



OFFICE OF TECHNOLOGY ASSESSMENT
AT THE GERMAN BUNDESTAG

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Medical technology innovations - challenges for research, economic an health policy

Summary

December 2009
Working report no. 134



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The medical technology industry is regarded as a branch with excellent future prospects, not only because of its strong innovative capability and high knowledge intensity, but its contributions to the healthcare of the entire population imbue medical technology with a growing societal and economic significance. In an international comparison, the German medical technology industry is among the front runners, and even in the most recent economic and financial crisis medical technology was one of the few branches in manufacturing industry that remained on a growth path. On the whole, German medical technology is in a good position – a finding which is based on numerous indicators, such as the strong export orientation, the growth dynamics and the R&D intensity. Simultaneously, the industry is confronted by a series of challenges which result from the increasingly tough international competition, the internationalization of production and marketing structures and the changing framework conditions in the health care system.

OBJECTIVES AND APPROACH

The present TAB policy benchmarking report tackles the question of how the German government should design framework conditions and funding policy for medical technology, in order to better meet the challenges of the future and to lower existing barriers to innovation. Due to the characteristic heterogeneity of the medical technology branch and the complex framework conditions, the design and implementation of consistent policies for medical technology are by themselves great challenges:

- > Compared with other industrial sectors, the medical technology industry is especially complex. The product range is very broad and reaches from everyday medical supplies (e.g. dressing materials, rubber gloves), surgical instruments (e.g. scalpels, forceps), wheel chairs, prostheses, implants, artificial hip joints, heart pacemakers, catheters, and instruments for microtherapy, up to medical devices for diagnostics (among others, ECG and ultrasound equipment, computer tomography and magnetic resonance imaging apparatus, including the necessary software).
- > According to this impressive scope, widely differing qualification profiles are required in the cross-cutting technology that is medical technology, with a view to the knowledge base and R&D processes. Not only is the know-how of medical doctors, engineers, pharmacologists, microsystems technicians, biotechno-



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- logists, microbiologists and technicians required for the successful development of medical devices and their application in health care, but increasingly the intensive interdisciplinary cooperation of these subject areas is indispensable.
- > The complexity is additionally reflected in the diverse regulations. They cover such different areas for instance as clinical research, procedures to obtain market access, pricing and reimbursement of products, or the monitoring of the application in health care.
 - > In addition, the large number of actors participating with their unique structures (e.g. the autonomous self-organization of doctors and health insurance companies in Germany) increase this complexity. The players in the health care system (in particular the insured persons, patients and doctors, but also those from government, science and industry) have very multi-layered and quite often conflicting expectations and interests, which they associate with new processes, products, treatment methods or services and care.

This cross-sectional nature of medical technology is reflected not last in the parts played by the federal ministries: the main responsibilities for this policy area fall into the competences of the Ministry of Education and Research (BMBF), the Ministry of Economics and Technology (BMWV) and the Ministry of Health (BMG) – policy areas which are known to pursue partly diverging objectives and are committed to different rationales. The innovation policy challenge consists in coordinating the priorities, instruments and decisions of the departments involved in such a way that the most favorable conditions for medical technology are maintained or created. Indeed, in the past studies on the situation of German medical technology have repeatedly recommended that an improved coordination and pursuit of an integrated funding strategy across all policy areas could provide important contributions in support of medical technology.

Against this background, this study mainly adopts a cross-policy or cross-departmental perspective, in order to capture and classify as comprehensively as possible the funding policies and the setting of regulatory framework conditions by the public sector over the various value added stages of the medical technology innovation chain. The substantive focus lies on providing the knowledge base for innovations in medical technology. A comprehensive analysis and evaluation of health care policy is not the objective of this report.

THE SITUATION OF THE GERMAN MEDICAL TECHNOLOGY INDUSTRY

The situation of the German medical technology branch is on the whole satisfactory. The assessment of the position of this small, but innovative and strongly

growing branch is based on numerous indicators, especially when medical technology is compared with the situation of manufacturing industry as a whole. Here is a summary of the most important indicators:

