Schweizerisches Heilmittelinstitut
Institut suisse des produits thérapeutiques
Istituto svizzero per gli agenti terapeutici
Swiss Agency for Therapeutic Products

MDR/IVDR amendment: Equivalence with EU Regulation on Medical Devices ensured

During the transitional phase, until the Medical Devices Ordinance (MedDO) and the Ordinance on In Vitro Diagnostic Medical Devices (IvDO) are amended, Swissmedic is already going ahead with enforcement according to the EU amendment to avoid jeopardising the supply of medical devices in Switzerland.

In the EU, amendments of the EU-MDR 2017/745 regarding transitional periods for certificates, and of the EU-MDR and EU-IVDR 2017/746 regarding the elimination of deadlines for putting devices into service and placing on the market, were published on 20th March 2023. In view of bottlenecks at the notified bodies, these amendments implemented a number of measures in the EU, including extension – under certain circumstances – of the validity of certificates issued under the old legislation until 2027/2028 (depending on classification) and lifting of the deadlines for putting into service and placing on the market (EU-MDR and EU-IVDR).

In its media release dated 29 March 2023, the Federal Council stated that these amendments must also be implemented in Switzerland to avoid any potential supply shortages. Amendment of the MedDO and IvDO is planned for autumn 2023.

Until then, as part of its enforcement of therapeutic products legislation, Swissmedic will tolerate the placement of devices on the market in Switzerland which are covered by a valid certificate according to the MDR and IVDR amendments. Anticipating the amendments to the ordinances in enforcement prevents discrepancies in market supply conditions between Switzerland and the EU and ensures legal compliance during the transitional phase. These measures ensure that the devices marketed in the EU continue to be available for Swiss patients. Thus, the issuing of confirmation letters in accordance with the EU position paper MDCG 2022-18 is now also unnecessary in Switzerland.

Swissmedic will base its enforcement on the relevant EU interpretation documents.

Swissmedic is responsible for market surveillance in Switzerland. It may at any time order corrective measures in the context of a review procedure if necessary and in the interests of protecting health.

https://www.swissmedic.ch/content/swissmedic/en/home/medical-devices/market-access/abgelaufene_bescheinigungen.html