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Hot from the press!

The New, Stringent MDR and IVDR Regulations: Viewing this Change as an Opportunity

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Abstract: The healthcare and life science sector is growing inexorably, and is now a multi-billion dollar industry. In 2016 the companies in this sector posted sales of USD 140 billion, and their profitability more than doubled by comparison with 2010. The pharmaceutical, diagnostics, medtech and chemical sectors have become Switzerland's most powerful export industry, and significant number of approved medications and diagnostics contain biotech elements.

Today biotechnology is a multi-billion dollar industry that has achieved its profitability target. The sector has an annual turnover of some USD 140 billion (2016). This is more than double the 2010 figure, and is set for further growth. But the future will bring obstructions on the way to the market. Regulation has been tightened up, and activity on the regulatory front has risen to fever pitch. Multinational organizations are seeking close cooperation with small and medium enterprises (SMEs) as they have lost some of the necessary elbow room for innovation. Although no objections can be levelled against quality assurance and quality control, the question is whether the growing regulation will strike a fatal blow to creative and innovative spirit in Europe.

New regulations – incalculable effects

The current EU regulations for medical devices (MDR) and *in vitro* diagnostics (IVDR) have been in force since 25 May 2017, but many affected companies do not know what the requirements to be met are. All companies will have to comply with the new MDR and IVDR as of 26 May 2020 and 26 May 2022 respectively. Depending on the risk classification of the products, the IVDR stipulates how manufacturers have to provide proof of product safety, performance and quality. Many medtech products are affected by this new classification, which extends from class A (low risk) to class D (highest risk). New and still more demanding requirements are to come. As this '*sine qua non*' will affect many products simultaneously, massive delays will occur due to a lack of resources both at the 'Notified Bodies' (Conformity Assessment Bodies) that have to carry out conformity assessments and at all manufacturers. Even optimizing a product proves time-consuming and expensive.

This situation is particularly sensitive for diagnostic companies: they complain that some of their products will be up-classified from lowest-class (class A) devices – *i.e.* where only a limited amount of data is required – to class D, the highest risk class, where a great deal of data is required. The truth is that today's EU regulation (directive 98/79/EC on *in vitro* diagnostic medical devices) does not recognize high-risk diagnostics and thus these products are classified as lowest-risk applications, which satisfies the needs of the diagnostic industry. As a partner to the pharmaceutical industry you can develop such companion tests with less effort. Or, in other words: given the nature of the risk in question, tests should be graded considerably higher, but the fact that they are classified as lower-risk means they can be

produced more cheaply. Manufacturers are thus able to put such risky products on the market without the involvement of a control body that assesses data.

A look behind the scenes

But even companies that have behaved correctly will find that things become difficult. We will take an example from practice and talk to BÜHLMANN LABS, an independent, medium-sized and family-owned Swiss company, which, within just a few years, has become the prime supplier of calprotectin. Dr **Thomas Hafen**, the company's CEO, is increasingly concerned about the growing amount of regulation in the industry. Let's look at ISO 13485, the Quality Management System for manufacturers, intended for organizations engaged in both the development and manufacture of medical devices. "When it comes to quality management and regulatory affairs, anyone who wants to be a player here must run their business like a Champions League football club, even if the team plays in the lower league", says Thomas Hafen, who studied International Affairs at the University of St Gallen and has worked for the Swiss State Secretary for Economic Affairs. "Large corporations and regulators set the hurdles so high that many SMEs will be forced to give up. The big corporations play the regulators' game because it results in less competition and creates competitive advantages for them. That's what we are seeing with the new IVDR but also in other domains like REACH (Registration, Evaluation, Authorization and Restriction of Chemicals), an area of EU regulation, or the EU Privacy Policy, to name but two. What can we do about it, given that our main market is Europe?"

The new regulations will presumably create thousands of new jobs in the regulatory segment. Thomas Hafen is dismayed: "Who will pay for that?" Experts think that about a third of all IVDs and a third of all IVD companies will disappear from the market in the next four years, *i.e.* until the transition period for IVDR expires. "The companies to survive will be the 'big boys', who can absorb costs more easily than the 'little guys' thanks to their economies of scale. How can we curb this excessive regulatory zeal?"

Another development is that big companies sometimes seek collaboration with SMEs because – in their own words – they are no longer in a position to develop innovative solutions within a reasonable time. "Internal bureaucracy is overwhelming them!" warns Thomas Hafen. "Because of this situation, the market for diagnostics and medtech products has deteriorated: there is less competition and innovative products are becoming few and far between."

Another consideration is that when SMEs are forced out of the market by the big boys, all the niche products with high patient value, which do not interest large companies, will be eliminated at the expense of patients.

