

Medical technology in transition – Innovation as the key to sustainable success

Innovation in medical technology offers great potential for the health care system of the future – and great economic opportunities for companies in Germany at the same time. Innovative medical technology makes important contributions towards better patient care, improved quality of life, and independence and social participation in old age.

Germany's medical technology industry is a highly innovative sector with a strong rate of growth. A number of large companies as well as around 1,200 small and medium-sized enterprises (SMEs) are the industry's innovative backbone. With a 66 per cent share of exports in 2011, German companies are well placed internationally and are world leaders in a number of fields. Its many innovative products are the basis for the economic success of the German medical technology industry at home and abroad. In fact, products that are under three years old account for almost a third of turnover.

A number of challenges must be tackled in order to strengthen Germany's position as the leading supplier of medical technology products in the face of international competition and to ensure that German medical technology companies can continue to live up to their reputation as innovators on the world market. In particular, this means increasing the effectiveness of research and development, shortening development times, stepping up investment activities in Germany and ensuring rapid access to a regulated market for innovative medical products which will benefit patients. All stakeholders in the innovation system of medical technology will continue to face increasing demands against the background of demographic change and new health care concepts

which increasingly unite diagnosis, therapy, after-care and rehabilitation and where concepts for individual treatment are becoming more and more important. With its considerable innovative capacity, medical technology can actively shape this change in care concepts and further improve cost-benefit efficiency when using resources in the health care system.

The environment in which innovative medical products are developed is considerably more complex than in many other sectors. This applies at the research and technology level as well as in the context of clinical trials, certification for market access and the development of markets. The three central success factors for strengthening the innovative system of medical technology are the competitiveness of the industry, the efficiency of the health care system and the innovative strength of the research sector. In view of the complexity of the innovation system, it is essential that all groups of stakeholders – despite their very different fields of interest – focus on these key factors for success and aim at joint strategic objectives on this basis. Only if all stakeholders work together constructively Germany will be able to assert its position in the face of global competition in the long term and at the same time contribute towards strengthening its health care system.

It was against this background that the Federal Ministry of Education and Research (BMBF), the Federal Ministry of Health (BMG) and the Federal Ministry of Economics and Technology (BMWi) launched a national strategy process entitled "Innovations in Medical Technology" in June 2011. The aim for representatives of industry, science and the health care system was to draw up joint recommendations for developing the innovative system of medical



technology. As a first step, the strategy process brought together more than 150 experts from the various groups of stakeholders to define the most important challenges and derive recommendations for action.

The results of the discussions are summed up in the final report of this national strategy process and focus in particular on how stakeholders in Germany:

- can increase the competitive ability of this sector;
- can enhance the efficiency of the health care system;
- can reinforce the innovative strength of medical technology research.

Improving the competitiveness of the medical technology sector

The German medical technology sector is facing intensive global competition but still draws a considerable part of its innovative strength from the domestic market. Small and medium-sized enterprises in particular develop and market innovative medical products primarily on the German market. If Germany wants to continue to be a leading supplier of medical technology products, it is important not only to strengthen the sector with regard to exports but also to the domestic market and at the same time improve the efficiency of our health care system. Priority should therefore be given to measures which:

- promote interaction between the medical technology sector and other branches of industry – particularly in the field of information and communication technology;
- establish business models involving several companies, providers and funders; and
- improve framework conditions in order to make clinical trials both effective and affordable.

The industry's competitive and innovative strength is also largely determined by the legal framework. This framework is a constant field of tension: In the first place, it

serves the purpose of ensuring patient safety and a benefit for patients as well as assuring the quality of health care and the efficiency of the health care system. However, this can also contribute to making it more difficult for new products to enter the market. The medical technology industry differs from other sectors in so far as the most significant innovation risks occur at the end of the innovation process. One must therefore consider whether these risks can be reduced without a loss of quality or efficiency in health care. Ensuring patient safety and meeting the demands of needs-based health care are essential criteria. A key role is played by activities that:

- establish an environment that rewards application-based and market-oriented efforts in research and development, creates more incentives for innovations in the market for medical technology and avoids distortions of competition in favour of imitation products;
- improve interaction between the different sectors and thus make greater use of the potential of cross-sectoral innovations; and
- secure the standardized application of EU-wide regulations and promote the harmonization of regulations at international level.

Strengthen the efficiency of the health care system

Innovations in medical technology can only establish themselves if they contribute to an increasing efficiency in the health care system without jeopardizing the affordability of health care as a whole. It is important to continue to improve patient care in general and aim for individual patient benefit in particular. Against this background, research strategies in medical technology should be more needs-oriented than it has been the case in the past. However, this calls for reliable information on the precise quality and benefit of new examination and treatment methods involving innovative medical products in regular treatment. The aim must therefore be to:



- establish a data-based analysis of the care situation as a basis for developing needs-oriented innovation strategies;
- switch the focus of quality evaluation in health care from the analysis of structures and processes to patient-related, outcome-oriented criteria;
- examine the effective use of innovative medical products, not only in clinical studies but also increasingly in everyday care situations; and
- study the potential of medical registers for health care and innovation as well as their benefit within the framework of innovative health care research.

Enhancing the innovative strength of medical technology research in Germany

In order to increase the efficiency of research and development in medical technology it is no longer sufficient to approach new products from a merely technology-driven perspective. Among other things, rising costs in the health care system means that in future it will become increasingly important that innovations meet the demands of everyday health care and are selected accordingly. Here it is an obstacle that it is becoming increasingly difficult to assess the care situation and the regulatory framework for innovative companies. At the same time, medical technological research is becoming increasingly more complex, and research clinics are experiencing growing tension between their twin remits of providing health care on the one hand, and conducting research on the other. This means that the long-standing, successful model of close cooperation between innovators and clinical research in the field of medical technology is more and more at risk.

In order to enhance the innovative strength and sustainability of medical technology research in Germany in the long term, research and development strategies should be geared more strongly towards actual clinical and medical needs than in the past. At the same time, research processes should be designed to be more innovation-

oriented and effective. Furthermore, measures must be taken to tackle the skills shortage in medical-clinical and scientific-technical occupations. Here measures should be taken to:

- improve the market effectiveness of innovation-oriented research funding;
- clearly define concrete needs in the field of health care as a starting point for research funding and design R&D cooperation projects against this background;
- initiate an exchange between industry and health care research as partners and make more targeted use of the respective competencies;
- make optimal use of the limited resource of "medical expertise" for innovation processes; and
- overcome interdisciplinary obstacles in initial and continuing training.

The final report of the national strategy process provides food for thought for all groups of stakeholders regarding the sustainable development of the innovative system of medical technology in Germany. The report is divided into seven chapters – corresponding to the strategic objectives defined in the process. It names the most important challenges and proposes measures for tackling these challenges in a joint effort which involves policy-makers, industry, science and the health care system.

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