SCTO PLATFORMS

Clinical evaluations and investigations: Changes ahead in Swiss medical devices laws

Authors: Olivier Goarnisson (1) and Josefine Sommer (2)
Affiliations: (1) Counsel and (2) Senior Associate at Sidley Austin LLP*
October 2019

Companies conducting clinical investigations with medical devices in Switzerland should be particularly aware of the following new requirements to become effective with the Ordinance on Clinical Trials with Medical Devices (ClinO-MD), once adopted in its final form and applicable.This article comments on changes that lie ahead relating to: clinical evaluations, in particular exceptions for equivalence; and to clinical investigations (focusing on: pre-market, post-market, monitoring, protecting personal data, and Eudamed.

The draft ClinO-MD is based on Chapter VI of the MDR. The text is largely in alignment with international standards for the conduct of clinical investigations with medical devices set out, inter alia, in ISO 14155:2011 and the Declaration of Helsinki. In the EU, the MDR leaves the Member States with a broad scope of discretion regarding the organisation of the assessment of clinical investigations and the applicable authorisation procedures.

Companies conducting clinical investigations with medical devices in Switzerland should be particularly aware of the following new requirements to become effective with the ClinO-MD, once adopted in its final form and applicable.

This article comments on changes that lie ahead relating to: clinical evaluations, in particular exceptions for equivalence; and to clinical investigations (focusing on: pre-market, post-market, monitoring, protecting personal data, and Eudamed.

Clinical evaluations

Today, a clinical evaluation of a device must be based on clinical data in relevant scientific literature and on any existing results of clinical investigations performed on the device. The new rules introduce the requirement for a clinical evaluation to consider also any “currently available alternative treatment option” (art. 44(2) of the draft Medical Devices Ordinance (MedDO), which states that art. 61 of the MDR is applicable in Switzerland). This requirement will place an additional burden on companies when evaluating

the risks and benefits of their devices.

In particular, additional emphasis must now be placed on whether the clinical risks associated with a device being evaluated are comparable to other treatments for the disease in similar patient populations. Overall, the new requirements may appear burdensome at first. But once implemented, a well-executed clinical evaluation plan is likely to guide many companies through otherwise difficult conversations with their NB and competent authorities.

Exceptions for equivalence

Medtech companies have long used existing scientific literature and equivalent device statements in their clinical evaluation reports. This reuse of existing evidence can facilitate equivalence (as explained below), which saves the industry from conducting new and costly pre- or post-market clinical investigations to prove safety and performance.

Under the current rules, it is possible to claim equivalence from a given device with another similar device that another manufacturer has already placed on the market. However, that possibility has already been significantly reduced in the past few years with the EC's MEDDEV guidance on clinical evaluations (as MEDDEV 2.7/1 rev. 4), which, i*nter alia*, introduced stricter expectations with respect to the demonstration of equivalence. Although the MEDDEV guidelines are not directly binding for devices placed on the Swiss market, they set the interim standard which should be respected by all manufacturers of devices in Switzerland until the new ClinO-MD is applicable.

The draft ClinO-MD is set to further diminish the chances of success for companies relying on data related to equivalent devices. Under the new rules, which further tighten the requirements set out in the MEDDEV guidance, a device for which equivalency is claimed must share the same technical, biological, and clinical characteristics. If, for example, a device, which is being compared to another device, has the same technical and clinical characteristics, but uses different materials or the materials are not intended for the same duration of contact with the skin, the devices will not be considered "equivalent".

The EC is meant to issue further guidance on the interpretation of "equivalence". This guidance will be indirectly applicable to the Swiss medtech industry as well.

Clinical investigations

Pre-market: The draft ClinO-MD sets out new minimum requirements for pre-market clinical data with a reference to the MDR (Annex XV, ch. II). The new requirements reflected in the ClinO-MD are much more detailed than the currently applicable guidelines set out in the EC's guidance to competent authorities for making a validation or assessment of a clinical investigation application (MEDDEV 2.7/2, rev. 2).

Post-market: The current standards require that the regulatory authorities be notified of pre-market clinical investigations. The new rules will require that manufacturers of medical devices also notify the competent authorities about the conduct of all post-market clinical investigations.

Monitoring: Another new requirement is that the sponsor of a clinical investigation must appoint a monitor to ensure that the investigation is conducted in compliance with the Clinical Investigation Plan, the principles of good clinical practice, and applicable law. The monitor must be independent from the investigational site (art. 3, para. 1(b) of the draft new ClinO-MD).

Protection of personal data: One novel aspect of the new clinical investigation requirements is its strong

focus on the protection of personal data. Companies should pay particular attention to the new data protection rules currently being introduced into the Swiss data protection legislation in order to align it with the EU General Data Protection Regulation (EU) 2016/679 (GDPR). (For a thorough overview of this topic, see the RA Watch Issue1.)

The EC has issued several guidelines on the consent required by patients participating in clinical trials, for example, a Q&A on the interplay between the EU Clinical Trials Regulation (EU) 536/2014 (CTR) and the GDPR. In this Q&A, the EC has ruled that the current practice of obtaining the data subject's consent for the processing of their personal data is inappropriate in most circumstances, prompting companies to revise their informed consent forms and to indicate another legal basis for data processing. These considerations and guidelines are also relevant for companies conducting clinical investigations with medical devices.

Eudamed: Companies conducting clinical investigations in Switzerland will benefit from Eudamed (in addition to the data-processing systems set up in Switzerland), the new electronic registration of clinical investigations, which must still be set up by the EC. Eudamed will allow sponsors of clinical investigations conducted in more than one Member State of the European Economic Area or in Switzerland to submit applications for clinical investigations centrally. It will also feature a central location for vigilance reporting and submission of clinical investigation data.

Compliance with the new rules, which align Swiss legislation for medical devices to those of the EU, will benefit patients due to the higher standards that have to be met by Swiss manufacturers of medical devices, including the conduct of clinical investigations. Moreover, it is designed to ensure a continuing supply of devices to both the Swiss and EU markets. Medtech companies should familiarise themselves with the new requirements of the ClinO-MD to ensure a smooth transition to the ClinO-MD and to keep their products on the market.

**The views expressed in this article are exclusively those of the authors and do not necessarily reflect those of Sidley Austin LLP, its partners, and its clients. This article has been prepared for informational purposes only and does not constitute legal advice.This information is not intended to create, and receipt of it does not constitute, a lawyer-client relationship. Readers should not act upon this without seeking advice from professional advisers.*