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CHANGES TO THE MEDICAL DEVICE REGULATORY FRAMEWORK: LOOKING BACK – AND FORWARD

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The new regulatory framework for medical devices was long due. It aims to improve the safety and performance of medical devices and ensure a high level of protection for public health. Yet complying with the new legislation requires greater administrative effort and more resources, thus making compliance more expensive. In addition, there has been some uncertainty among researchers about how to correctly comply with the new legislation. This article looks back at the measures swissethics has taken to address some of these challenges and looks forward to additional measures to be implemented in the future.

NEW REGULATORY FRAMEWORK FOR MEDICAL DEVICES: ADVANTAGES AND DISADVANTAGES

On the one hand, swissethics welcomed the implementation of the two new EU Regulations on medical devices (Medical Device Regulation (**MDR**) and In Vitro Diagnostic Medical Devices Regulation (**IVDR**)) as well as Switzerland's modification of its Medical Devices Ordinance (**MedDO**), its new Ordinance on In Vitro Diagnostic Medical Devices (**IvDO**), and its new Ordinance on Clinical Trials with Medical Devices (**ClinO-MD**). This legislation brings significant improvement to ensuring that only medical devices of high quality and with proven performance and safety are put on the market. In fact, there were numerous scandals due to defective and dangerous medical devices just a few years back, for example defective metal hip prostheses in Germany in 2015 and breast implants with unapproved silicone made by the company Poly Implant Prothèse (**PIP**) between 2001 and 2010 (see **DEEP DIVE**).

On the other hand, the new regulatory framework has come with additional burdens and costs. For medical device developers and manufacturers, the new regulatory framework translates into an obligation to prove performance and safety by conducting clinical trials for some classes of medical devices. This requires additional resources, thus increasing costs and resulting in significant administrative burdens. Indeed, the EU regulation has been criticised by the medical technology (**medtech**) industry as being too burdensome administratively, inhibiting innovation, and placing insufficient focus on technological advancement (see **VIEWS AND OPINIONS: SWISS MEDTECH**).

LOOKING BACK: HOW DID SWISSETHICS RESPOND TO THE NEW FRAMEWORK?

Harmonised process for reviewing and approving clinical trials

swissethics approached these challenges with one primary objective: to implement the new regulatory framework as simply and smoothly as possible for all stakeholders, including manufacturers, developers, researchers, and authorities. The main step taken toward this objective was to establish with Swissmedic a synchronised review and approval process for clinical trial submissions. This would make it possible to issue a single national decision letter that would include the requirements and conditions set by ethics committees and by Swissmedic.

In 2019, swissethics formed a core team and a working group to manage this first step. The core team, which consisted of three people, was responsible for creating a harmonised clinical trial approval process across the seven different ethics committees that was synchronised with Swissmedic. The working group, composed of a representative from each ethics committee, pooled the experience of the individual committees, identified pitfalls, and tested and validated the process. The working group also ensured direct, two-way communication between the core team and individual ethics committees. This simple set-up allowed the two teams to be agile and flexible while at the same time remain focused and productive, not only as the process was being reviewed and improved but also throughout its final implementation and beyond. In early 2022, one year after implementation of the new synchronised process, the working group analysed the feedback from sponsors and researchers up to that point and then worked together with Swissmedic to further simplify the process based on the experience gathered by the ethics committees.

New submission forms, templates, and guidance documents

The core team was also responsible creating a new, dedicated submission form in the Business Administration System for Ethics Committees (**BASEC**). One of the considerations that influenced the original design of the submission form was the future possibility of interchanging data with the European Database on Medical Devices (**EUDAMED**). This approach was not changed when the submission form was revised to accommodate performance studies on in vitro diagnostic medical devices (**IVDs**) in May 2022, despite the fact that one year earlier the Federal Council had decided to terminate negotiations of the EU Swiss Institutional Framework Agreement. For researchers and sponsors, the core team also created and published templates for writing a clinical investigation plan (**CIP**) and a clinical performance study plan (**CPSP**) as well as guidance documents for safety reporting and for notification of substantial amendments; the latter two documents were the result of a joint effort with Swissmedic. The CIP and CPSP templates were distributed to the clinical trial units (**CTUs**) and to Swissmedic for comments and corrections prior to publication. swissethics greatly appreciates the feedback from these institutions!

Training on the new regulatory framework

After receiving input from swissethics and other stakeholders, the Coordination Office for Human Research (**kofam**) organised training sessions for ethics committees on the new regulatory framework. In addition, swissethics organised internal training sessions for the scientific and administrative secretariats of the ethics committees. These training sessions focused on the project flow in BASEC with its working instructions (first submission, amendments, safety), synchronisation with Swissmedic of the various review steps and final decisions, templates of decision letters, checklists, and other matters. The way the individual ethics committees informed and trained their members varied from ethics committee to ethics committee, with some holding specific training sessions during their regular monthly meetings. The new regulatory framework was also a topic at the annual further education training events for members of ethics committees that take place each autumn (in Zurich, Lausanne, and Geneva).

swissethics, kofam, and Swissmedic agreed upon an approach for external communication to stakeholders. The goal was for the three institutions to align and distribute their communication in parallel, with each one focusing on its own role and responsibilities.

Ongoing support for sponsors and researchers

The ethics committees and swissethics continue to support sponsors and researchers and address their questions through different channels. In most cases, this involves clarifying the applicable ordinance and risk categorisation of a research project. Another frequent question concerns which ordinance and risk category apply to companion diagnostic studies, with all imaginable case scenarios (e.g. one or two protocols with one or two independent sponsors for the investigational medicinal product (**IMP**) part and the IVD device part, a marketed/non-marketed IMP and an IVD device with CE marking/without CE marking, or an IMP tested in Switzerland and an IVD device partly done abroad or vice versa).

LOOKING FORWARD: WHAT'S NEXT?

The ClinO-MD requires a clinical trial's sponsor to submit a final report with a summary in easily understandable terms to the ethics committee within one year of the end of the clinical trial. To promote transparency, swissethics is currently putting a system in place that will make these summaries in lay language available to the general public. The ethics committees and swissethics will also continue to collect feedback from sponsors and researchers. Moreover, they will regularly assess whether the current review and approval process, templates, and guidance documents continue to fulfil their intended purpose and, if necessary, modify them. Despite all the changes the new regulatory framework has brought about, it has not changed swissethics' ultimate aim: to make Switzerland an even more attractive place for medical device development and research.