- > According to a narrow statistical definition, ca. 90,000 persons are employed in the medical technology branch; this represents 1.6% of the jobs in the manufacturing sector.
- > In 2006 the turnover of medical-technical goods in Germany amounted to 16.2 billion euros. This corresponds to a share of 1.2% of all turnovers in the production industry.
- > The strong export orientation of medical technology is reflected in an export quota of 64.4%. This lies clearly above the average of manufacturing industry, which has an average rate of 43.3%.
- > Important indicators are also characterized by a strong growth dynamic. The sales abroad of the branch between 2002 and 2006 rose on average by 12.3% p. a., whereas the average growth in the manufacturing sector amounted to merely 7.8% p. a. In the same period the domestic turnover of medical technology rose by only 1.7% p. a. The number of employees also developed positively. So the branch recorded an increase of 1.5% p. a. between 2002 and 2006, while in the same period the number of employees in manufacturing decreased by 1.2% p. a.
- > The research intensity (R&D expenditures of turnover) of the branch reaches nearly 10%. This is approximately twice as high as in the whole of manufacturing industry.
- > Small and medium-sized enterprises with less than 100 employees represent 93% of the German medical technology firms. This means that the German medical technology branch is more strongly characterized by SMEs than is the case in the USA or Japan.

The assessments of experts as well as patent and publication analyses further reveal that above all the strong technological knowledge base with its well differentiated research infrastructure is among the strengths of Germany as a location for medical technology. Not only basic research, but also the outstanding performance of university and non-university research institutes is repeatedly singled out for praise. The public funding of research in Germany is also positively perceived. Further strengths are the present good availability of highly qualified personnel (among others, scientists, engineers, technicians), the competitiveness of industrial companies (incl. the supplier industries), a large domestic sales market and good access of the (primarily large) industrial corporations to the most important export markets. Furthermore, cooperation analyses indicate that the knowledge and technology transfer among public R&D institutions, as well as



between public and industrial actors and thus the networking of all innovation players in Germany in medical technology appears to function well on the whole. Thus enormous innovation potentials and many opportunities will result for Germany in the future to play a central role in the area of medical technology, also in international competition.

But the medical technology location Germany also has weaknesses. Besides the coordination and fine tuning processes among the central innovation policy players which are in need of improvement, above all the overly strong technical orientation and a too low orientation of the R&D strategies to the needs of patients or insured persons on the part of the innovation players, an inadequate integration of SMEs in clusters and networks and too little willingness on the part of industry to engage in risks and investments to adopt new technologies (among others, too low a volume of available venture capital) are regarded as »bottle-necks«. Moreover, the uncertainty about the development of future (health care) policy framework conditions, the high level of regulation, a time-consuming and not always transparent reimbursement procedure, as well as the low growth dynamic of domestic demand (among other factors, due to the limited scope for public investments in public health care facilities) are regarded as weaknesses in Germany as a medical technology location. The results also show that in the future considerable bottlenecks with regard to highly qualified personnel will have to be reckoned with in the health care sector.

GUIDELINES FOR SUCCESSFUL FUNDING POLICY

Designing and implementing successful support policies for medical technology is an especially complex task, in view of the decidedly cross-sectional character and the high degree of inter-disciplinarity involved, which is increasingly complicated by the market conditions prevailing in the health care system. The current findings of international innovation research cannot offer »patent remedies« for the challenge, but can supply useful orientation about the main outlines of modern research, technology and innovation policy.

The conceptual paradigm of innovation research which has been dominant since the 1990s is the innovation systems approach, which has now also established itself as a framework for orientation for many governments in the OECD world. This fundamental perspective also forms the conceptual guiding principle for the evaluation of the promotional policy measures which are analyzed in this TAB report. The central premise of the approach consists in the assumption that innovations are the result of interactive and interdependent process-

es with the participation of players from different sub-systems (among others, the education, research, economic and finance system). The behavior of these actors and knowledge-generating and learning processes taking place between them are once again strongly influenced by laws, regulations, standards and routines. Governmental innovation policy which pursues a systemic approach, aims to improve the exchange relationships and knowledge transfer between the sub-systems and to remove systemic errors. Accordingly, the significance of cooperation, integration and consensus-building has increased in the design and implementation of innovation policy.

