Abstract

The recent COVID-19 pandemic, the impact of climate change as well as unrest around the world have repeatedly highlighted the importance of responding swiftly to unanticipated medical needs and supply shortages. International cooperation and reliance on other systems were crucial to address those needs and secure safe medical products for all. In Europe, medical device manufactures struggling with the teething troubles that accompany a young regulatory system are looking to access more predictable markets elsewhere. As international regulatory cooperation is gaining momentum and access to the domestic market involves a certain waywardness, the Swiss medical device manufacturer Effectum Medical is also planning to tap into markets outside of Europe. This thesis aims to develop a strategy for the internationalisation of a system for the market authorisation of medical devices based on concepts of regulatory cooperation and taking into account specific manufacturer constellations. Based on the review of such concepts of regulatory cooperation and a country-specific analysis regarding the presence of the same it was possible to identify regions that may be more easily accessible than others along with a list of established and emerging reference regulatory systems. It is recommended that obtaining market authorisations from such reference authorities are obtained first because other regulators may rely on the output of these reference authorities and offer simplified pathways based on their assessments. The preconditions for efficient internationalisation in a company and Effectum Medical's quality management system in particular were examined alongside potential challenges and opportunities that may arise in the context of internationalisation. While the company's quality management system is in a good position for further internationalisation, special attention needs to be paid to the supply chain situation and related procedures. Once a certified quality management system that addresses requirements of multiple reference authorities is in place, solid local networks of economic operators have been established, and the focus on low to medium risk devices is kept, time to market for certain products in certain regions can be reduced considerably. An internationalisation scheme is proposed for a Swiss manufacturer based on reliance mechanisms that prioritises market authorisation in the EU and the U.S. as a first step, followed by Australia and Singapore in a second step, and tapping into the greater Asian market as well as into South America in a third step. As there is a lot of movement with regard to trade agreements, mutual recognition agreements and other reliance mechanisms, it is vital that these be monitored on a regular basis in order to be able to leverage resulting simplified pathways for the advancement of the company's internationalisation efforts.