Regulatory Writing

Briefing documents: A case apart

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Health authority briefing documents (also known as briefing packs, briefing packages, and briefing books) are documents prepared by a pharmaceutical company to support its interactions (e.g. pre-submission meetings, requests for scientific advice, and protocol assistance) with health authorities. These interactions can shape the clinical development of a product and as such are clearly of great importance to companies. A well-written and presented briefing document may be crucial, or at the very least, can smooth the path to the desired outcome.

A neglected document type

Although medical writers are often involved in the preparation and drafting of briefing documents, and given their strategic importance, it is perhaps surprising that very little is actually offered in terms of training for their preparation. For example, although EMWA offers training on a wide variety of document types (clinical study reports [CSRs], investigator's brochures [IBs], components of the common technical document [CTD], informed consent, etc.), to my knowledge briefing documents have so far escaped attention. Likewise, in a search inside the books about medical writing on Amazon, I did not see any references to briefing documents.

The explanation why briefing documents have been neglected in training courses and by authors of books on medical writing may in part be related to the lack of guidance for their preparation. CSRs and many other regulatory documents are subject to specific guidance which is relatively easy to teach and write about. Little guidance is available, in contrast, for briefing documents (though the European Medicines Agency does have a template for protocol assistance/scientific advice, as discussed below). Another factor is perhaps that briefing documents are rather unique documents, which need to be tailored to the particular needs of a given situation and perhaps also to the requirements of the health authority to which they will be submitted. They are also often interdisciplinary documents (so rather like investigator's brochures, in this respect) requiring input from different functions within a pharmaceutical company. Perhaps the diversity of types of briefing document and the fact that they are rarely purely clinical documents are further reasons why they have not been accommodated in more clinically oriented training programs. Nevertheless, some basic principles nevertheless apply.

Basic principles

Unlike many other regulatory documents, a briefing document is not intended to be an exhaustive presentation on the subject in question. For example, in a CSR, failure to include comprehensive data may be interpreted as a sign that the company has something to hide. Such considerations do not really apply to briefing documents. It is up to the company to decide what is interesting and important for the project in question, and bring these to the table. Indeed, piles of data may be off-putting to hard-pressed reviewers. In a recent survey on how FDA Advisory Committee members prepare for a public advisory committee meeting, the authors found that 20% of members spend less than four hours preparing for the meeting.[1] Bearing in mind that this time also includes review of the sponsor's slides as well as the briefing pack prepared by the FDA, the time spent actually reading the sponsor's material can be minimal. In addition, as the outcomes of most of these meetings are not binding, a reviewer will perhaps be less inclined to focus on the detail and look more at the big picture. Interestingly, many of the advisory committee members surveyed in the aforementioned study generally preferred less text and more tables while the vast majority wanted the document to be less than 100 pages long (excluding appendices). Admittedly, the public advisory committee meetings covered by the study represent a special case and may not be representative of other types of meeting sought with other health agencies (see McIntyre and colleagues for some background on public advisory meetings[2]), but it is likely that reviewers in other situations will also be hard-

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pressed for time, and so considerations about brevity will also be applicable.

The EMA template for protocol assistance/scientific advice

Most briefing documents will begin with some sort of short executive summary, followed by questions with the company's positions. Then, there will usually be a background information section where a reviewer can go for more detailed information, followed in turn by any annexes or appendices. Faced with the lack of examples of briefing books and documents, it is perhaps illustrative to look at the European Medicines Agency template for CHMP protocol assistance/scientific advice, available from: http://www.ema.europa.eu/ema/pages/includes/document/open_document.jsp?webContentId=WC500093259. This template also includes guidance text for each of the main sections (summary, questions and company's positions, and background information).

According to the EMA template, the summary section should be limited to three pages and include the following subheadings: background information on the disease to be treated, background information on the product, clinical development, regulatory status, and rationale for seeking advice. Optionally, this section can also include subheadings for quality development and non-clinical development, if appropriate.

It goes without saying that this section should be well crafted and to the point. Ideally, the text should give the reviewer a good idea as to why the company is seeking advice.

The questions and company position are the crux of the document. The questions need to be carefully formulated; questions that are too vague will likely get answers that are also vague (and so not particularly useful). But specific questions can also be dangerous in that they can elicit specific responses that can tie the company to unwanted commitments; although the outcomes of many of these meetings are non-binding, they will be taken into account in subsequent submissions. Normally, medical writers will not be responsible for drafting the questions (although their input on language issues may be welcome). Often, when producing a briefing document, the questions are drafted first and the rest of the document constructed around these questions. Each question is followed by the company position, which according to the EMA template should function as a stand-alone argument, although cross-referencing to background information can be used to further substantiate the company's position. These positions should be objective and critical. Ideally, each company position should not exceed three pages.

The background information section provides additional supporting information to allow further assessment of the development programme (though essential information should be presented in the corresponding company's position). This section is not intended to be an exhaustive overview. According to the guidance, tabular presentations and graphs should be considered to facilitate rapid understanding. If necessary, further information in the form of study protocols, study reports, and investigator's brochures, for example, can be provided as annexes.

The benefits of a well-structured briefing document

Thus, the overall structure of briefing documents is similar to that of many other regulatory documents, with summarised and selected information at the beginning of the document, but with the opportunity to drill down to greater detail if desired. As with any other type of regulatory document, a logical and well-organised structure will help the reviewers quickly find the information they want at the level of detail they want and so put them in a better position to provide useful feedback.

References

1. McIntyre TD, Pappas M, DiBiasi JJ. How FDA Advisory Committee members prepare and what influences them. Drug Inf J 2012;47:32–40.
2. Ciociola AA, Karlstadt RG, Pambianco DJ, Woods KL, Ehrenpreis ED. FDA-Related Matters Committee of the American College of Gastroenterology. The food and drug administration advisory committees and panels: how they are applied to the drug regulatory process. Am J Gastroenterol 2014;109:1508–12.