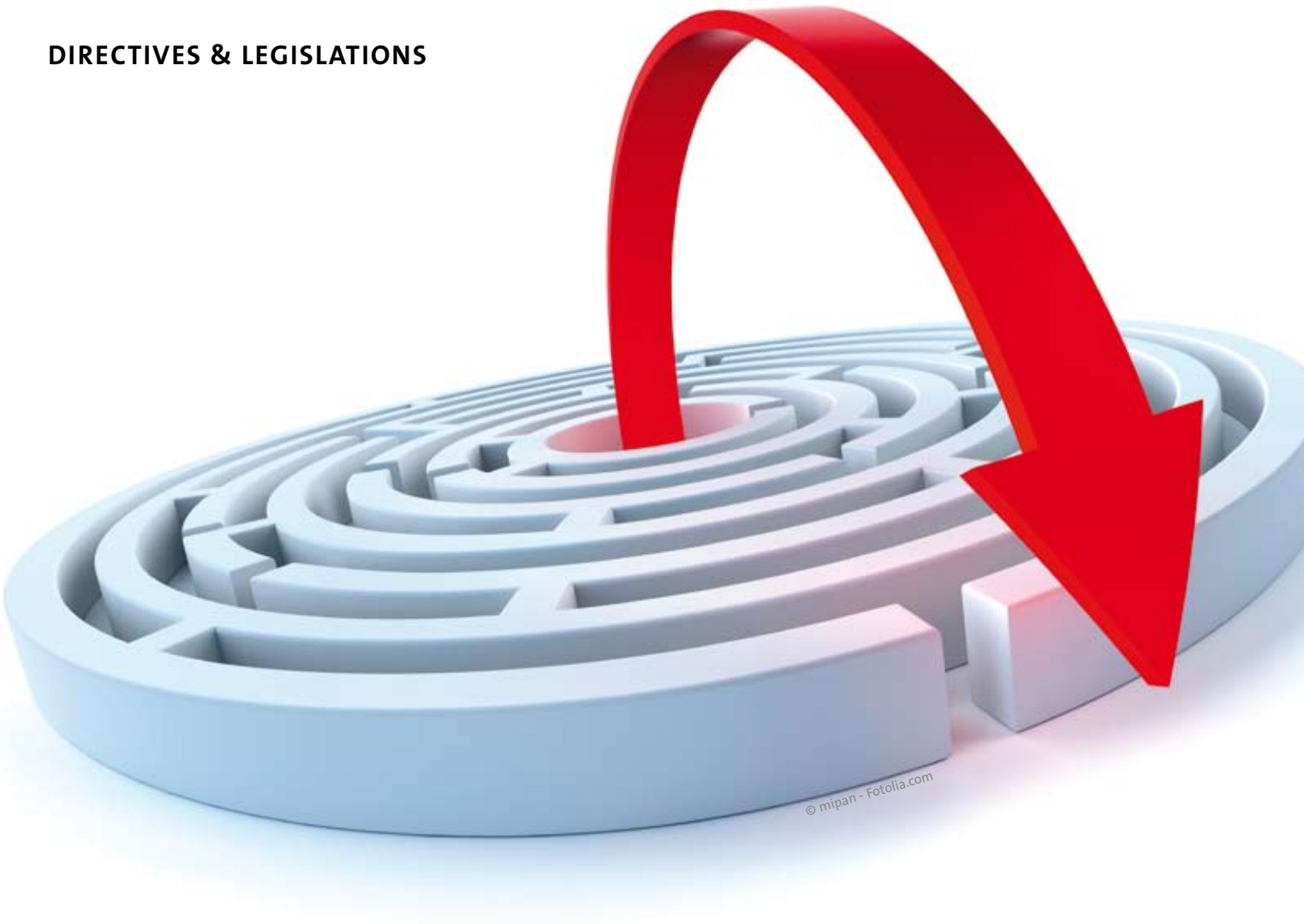

Proving a medical benefit faster

The cost of medical products and devices only becomes classed as eligible for reimbursement if the health system as a whole profits from the innovation and this benefit is also documented. Medtech companies often find it difficult to prove such a benefit because any evaluation of it depends on drugs and accordingly is very closely linked to a direct benefit to the patient. But medtech can also be beneficial, for example when its use relieves a doctor's workload, or helps to simplify the whole clinical process. There is now a new tool for the German Joint Federal Committee (GBA), intended to lighten the burden of proof somewhat in the future.

Medical products and devices gain access to the market in a two-step process. First, there is the marketing authorisation involving the CE symbol. This allows a product on to the market, but in no way does it mean that the cost is eligible for reimbursement. The benefit delivered by the product or device first needs to be assessed and proven in a second step. In Germany, the Institute for Quality and Efficiency in Healthcare (IQWiG) and the G-BA are the authoritative bodies in this process. They assess, test and determine which medtech innovations can be adopted into the cost reimbursement system.

