Medical affairs writing: A key role to relay medical information to everyone

Marie-Odile Faure
Scientific Consulting For You, Paris, France

Correspondence to:
Marie-Odile Faure
Scientific Consulting For You
266, avenue Daumesnil
75012 Paris, France
+33 1 34 78 66 57/+33 6 74 68 37 81
mofaure@scientificconsultingforyou.com

Abstract
Medical Affairs is a link between the scientific and marketing units of a pharmaceutical company. Medical writers in this field are responsible for writing varied document types from regulatory reports to scientific publications, and marketing supports. Sources of medical information include scientific literature, pharmaceutical company internal data, and regulatory guidelines. For each of these documents, the final reader is different. Consequently, the key message and writing style should be identified and adapted accordingly. The medical writer has a responsibility to ensure that the right medical information is relayed to the target reader.

Introduction
The scope of the term 'medical affairs' varies between pharmaceutical companies nevertheless, it is a delicate role that balances scientific and clinical research information with communication activities for sales and marketing needs. From the scientific side, medical affairs means highlighting the right data in the right context required for prescribers to correctly use the product. And, from the marketing side, it means enforcing regulatory requirements that sometimes constrain more attractive wording for advertising.

Pharmaceutical companies have a responsibility to sell high-quality, effective, and safe products for treating illness or relieving patients from pain or symptoms. However, they need to clearly communicate accurate information about their products to their customers (practitioners and patients). Medical information is also provided by health authorities and general public media. Medical writers are well placed to ensure that this information is communicated appropriately and ethically.

"Medical information comes from everywhere"

What type of documents are written?
Depending on the size and structure of the company, essentially any document linked to drug development may be required to be written at medical affairs, from preclinical to post-marketing documents as well as, communication brochures and conference or sales materials. An example of documents is listed in Table 1.

What are the sources of medical information provided for patients/practitioners?
Medical affairs writers are involved in creating content for a variety of channels. Increasingly, internet sources, scientific internet databases (e.g. Pubmed/Medline or TOXNET) have become the first entry point for practitioners to obtain a better knowledge of a therapeutic area. Health authority websites provide more specific treatment guidelines and recommendations based on robust meta-analyses practices in

Reader Document	Health Authority	Key Opinion Leader	Scientist	Practitioner	Patients & General Public
Marketing Authorisation dossiers, study protocols and reports, oral defence, safety reports	X				
SmPC, package insert/ leaflet	X				X
Specialised/ generalised articles		X	X	X	X
Abstract, poster, oral presentation for congress, conference brochures, information meetings		X	X	X	
Advert support (sales guides, website, journal, television)	X	X	X	X	X

Abbreviations: SmPC, Summary of product characteristics.

Table 1. Examples of documents and their target readers.

the therapeutic area. Moreover, professional societies give additional details on the current practice established with literature, practitioner's perception of real life, and surveys. Patient websites delivered by clinics or by pharmaceutical companies also deliver comprehensive information for patients. Lastly, practitioner and patient forums can provide anecdotal information to highlight a misunderstanding, miscommunication or lack of medical information.

What are the sources of medical information for medical writers?

Medical affairs writers have a plethora of different source types to use in creating medical information. Information concerning efficacy and safety come from the clinical development programme, such as clinical study reports, publications, and other research data. However, many studies now also collect other types of data, such as from patients concerning their opinion about the efficacy or safety, their adherence to the intervention, or changes in their quality of life. Quality of life questionnaires provide valuable data on how a product affects the patient's daily life, a non-negligible aspect that goes beyond clinical efficacy. This type of data is useful for writing patient materials. Specific populations (e.g. elderly or hypertensive patients) will be concerned by clinical data such as efficacy of a drug in their population but are also particularly interested in the adverse events or risk-benefit profile. Other (often forgotten) sources include preclinical studies, post-marketing pharmacovigilance data, and sometimes marketing research data. Preclinical studies, such as *in vitro* or *in vivo* models, can provide evidence about mechanisms of actions that lead to product efficacy or safety. Moreover, images from *in vitro* studies can illustrate certain concepts. For example, a drastic increase in immunofluorescent cell number due to an effective drug is more meaningful for people than a schematic graph. Pharmacovigilance can highlight adverse reactions or susceptible sub-populations, often leading to post-marketing surveys.

