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Swiss Medtechs Contrast EU MDR 'Chaos' With Picture Of US Regulatory Efficiency

The EU is dropping down the list of launch markets for medtech innovation

by Ashley Yeo

The ongoing failure of Swiss and European Commission decision makers to resolve the issue of Switzerland's institutional agreement is hampering EU market access for Swiss innovators like IVDs company Abionic. More pressingly, the EU must address the wider issue of the MDR's negative impact on innovation and start-ups, says Abionic co-founder Iwan Märki.

Swiss medtech innovators find themselves between two stools – one in Brussels and the other in Berne. Politicians on both sides are unable or unwilling to resolve the thorny issue of Switzerland's institutional agreement with the EU, and for the medtech industry, the EU-Swiss mutual recognition agreement (MRA).

Lausanne-based *Abionic SA* has a pancreatic stone protein (PSP) test on its abioSCOPE platform to detect sepsis in the ICU. The company's co-founder Iwan Märki spelt out for *Medtech Insight* how the EU's medical device regulations, the MDR and IVDR, are having negative impacts on the ability of start-ups to access the EU market. By contrast, the US is being seen as a more compelling launch market for EU and Swiss innovators alike.

Under the EU MDR and IVDR, and in the absence of the MRA, new products developed in Switzerland must be submitted to notified bodies in the EU to receive CE marking. But there are at present only 10 notified bodies for IVDs under the IVDR , and the process under the IVDR takes 12-18 months, Märki said.

"If you are a young company without big revenue support, it is difficult to come to the EU market – even if you have everything ready and in place," he added. "The cycle up to the market is becoming too long in Europe, which has meant companies have looked to the US." (Also see

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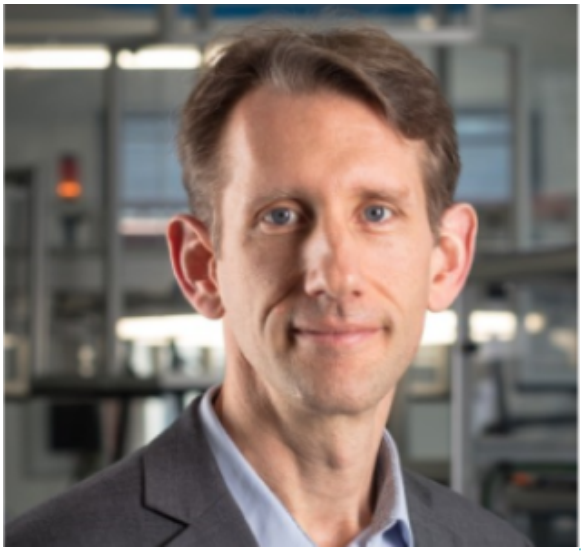

IWAN MAERKI

"*Switzerland: US FDA's Medtech Can Bridge Innovation Gap Left By MDR*" - Medtech Insight, 22 Mar, 2023.)

Most of Abionic's range is in classes B to D under the IVDR. Its reader device is a class A IVD device, which is a self-declaration. But only 20% of IVDs across the industry fall under class A under the IVDR; the other 80% of IVDs in classes B, C and D require notified body input.

Abionic has CE-marked its sepsis test under the IVDR. For other portfolio products, the company achieved CE markings under the precursor IVDD. "Now, with the extended transition times we can keep them on the market," the co-founder said

Swiss notified bodies (which have dwindled in number) cannot be used for innovations by Swiss based companies – they must use an EU-based notified body, increasing the time and expense. The US has in contrast become an attractive launch market. "Even the bigger companies are saying they will focus more on the US for innovative products and only later come back to the EU market." (Also see "*Switzerland: US FDA's Medtech Can Bridge Innovation Gap Left By MDR*" - Medtech Insight, 22 Mar, 2023.)

Märki continued: "In the US, the FDA turnaround for companies is 90 days for a 510(k)." In future, if, as envisaged, the Swiss parliament approves the proposal to allow US-registered medtech onto the Swiss market, Swiss medtech innovations could in theory reach the local market via the US and with a shorter lead time than in the EU.

"It makes sense for Switzerland to have this option if we are not integrated in the EU. It would open a door to big companies in the US as well as well as in Switzerland to use this route and bring innovative products to Switzerland," Märki said.

EU Must Reopen Door To Medtech Innovation

Crucially, the EU must address the topic of innovation, Märki said. With its strong twin regulations, the EU has more or less closed the door on – or considerably slowed – innovation, he added, urging politicians to find an approach that allows innovation to get to the EU market faster.

If not, and the EU cannot find a way to accept innovate products more easily, "the EU will be one of the last markets to receive new products." He added: "Eventually they will have to address this issue because they will see innovation shifting into the US or other markets."

A recent article in *Neue Zürcher Zeitung*, also citing Märki, was critical of how the EU's medtech "regulatory chaos" was leading to bottlenecks in Switzerland.

What the trigger for change will be, and when, is not known. But it is known that Swiss politics can be quite complex, making for slow progress in terms of negotiations, reaching agreements and finding common ground.

Avoid A Repeat Of A Bitter Experience

Yet the EU can also go fast in regulatory terms, as seen during the COVID pandemic.

However, EU/Swiss political misalignment has already impacted Abionic negatively on one particular occasion, as the company found when it fell foul of changing protocols in the EU for COVID diagnostic listings. In not using an EU lab to validate its diagnostic, Abionic's test was held up while testing had to be redone.

It was a bitter experience for a company who had complied with the rules but was a little delayed in bringing its diagnostic forward for a listing. By the time it did, the Swiss authorities had abandoned their own listing and decide to use the EU's alone. "A political decision impacted us heavily and meant that we were almost 18 months behind in being allowed to put the test on the market," Märki observed.

He warned that similarly needless disruption should not happen for EU medtech innovation in the wider sense.