

Adding to the post market stage is an article by **Karelia Tecante** and **Andre Sokija** that introduces the periodic safety update report (PSUR) and post market surveillance report (PMSR) documentation requirements under the MDR. The lack of a final guidance for creating these documents has been a challenge for everyone tasked with creating PSURs, even 1 year after MDR implementation.

With all the stages of device development covered, we then look towards the future of the MedTech domain which brings us back to the digitisation within the field over the past decade. When speaking of digitisation, one cannot ignore the introduction of artificial intelligence (AI). The last article by **Kirsten Dahm** introduces to us the new rules governing AI for devices in Europe owing to the limited guidance documents available to this rapidly growing and popular field.

We would like to thank all the authors for their contribution towards this issue of *Medical Writing* and welcome our readers to enhance their understanding of the inner workings of the medical device world. We hope that our readers enjoy this medical device focused journal issue as much as the authors and editorial team have enjoyed putting it together for them.

Happy reading!

**Namrata & Kelly**

### About the Guest Editors



**Kelly Goodwin Burri** has a background in biomedical engineering and epidemiology with 20 years of professional experience in medical writing, clinical

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# The first year of application of the Medical Devices Regulation:

## Foreword from the European Commission

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**A**lready 1 year has passed since the date of application of the new Medical Devices Regulation (EU) 2017/745 (MDR), replacing the previous Directives 90/385/EEC and 93/42/EEC from 26 May 2021, while for the new *In Vitro* Diagnostic Medical Devices Regulation (EU) 2017/746 (IVDR) the date of applicability is 26 May 2022, replacing the previous Directive 98/79/EC.

The medical devices sector is essential to the provision of healthcare to citizens and is an important player in both the European and global economy. As such, medical devices and *in vitro* diagnostic medical devices play a fundamental role in saving lives by providing innovative healthcare solutions for the diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease. Keeping this in mind, on 5 April 2017, two new Regulations were adopted, establishing a modernised and more robust EU legislative framework for medical devices to ensure better protection of public health and patient safety and improve the functioning of the internal market in medical devices.

Both Regulations require particularly far-reaching changes in the way the sector operates and important efforts for adaptation. This was made even more difficult with the COVID-19 pandemic in 2020-2021, seriously affecting the ability of the different actors involved to prepare for these changes.

The European Commission has been very active during these years and working closely with national competent authorities, notified bodies, and European associations representing health professionals, patients, and industry to ensure the smooth and effective implementation of the Regulations. This has included the adoption of a number of key implementing acts for designation of notified bodies, the availability of harmonised standards and common specifications, the ongoing development of the new European database on medical devices ("Eudamed"), the assignment of Unique Device Identifiers (UDI), the European Medical Device

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Nomenclature (EMDN), the designation of expert panels, the setting up of the Medical Device Coordination Group (MDCG) and its 13 subgroups, and other important work.

In order to address the serious challenges caused by the COVID-19 crisis as well as the situation related to the lack of notified bodies, notably under IVDR, the Commission also prepared amendments to the MDR and the IVDR concerning the dates of application of certain provisions and the related transitional regimes. This was necessary to take some pressure off national authorities, notified bodies, manufacturers and other actors coming from the handling of the COVID-19 crises and at the same time securing a smooth implementation of the new EU legislative framework for medical devices. The proposals were adopted within very speedy co-legislation procedures by the European Parliament and the Council.

As a necessary support to the legislative initiatives, to help all the interested parties to apply the MDR and the IVDR in practice, more than 90 guidance documents have been published following discussions and endorsement by the Medical Devices Coordination Group (MDCG), chaired and managed by the Commission (DG SANTE), with the participation of competent authorities and

stakeholders. Several other guidance documents and factsheets have been also developed and published directly by the Commission.

With respect to conformity assessment, the new Regulations strengthened the requirements and the procedures to designate notified bodies, including the participation of experts from Member States and the Commission in Joint Assessment Teams, to ensure adequate compliance. The number of notified bodies under the MDR and IVDR is continuously growing and they have increased their capacity and resources, but the situation is still challenging and more progress is needed.

It is worth mentioning also the international aspects related to the EU legislation on medical devices, to promote it to international partners and other jurisdictions, to ensure the same high level of protection of public health, as well as to facilitate exports for EU-based manufacturers. The related work includes the active representation of the Commission (DG SANTE) in the activities of the International Medical Device Regulators Forum (IMDRF) and the development and implementation of different types of international agreements with third countries in the field of medical devices.

A lot of work has been done so far, but there is still a lot of work to deliver in the next months

and years, to continue to successfully deal with all the challenges posed by the new EU regulatory framework for medical devices and avoid shortages of critical devices. Such challenges affect in different ways the relevant parties, including Member States, economic operators, conformity assessment bodies, patients, and users, as well as citizens in general. To jointly respond to these challenges, the European Commission services are always working and making all the best efforts to provide support, at the same time counting on the commitment and active participation of all the parties, to address a secure, smooth, and timely implementation of the regulatory framework.

#### Author information

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