

## ■ In the bookstores ...

### Practical advice on how to stay compliant with the ABPI and EFPIA Codes



*Judith Grice. Compliance, Codes and Communications. A practical guide to pharmaceutical marketing in the UK, with important European insights. Stanford Publishing Limited, 2009. ISBN: 978 0 85369 7176. 29.95 GBP. 127 pages. Available to buy direct from the author: <http://www.pharmacodes.com/Pharmacodes%20Publications.html>*

It is well known that regulatory writers have to follow guidelines in order to write compliant documents, however what might be news to some is that medical writers working in the medical communications arena also have guidelines and codes of conduct that they must adhere to. Applicable across Europe, these guidelines are based on the European Federation of Pharmaceutical Industry Associations (EFPIA) Code (1) which “provides the minimum standard that national associations must adopt.” Each country has interpreted these guidelines separately. In the UK those involved in reviewing and writing promotional and communications material for prescription medicine must adhere to the Association of British Pharmaceutical Industry (ABPI) 2008 Code (2).

In this book the author provides practical information and guidance on interpreting and implementing the ABPI Code. A useful summary of the key differences and similarities between European countries is also provided for those working across European countries. As well as suggestions on how to interpret the code, each chapter also contains case studies with learning points highlighted for each one.

The first chapter reviews the principles and procedures of the code. As the author points out these are applicable whether “it is an electronic or printed advertisement or a detail aid used by sales representatives or a booth panel.” Therefore if you work in this area of medical writing it is essential that you understand and interpret these basic principals correctly. This chapter is essential reading for those new to the industry or unfamiliar with the code of practice.

Additional chapters deal with individual topics in greater detail. For example, chapter 3 discusses how the code relates to printed material and highlights the need for it to be applied to both promotional and non-promotional material such as educational information. The types of written material that must adhere to the code include journal advertisements, detail aids, leave pieces, booth panels,

product monographs and formulary packs. Helpful and relevant suggestions for interpreting the code are provided throughout, which if followed, will allow writers to maintain compliance.

The internet and electronic media are vital methods of communication for many companies and the need for promotional compliance covers webcasting, podcasting, blogs and e-mails as well as the content of company websites. The issues relating to this form of medical communication are addressed in chapter 7. The provision of patient information is also tightly regulated and prescription-only medicines must not be advertised to the public. The difficulties encountered in this area are discussed in detail by a guest author, Paul Woods, in a separate chapter.

The code also has implications for clinical research, investigator meetings, and advisory boards and issues surrounding compliance in these areas are discussed. In principal, research carried out by a company should not be disguised promotion and key related issues are covered in several chapters. There are also chapters dedicated to public relations, gifts and company representatives each providing useful and practical advice on successfully interpreting the code in these areas.

Although there are similarities relating to how prescription medicines can be promoted across Europe the difference in interpretation and implementation of guidelines leads to variation in different European countries and the author has provided summary tables highlighting many of these important differences. For example, do you know the standards of proof required to substantiate a promotional claim in a particular country, e.g. whether ‘data on file’ is acceptable and if so, in which Country? Some countries require a head-to-head study to make a competitive claim, do you know which ones? If you don’t know the answer to these questions and you feel you should then you need to read the book to find out!

If you are working in this area of medical writing and this is the kind of information you are required to know, I thoroughly recommend you add this book to your reading list.

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#### References:

1. European Federation of Pharmaceutical Industries & Associations. Code of conduct for the promotion of Medicines (November 2007).
2. The Association of British Pharmaceutical Industry (ABPI). Code of Practice 2008. (available from <http://www.pmpa.org.uk/>)

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### The book's author is giving the plenary lecture at the EMWA Conference 2010

Judith Grice will be giving a plenary lecture titled 'Stand out from the crowd—by having an understanding of European pharmaceutical industry codes and compliance' at the EMWA Conference in Lisbon on 15 May 2010. The lecture will focus on providing a basic understanding of Compliance, Codes and Communications across Europe and how an awareness of these can help in making you 'stand out from the crowd'. The areas covered will be

- How promotion is controlled in Europe
- Why codes exist & what is covered by them
- Why complying with them is important
- What is the scope of the codes
- Focus on written materials
  - Basic Principles
- Differences between the codes/regulations across Europe
- Some practical examples of where an understanding of the codes may help when producing communications.

Judith is a director of PharmaCodes Medical Communications Limited. She has extensive experience in approving promotional materials. This included regulatory accountability for the compliance of international marketing campaigns for a major global company. She also delivers compliance training courses and details of these can be found at [www.pharmacodes.com](http://www.pharmacodes.com).

### Thanks we all deserve

Carol Norris teaches medical students in Finland and came across the following acknowledgement from a Swedish native-speaker Finn enamoured of thesauruses, "I thank my thesis director for his relentless aid in making my writing translucent."

