Regulatory Writing

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The EMA, the FDA, and Health Canada head to head

A recent issue of the *New England Journal of Medicine* carried an article comparing the regulatory review times of novel therapeutics by three different regulatory agencies (FDA, EMA, and Health Canada).[1] In the comparison, the FDA appears to come out rather well, with significantly shorter review times (303 days for the first review) than the other two agencies (both with review times over 350 days for the first review). The article (which seems to be written by people sympathetic to the FDA cause) should be seen in the context of the upcoming renewal of the Prescription Drug User Fee Act, which originally came into force in 1992 to allow the FDA to charge fees for reviewing drug applications. The revenue generated from these fees is dedicated to providing sufficient resources for the review processes. At each 5-year renewal, stakeholders get to voice their opinions about whether they are getting value for their fees.

A recurrent criticism of the FDA has been that the review cycles take too long, and so review times is one of the focuses of the upcoming renewal. The findings, as the authors point out, would seem to contradict this criticism. There are some caveats when interpreting these data. For instance, the FDA was more likely to require more than one review cycle than the EMA. But even when this was taken into account, the overall review times were still shorter. Another caveat would be that some of the applications for novel therapeutics in the European Union would follow a mutual recognition procedure rather than a centralised one, and these applications may well be the smaller ones that are faster to review. In addition, the analysis only includes successful applications (information about unapproved publications is not publicly available) and focuses only on novel therapeutics. Manufacturers of generics, for example, have been complaining of a backlog in the review of their applications.

Short review times are desirable (for the pharmaceutical companies because they enjoy longer market exclusivity and for the patients because they can benefit earlier from new treatments), but they should not be attained at the expense of thoroughness, particularly concerning safety; after all, the primary remit of regulatory agencies is to protect patients. The quality of a regulatory review from a safety perspective is harder to assess. One way would be to look at label changes and drug withdrawals, though as far as I am aware, there have been no attempts at such an evaluation.

In any case, I don't think that the EMA comes out that badly from the comparison, even if we only take into account review time as a limited metric of efficiency. The organisational setup of the pan-European EMA is, by necessity, more complex than the more homogeneous FDA, so a somewhat longer review time could be expected (which is not to say that there is no room for improvement).

References

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Resolving conflicts – 'soft skills' that a regulatory writer needs

In a previous column, I talked about the importance of review cycles, and also about how inefficient they can be. In particular, the column talked about how some reviewers inappropriately focus on certain details while failing to address high-level failings. Another essential aspect of a successful review cycle is of course the resolution of comments. Most regulatory documents receive input from different departments (or functions to use pharma jargon). Often though, these functions have different, and sometimes conflicting, priorities, and these may come through in the comments on a draft regulatory document. If a comment from one function is resolved, a conflict with another function may be generated.

And sometimes medical writers can find themselves caught in the crossfire. I would hesitate to draw an analogy with the UN peacekeeping forces or marital guidance counsellors, but nevertheless, some situations can require plenty of tact (perhaps this is one reason why women – who as a generalisation can be said to be more inclusive in their approach to problem solving – are strongly represented in medical writing). Any tips for handling such situations will no doubt sound like some staid advice column, but here goes.

First, organize a teleconference (or a face-to-face meeting if possible; I generally work offsite though so this is not an option). Teleconferences can be the most interminably dull things, but they have some advantages. For one thing, I find that people are more prepared to compromise when talking on the phone rather than using email. Email depersonalises things and people find it easier to pick an argument with an anonymous string of words on a computer screen. (I say anonymous because in large companies, often team members don't know one another in person.) While you still might not be able to put a face to the voice on the phone, the level of human interaction is higher.

Also, after a couple of hours on the call, when fatigue is starting to set in, and the end of the scheduled slot is approaching, people may soften their views. Email exchanges, on the other hand, are open-ended, and people can come back to them with renewed vigour after lunch, or the next day, or whenever. Email does have the advantage though that you have something in writing. After a teleconference is over, it is therefore useful that you jot down some minutes, even if they are very high level, summarising what was decided. This summary should be distributed to the participants to provide a written record of the meeting and avoid revisionist interpretations of any decisions made.

Next, as in any negotiation, I think it is important to show a spirit of compromise. Most people will be keen to move on, so if you are able to offer them something, they will usually be prepared to budge from their entrenched position. It is also helpful to save your time and energies for things that really matter. For instance, if someone insists on hyphenating a certain compound noun, then you could probably safety let that go. Another matter would be if someone insists on omitting a certain piece of information that in your opinion is important (based on your interpretation of applicable guidance, for example). Deciding what is important and what is a distraction is where experience comes in. Experience is also helpful because as you get more expert so you will be more likely to command respect. This in turn will make it easier to browbeat dissenters within the team.

In short, soft skills can be important for resolving conflicts in review rounds, and some people are inherently more gifted in this respect than others. The good news for those of us born with less developed skills is that they can be acquired to a certain extent through experience.

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