016 Feb]. Available from: http://www.icmje.org/icmje-recommendations.pdf.
10. Battisti WP, Wager E, Baltzer L, Bridges D, Cairns A, Carswell CI, *et al.* Good publication practice for communcating company-sponsored medical research: GPP3. Ann Intern Med. 2015;163(6):461–4.
11. Schulz KF, Altman DG, Moher D, for the CONSORT Group. CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. Ann Intern Med. 2010;152(11):726–32.
12. von Elm E, Altman DG, Egger M, Pocock SJ, Gotzsche PC, Vandenbroucke JP. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. Ann Intern Med. 2007;147(8): 573–7.
13. Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. PLoS Med. 2009;6(7):e1000097.
14. Hamilton CW, Gertel A, Jacobs A, Marchington J, Weaver S, Woolley K. Mythbusting medical writing: goodbye, ghosts! hello, help! Account Res. 2016;23(3):178–94.
15. Gattrell WT, Hopewell S, Young K, Farrow P, White R, Wager E, *et al.* Professional medical writing support and the quality of randomised controlled trial reporting: a cross-sectional study. BMJ Open. 2016;6(2):e010329.

Author information

Sharon Smalley, BSc (Hons) is a professional medical writer with almost 20 years' experience in medical communications. She has been Director/Owner of Precision Medical Writing Ltd since 2012 and prior to that served in various medical writer roles within the medical communication agency environment.