Eine Kooperation von

Interview
Gottfried Ludewig,
German Ministry of Health

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The Accelerator Act
Digital healthcare
The Accelerator Act

With the new German Digital Health Care Act, the digital health scene is gaining momentum. Medtech industry representatives agree that we are heading in the right direction, but that there is room for improvement when it comes to the details.

The German Digital Care Act (DVG) and corresponding “better care through digitisation and innovation” law was very much anticipated by the medical technology sector. Hopes are high that digital healthcare in Germany will finally gain momentum and not fall behind at an international level. Public health insurance funds should now be able to reimburse digital applications such as digital therapeutics and telehealth video consultation hours for the first time. Gottfried Ludewig, Head of the Digitization Department at the German Federal Ministry of Health (BMG) comments that “Our task must be to offer everyone the most promising technologies, if they specifically improve healthcare outcomes. Thanks to the DVG, this will now include apps” (see his interview in page 4). He also sees this as an opportunity for innovative companies that previously were more likely to first enter the US or Chinese markets because of the high barriers to entry in Germany. Now, they will be able to bring their products and services to the German market more easily.

Critics say scope is too narrow

The lower barrier to entry and patient-friendly approach makes it possible “for novel solutions to actually find their way into the care system”, comments Marc-Pierre Möll, Managing Director of BVMed. However, the Medtech Association criticises the scope of the regulations as it only applies to medical device classes I and IIa and would not cover higher risk classes IIb and III. “The DVG only grants the right to medical devices with the simplest digital
technology,” says Natalie Gladkov, BVMed’s expert for digital medical devices. “The possibilities offered by digital health applications for the improvement of care and care processes cannot be bolstered at all.” Because of this, the industry is calling for an extension to higher risk classes, such as products that also measure and control vital physiological parameters.

Many digital health applications offered by BVMed members fall under these higher risk classes, such as software or apps that process information from other medical products like pacemakers or insulin pumps, before this information is sent back to the doctor or patient. The app itself, like the pacemaker, belongs in Class III and therefore would not be covered under the DVG’s scope. According to the BVMed, these additional tools “are suitable to uncover complications in the supply or to increase the compliance of the patient.” Based on the new EU Medical Devices Directive (MDR) only a few digital products remain in the lower risk classes. “The DVG must therefore be adapted urgently,” says Möll.

Fast cost-benefit-analysis by BfArM

It remains to be seen whether changes will be coming in the near future. In November, the German parliament has passed the bill. In mid-October, a hearing took place in the health committee of the Bundestag, the German parliament. Much of the criticism revolves around the details of the new cost-benefit-analysis of digital medical devices. The DVG proposes a new “accelerated procedure” and instead of keeping it within the self-governing administration in the health care system as before, the Federal Institute for Drugs and Medical Devices (BfArM) will check the application for data security and functionality. For a period of one year, the product will then be provisionally reimbursed by the public health insurance scheme (GKV). During this time, the manufacturer must prove positive beneficial effects. Afterwards, the manufacturer will have to negotiate pricing with the GKV point federation. Currently there are no plans to extend this process to high-risk products in line with BVMed demands. Even the proposed regulation is causing criticism by both the health insurance companies and physicians. According to them, the criteria for the inclusion of medical devices in the BfArM’s scheduled list of digital care offerings is insufficient and they oppose to an approval system without including physicians.

Lack of clarity around guidelines and standards

Many digital health start-ups have a positive attitude towards the DVG, but they still struggle with the specifics of implementation. “We need a success-based reimbursement system that takes into account the added medical value that we create with our digital solutions for patients,” stresses Jesaja Brinkmann, founder of HiDoc Technologies GmbH. The issue of guidelines and standards has also yet to be clarified in many cases (see page 5). This topic is already on the BMG agenda, as digital expert Gottfried Ludewig emphasises: “Nowadays, data often does not flow the way we want it to. That’s why we will continue to increase our speed.” Investor Anke Caßing from High-Tech Gründerfonds believes the DVG is on the right track: “Everything may not yet be perfect, but it offers a great opportunity to break new ground.”

About the DVG

On 7th November, the German Parliament has passed the Digital Care Act (Digitale-Versorgungsgesetz, DVG, DS 19/13438). It will come into effect in January 2020.

More information:
www.bundesgesundheitsministerium.de
**MEDTECH RADAR |** Mr. Ludewig, where does Germany stand in terms of digital healthcare?

Gottfried Ludewig | We haven’t reached our goal yet. But we are on the right track. In the past two years we have launched several legislative initiatives. We have started projects in the field of artificial intelligence and initiated a future workshop around blockchain. And we want to continue at this pace: whether its electronic patient records, electronic prescriptions, or data use.

