Medical Communications

SECTION EDITOR

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Editorial

Dear all,

The legal side of our job is something that most of us usually give little thought to. We assume that as scientists, we are automatically on the "right side" and therefore pretty bullet-proof. Why should the law affect us, as long as we have the data to back us up? However, the reality is that this is a huge and complicated issue that can land not only medical writers, but their clients or companies in very deep hot water, very quickly.

Considering the high stakes in the pharmaceutical industry and the highly competitive environment, it shouldn't be a surprise that rival company lawyers monitor all information coming from competitor companies, but the extent of liability that we have as medical writers might surprise and possibly scare you.

In this issue, we hear from Joanne Flitcroft. Joanne is a lawyer who has worked in the pharmaceutical industry for 17 years. She specialises in navigating the very tricky waters of defending product safety issues and maintaining corporate reputations. In her article, she explains some common pitfalls and why we should all be paying very close attention to the legal side of our work and its implications. With Joanne's guidance, we will hopefully stay on the "right side" of the law and protect both ourselves and our clients/companies.

I'm sure you will enjoy her article, and it only leaves me to wish you the best wishes for the season – a happy and healthy 2018, and I hope Santa is kind to you all.

Bestest,
Lisa

Introduction to the legal implications of medical writing

Many high-profile individuals and companies have suffered harm to their reputation as a result of the content and use of emails and social media. While they may recover from such damage, reputational damage in the life sciences industry may affect the success of a company and its ability to attract investors.

However, it is not solely the use of email and social media which poses a risk. All clinical, regulatory and patient safety documentation, if inappropriately written, without regard to legal implications, has the potential to have an impact on patients, corporate reputation and affect the ability of the organisation to work effectively and efficiently.

Failure to identify and mitigate risks associated with pharmacovigilance and regulatory writing may force a company to divert resources away from drug development and into defending patient safety or clinical issues – as well as time lost handling protracted discussions with regulatory authorities.

My aim is to help you to get it right first time and to produce more effective communications and documentation. As medical writers, you work in a highly regulated environment where the documents and communications you produce may become public. The life sciences industry is subject to close scrutiny from regulatory and governmental authorities, competitors, patients, media and lawyers acting for potential plaintiffs. My aim is to provide you with some additional tools to help you become a better writer and more effective communicator.

The risks

The two principal legal risks arising from inappropriately written documentation are:

- damage to corporate reputation related to the handling of pharmacovigilance and regulatory issues
- product liability claims and litigation

If a product pharmacovigilance issue is subject to litigation or an investigation, it is likely that any related documentation will be thoroughly investigated and could become public. Relevant government authorities or potential plaintiffs and their lawyers may be granted permission to obtain any documentation or communications that are relevant to the particular investigation. The impact of investigations or litigation on life sciences companies is significant. There are potentially large awards of damages, costly settlements, litigation expenses and it may impact on the financial security and viability of the company. In addition, money spent on investigations and litigation is diverted from the core business activity of the company. This may result in negative publicity and damage to reputation as well as to the product brand.

An investigation will necessarily focus on documentation dealing with sensitive information such as knowledge, data, opinions, hypotheses, analyses, ideas, which may implicate an organisation's legal position or its reputation or both, if disclosed to third parties. Pharmacovigilance and regulatory documentation is by its nature sensitive information.

Mitigation of risks

The effective communication and management of sensitive information is a skill which is essential for all medical writers. It is important to recognise that clarity and method are critical, coupled with the appropriate classification of documents e.g. whether they are confidential or subject to legal privilege, equally important is the need to avoid concealing or censoring sensitive pharmacovigilance information or limiting the amount of information which is communicated. Sometimes documents written by medical writers may need to be disclosed to third parties through a process of discovery. Discovery is the legal process concerned with obtaining evidence by searching of documentation or conducting interviews with the authors of the documentation. The rules relating to the disclosure of documents for evidence in legal proceedings are wide-ranging and liberal and vary according to the legal jurisdiction. In addition, discoverable documentation is not limited to, for example, pharmacovigilance or regulatory documents, but may also include e-mails, calendars and even SMS messages which pertain to the medical issues discussed in such documentation.

Before you begin any medical communication, consider what it is that you are intending to achieve. Sharing medical and scientific information is not the same as communicating the information; what an author says is not necessarily what others actually hear. Therefore, always consider the following four questions:

- What is it that you want to say?
- How do you want to say it?
- What does your audience need to know?
- What exactly do you want the audience to do with the information?

Having addressed these questions, you must then reflect on the different needs, including potential cultural differences, and perceptions of your audience and consider how the document may be viewed from an internal corporate perspective and external regulatory or public perspective.

Practical guidance

The following is a set of guidance principles designed to assist you in your writing and to promote clarity and avoid confusion and misinterpretation:

1. Method of communication

Consider whether the method of communication you have chosen is the right way to document the issue. You should write documents concerning sensitive subjects with the expectation that they may be disclosed in the public sphere at some point in the future.

2. Facts and opinions

State facts and not opinions unless you are specifically asked to do so; you are qualified to make them and it is the purpose of the document. Avoid commenting on issues that are outside your area of expertise. If you are required to document opinions or conclusions, identify the source of the opinion or conclusion or information received. This is because it would be easy for a third party to argue at a future date that they are your opinions and that the information has been verified by the author.

3. Accurate and concise

Be accurate, clear and concise in your writing. Inadvertent errors of fact may be interpreted as incompetence. Do not speculate or embellish with adjectives or adverbs which can lead to misinterpretation of the information you want to communicate. By nature, they are susceptible to more than one interpretation and can easily create ambiguity. Similarly, avoid sarcasm, irony and exaggeration and gratuitous or flippant language. The recipients of your documentation or communication may forward the information to other recipients without you knowing. Your audience may misunderstand the communication and draw the wrong conclusion. Furthermore, beware of using abbreviations and technical vocabulary. When writing your documents, assume your reader may have less specialised knowledge than you and may have a more limited understanding of the terminology. This will prevent ambiguity and promote clarity.

4. Neutral tone

Retain a neutral tone in your writing and avoid expressing strong feelings which have the potential to overwhelm clear thinking. Emotionally-charged expressions may also carry with them unintended weight or meaning and may be subject to misinterpretation. Similarly, avoid making defensive or critical comments.

5. Recording of information

Only record information which is necessary to perform your role. Don't record information which is unnecessary or considered "nice to have". Make sure you understand how to store information appropriately to ensure compliance with document retention requirements.

6. Documents based on limited information

Many documents which you write will take the form of more than one iteration before being finalised. If a document relating to a sensitive subject is incomplete, then indicate that the document is in draft form and is subject to change. If there is more than one draft, use numbers to denote the order in which they have been written. If you are required to write a document based on limited information it is perfectly acceptable to do so. However, it is best practice to indicate clearly that the document is based on incomplete information and that further work is needed.

Conclusion

Poorly drafted documents can be open to misinterpretation. It is important to remember that the language you use when creating any kind of document can create the wrong impression if it is taken out of context. Choose your language carefully and always ask yourself "How would I feel if this document became public?". I hope these points have illustrated the critical nature of your medical writing and the implications from a legal perspective. The importance of being careful about everything you write about a sensitive subject cannot be overstated and I hope the practical tips help you approach your writing with confidence.

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