It is comparatively easy for pharmaceutical companies to prove a benefit, because – crudely simplified – a pill is taken and the effect on the patient can be measured. It is equally easy to demonstrate the direct benefit of a heart pacemaker. But with many medical products and devices, more careful thought is needed. Says Stefan Nardi-Hiebl, Director of Siemens Healthcare Consulting, "Even a relatively high degree of patient satisfaction is not covered by clinical parameters. The effects of new technology on organisation, working methods or even efficiency increases and cost reductions achieved through changed methods – these are all values which ought to be taken into consideration as well." And Dr. Cord Schlötelburg, General Manager at the German Association of Biomedical Technology in the Association for Electrical, Electronic & Information Technologies (VDE) says as follows, "It's a complicated issue. Which benefit is relevant? Savings achieved through medical innovations and which benefit society are not taken into consideration at the moment."

Apart from the focus on patients, problems are presented by other aspects of the methodology of actually evalua-

ting benefit. If a new development can prolong the useful working life of an artificial joint for two years, the benefit cannot be demonstrated by referring to the patient. Long-term improvements or a benefit which only becomes apparent later slip through the methodological net. Even high investment costs, such as are incurred in acquiring a magnetic resonance tomography machine with the benefit felt only through the passage of several years, hardly get a look in in the evaluation process, So Stefan Nardi-Hiebl makes a plea for broadening the way in which technology is currently looked at. "Looking at things like that, you never get more than just a snapshot. Instead, the whole process in which medical services are delivered, with technology playing its part, must be integrated in evaluation."

The product lives and innovation cycles of medical devices are also quite different from those of drugs. Whereas the pharma industry can count on approx. 15 years, medical devices generally have approx. five to seven years.

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Dr. Cord Schlötelburg, General Manager at the German Association of Biomedical Technology in the Association for Electrical, Electronic & Information Technologies (VDE) emphasizes, "It's a complicated issue. Which benefit is relevant? Savings achieved through medical innovations and which benefit society are not taken into consideration at the moment."

Products trailing behind markets

Consequently, there is a high risk of medical devices soon becoming obsolete when results only become available after long running product studies. This means simply that there is not enough time for the product in question to be of interest to the market. In many cases, the route from application for reimbursement status to approval is too long, making the process impossible for manufacturers to envisage commercially. This route needs to be shortened.

A solution for precisely this problem seems to be in the offing. There is in fact a draft report from the Federal Minister of Health dated June 2011, the purpose of which is to introduce a new instrument for trialling non-medicational examination and treatment methods for the GBA. Accordingly, the GBA can authorise a procedure for a certain period of time and assess the benefit of an innovative technology (under the conformity procedure) while it is in operation.

In the eyes of the industry, this is a step in the right direction. However, thought still needs to be devoted to the matter of identifying which evidence criteria the medtech industry can supply. This is a matter, considers Dr. Schlötelburg, in which the companies should have greater involvement. "Of course, commercial interests will play their part in this; even so it makes no sense for the industry to be completely cut off from the process. At least, if the industry had the right to sit in on the process, that would improve the situation."

It would be helpful, especially for smaller medtech companies, if the whole process were made more transparent. The underlying conditions are in a constant state of flux, especially since there are several routes to reimbursement, not just one. That is difficult for these companies to grasp. Decisions are often taken at early stages, which then don't have a particularly positive effect on the reimbursement situation later on.

"In the past, patient benefit and added value have been undervalued in the clinical field. They must be valued more highly when considering the market-readiness of technologies." Of that Stefan Nardi-Hiebl is quite sure. He advises smaller companies and start ups in particular to seek advice in good time, "People should start thinking as early as possible about patient benefit and exchange views with patient associations, for example." Even so, Dr. Schlötelburg believes that companies lack a neutral, if at all possible, supply of information, "Because of the dearth of information, manufacturers take one look at the risks and shy away from developing certain things because they cannot count on them ever being eligible for reimbursement. The salient point then is that the patient will ultimately not be able to benefit from the innovation because things don't get that far." At this late point the process becomes an obstacle to innovation, and patient benefit, which no one doubts should be at the centre of activities, gets lost on the way.

Ramona Riesterer ←

German Summary

Medizinprodukte werden nur dann in den Katalog erstattungsfähiger Leistungen aufgenommen, wenn das Gesundheitssystem als Ganzes von der Innovation profitiert und dieser Nutzen auch dokumentiert ist. Dieser Nachweis ist für Medizintechnik häufig nicht einfach, denn die Nutzenbewertung ist an Arzneimitteln angelehnt und dadurch sehr eng mit einem unmittelbaren Patientennutzen verknüpft. Aber Medizintechnik kann auch nützlich sein, wenn sie bspw. zur Entlastung des Arztes führt oder dabei hilft, den klinischen Gesamtprozess zu vereinfachen. Ein neues Instrument für den deutschen GBA (Gemeinsamer Bundesausschuss) soll den Nutzennachweis zukünftig etwas erleichtern. Der deutschsprachige Beitrag ist nachzulesen unter www.meditec-international.com/medi0611gba