Post-marketing data obtained from practitioners or patients may reveal information about the product that did not surface during clinical development. Post-marketing studies can also be useful for evaluating the impact of an identified risk, a new indication or a new technique to complement scientific data on the product. Market research data can help position the product regarding its use in the therapeutic arsenal available to practitioners and patients. It is essential that practitioners have a good knowledge of product characteristics when prescribing new products. However, patients also need to be adequately informed about managing side effects to ensure they continue to adhere to the treatment. Questionnaires regarding patient satisfaction and the commercial experience due to the direct contact with the clients are essential for understanding the product market. Medical affairs writers

"Medical writers require interdisciplinary skills in order to fully understand data sources and to highlight the key medical information"

"Medical writers have a key role for adding value to product and pharmaceutical company perception"

need to take these different sources into account and weigh their level of evidence carefully with the key communication messages.

How do medical writers transmit the medical information?

Who is the target reader and what is the key message?

Like any document, before writing, the first question to ask is "Who is the final reader of this document?" Some examples can be found in Table 1. The writing style and vocabulary should be adapted to the reader to be meaningful. When writing for patients for example, many technical and scientific terms are inappropriate. For example, the term "headache" is preferred to "cephalgia" for patients or practitioners whereas "cephalgia" may be preferred in a specialised published article. The second question one should ask oneself is: "What is the key message is to be communicated?" The clearer your message the better the readers will understand. To ensure that the message comes across clearly, particularly for non-native speakers of English, simple sentence structure is paramount. The vocabulary can be adapted to the reader where specific medical terms can be replaced with common terms for a given text. Involving the medical affairs writer should be critical in the process of key message development as they provide the link between the data and the communication objectives. The medical affairs writer adapt their writing style to transparently convey the scientific content and to best present the marketing tone and the company image.

How to write and what help do you have?

Each document is written in a particular style. Regulatory dossiers are written in simple direct informative style, whereas scientific articles tell a story about the research performed. Sometimes specific sentences or key words are recommended. For example, standard statements need to be followed, such as, "X is contraindicated in children aged x to y <years, months> <or any other relevant subsets e.g. weight, pubertal age, gender> <in the indication … > (cross-reference to section 4.3)."[1] Guidelines for writing the Common Technical Document (e.g. safety part) or Clinical Evaluation can be found on the ICH or European Commission websites.[2,3] For publications, instructions for authors are available on journal websites, and several guidelines are available such as GPP, CONSORT, STROBE, and ICMJE.[4-9] The EASE guidelines provide some useful tips for non-native speakers of English. Lastly, to improve readability, medical affairs writers can apply many of the plain English language techniques such as simple sentence structures, to their documents.[10] Concise language, specific tone adapted to the audience, clarity in wording and presentation are the main components for relaying your key message and answering your readers' expectations.

Conclusion

Medical affairs plays a key role in effective communication of medical information to various target readers guaranteeing the scientific value. Moreover, the appropriate, unbiased scientific and clinical published data is a bonus for the good image of pharmaceutical companies.

References

1. European Commission. Notice to applicants. A guideline on summary of product characteristics (SmPC)-September 2009. Revision 2 ed: European Commission; 2009. p. 1-29.
2. European Commission. Guidelines on medical devices. MEDDEV. 2.7.1 Rev.3. Clinical evaluation: A guide for manufacturers and notified bodies Revision 3 ed: European Commission; 2009. p. 1-46.
3. (ICH) ICoH. ICH harmonised tripartite guideline. The common technical document for the registration of pharmaceuticals for human use: Safety – M4S(R2) Nonclinical overview and nonclinical summaries of module 2, organisation of module 4 Revision 4 ed: International Conference on Harmonisation (ICH); 2002. p. 1-115.
4. Battisti WP, Wager E, Baltzer L, Bridges D, Cairns A, Carswell CI, *et al*. Good Publication Practice for Communicating Company-Sponsored Medical Research: GPP3. Ann Intern Med. 2015;163(6):461-4.
5. Graf C, Battisti WP, Bridges D, Bruce-Winkler V, Conaty JM, Ellison JM, *et al*. Research Methods & Reporting. Good publication practice for communicating company sponsored medical research: the GPP2 guidelines. BMJ. 2009;339:b4330.
6. Jacobs A, Wager E. European Medical Writers Association (EMWA) guidelines on the role of medical writers in developing peer-reviewed publications. Curr Med Res Opin. 2005;21(2):317-22.
7. CONSORT website. Available from: http://www.consort-statement.org/.
8. STROBE statement: STrengthening the Reporting of OBservational studies in Epidemiology Available from: http://www.strobe-statement.org/.
9. IJCME: International Committee of Medical Journal Editors. Available from: http://www.icmje.org/.
10. Federal government to the public. What is Plain Language? 2016 [cited 2016 Jan 3]. Available from: http://www.plainlanguage.gov/whatisPL/.

Author information

Before starting out as a freelancer in 2015, Marie-Odile FAURE, PhD was Head of Medical Affairs in a pharmaceutical company. She provides expertise and writes scientific and medical documents.