SIDLEY

Switzerland: Public Consultation on Draft of New In Vitro Diagnostic Ordinance

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Since 2002, based on a mutual recognition agreement between the European Union (EU) and Switzerland (MRA), Swiss manufacturers of *in vitro* diagnostic medical devices (IVD) are able to participate in the European single market for medical devices without having to overcome technical hurdles their EU competitors do not have to face, and vice versa. The basis for this mutual market access is the equivalence of the EU and Swiss regulations in the field of IVDs.

In 2017, the EU put into force its new regulations on medical devices and IVD. This development obligated the Swiss government to adapt the Swiss regulation accordingly in order not to put the MRA in jeopardy. In a first step, the Federal Counsel issued new Ordinances on Medical Devices (MDO) and on Clinical Research with Medical Devices (ClinO-MD) that will become applicable on May 26, 2021.

Adaptation of the Swiss Regulation to the EU IVDR

The transition of the new EU regulatory framework for IVDs, the IVDR, into Swiss law will be achieved through a further Ordinance on *in vitro* Diagnostics (IVDO) and a revision of the ClinO-MD. On April 14, 2021, the Federal Counsel put drafts for both legal texts into public consultation until July 14, 2021 (the respective documents can be found here, albeit only in German, French, and Italian).

Of course, this consultation procedure and the draft legislation discussed below will have no influence whatsoever on the still unresolved question whether the MRA will be revised so as to continue to provide the necessary basis for a mutual EU/Swiss market access for medical devices including IVD.

The draft of the IVDO contains the key elements of the IVDR and refers to the latter throughout the legal text.

In a transitional provision, the IVDO amends the MDO in some instances, notably these:

(i) regarding the point in time when medical devices are perceived to have been put on the market if they are sold online to Swiss consumers

(ii) obligating economic operators (according to the definition of the term in the MDR and IVDR) as well as healthcare organizations (HCOs) to file the unique device identifiers of implantable products of class III

(iii) allowing importers to deviate from the principle that the information for use for medical devices put on the Swiss market has to be supplied in German, French, and Italian in certain cases

(iv) imposing on economic operators as well as professional users, HCOs, and IT service providers the obligations to cooperate with the competent authorities and to inform them about possible contraventions of the regulations and risks emanating from medical devices

Adaptation of the ClinO-MD

Based on the proposed amendments to the ClinO-MD, clinical studies for medical devices and performance studies for IVDs form the two parts of the legal definition of clinical trials. Performance studies will be submitted to approximately the same regulatory framework as clinical studies with medical devices and are classified within the same categories of clinical trials.

The Federal Counsel intends to put these legal texts, finalized on the basis of the public consultation, into force on May 26 2022, that is, on the date the IVDR becomes applicable.