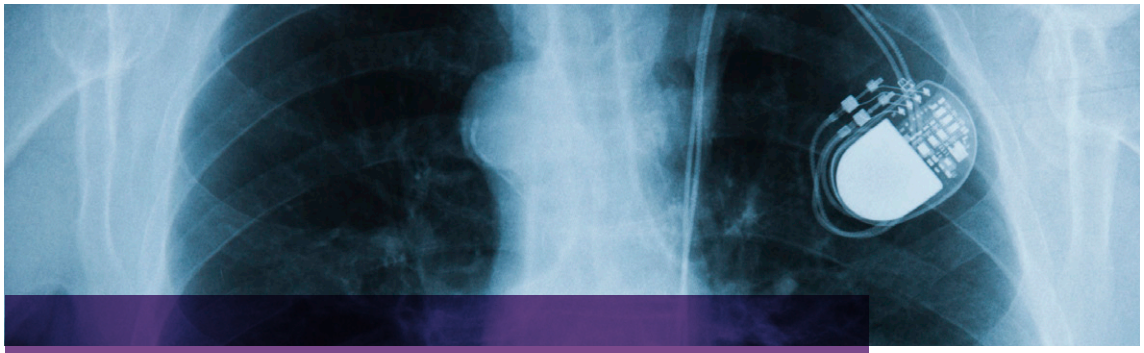
Gimv Insights

Useful business insights that inform our investment strategy



Med-Tech Innovation in Germany as Reference Case for Europe: Who Will Pay the Bill?

We are pleased to share the sixth edition of Gimv's Insights. In addition to a brief update on Gimv's strategy and portfolio, our goal is to provide you with a number of important business insights that illustrate our investment strategy. In this edition we take a closer look at healthcare innovation from a German perspective, specifically because it illustrates a wider trend that all med-tech companies need to be aware of.

We hope you enjoy the article.

Kind regards from the Gimv team

MED-TECH IN GERMANY

Med-Tech Innovation in Germany as Reference Case for Europe: Who Will Pay the Bill?

Imagine you are diagnosed with a rare and potentially fatal disease that requires treatments costing hundreds of thousands that you do not have. Should tax payers - through publically funded health insurance - be obliged to carry that cost? "It depends", you may think, on factors such as how old you are and how effective the treatment is. But how should such decisions be made, and who should be burdened with making such life and death decisions?

Over the last decade, German policy makers have been introducing new legislation that starts to address exactly these questions. Unsurprisingly, such initiatives are proving contentious, not only because they pose fundamental ethical questions about healthcare entitlement, but also because they **determine how innovations in medical technology** (in the broadest sense, including pharmaceuticals, medical devices and procedures) **gain access to the market, how they are priced, and thus ultimately how innovation is rewarded and incentivised**.

Germany is Europe's largest market and most important reference point for pricing medical technology elsewhere in the EU. Many innovative medical device companies from around the world have used Germany as entry market, given a) the easy approval process for medical devices through the CE marking procedure, which is mainly focused on safety (rather than clinical benefit) as compared to the centralized FDA approval process in the US, and b) given the ability for fast market entry.

Hence, the new evolutions matter a great deal to the entire medical technology industry.

Gimv's Health & Care investment team is watching these developments closely. To explore the challenges and opportunities in med-tech innovation we recently organised **a panel debate** with Dr. Timo Krüger (CEO of medical device company Fiagon AG), Prof. Dr. Herbert Rebscher (Chairman of the Board of health insurance fund DAK), Prof. Dr. Volker Ulrich (a prominent health economist lecturing at the University of Bayreuth), and Dr. Karl Nägler (Partner Health & Care at Gimv). The event took place at the "Hörsaalruine des Berliner Medizinhistorischen Museums der Charité" in Berlin and was attended by 30 senior executives of medical device companies.

Panel members (in the photo from left to right): Prof. Dr. Herbert Rebscher (Chairman of the Board, DAK), Dr. Timo Krüger (CEO, Fiagon AG), Prof. Dr. Volker Ulrich (health economist, University Bayreuth), Dr. Karl Nägler (Partner, Gimv Health & Care)

Questions of Quality and Cost

There are two underlying challenges driving the impetus for new legislation: one, ensuring quality, and two, controlling costs.

