

Medical Writing

European Union regulations

When we first sent out the call for papers for the Autumn 2020 issue of *Medical Writing*, there were only a few reports of a novel coronavirus. Today, of course, COVID-19 is a pandemic. Welcome to the “new normal”, where many of the routines, activities, and work processes we once took for granted have changed significantly or vanished entirely.

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Indeed, COVID-19 is not a specific topic in this issue, but it has had a subtle effect. This issue includes substantial articles on medical devices. As you may know, the European Council has voted to delay implementing the Medical Device Regulation (MDR) until May 26, 2021, recognising “the need for an increased availability of vitally important medical devices across the EU, and at the same time continues to guarantee patient health and safety until the new legislation becomes applicable”.

However, industry still needs to prepare for this particular new normal as certain associated deadlines have not changed, such as the date for the In Vitro Diagnostic Regulation (IVDR). **Raquel Billiones** and her colleague, **Gauri Jawdekar-Abraham**, compare the regulatory requirements of the IVDR and the MDR. Raquel also explores the impact of delaying the Eudamed launch on clinical investigation disclosure requirements.

Shalini Dwivedi and her colleagues provide an overview of regulatory changes in the EU, while **Kelly Goodwin Burri** examines new documentation that will be required under the MDR. These informative articles remind us that medical writers will have a key role in guiding manufacturers as they adapt to changes.

As our adaptation to the new normal inside and outside the workplace continues, **Tiziana von Bruchhausen**

and her colleague, **Sven Schirp**, draw our attention to risk management plans, while **Daniela Kenzelmann Broz** and her colleagues discuss the regulatory background of scientific advice procedures. These features will be of particular interest to medical writers involved in development plans.

Is change always a good thing? **James Monroe** ponders this question as he explores EU software regulations. **Micha Feld** and his colleagues examine the changes to PubMed and their potential effects on regulatory affairs.

As you continue your own adjustments to this new normal and those yet to come, I hope you will find the insights and ideas in this issue helpful. I wish to thank all the authors for taking the time to contribute to this issue. I owe special thanks to the Editorial Board for their invaluable help in editing the articles and bringing the issue together.

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About the Guest Editor

Ana Madani, MA, is an active EMWA member and freelance medical writer/editor. She is completing a graduate certificate in Clinical and Translational Research to augment her training in regulatory affairs.



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