SCTO PLATFORMS

Stakeholders’ views on the Swiss draft ordinances on medical devices

Regulatory Affairs Platform of the SCTO
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To provide our readers with a good forecast of the changes ahead, the RA Watch editorial team asked different representatives – of the ethics committees umbrella organisation, the industry, and the SCTO network of CTUs – their views about the two ordinances proposed for consultation by the Federal Office of Public Health (FOPH). Their views and opinions refer to the drafted versions of the Medical Devices Ordinance (MedDO) and the ordinance on clinical trials for medical devices (ClinO-MD) as open to comments on 15 May 2019.

We asked the stakeholders to identify: three crowning features of the ordinances, key modifications they thought necessary, and two central consequences they would expect, as a result of the changing of the laws.

The SCTO and its network of CTUs commented only on the ClinO-MD.

Three crowning features

For your organisation, what do you believe will be the three most positive features of the draft ordinances currently underway?

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- The two new ordinances will be essential to keeping the equivalence with the EU Regulation.
- As for ClinO-MD, we believe it makes sense that not only the *safety* of medical devices be assessed, but that also their *efficacy* be systematically proven (as is the practice for investigational medicinal products), including in the post-market phase.
- The shift to full electronic systems will be warmly welcomed.

Swiss Medtech

- For both MedDO and ClinO-MD: Fortunately, both ordinances already contain many references to articles of the Medical Devices Regulation (MDR). These points provide the best guarantee of implementation equivalency with the EU.
- ClinO-MD: This ordinance has been designed specifically for the clinical trials of medical devices. It will thus enable Switzerland to fully harmonise its handling of clinical trials with EU laws – from the first application request, right through to the completion of a trial.
- ClinO-MD: This version released for consultation already provides Switzerland with the possibility of participating in coordinated assessment procedures for clinical investigations – one submission of an application of a clinical investigation to be conducted in more than one EU Member State. As a result, the Swiss competent authority is already able to establish the corresponding procedures – in good time, without needing so much time as to depend on the deadline of May 2027.

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- ClinO-MD: The future harmonisation with the EU is welcome. More rigorous clinical evaluations and investigations will be of benefit to the quality of medical devices and to patients' safety. Furthermore, harmonised rules will make it easier to run multicentre clinical studies, having sites in both the EU and Switzerland.
- ClinO-MD: We are in favour of the increased transparency guaranteed by the traceability of individual devices and the publication of information regarding clinical trials and their results.
- ClinO-MD: Having an ordinance specifically for clinical trials for medical devices will make it easier to identify and understand the given requirements.

Possible modifications

Can you mention three points of these ordinances that you believe should be modified?

swissethics

- swissethics and Swissmedic are working closely together to guarantee that the interfaces connecting Eudamed with the Swissmedic portal and with the Business Administration System for Ethics Committees (BASEC, the online platform for submitting research projects to Swiss ethics committees) will be ready on time and function smoothly.
- The cantons and the ethics committees will face additional costs. These are the current costs of building the interfaces, future costs for their maintenance, and those for the maintenance of the Swiss electronic portals. How these costs will be divided and borne needs to be addressed.

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- MedDO and ClinO-MD: Both ordinances should function, even without an MRA. If the MRA is not updated before the Swiss ordinances enter into force, individual passages of the regulations will:
  a) be partially non applicable, e.g. ClinO-MD: category C1 or C2 clinical trials for CE marking purpose (conformity-related trials) may not be carried out in a legally binding manner,
  b) contradict the MDR, e.g. the MedDO: the obligation to register a Swiss importer in Eudamed is not in line with the registration of the EU importer, as defined in the MDR, or
  c) affect the current safety standards, e.g. MedDO: the obligation to report incidents and field safety corrective actions is now only applicable for Switzerland. As a consequence, Swiss manufacturers are no longer required to inform the Swiss competent authority about field safety corrective actions that are implemented in the EU.
- MedDO and ClinO-MD: The terminology in both ordinances must be fully aligned with the MDR. A respectable adaptation has already been carried out, but some terms still vary. For example, the differing usages of “supply” (termed “Abgabe” in the German version), appearing in the definition of “making available on the market”, could lead to considerable uncertainty in Switzerland.
- ClinO-MD: Deadlines and trial procedures should be 100% aligned with MDR. Regarding deadlines, it would be sensible to align all the national options for deadline extensions with the EU regulation. Full compliance with the EU regulation should be the goal, with regard to trial procedures, too. For example, individualised time slot extensions to authorise “first-in-human trials” appears to be a national matter.

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- ClinO-MD: Several aspects bringing a worrisome complexity should be rethought: the proposed categorisation system which take into account both the current categorisation defined by the ClinO (A and C categories) and the MDR; the multiple data processing systems (BASEC, the Swissmedic system, and Eudamed); the multiple and short deadlines.
- ClinO-MD: The readability of the text should be greatly improved by incorporating important references (such as the ISO 14155:2011 standard or the applicable provisions) in the text itself.
- ClinO-MD: Before this new ordinance comes into force, the competent authorities will need to make available to researchers appropriate, easy-to-use, and interoperably robust processes, with good explanatory and supporting documents to ensure the transition is as smooth as possible.

Expected consequence

What are the two most likely consequences of the changing laws for your organisation?

swissethics

- The ethics committees will be required to carry out a more comprehensive review of the applications than they have done to date with the current legislation.
- The challenges are the new categorisation, which is not easy to convey in a simple and concise way, and to ensure that the members and the scientific secretariats of the ethics committees have the necessary expertise to handle these complex applications.

Swiss Medtech

- As an association, we share our findings together with other associations to receive remarkable support in extending the existing consultation drafts – to ensure their functionality, even without the MRA.
- As far as manufacturers are concerned, we inform them that the EU acceptance of conformity-related trials is uncertain at the moment – when applications are submitted to the Swiss competent authority.

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- ClinO-MD: Possibly the number of clinical trials to perform with medical devices in our CTUs will increase. More certain to increase will be their complexity and the associated administrative tasks with constraints in term of costs and resources. We must prevent the discouraging of investigator-initiated trials and of scientific innovation in Switzerland, more broadly.
- The SCTO, through its CTUs, will support academic researchers as they endeavour to apply this new ordinance to their work. We will consider providing training, regulatory guidance, and services for the running of clinical trials with medical devices.