

Switzerland: Update on Life Sciences Regulations — It's Not All About COVID-19

[Andreas Balsiger Betts](#)

Introduction

The Swiss medtech sector is still hoping that the EU will not add insult to injury by declaring Switzerland a “third country” when it comes to the common market for medical devices after the much stricter EU Medical Devices Regulation (MDR) becomes applicable on May 26, 2021. The Swiss Federal Council seems to be optimistic that it will not come to the worst — or how else to interpret that it decided that the new Swiss medical devices legislation will come into force in parallel with the MDR?

In another show of optimism, the Federal Council submitted a revision of the Swiss narcotics regulation to the Swiss Parliament with which the use of cannabis in medicinal products should become legal.

New Swiss Medical Devices Regulation Coming Into Force on May 26, 2021

The Swiss medtech sector is still hoping that it will be able to compete on an even playing field in the EU. This would not be the case if the EU should decide that the Swiss medical devices regulation is not equivalent with the MDR. If the EU should declare that Switzerland is a “third country” with regard to medical devices, the Swiss manufacturers would have to meet substantial additional technical hurdles. They would notably have to appoint an EU-based authorized representative for all their products put on the EU market and bear the considerable costs resulting from this.

The Swiss Federal Council seems to be optimistic that the issues between Switzerland and the EU threatening the discontinuation of the free access Swiss manufacturers currently have to the European common market can be resolved in time. This, at least, is one way to interpret the Federal Council's decision of July 1, 2020, to put the new Ordinance on Medical Devices and the revised Ordinance on Clinical Trials with Medical Devices in force on May 26, 2021. Both ordinances were drafted on the basis of the MDR and with the objective to keep the Swiss medical devices regulation equivalent to the MDR.

But perhaps this decision is only a signal to the EU and the concerned Swiss industry that the Federal Council will do everything it can to get the treaty with the EU on the mutual recognition of conformity assessments updated in due time. Otherwise, over 5 billion Euros worth of exports to the EU and over 2 billion Euros worth of medical devices imported from the EU would be put in jeopardy.

The Swiss Ordinance on In Vitro Diagnostics (IVD) is still in the legislative process but should be ready to be put into force on May 26, 2022, in parallel to the respective new IVD regulation of the EU.

Sidley Austin LLP provides this information as a service to clients and other friends for educational purposes only. It should not be construed or relied on as legal advice or to create a lawyer-client relationship. Readers should not act upon this information without seeking advice from professional advisers. In addition, this information was not intended or written to be used, and cannot be used, by any person for the purpose of avoiding any U.S. federal, state or local tax penalties that may be imposed on such person. Attorney Advertising—Sidley Austin LLP, One South Dearborn, Chicago, IL 60603. +1 312 853 7000. Sidley and Sidley Austin refer to Sidley Austin LLP and affiliated partnerships, as explained at www.sidley.com/disclaimer.

Drugs in Drugs: Draft Legislation for Use of Cannabis in Medicinal Products

In Switzerland, at least in the Swiss Parliament, the question whether the use of cannabis, containing more than 1% of the psychoactive component tetrahydrocannabinol, in medicinal products should be allowed, has been discussed controversially for decades.

According to current Swiss law, cannabis is a prohibited narcotic. It is subject to a comprehensive traffic ban. Cannabis may not be grown, processed, imported, or passed on. This state of the legislation also influences the medical use of cannabis, which is very limited and subject to individual, exceptional approvals from the Federal Office of Public Health (FOPH). The demand for the use of cannabis for therapeutic reasons has grown exponentially during recent years, and in 2019 the FOPH issued close to 3,000 “exceptional” approvals to physicians wanting to treat a patient with cannabis.

The discussions about the medical use of cannabis will flare up when the dispatch the Federal Council issued on June 24, 2020, containing a draft for a revised Federal [Act on Narcotics and Psychotropic Substances](#) will be discussed in the Swiss Parliament. The revision centers on lifting the traffic ban on narcotics of the type of cannabis for medical purposes. If Parliament agrees, growing, processing, importing, and exporting cannabis for medical purposes will be allowed, and medicinal products containing cannabis will be subject to the market surveillance and marketing authorization system of ordinary drugs.

Still open is the question of whether the costs for therapies with medicinal products containing cannabis shall be reimbursed.