

## Oxygen for the Industry Providing Ventilators: EU Commission to Propose New Date for MDR Implementation

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### Introduction

These days, the strain on medical devices manufacturers is manifold. However, there might be some relief regarding one big headache: the imminent implementation of the new EU Medical Devices Regulation (**MDR**). On March 25, exactly two months before the planned end of the Medical Devices Directive, the current, “old” EU regulation on medical devices, the EU Commission let it be [known](#) that it was working hard on a proposal to postpone the implementation of the MDR by one year. With this spectacular move, the EU Commission breathes some badly needed air into the lungs of a struggling industry. For Switzerland’s medtech industry, the postponement could be particularly beneficial, as it gives the European Union and Switzerland the leeway to come to terms on the pending Institutional Framework Agreement (**IFA**) whose conclusion is an EU-imposed condition for revising the Mutual Recognition Agreement that is the basis for Swiss medtech manufacturers’ participation in the EU market for medical devices.

### Many hounds soon catch the hare

The medical devices industry in Europe currently faces a plethora of challenges. Since May 2017, the manufacturers of medical devices have invested huge amounts of money and human resources in order to adapt to the MDR. Especially for small and medium-sized enterprises (SME), which represent more than 90% of the industry, the investments needed are barely sustainable, and they are fighting for their survival. Furthermore, this struggle takes place on uneven ground, as guidance on important issues is still missing. On top of that, the measures taken by the different governments in order to contain COVID-19 have a negative effect on the supply-chain and production lines of medtech manufacturers. And at the same time, the governments beg the industry to increase its output because much-needed medical devices are missing in clinics all around the globe (as governments and healthcare systems did not prepare in time for a possible pandemic).

Each of these issues is a challenge to the industry as a whole and to each manufacturer. They can be overcome in due time but not at the same time. Asking the industry to do the latter risks disrupting the whole system.

### EU’s answers to requests for postponement of MDR

Already before COVID-19 struck, there were repeated complaints by the industry about the feasibility of MDR’s application as of May 26, 2020, and many a manufacturer secretly hoped there would be some delay. However, the EU Commission seemed impervious to requests for a prolongation of the implementation period.

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After the COVID-19 pandemic was declared, industry associations like MedTech Europe, BVMed and Swiss Medtech formally requested that the implementation of MDR be extended for six months after the date the WHO declares the pandemic to be over.

It seems that the EU Commission now agrees. As it stated on March 25, it is working on a proposal to the European Council and the European Parliament to move the date when the MDR will become applicable from May 26, 2020 to May 26, 2021 (there is no mention of the IVDR, so presumably it will not be covered by this proposal). The Commission plans to submit the proposal in early April, hoping that a final decision can be made within that month.

Provided the COVID-19 pandemic will not stop public life, hinder industry production and demand increased output of medical devices like ventilators, masks, etc. longer than autumn 2020, the Commission's proposal should give the industry the necessary time to regroup and prepare for the MDR implementation. If, however, the pandemic should haunt us for longer than we expect and hope, then the EU Commission hopefully will work on a further prolongation.

## **Two sides of the coin**

If the expected prolongation gives some relief to EU medical devices manufacturers, it might be a relief for Switzerland and its manufacturers. As reported in our [September 2019 Briefing](#), the European Union firmly linked the acceptance of the EU/Swiss IFA to its readiness to review the MRA with Switzerland regarding medical devices, in its own a pre-condition for a barrier-free participation of Swiss medtech manufacturers in the EU market. There are some elements in the draft IFA that are questioned by a majority of the Swiss political parties. Furthermore, and more importantly, the Swiss citizens will have to vote on a popular initiative demanding that the whole set of bilateral agreements between Switzerland and the European Union, i.e., also the MRA regarding medical devices, be terminated. The date for this popular vote was set for May 17, 2020. Although the general expectation is that the initiative will be rejected, the Swiss government and the European Union decided on a truce regarding the IFA until the vote.

However, in view of the COVID-19 pandemic, on March 18, the Swiss government had to make the decision to cancel the public vote on May 17. Currently, there is no new date, but it will be set as soon as the end of strict containment measures is foreseeable. If it should be possible to still hold the vote this year, there would be enough time for Switzerland and the EU to hopefully agree on the IFA and thus open the door for the revision of the MRA. Nobody should get their hopes too high, but still, there is a silver lining on the horizon.