The findings of systemic-oriented innovation research can be summarized in the following brief and abstract principles for a successful innovation policy:

- > *Promote the cross-sectoral networking of actors:* Exchange processes between basic and applied research as well as industry are of crucial significance for the innovation system. Supporting and co-designing these interactions is an important task for innovation policy. It is important to understand the often conflicting interests and orientations of the actors.
- > *Promote fine tuning and coordination processes:* The systemic perspective poses increased demands of the collaboration of the different innovation policy players. Coordination can be improved through an appropriate design of institutions, including the establishment of suitable coordination bodies, and by building and maintaining a culture of coordination, which can be helpful in overcoming departmental self-centeredness. A decisive factor in achieving better coordination between different ministries and organizations is ultimately the clear backing of the political leadership for a certain innovation policy strategy.
- > *Strengthen strategic intelligence:* Strategic intelligence (SI), in particular foresight, evaluations and technology assessment, do not only supply an important information base for innovation policy decisions and their realization. Through their contribution towards rationalizing discourses, they can support the creation of a joint orientation among the innovation policy players. Appropriate infrastructures to build strategic intelligence are therefore required; at the same time it must be guaranteed that the relevant actors also have access to strategic intelligence.

PROMOTION OF MEDICAL TECHNOLOGY IN GREAT BRITAIN AND SWITZERLAND

The analysis of public promotion of medical technology in countries which are significant competitors for Germany's medical technology branch in the world



market provides insights which can be utilized to further develop and improve German medical technology policy. Great Britain and Switzerland were selected for in-depth analysis with this end in view. These countries, which – like Germany – belong to the internationally leading producers of medical technology, pursue different innovation policy approaches and funding strategies. A warning against simply transferring examples of good practice in these countries to Germany should be given, however, as the framework conditions and structural differences between the countries must be taken into consideration.

Great Britain and Switzerland differ in central aspects of their innovation policy approaches. For instance, the Swiss federal government is relatively restrained in formulating guidelines in research and innovation policy. The determination of the thematic and substantive focus of funding policy is mainly characterized by bottom-up processes, in which extensive consensus-building takes place among all stakeholders. In Great Britain, on the other hand, the emphasis is much more on the strategic intelligence toolbox. The high value placed on these instruments in research and innovation policy is expressed not least in its relatively high degree of institutionalization – for example, in the form of horizon scanning which is based at the ministerial bureaucracy level. At the same time, considerable efforts are made to integrate the relevant actors from science, R&D and industry in the decision-making processes in a consulting capacity. Great Britain appears almost to be a role model in the extraordinarily high degree of transparency of all policy formulation and strategy development processes.

According to their fundamentally different innovation policy approaches, Switzerland and Great Britain pursue different promotional strategies in the area of medical technology. Switzerland does not possess a specific national strategy to promote medical technology. Only medical technology developments close to the market are supported, by an initiative of the Commission for Technology and Innovation (KTI-MedTech). This sponsorship which is regarded as very successful is characterized in particular by the intensive consulting and continuous monitoring of the projects by experienced experts in the framework of the militia system, in which certain public tasks are carried out by volunteers as a sideline. In contrast, the public sector in Great Britain undertakes much more efforts to promote medical technology. It is striking that the activities focus less on conducting classical funding programs, but increasingly on identifying and addressing structural obstacles to medical technical innovations (among others, public procurement, regulation, education). Numerous governmental commissions, working and strategy groups play a crucial role in this context. In addition, the design of governance processes in medical technology policy is accorded a high significance, which is reflected, for example, in the active inter-

face management between the ministries involved and inter-ministerial working groups. It is further remarkable that specific coordination institutions have been established in the area of medical technology, not only for the processes of policy development, but also for the implementation phase, in order to be able to react directly to problems with the realization.

From the comparison of these two cases, some exciting results emerge for medical technology policy in Germany. Regarding the role of strategic intelligence in their innovation policy, the approaches practiced in Britain appear to be exemplary. The regular conduct of program evaluations, foresight and strategy development processes fulfill important functions in the design of medical technology policy, particularly in larger countries with correspondingly large numbers of actors involved and greater communication requirements. Both case studies emphasize the growing significance of cooperative governance approaches in research and innovation policy. The integrative organization of policy formulation not only brings benefits in the form of an improved information base for decision-making processes, but also raises the acceptance of these decisions within the relevant groups of actors. So the most transparent design of strategy formulation processes appears to be more than a value in itself, because increased transparency also provides more opportunities for constructive, critical debates among the stakeholder groups.

MEDICAL TECHNOLOGY POLICY IN GERMANY: A FOCUS ON THREE CENTRAL AREAS

Three areas which emerged as particularly significant for German medical technology in the course of the first investigative phase of this study, and simultaneously cover the most crucial phases in the medical technology innovation chain, were subjected to an in-depth scrutiny: (1) the design of the innovation and medical technology policy of the German federal government, (2) the regulatory framework conditions for the approval of medical products as well as (3) the specific situation of the medical technology SMEs and their opportunities to cooperate with research institutions, as well as exploiting new financing models. These three areas also provide starting points for the further development of an innovation-promoting medical technology policy.