With thanks to Carol Norris ([carol.norris@helsinki.fi](mailto:carol.norris@helsinki.fi)) for sending this example to *TWS*

## Advice and information on a medical writing career in medical communications



*Annick Moon: From academic to medical writer: A guide to getting started in medical communications. 28 pages. Published by NetworkPharma and available free from <http://www.medcommsnetworking.co.uk/startingout>*

Written by a freelance medical writer working in the UK as a medical communications consultant, this booklet provides useful

advice and information for those considering a career as a medical writer in a medical communications environment. As the author explains, the main aims of the guide are to give industry information on the role of a medical writer and to provide the "insider knowledge needed to excel at interview".

The booklet introduces the different phases of clinical development as well as describing the types of job opportunities that can be encountered in a medical communications environment. Job titles include account manager, medical editor, editorial project manager, conference manager and medical writer and as explained all have different roles within the medical communications field. By reading the descriptions a potential candidate will learn what each role involves and which attracts them most.

When desperately trying to find your first job as a medical writer, the need to demonstrate relevant industry experience coupled with the relevant skills seems an insurmountable task. Many people who want to begin a medical writing career are postdoctoral scientists, and at first glance they do not appear to have the necessary experience or skills. In this booklet, useful ideas to translate existing scientific skills into essential medical writing skills are presented. Examples include "*Teamwork*: liaising with colleagues and collaborating with other research groups" and "*Project Management*: designing experiments and scheduling resources."

Candidates applying for a medical writing post should not be surprised when asked to complete a writing test. The test is often set as a means of selecting candidates who will be considered further and interviewed. There is no industry standard for the writing test and many companies design their own. Faced with the writing test for the first time when candidates are not familiar with the therapeutic

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> area, or style of writing, can be quite daunting. Examples of the types of writing test that can be set are presented in the booklet. Some suggestions for completing a good writing test are paying attention to detail, and structuring the text well to ensure information flows in a logical sequence. The booklet also contains an exercise (with the answers) to check and improve editorial skills.

Testimonials from those already working as medical writers for communications agencies are presented, and provide interesting background information on the many routes that can be travelled before becoming a medical writer. Overall, the booklet provides a good introduction to what is expected from a medical writer working in the medical communications environment. By studying the information, those who are considering the leap into medical writing can make an informed career choice, as well as prepare themselves for the writing test and interview. For those choosing medical writing as a new career option it will help make that elusive first medical writing job an attainable goal.

This careers guide is an annual publication and will be updated in March 2010. The update will ensure that the directory of agencies is current. The core copy will not change unless any changes are needed but more profiles might be added.

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## Practical help for beginning scientific writers



Margaret Cargill and Patrick O'Connor. *Writing Scientific Research Articles: Strategies and Steps*. Wiley-Blackwell, 2009. ISBN 978-1-4051-9335-1. Approximately 18 GBP, 20.00 euro, 173 pages.

I can honestly say that I found nothing wrong with this book. I thought that my New Yorker's critical and judgmental eye would uncover something to criticize, but I was mistaken. The authors, a linguist and a researcher from the University of Adelaide, aim to teach beginning researchers how to prepare a scientific research article for submission to an international journal, and they succeed. The keyword here is 'prepare'—the authors focus not only on writing articles but also on the entire submission process from choosing a journal to responding to reviewers. The book includes many examples and exercises to support a learning-by-doing approach. Both writers and teachers will find this book valuable, as will experienced writers looking for a little

metaphorical pencil sharpening while working on their own articles. Now to the specifics.

The book is organised into five sections: four sections of instruction and one section with two sample articles for completing exercises. The first section prepares the writer and includes information about article structures, selecting titles, and reviewers' criteria for evaluating articles. A list of typical questions that reviewers use to evaluate articles is very helpful. By doing the exercises before writing my article, I learned what information reviewers look for and where in my article they expect to find it.

The second section addresses writing articles section by section, starting with the results and ending with the abstract. All chapters are brief but thorough. However, to get the most out of the book, I strongly recommend that writers complete the exercises. Matters of English grammar are treated judiciously. Rather than laying down the law to avoid using the passive voice, the authors explain when and why to use which voice for clear and effective writing. The chapter on tables and figures covers the basics, and writers can quickly improve their articles by following the suggestions.

The third section explains how to get your manuscript published. The chapter on selecting a journal seemed a little out of place to me because I prefer to choose before I start writing. Nonetheless, I was very grateful for an exercise on how to analyse journal scope, time to publication, and impact factor across several potential journals. Responding to editors and reviewers is always tricky, but the authors' systematic recommendations make me believe that it is at least manageable. A table including comment type and possible responses goes a step further and tells me what I need to do to improve my article and which section in the book to review.

The fourth section on developing publication skills is targeted primarily at writers of English as an additional language. Common grammar and usage mistakes are reviewed to the benefit of most writers of English, native or not. The two example articles provided in the fifth section are good for working through the exercises, but, although I started out using both, I settled into using the one most similar to my research area. It seemed to work well enough.

A final and potentially helpful benefit of this book is the authors' website [www.writeresearch.com.au](http://www.writeresearch.com.au). However, the website is pretty sparse at this time and is not much use. I plan to check back in the future and expect to find more exercises and checklists to support the book. All in all, this book is very helpful, and I will use it again when I write my next article. And, at about 20€/18£ for the soft-cover version, it makes my bargain-hunter's heart sing.

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