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Addendum to Life Science Law Newsletter No. 3

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

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As of this week, the former implementation timeline of the EU Medical Device Regulation (MDR) would have expired. As indicated in our Life Science Law Newsletter No. 3, we would like to update you by means of a short addendum to this Newsletter.

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As of this week, the former implementation timeline of the EU MDR would have expired. As already addressed by our Life Science Law Newsletter No. 3, the European Parliament has decided on 17 April 2020 to postpone the transition timeline to implement the EU MDR, 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 and takes the pressure off national authorities, notified bodies, manufacturers and other involved actors. On 24 April 2020, the EU MDR postponement entered into force on the day of its publication in the Official Journal of the European Union Link.

Although there is no official statement from the EU, the competent **Swiss authorities consider it as granted that the status quo regarding medical devices continues to apply to Switzerland.** Upon our inquiry, the Federal Office of Public Health (**FOPH**) and the State Secretariat for Economic Affairs (**SECO**) have confirmed the following presumed consequences for the Swiss medtech industry:

i. the extended implementation timeline also applies to Switzerland, as a result of which medical devices may be placed on the EU internal market until 25 May 2021 under the current European and Swiss legal framework; and

ii. the current legal framework also includes the current Mutual Recognition Agreement (**MRA**) between Switzerland and the EU. Thus, the provisions in Chapter 4 of the MRA for medical devices will continue to apply beyond the stipulated date of application on 25 May 2020, until 25 May 2021.

Consequently, medical devices can still be placed on the EU internal market until 25 May 2021 as before, i.e. without having to meet the EU requirements. Therefore, according to the FOPH, the entering into force of the revised Swiss medical device legislation, which should have been implemented as of this week (e.g. Therapeutic Products Act [TPA], Human Research Act [HRA] and related Ordinances), has also been postponed for one year to maintain equivalence with the EU law. The SECO has stated that the adaption of the MRA between Switzerland and the EU was their highest priority. However, Swiss Medtech recommends Swiss companies to consider that the MRA might not be updated within one year. Should this be the case, all medical devices would have to meet the EU requirements in one year at the latest to continually and successfully be placed on the EU internal market.

According to a survey Link initiated by Swiss Medtech in March 2020, most of the Swiss medtech industry actors consider it feasible to be compliant with EU requirements by May 2021.