Welcome to this special edition of Medical Writing focusing on medical devices. When I volunteered to act as the guest editor for this issue, I did so knowing that we are at a crossroads in Europe. The Medical Device Directive is about to be replaced by more stringent Medical Device Regulation. This legislation will have all kinds of repercussions within the industry, so it is timely indeed that we focus on this topic in this issue.

I have spent over a decade in the world of medical devices and continue to find it fascinating. Although regarded by some as being quite niche, the medical devices industry should not be ignored. According to the European Commission, over half a million people are employed in the medical devices industry in Europe, with total sales of over €100 billion.¹

And precisely this is what I find so fascinating. Although the medical device industry is large, it is relatively unknown – quite surprising, given that we all use them. There are more than 500,000 types of medical and in vitro test devices on the EU market.² These include simple everyday items like plasters and contact lenses. Of course, items like x-ray machines and hip replacements are probably more the kind of product that springs to mind when the average person thinks of medical devices. There are many others even more obscure. For example, did you know that medical leeches are classified as medical devices?³ If you would like to know more, Karin Eichele in the Webscout section outlines some useful online resources related to medical devices.

In this issue of Medical Writing, you are well served with an array of information from medical writers who also work in the medical devices “bubble.” Throughout the issue, and on a range of topics, they provide you with valuable information and insights.

The research (and marketing) budgets of pharmaceutical conglomerates dwarf those of medical device companies. As a result, Big Pharma commands attention well beyond the boundaries of the scientific world. Meanwhile, those of us in the medical device industry sometimes feel as though we have to fight to be heard. Beatrix Doerr, Sophia Whitman, and Steven Walker very succinctly sum up the differences between writing for the medical device industry and writing for pharmaceuticals. If you are mulling over a possible move into medical devices, this is an excellent introduction. Gillian Pritchard then drills down a little deeper to examine how medical device writers deal with Clinical Evaluation Reports.

The changing European legislation is the number one story for the medical device industry. Not surprisingly, we have several contributions on the subject. Robert Behan, Mark Watson, and Abhay Pandit outline what this means EU-wide, and how Ireland is preparing for the new playing field. Claudia Frumento, who was the guest editor the last time that this journal – then called The Write Stuff – focused on medical devices, explains why the evermore demanding medical device legislation is a positive step. In a second article, Claudia outlines the background to the Poly Implant Prothèse scandal. The actions of this French medical device company, which produced breast implants from low quality materials, was a contributing factor for regulators to review the Medical Device Directive. Raquel Billiones in the Regulatory Matters section also highlights how the coming EU requirements present opportunities for medical writers. In the same section, Greg Morley examines how leaving the European Union affects the United Kingdom’s hosting of one EU regulatory body.

While the subject of governance in the pharma industry is well-known, the medical device industry also has its own set of issues around governance. This topic is addressed in two articles: Fiona Dunlevy examines transparency in the medical device world, and Raquel Billiones tackles disclosure and the repercussions for medical writers.

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Although I have never worked in the pre-clinical world, I was intrigued by Jayna Patel’s article, which examines the role of standardisation on animal testing of medical devices.

I was a little worried that this issue might be too heavy on EU law, so I was glad to welcome two lighter contributions. Raquel Billiones looks at the humorous side of medical device trade names. I also asked Michael Todd to pen something on his working life. His short piece reminds me of a medical writing version of Nicholson Baker’s The Mezzanine. Now that is a sentence I never thought I would write!

If this issue has whetted your appetite, please don’t miss the forthcoming webinars by two of the contributors to this issue – and comrades of mine on the EMWA Executive Committee! Writing Clinical Study Reports for Medical Devices by Beatrix Doerr is slated for July, while the Introduction to Clinical Evaluation Reports for Medical Devices by Raquel Billiones will be confirmed for later this year.

I hope that you enjoy this issue of Medical Writing as much as we have putting it together for you. My sincere thanks to all of the contributors, as well as to Phil and his editorial team for helping to make it happen.

References