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Postponement of EU Medical Device Regulation implementation due to COVID-19

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In extraordinary times, extraordinary measures have to be taken. As of today, the European Parliament has decided to postpone the transition timeline to implement the EU Medical Device Regulation, which would have expired on 26 May 2020 until 26 May 2021. The postponement allows the healthcare systems to devote their efforts to the fight against the COVID-19 pandemic. Read about the consequences below.

Introduction

Healthcare systems across the globe are fighting one of the worst pandemics in recent history. According to the trade association MedTech Europe's (**MTE**) press release of 23 May 2020, the medical technology industry is currently fully engaged in supporting these efforts by providing personal protective equipment and medical devices to healthcare workers, hospitals and patients. At the same time, the medtech industry needs to maintain seamless availability of all medical technologies needed to diagnose, treat and monitor patients suffering from other critical or chronic health conditions. This is severely disrupting healthcare / life sciences stakeholders' efforts to implement the new Medical Device Regulation (**MDR**), which will replace the current Medical Device Directive (**MDD**), within the fixed transition timeline, which was meant to expire on 26 May 2020, respectively on 26 May 2022 with regard to the implementation of the In Vitro Diagnostics Regulation (**IVDR**) (MDR and IVDR together EU Medical Device Revision, **EU MDR**).

The EU MDR is key to ensure patient health and safety, i.e. protection from defective medical devices, and increase transparency on medical devices across the EU. Inter alia, the new EU MDR provides for additional obligations for economic operators, particularly with regard to the traceability of medical devices after they have been placed on the market. Furthermore, it strengthens obligations regarding vigilance (i.e. monitoring the medical devices and reporting incidents), lays more stringent criteria in the certification of medical devices down and regulates the approval of clinical trials. The revision has been triggered by various serious incidents in the past like defective silicone breast implants or defective hip prostheses.

Switzerland is adapting its regulations for medical devices to the EU MDR for the benefit of Swiss patient interests and to ensure future EU market access for the Swiss medical device industry. To implement the EU MDR in Switzerland, a total revision of the Medical Devices Ordinance (**MedDO**) and the introduction of a new Ordinance on Clinical Trials for Medical Devices (**CTMedDO**) as well as several adaptions to the Therapeutic Products Act (**TPA**) and the Human Research Act (**HRA**) with its related Ordinances are necessary. The intention has been to implement the new Swiss medical devices legislation simultaneously to the implementation of the EU MDR. Moreover, several adaptions to the Mutual Recognition Agreement in relation to conformity assessment (**MRA**) between Switzerland and the EU, whose provisions in Chapter 4 for medical devices were to expire on 25 May 2020, need to be negotiated in order to introduce mutual obligations and to ensure Switzerland's continued participation as an equal partner in the European internal market (all Swiss legislation which has to be implemented / amended for compliance with the EU MDR together Swiss Medical Device Revision, **Swiss MDR**, further information here).

Recent Developments

As of 20 March 2020, MTE has requested a temporary postponement and resumption for the national implementation of the MDR and the IVDR six months after the COVID-19 pandemic has passed. Swiss MedTech, a member of MTE, has welcomed MTE's proposal, since maintaining maximum liability of all medical technologies necessary has become top priority. The European Commission has followed MTE's example and has submitted a proposal to the European Parliament and Council (together **EU Institutions**) on 3 April 2020 to postpone the MDR application date for one year. The European Commission's proposal has focussed only on the postponement of the MDR application and did not include any proposal to postpone the implementation timeline of the IVDR which expires on 26 May 2022 (whole proposal here).

In the light of the imminent MDR timeline, the EU Institutions have treated the Commission's proposal with priority and have adopted the proposal through an accelerated co-decision procedure. The EU Council has already stated its support in early April. As of today, the EU Parliament has voted by urgent procedure in an extraordinary plenary on the recent legislative proposal and has decided with a majority to postpone the application of the MDR for one year until 26 May 2021 (more than 99% voted in favour of the postponement). The date of application of the IVDR is not affected by the decision and becomes therefore applicable from 26 May 2022, as planned. Through its decision, the EU Parliament has not only extended the MDRs transition timeline but has also stated to postpone the date of repeal of the MDD by one year to safeguard an effective regulatory framework for medical devices.

Impacts of Postponement

The postponement strives for patient health and safety as a guiding principle. It is certain that the effect of the COVID-19 on the medtech industry at the time of implementation of a major overhaul of its regulatory system would have had a detrimental impact on availability of life-saving medical technologies. The decided postponement will relieve pressure from national authorities, notified bodies, manufacturers and other involved actors and will allow them to fully focus on urgent priorities related to COVID-19. The decided postponement seeks to temporarily alleviate the burden on available resources but efforts already taken to the implementation will not be lost, they will be used for a longer upgrade and transition of the system.

The MRA ensures that Swiss manufactures have the same access to the EU market as their EU or EEA competitors and covers more than a quarter of the value of all Swiss exports to the EU, and more than a third of all imports of goods from the EU (further information here). Due to the decided postponement of the EU MDR, the status quo of Switzerland under the current MRA appears questionable and will not automatically remain during the extended timeframe, since the EU Institutions have not explicitly addressed the future role of Switzerland within its decision-procedure.

The responsibility of the amendment of MRA's provisions on medical devices between Switzerland and the EU lies with the State Secretariat for Economic Affairs (**SECO**). According to our inquiry at the SECO, it assumes that the postponement of the EU MDR implementation timeline has the following consequences: (i) the extended implementation timeline also applies to Switzerland and (ii) the provisions in Chapter 4 for medical devices of the MRA will continue to apply beyond the stipulated date of application on 25 May 2020 until 25 May 2021. Upon request, the Federal Office of Public Health (**FOPH**), the competent Swiss authority for the amendments of the Swiss MDR, has stated that discussions with the EU on updating the MRA are ongoing and that the Federal Council has prepared appropriate measures for all eventualities. According to the FOPH, it remains Switzerland's primary objective to maintain equivalence with the EU law. Yesterday the FOPH has announced that if the postponement of the EU MDR is confirmed, Switzerland will follow the European solution and postpone the implementation of the Swiss MDR by one year. The implementation modalities are currently being prepared by the FOPH and will be communicated in due course. According to the FOPH, the postponement of the MDR in the EU also means that the current MRA would remain valid beyond 25 May 2020 (Switzerland would thus not be considered a third country until 25 May 2021). As matters currently stand, Swiss authorities are taking any effort to ensure that Switzerland continues to be regarded as an equivalent trading partner within the EU internal market, even during this postponement phase. As soon as Switzerland and the EU have released a common understanding, we will update you by means of a short addendum to this Newsletter.

Conclusion

The decided postponement of the MDR implementation timeline until 26 May 2021 is welcomed by national authorities, notified bodies, manufacturers and other involved actors, also in Switzerland. Given the current situation and taking into consideration the common global target to fight the current COVID-19 pandemic and its numerous consequences on the healthcare systems, the postponement is the right decision. Today's postponement decision means with a very high likeliness that (i) the implementation of the Swiss MDR is postponed accordingly and (ii) the provisions in Chapter 4 for medical devices of the MRA will continue to apply until 25 May 2021.