1. Rebuilding Trust through Regulation

The recent scandal of defective breast implants manufactured by a French company has understandably horrified the general public and eroded trust in the quality of medical devices. In Europe, medical device products must be CE marked by an authorized national entity in a European member state before they can be legally used in the market. The evaluation procedure is often subcontracted to private firms, so-called Notified Bodies. This process, which also applies to high-risk medical devices (such as implants), is criticized as being far less stringent than the FDA-governed process in the US, with some in our panel debate comparing it to the process of registering an electric toaster.

Moreover, some panel members pointed to the lack of registries that monitor the use of high-risk medical devices, making it nearly impossible to monitor the longer-term outcomes of say artificial hip implants. **Prof. Rebscher** argued in this regard that while hospitals might be driven to buy the lowest-cost implants, for patients and insurers it might be worthwhile to pay more for better quality, especially if this can reduce the risk of having to be re-operated in a few years. The problem is that today it is impossible to make such decisions, since in the absence of registries it is difficult to compare the longer-term performance of different devices.

As a result of such concerns, in 2012 the EU Commission has advised member states to improve market vigilance and has provided a draft for a new Medical Device Regulation. One of the changes it foresees is a scrutiny process, enabling authorities to take a second look at the Notified Body's review of high risk devices. However, there also are calls to reform the system entirely by centralising the regulatory approval process at a European level and bring it in line with the way pharmaceutical products are regulated. While there are as of yet no concrete plans to implement such a system, Prof. Rebscher was convinced that within the next few years there will be a centralised procedure for approval of medical devices. Moreover, he argued that this was both desirable and necessary.

> "Today it is impossible to make quality based decisions, since in the absence of registries it is difficult to compare the longer-term performance of different devices."
>
> ***Prof. Dr. Herbert Rebscher*** *- Chairman of the Board, DAK*

2. Sustainable Healthcare through Systematic Cost-Benefit Assessment

As pointed out by our panel moderator, **Prof. Dr. Volker Ulrich**, the cost-efficiency of healthcare is an increasingly pressing issue for policy makers. Demographic trends such as an ageing population and the increasing prevalence of chronic diseases, in combination with ongoing advances in medical technology, will ensure continued growth in the demand for healthcare services. Since public coffers will not be able to cope with uncontrolled growth in healthcare

spending, some hard decisions will need to be made about how society places a value on particular healthcare services. How do we decide which treatments will be reimbursed using public funds, in which contexts (for which patient groups), and by how much (pricing)?

In response to such questions, policy makers in Germany (as elsewhere in EU) are taking recourse to Health Technology Assessments (HTA) to inform decision making. HTA is a process that tries to evaluate not only the medical but also the social and economic benefits of a particular health technology. In essence, it tries to support decision making in healthcare using a broader cost-benefits perspective. Germany has taken several important steps towards the use of HTA, in 2004 by establishing the Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG), and in 2011 by enacting the Law on the Reorganisation of the Pharmaceutical Market (AMNOG), which is a significant change in the country's pharmaceutical pricing policy for innovative medicines.

> "How to decide which treatments will be reimbursed using public funds, in which contexts (for which patient groups), and by how much (pricing)?"
>
> ***Prof. Dr. Volker Ulrich*** *- Health Economist, University Bayreuth*

Today, if a pharmaceutical company aims to introduce a new drug in the German market that product will first be subjected to a benefit assessment by IQWiG. If the assessment concludes that the new drug has no additional benefits compared to a 'comparator' product already in the market (which often is a cheap generic product), then the government will negotiate significant price rebates or ensure that the cost of the product is not covered by public funds. This has made market access in Germany significantly more difficult and in some cases has led manufacturers to withdraw new products from the German market. A number of pharmaceutical companies are currently lobbying the German government to reform the system because they argue it stifles innovation.

But instead of backtracking, the German government is in fact aiming to extend this HTA-based approach to cover not only drugs but also other health technologies, including medical devices and medical procedures, a trend that we anticipated in our white paper: "Die neue Realität im Gesundheitswesen". In October 2014, a proposal for new legislation was submitted to the German Parliament ("Referentenentwurf zum Versorgungsstärkungsgesetz"), which would make HTA assessments a prerequisite for new high-risk medical devices being eligible for reimbursement through the so-called NUB (Neue Untersuchungs- und Behandlungsmethoden) procedure. This procedure allows for accelerated reimbursement of innovative devices used in hospitals.

When this new legislation comes into effect, it would mean that access to the largest EU market for medical device manufacturers is conditional on providing data that go beyond safety, and include demonstrating effectiveness through an HTA. In other words, the onus is now also on medical device manufacturers to prove that their new products deliver the best patient outcomes and the most cost effective solution for all concerned.

