Volume 26 Number 2 | June 2017

Medical Writing

Medical Devices

An exciting industry at a crossroads

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.

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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.

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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.

Also in this issue

Nico Pitrelli talks about the future of science journalism, and Editor-in-Chief **Phil Leventhal** discusses whether medical writers can submit articles to journals on behalf of corresponding authors.

This issue also includes two special sections. The first are the winning essays from the annual Geoff Hall Scholarship essay competition, which this year, was on 'Good Medical Writing Saves Lives'. This year's winners are **Sophia Whitman** and **Cirsten Verleger**. We wish them both luck in their new careers in medical writing.

The second special section includes abstracts from the second annual spring conference poster session. The poster session is an excellent way for EMWA members to see the latest thinking and research in a 'snapshot', and has been introduced as an annual addition to the educational offering from EMWA.

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

1 European Commission. Medical Devices. 2017 [cited 2017 April 14]. Available from: http://ec.europa.eu/growth/sectors/medical-devices/.

2 European Commission. Commission welcomes new agreement for safer use of medical devices. 2016 [cited 2017 April 17]. Available from: http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_id=8863&lang=en.

3 Medicines & Healthcare Products Regulatory Agency. Borderlines between medical devices and medicinal products. June 2013.

President's Message

From EMWA's New President

Dear EMWA Members,

What an exciting and proud moment this is for me to serve as President of an association that I have seen grow in professionalism over the years since first becoming an EMWA member in 1996! We have come a long way since those days and I can appreciate this even more since joining the Executive Committee (EC).

I want to thank Alison and the EC for sharing their experience and ideas with me while serving as Vice President. It has been both an energising and enlightening experience.

The spring conference in Birmingham was a success, with 49 workshops, 3 half-day ESS sessions covering topics related to medical communications, pharmacovigilance, and regulatory topics combined with an excellent Symposium on "Transparency and Disclosure of Clinical Regulatory Documentation." We had a number of outstanding speakers and panelists including a representative from the European Medicines Agency. There was something for everyone and plenty of networking opportunities including the Freelance business Forum and the Internship Forum as well as a full social programme including the Spring Dinner and Dance. A great time was had by all.

As EMWA's President, I intend to both hold the course and build on our strengths as the foremost educational organisation in Europe for medical communicators.

I believe that EMWA has an important role in promoting public awareness about our profession. We will intensify our efforts to broaden contacts with universities and research institutions to get the word out to undergraduate and graduate students about our organisation and careers in medical writing.

In recent years, increasing numbers of people have been attending local informal meetings to listen and learn about medical communication and to network. EMWA members who attend such meetings can act as ambassadors to talk about the profession and the benefits of membership. I think EMWA should continue to support such groups by publicising their meetings via our social media networks and website as well as by reporting on these events in the MEWs.

We plan to further develop our contacts with other