Shared concerns in Brussels

Thomas Hafen is not alone in foreseeing the dangers. "The IVDR requires developers of diagnostics to collect evidence demonstrating a clinical benefit, and changes classifications that affect product certification renewal", says **Serge Bernasconi**, CEO of MedTech Europe. "What's more, under the IVDR, around 80% of IVD products will require CE approval issued

by a Notified Body for the first time. Depending on how much it costs to obtain the required clinical evidence, for instance, companies may decide it makes more sense to divest an asset than invest in the mandatory product changes. While the costs of implementing the MDR and IVDR are significant no matter how big manufacturers are, they are particularly challenging for smaller players. But these smaller medical device players are the lifeblood of innovation!" The impact is huge, as these regulations could negatively affect the financing of innovation, too, as Serge Bernasconi says: "Venture capitalists are already asking tough questions about the capacity of medtech innovators to develop and market their products under the new regulations. The cost of launching products in Europe is going to go up!"

Let's roll up our sleeves!

Peter Biedermann, Managing Director of SWISS MEDTECH and his team, will not just stand by and watch this happen. At SWISSEXPO on March 28, 2018 he organized the second National Conference on the new EU regulations entitled *Impact on Switzerland*. "Industry representatives and users got together with experts from the authorities and Notified Bodies to analyze the status of implementation in Europe and Switzerland", explains Peter Biedermann. "The program also included discussion forums and information services. It was a chance for decision-makers and executives to obtain and share information, as well as to become actively involved with specialists in this rather complicated area." To ensure efficiency, SWISS MEDTECH is cooperating with four Federal agencies to arrange lectures and discussions on removing obstacles to trade.

Peter Biedermann has strong support from **Peter Studer**, Head of Regulatory Affairs at SWISS MEDTECH. Drawing on his extensive experience, he is suggesting exchange programs and cooperation between the SMEs concerned, both among medtech companies and those in the IVD sector who are involved with medtech products on the market. "The upcoming changes require an open approach and above all openness to dialogue" explains Peter Studer, coordinator of the Swiss Implementation Task Force. "Everybody can put his hands on it, whether competent authorities or Notified Bodies, especially all the biotech companies and other business players with medical device products." Together with the internationally operating Helbling Group, SWISS MEDTECH is preparing questions concerning the impact of the MDR and IVDR on the new SMTI report (*Schweizer Medizintechnik Industrie Branchenstudie 2017*) due to be published at the end of 2018. Peter Studer doesn't mince his words: "Once we have this study and see the answers from participating companies, we can prioritize and focus the task force's activities in a more evidence-based way." And he continues: "These new EU regulations will ensure that product transparency continues to increase – that's something we owe to society today. But instead

of complaining we should sit together and think about how we can handle the situation." That sounds very optimistic, but it is going to be a tough time, especially for small and medium-sized businesses – and even the very dynamic ones!

Viewing change as an opportunity

"The prevailing uncertainty among companies – especially SMEs – regarding the MDR/IVDR is understandable as the changes will be substantial", admits **Shayesteh Fürst-Ladani**, founder and CEO of SFL (Solutions for Life Sciences) in Basel. Her team provides companies with global strategic support for the development of healthcare products. "We have been involved in discussions about the new MDR/IVDR since 2010, *i.e.* since before the first drafts of the regulations were published in 2012. Further details on the MDR/IVDR will be published in implementing ordinances, before full implementation of the MDR in 2020 and the IVDR in 2022". Under certain circumstances, devices and diagnostics may remain on the market until 2024/2025, which gives industry another 6/7 years to achieve full compliance with the new EU-wide regulations. **Karin Schulze**, Head of Medical Devices and Combination Products at SFL adds: "In particular, *in vitro* diagnostics companies are facing dramatic changes as the reclassification changes the situation entirely: it is estimated that about 80% of their products need a Notified Body for market approval".

"The change affects everybody" says Shayesteh Fürst-Ladani, who has extensive experience in negotiating on behalf of companies at a senior level in meetings with regulators. "Companies have to ask themselves if they want to continue in this sector and, if so, what their success hinges on. In doing so, they can improve their processes and optimize product portfolios in light of ongoing developments so that they continue to offer patient benefit and keep abreast of competitors. Several companies have already begun to evaluate their product portfolio; this may be an opportunity for SMEs. It's true that the new regulations mean adjusting business strategy and will impose a new financial burden, but Switzerland lives through innovation, has always been flexible and has adapted to new situations quickly. We may also see this change as a chance to boost innovation and stand out from the other markets".

Note: The interviewees have reviewed and accepted all statements made in the interview.

Further information:

<http://www.bbbiotech.ch/de/bb-biotech/biotech-sektor/sector-inzahlen/>

www.swissmedic.ch: 'New ordinances regarding MDR / IVDR'

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