SIDLEY

New Swiss Rules on Clinical Evaluations and Investigations of Medical Devices: Important Changes Around the Corner

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Swiss legislation is being amended to include new comprehensive rules on medical devices. The new rules are intended to provide greater clarity and harmonization for the Swiss medtech industry. Some of the new rules are set out in the Ordinance on Clinical Trials with Medical Devices (ClinO-MD), which will introduce requirements regarding the conduct of clinical evaluations and investigations for medical devices in Switzerland.

Most requirements in the draft ClinO-MD mirror those set out in Chapter VI of the Medical Devices Regulation (MDR) and are essentially aligned with international standards for the conduct of clinical investigations with medical devices, such as ISO 14155:2011 and the Declaration of Helsinki. It is expected that the ClinO-MD will apply on the same date as the MDR, May 26, 2020. Medtech companies conducting clinical investigations with medical devices in Switzerland should be particularly aware of the following requirements in the draft ClinO-MD, which is expected to be adopted in its current format.

Clinical Evaluations

(a) *"Currently available alternative treatment option."* The clinical evaluation of a device will have to consider any currently available alternative treatment option (art. 44(2) of the draft Medical Devices Ordinance (MedDO) stating that art. 61 of the MDR is applicable in Switzerland). While this new requirement may appear burdensome for companies evaluating the risks and benefits of their devices, a well-executed clinical evaluation plan is likely to guide many companies through otherwise difficult conversations with their notified bodies and competent authorities.

(b) *Equivalence*. The draft ClinO-MD significantly reduces the possibility for companies to rely on existing data to claim equivalence of devices. The new rules state that devices for which equivalency is claimed must share the same technical, biological and clinical characteristics. In the past few years, the European Commission's MEDDEV 2.7/1 (rev. 4) guidance on clinical evaluations already tightened the requirements for the demonstration of equivalence in the EU. Although MEDDEV guidelines are not directly binding for devices placed on the Swiss market, they are considered as best practices that Swiss medical devices manufacturers should follow. The European Commission is supposed to publish additional guidance on the interpretation of "equivalence," which will indirectly apply to the Swiss medtech industry.

(c) *Premarket*. The draft ClinO-MD contains new minimum requirements for premarket clinical data with a reference to Annex XV, Chapter II, of the MDR.

(d) *Postmarket*. Manufacturers of medical devices will have to notify the competent authorities about the conduct of all post market clinical investigations.

(e) *Monitoring*. Sponsors of clinical investigations will have to designate a monitor—who will be independent from the investigational site—to ensure compliance with the clinical investigation plan, the principles of good clinical practice and applicable law.

(f) *Protection of personal data*. The new ClinO-MD's requirements contain stricter requirements for the protection of personal data, in the context of the alignment of the Swiss data protection legislation with the EU General Data Protection Regulation.

(g) *Eudamed*. Sponsors of clinical investigations conducted in more than one member state of the European Economic Area or in Switzerland will be allowed to use Eudamed for the submission of applications for clinical investigations centrally, vigilance reporting and submission of clinical investigation data.