

30 medical books and several hundred published articles to his name, Dr Taylor is highly practised in medical writing and uses both his own knowledge and that of renowned writers to highlight some of the pitfalls medical writers have experienced or may experience in their careers. My only criticism would be that the examples in this book are arguably tailored more towards

physicians rather than professional medical writers and are also more applicable to writers whose work focuses on manuscripts, literature reviews, book chapters, and books, rather than regulatory writing. I would recommend this book primarily to freelance writers and writers who specialise in medical communications, rather than regulatory writers, and would especially

recommend it to those wishing to become medical writers.

Reviewed by
Nicholas Churton
ICON, Eastleigh, UK
Nicholas.Churton@iconplc.com

Regulatory Matters

SECTION EDITOR



Greg Morley
greg.morley@docuservicio.com

Brexit and the European Medicines Agency

The British government has formally triggered Article 50, setting in motion Brexit and negotiations can begin in earnest. If before, politicians could gloss over the complexities, they are now obliged to start getting to grips with the details (where the devil often is if the popular saying is to be believed). With such a complex process, some unintended consequences will inevitably start to become apparent. One example is the future of the European Medicines Agency, currently located in Canary Wharf in London. During the referendum campaign, I don't recall any talk about what fate might befall this prestigious agency. Obviously, with the UK leaving the European Union, it seems untenable to keep the EMA headquarters in London, regardless of how "soft" Brexit finally turns out to be. In fact this seems one of the few aspects of Brexit where there is some agreement.

The loss of the EMA will have a big impact for London and the UK. In addition to the prestige of hosting such an important Agency, the revenue generated by the Agency is not negligible. Indeed, the EMA budget for 2017 is €322 million, much of which would be money spent in the UK. Currently, 900 permanent agency employees (who pay taxes and spend EU money in the UK) work in prime premises in central London. The decentralised nature of the Agency also means that many others need to travel to and stay in London on a regular basis, where they occupy hotel beds. Although this may be a relatively small amount compared with the famous €350 million a week the Brexit campaign claimed was being sent to the EU, at least the



EMA was a tangible economic benefit for the UK, but that is water under the bridge now...

Given the prestige and potential economic boost that hosting the EMA could bring, it is not surprising that a long queue of countries have formed, jostling for position to be the chosen one. Denmark, Ireland, Italy and Sweden have all formally launched their candidacies, while others such as Spain, Portugal and Croatia also seem to be in the running.

Those who make the decision will take into account a number of factors. Good travel connections and plenty of hotel beds will clearly be major considerations. Given that morale at the EMA is already said to be low as a result of Brexit, and the current uncertainty has hastened the exit of senior figures, the impact on current staff will need to be minimised to limit any further loss of expertise (I suppose that this is code for establishing the headquarters somewhere that

people would want to live). These practical considerations may, however, be surpassed by political calculations. Countries that already host a major European agency may be ruled out (despite the clear opportunity for synergy with the European Centre for Disease Prevention and Control in the case of Sweden, for example). It may also be politically expedient to host the EMA in an Eastern European country.

Whatever the decision, there is some pressure to make it quickly. As mentioned above, the EMA is already facing loss of staff and nobody wants to see this further exacerbated, with the potential negative impact on the quality of such a crucial Agency's work. Ultimately, this is a question of public health and should not become a game of political football.

Greg Morley
greg.morley@docuservicio.com

The New EU Medical Device Regulation: New opportunities for regulatory writers

The new EU Medical Device Regulation (MDR)¹ has recently been released. The key changes that MDR brings (compared to its predecessor the Medical Device Directive of 2001) include more stringent requirements for manufacturers, more responsibilities for Notified Bodies, and more transparency and traceability. And I would like to add – more opportunities for medical writers because of additional regulatory requirements that entail writing more regulatory documents, some of them new in the field of medical devices. Some of these documents are described below.

Clinical evaluation reports (CERs)

As part of the implementation of the MDR, the new MEDDEV 2.7/1 revision 4 was released in June 2016.² This guidance explicitly mentions the necessity for medical writing expertise in the preparation of clinical evaluation reports (CERs) as follows: “As a general principle, the evaluators should possess knowledge of the following: – research methodology (including clinical investigation design and biostatistics); – information management (e.g. scientific background or librarianship qualification; experience with relevant databases such as Embase and Medline); – regulatory requirements; and – medical writing (e.g. post-graduate experience in a relevant science or in medicine; training and

experience in medical writing, systematic review and clinical data appraisal).”

The requirements to submit CERs (MDR Article 61) have become more stringent, with higher frequency of updates for certain device classes.

Clinical trial documents

In addition to the CERs, more clinical trials are required for CE marking and recertification of medical devices, hence it is expected that there are more clinical investigation plans (study protocols) and clinical investigation reports (study reports) to write (MDR Articles 61, 62).

Post-marketing documents

The preparation and submission of post-market surveillance plans (MDR Article 84) and reports (Article 85) for all device classes will now be closely implemented by the new MDR.

Periodic safety update reports (PSUR) – new requirement

The periodic safety update report PSUR was a regulatory requirement for drugs for many years (now replaced by the Periodic Benefit-Risk Evaluation Report [PBRER]). The new MDR requires device manufacturers to prepare PSURs (MDR Article 86), to be submitted every 2 years

for class IIa and annually for class IIb and class III devices.

Summary of safety and clinical performance (SSCP)

The MDR also requires submission of a summary of safety and clinical performance (SSCP, Article 32) for implantables, class III devices, and other than custom-made or investigational devices. The SSCP is supposed to be written with the intended device user and the patient in mind and shall be made available to the public.

References

1. Medical Device Regulation (EU) 2017/ ... of the European Parliament and of the Council of Europe on medical devices (draft). Available from: <http://data.consilium.europa.eu/doc/document/ST-10729-2016-INIT/en/pdf>. [Accessed 02 Feb 2016].
2. MEDDEV 2.7/1 revision 4 June 2016. Clinical Evaluation: A Guide for Manufacturers and Notified Bodies.

Raquel Billiones
Clinipace Worldwide, Zurich,
Switzerland



Save the date

Cascais, Portugal 2017

The 45th EMWA Conference in Cascais, Portugal will be held on 2-4 November 2017 at the Cascais Miragem Hotel.

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