The Elephant in the Room: How to Ensure Continued Innovation

While increasingly stringent regulation of medical technologies and HTA-inspired approaches to pricing and reimbursement policy may make sense from a consumers' and payer's perspective (as argued by Professor Rebscher in the panel discussion), these do create new challenges for medical device manufacturers. **Dr. Timo Krüger** argued that most young med-tech companies do not have the resources, nor the time from a competitive perspective, to collect the vast amounts of data required for comprehensive cost-benefits assessments. Neither was Dr. Krüger in favour of a centralised regulatory approval process for medical devices, arguing that it would make the process more time consuming and expensive than it currently already is.

> "Young med-tech companies do not have the resources, nor the time from a competitive perspective, to collect the vast amounts of data required for comprehensive cost-benefits assessments."
>
> ***Dr. Timo Krüger*** *- CEO, Fiagon AG*

Indeed, in the pursuit of more stringent and systematic healthcare decision making, payers and policy makers are leaving unanswered the question of how innovation in medical technology will be effected. **Dr. Karl Nägler** pointed out that compared to the pharmaceutical sector, the medical devices sector is a far more heterogeneous industry consisting of much smaller and more diverse companies. How can young innovative med-tech companies ensure that they survive that period of accumulating data for the regulatory approval and HTA procedures? How will they fund it? And what extra competencies do they need to build the health economics case of their products? In sum, how will business models in the sector need to evolve to ensure continued innovation and the building of strong investment cases?

It is clear that young med-tech companies must have opportunities to test their products in actual clinical settings and conduct necessary clinical research, before full regulatory approval and reimbursement is granted. Furthermore, they will need a measure of financial support to help fund that process. In other words, healthcare providers and clinicians should have opportunities to experiment with new innovative devices (in controlled settings) and the use of such technology should be reimbursed. The use of medical device registries could be particularly helpful for research purposes, to ease the burden of expensive clinical trials.

At Gimv we recognise the need for a more stringent and cost-orientated regulatory environment. The key stakeholders in the sector, however, all have a responsibility to ensure that innovation is not stifled in the process.

Collaborations with insurance companies are important as these are well placed to help medical technology companies build a strong health economics case. The panel debate organized by Gimv is useful in this regard, as a means to stimulate dialogue between innovators and investors on the one hand and payers on the other.

Finally, as investors we also play an important role supporting innovation in the med-tech sector. In this regard we have created a dedicated Health & Care investment platform that builds on our industry know-how, and thus allows us to play a more active advisory role, helping our portfolio companies navigate the regulatory environment and build a robust business model. Indeed, at Gimv our strategy is to focus on companies that can improve healthcare at reduced or same cost, in other words, companies that are well positioned in the current (and future) regulatory environment. Our strength is that we can support our portfolio companies in that journey.

WHERE WE COME IN

Health & care investment platform

The consequences of ageing and an increasingly health- and cost-conscious population are driving up demand for medical products and services. This is creating opportunities for Gimv to invest in ground-breaking life science research, innovative medical technology and pioneering concepts and business models in the broader health & care industry.

The Gimv Health & Care platform is therefore built around these three segments: Life Sciences, Medtech and Health & Care Services. In each of these, Gimv will look for companies with innovative technologies or business models; companies that have the capability to grow their business significantly, either organically or through a buy-and build strategy.

GIMV NEWS

Gimv News

- 3 December 2014 - Gimv invests EUR 7 million in the international expansion of Well Services Group, service provider to the oil and gas industry
- 28 November 2014 - Gimv sells its stake in EBT to the SEA-invest group
- 28 November 2014 - Gimv supports growth of Mackevision, a 3D visualization specialist
- 25 November 2014 - Melijoe.com raises EUR 9 million in a capital increase led by Gimv
- 24 November 2014 - Gimv successfully exits Prosensa
- 20 November 2014 - Increased operating profits in portfolio companies and profitable divestments give first-half profit of EUR 48.5 million - Net assets up 4.9% (EUR 39.46 per share)
- 12 November 2014 - Gimv invests in specialty chemicals formulator EcoChem International

Portfolio Company News

- 4 December 2014 - Onedirect elected best e-commerce site for professionals
- 4 December 2014 - McPhy Energy: Prix de l'introduction en bourse 2014