**MEDTECH RADAR |** What specific benefits should the Digital Care Act bring to patients?

Gottfried Ludewig | Patients should benefit from the progress of digitalisation as soon as possible. This is the guiding principle of the Digital Care Act. The ‘app on prescription’ is the best example of this: for digital products that have been shown to be useful in studies, for example in the treatment of chronic diseases, there is no clear path to reimbursement by public health insurance today. We think this is wrong. Our task must be to offer whatever is technically possible to everyone if it improves healthcare outcomes and proves it. This will now also be possible for apps thanks to the DVG.

**MEDTECH RADAR |** Do you expect the introduction of DVG to boost innovation?

Gottfried Ludewig | So far it has been almost impossible for German start-ups in the healthcare sector to launch their product on the German market. This is changing with the DVG. In a few years’ time, we’ll see whether that’s there will have been developed more innovative solutions. What is clear is that insured people in Germany will now have better access to innovations.

**MEDTECH RADAR |** The DVG is to become a research data centre. What should this infrastructure achieve?

Gottfried Ludewig | Large, comparable and structured amounts of data form the basis for qualitative leaps in medical care. With the Research Data Centre, for the first time we want to establish a centre that bundles the accounting data of all the health insurance companies and makes it possible to research institutions anonymously.

**MEDTECH RADAR |** What would have to change in Germany – even beyond the DGV – in terms of developing the conditions for the advancement of digital healthcare?

Gottfried Ludewig | The topic of interoperability and open interfaces is clearly one of them. Nowadays, data often doesn’t flow the way we want it to. The Americans have provided a good example of how regulatory intervention can enforce interface openness. There is also still a lot to be done regarding data donations and the standardization of data. The world is not waiting for us. We want to shape the digitalisation of the healthcare system in Germany and Europe ourselves and not just tolerate it from outside. That is why we will continue to increase our speed.
START-UP PERSPECTIVE

Shaping the digital change

Digital health start-ups welcome the DVG as the right step forward. But they demand clearer guidelines and constructive dialogue on an equal footing.

From a start-up’s perspective, the draft of the new DVG law represents a major step forward. Nevertheless, founders see areas where changes are needed. "We need binding specifications, uniform deadlines and clear regulations," urges Jesaja Brinkmann, Co-Founder of HiDoc Technologies GmbH and Florian Koerber, Managing Director of the migraine app developer M-sense. They add, that “it is good to formulate an entitlement to performance for digital applications. However, at the same time we also need appropriate conditions for reporting." For many of the young entrepreneurs it is still unclear as to how they should go about evidence procedures and success-based reimbursement of achievements whilst securing the liquidity of their companies.

Creating positive incentives

The sanction system is also viewed with scepticism. "Instead of initiating penalty and dunning procedures for the lack-of-use of digital solutions, we should create positive incentives and consider a reward system," emphasises Farina Schurzfeld, co-founder of Selfapy, an app which offers instant digital help for patients with depression. Another key aspect for start-ups is the creation of a networked ecosystem in which doctors are better informed about the new possibilities and where patients are also involved. It is said that patients are significantly underrepresented in current committees and decision-making processes.

With regard to data standards and integration, there is still a need for action as well. Brinkmann, who has been working with the Cara Care software solution for more than three years on digital tool for improved intestinal health, argues that market entry for new software and hardware providers must be made easier: "We need common industry standards and integration."

However, funding support for research and development is also of importance for companies starting out. “The time from research to the application of digital health tools can be incredibly long and can therefore entail risks for start-ups,” says Julian Haupenthal, who develops digital solutions for the early detection and monitoring of memory problems and is co-founder and CTO of Neotiv. “Here we would like to see low-threshold solutions from the German government enable us to evaluate supply routes fast and drive development cycles forward quickly."

Working closely together with start-ups

In addition, they say theory and practice should be thought together more closely. "Initiatives such as the Health Innovation Hub are valuable for dialogue," comments M-sense Managing Director Koerber. “Only together can we make the healthcare system fit for the future.” Constructive exchange and an overarching group of experts, in which start-ups are actively involved, are required.

MedTech Radar Live 2020
9 June 2020, Köln

Save the Date: BVMed, Earlybird Venture Capital, medtech zwo and High-Tech-Gründerfonds will organise again a start-up focused event.

www.medtechradar.live
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Earlybird is a venture capital investor focused on European technology companies. Founded in 1997, Earlybird invests in all growth and development phases of a company.

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The German Medical Technology Association (BVMed) is an industry association that represents over 230 industrial and commercial companies in the medical technology sector. Among its members are 20 of the largest medical device manufacturers worldwide in the field of consumer goods.

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The High-Tech Gründerfonds, an initiative of the Federal Ministry for Economic Affairs and Energy, the KfW and 34 companies, supports young technology companies with seed financing to advance research projects at least until a prototype status or until market entry.

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As an information specialist, BIOCOM AG has supported the life sciences with journals, websites, books and videos for more than 30 years. The magazine medtech zwo reports on recent developments relating to the medtech sectors of Germany, Austria and Switzerland.

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