EDITORIAL

NAVIGATING THE 2021 CHANGES TO THE MEDICAL DEVICE REGULATORY FRAMEWORK

How time flies! In October 2019, we published our second issue of *Regulatory Affairs Watch* – dedicated to the new medical device (**MD**) regulatory environment – ahead of the simultaneous entry into force on 26 May 2021 of Switzerland's Ordinance on Clinical Trials with Medical Devices (**ClinO-MD**) and the European Union's Medical Device Regulation (**MDR** 2017/745). Notably, 26 May 2021 was also the day on which Switzerland's Federal Council decided to end negotiations on the institutional framework agreement with the EU! The ClinO-MD was updated a year later to incorporate changes linked to the specifics of in vitro diagnostic devices in alignment with the EU's related In Vitro Diagnostic Medical Devices Regulation (**IVDR** 2017/746), which entered into force on 26 May 2022.

At the time, the anticipated changes raised many questions: How would medical device manufacturers acting as study sponsors manage this new regulatory situation? How would international trials be conducted? How would academic researchers navigate this new regulatory complexity? How would ethics committees handle the new categorisation of studies? How would the regulatory authority Swissmedic respond to these changes? And finally, how would patients and potential participants in medical device studies perceive all of these changes? This community of medical device stakeholders found itself in a completely reshaped regulatory world, facing many unanswered questions. And for all stakeholders, it was uncharted territory...

Learning how to navigate through this new regulatory world has required time. After two years of accumulating experience with the new MD regulations, stakeholders were asked by the *RA Watch*'s editorial board to share their experiences and to comment on the challenges they still face.

- **DEEP DIVE:** Regulatory progress in clinical research often seems more reactive than proactive. That is why we start off this issue of *RA Watch* with an article from the French patient organisation Ligue contre le cancer (**LCC**, league against cancer) that looks back at the medical device health scandals that triggered regulatory changes. The article also contains patients' perspectives on the new European regulatory framework.

- **FEEDBACK FROM:** Ethics committees and regulatory authorities play a key role in the regulatory process. Swissmedic and swissethics have remained at the forefront of this process, and they inform *RA Watch* readers how they prepared for the new framework and the tools they have made available to their stakeholders, sponsors, and investigators.

- **VIEWS AND OPINIONS:** The Swiss medical technology sector has not only been directly affected by the regulatory paradigm shift, but it has also felt the effects of Switzerland's shift to third country status with the EU and the resulting hurdles to the cross-border commercialisation of medical devices. In our first Views and Opinions article, Swiss Medtech reports on how the industry prepared for these new conditions and how it is now coping with and adapting to them. The new regulatory framework has undoubtedly strengthened the experimental validation of medical devices as well as the identification and reporting of safety issues. Yet at the same time, it has introduced additional complexity. Nevertheless, the increased involvement of patients in all stages of development will certainly help to prevent health-related MD issues such as those that triggered the recent MD regulatory changes. In our second Views and Opinions article, a patient advocate argues why patients' input into MD development is essential and presents concrete ideas on how to increase patient engagement.

- **CASE STUDY:** The new regulatory framework does not prevent researchers from conducting exploratory observational research, for instance at an early conceptual stage for a medical device. We report on a case study about an innovative device that could be categorised within the observational research framework (Human Research Ordinance (**HRO**), Chapter 2) since it does not impact research participants' health.

Some time has passed since we published the pilot issue of *Regulatory Affairs Watch* in December 2018 – and we are now publishing issue eight! After initiating the concept of this publication five years ago and overseeing all eight issues, backed by the SCTO's Regulatory Affairs Platform, my time with *RA Watch* has come to an end. As part of a local institutional reorganisation, I must step down from my responsibilities within the SCTO's CTU in Lausanne and the RA Platform. In just a few years, *RA Watch* has become a nationally registered and referenced Swiss publication, meeting almost all the criteria of a diamond-level open-access journal. It has a following of over 500 subscribers and also attracts readers on the SCTO's Tools & Resources website, most of whom are clinical research professionals.

I would like to thank all those who have contributed to *RA Watch*'s success. This includes authors, with a special mention of our counterparts at Swissmedic and swissethics (whom we have invited to contribute to almost every issue); patients and representatives of the public; RA Platform members; the SCTO's Executive Office, and in particular Pascale Wenger, who serves as the RA Platform's liaison officer and is currently the RA Platform's coordinator *ad interim*; and former platform coordinators Laure Vallotton, Séverine Méance, Loane Warpelin-Decrausaz, Isabelle Guilleret, and Olga Deckarm. And a special thanks to our publishing team under the excellent leadership of our publication coordinator Meg Züblin!

Happy reading and long live *Regulatory Affairs Watch*!

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