SWISS MEDTECH

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Policies to guide implementation of Motion 20.3211

Motion 20.3211 (Damian Müller) «For more room for manoeuvre in the procurement of medical devices for the care of the Swiss population»

On 28 November 2022, Parliament passed Councillor of States Damian Müller's Motion 20.3211 titled «For more room for manoeuvre in the procurement of medical devices for the care of the Swiss population». This tasks the Federal Council with amending national legislation in such a way that, in addition to medical devices with the European CE mark, Switzerland also recognises medical devices from non-European regulatory systems with comparably strict requirements – in particular, medical devices authorised for the USA by the Food & Drug Administration (FDA). Swiss Medtech expects the Federal Council to implement the parliamentary mandate swiftly and efficiently, and to observe the following three key principles.

Medical devices authorised in the USA may be utilised in Switzerland.

Medical devices in the USA must meet high safety and performance requirements. Switzerland can trust the US regulatory system (Regulatory Reliance). Medical devices that are legally authorised in the USA for the US population do not, under any circumstances, require a second approval procedure in Switzerland. The Motion should therefore be implemented without transposition. This means that no U.S. law should be incorporated into Swiss law and no references to U.S. law should be made.

National laws will only be adapted where absolutely necessary.

The legislative amendment should be limited solely to implementation of the Motion. It should be clear and comprehensible for all stakeholders. A legal review of relevant provisions in the Therapeutic Products Act (TPA) found that revising the TPA is not absolutely necessary in order to recognise medical devices with FDA approval in Switzerland. The necessary legal adjustments can be made at ordinance level. This satisfies the need for rapid implementation of the parliamentary mandate in view of the current critical supply situation.

The underlying concept can be applied for other non-European systems.

Implementation of the Motion must be forward looking. It must ensure that, in addition to medical devices with FDA approval, medical devices from other non-European regulatory systems may be recognised in Switzerland in the future. This should already be considered today. A legal expansion to other systems should be achievable without a fundamental overall revision.

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