Innovation policy strategy development

With the analysis of the federal government's research and innovation policy in the area of medical technology, the main focus of this report – the investigation



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of policy to provide the knowledge base for medical-technical innovations – has been taken into account. The findings from the examination of promotional policy in Switzerland and Britain undoubtedly supply a useful backdrop against which the current approaches and processes in German medical technology policy can be classified, and in some places, further developed. Before transferring individual examples of »best practice« into promotional policy, however, the national specifics should be taken into consideration.

First of all, it must be emphasized that the funding of medical technology in Germany, especially by the BMBF, can be given a good report card on the whole. Over the various innovation phases of medical devices, that is, from basic research up to application in health care, no gaps in funding or promotion emerge; also the broad instrument mix of classical funding projects, research clusters and competitions is mostly praised as appropriate. Nevertheless, improvements are possible at the level of specific funding offers and in the framework conditions for R&D. So it appears that at present the possibilities to implement innovative treatments into health care and to integrate new project ideas in the clinical workflow are suboptimal. Also, the coordination processes between the different funding agencies in the field of medical technology need to be improved.

Besides the concrete funding portfolios for medical technology, the governance activities and structures of the actors responsible for promotional policy are an increasingly important success factor in innovation policy. At the federal level, medical technology policy is confronted with the unique situation that the relevant competences are distributed among three ministries. And indeed there are clear indications that the coordination and consultation processes between the departments, and in part within the ministries, should be improved.

In supra-departmental coordination, the adoption of the High-Tech Strategy of the federal government was a considerable improvement with respect to agreeing priority-setting and strategy formulation. Already the cross-departmental approach in the development of the High-Tech Strategy can be fundamentally regarded as exemplary, as this essentially led to a joint innovation policy orientation of the ministries concerned. Implementation deficits are particularly to be seen in the departmental-internal allocations of funds, which in part led to a dilution of the strategic orientation striven for, in favor of the ministry's own logic. Basically, however, it also applies that medical technology and the Action Plan Medical Technology based thereon have benefited from the High-Tech Strategy approach. Striking is also that there are no long-term institutional mechanisms to coordinate the activities of the departments within the BMBF, BMWi and BMG concerned with medical technology issues, respectively, that the opportu-

nities offered by the existing bodies (e.g. the Health Research Council and the Medical Committee) are only inadequately utilized.

But also intra-ministerial coordination processes, which are required due to the cross-cutting nature of medical technology, prove in many cases to be in need of improvement. Thus the already existing health care task force within the BMWi was strengthened. The same applies to the BMG, where internal coordination processes between the units relevant for medical devices were optimized by means of inter-departmental working groups.

Forward looking further development of the approval process

The approval of medical products plays an important role in the medical technology innovation process, as they are the pre-condition for the market introduction. The current medical product law and its application in the conformity assessment procedures present an obstacle for the manufacturers, but on average this is overcome. Dealing with different facets of the complex approval procedure, however, shows that certain areas are particularly problematic from the perspective of the medical technology players. This applies first of all to the knowledge about the formal requirements of the approval procedure. Especially in research institutions and SMEs, the knowledge to competently carry out the procedure is not always available to the extent required.

In the current plans and discussions about the further development of the medical product law, the tendency becomes clear that the quality and testing requirements for certain medical product classes will become more stringent. In particular, it is to be expected that the number and the quality requirements of the clinical studies to be carried out for innovative medical products will increase. In addition, clinical trials will be required in future to a greater extent, also to assess the medical benefits and the health-economic impacts with a view to the reimbursement by the statutory health insurance companies. While the trend to introduce stricter testing, safety and quality requirements is fundamentally to be welcomed, from the perspective of the patients and those insured, this development presents the manufacturers with yet another obstacle due to the rising costs and the greater time outlay entailed. In addition, identifying suitable partners to carry out clinical trials is especially a problem for inexperienced SMEs.

Besides these two »classical« problem areas pertaining to the issue of product approval, in the course of this study further aspects emerged which until now have been hardly or only inadequately addressed in the discussions about Medical Product Law. This applies, on the one hand, to standardization processes



which under certain circumstances could enhance the competitiveness of German developments on the world markets. This aspect should be more strongly anchored in future innovation policy. On the other hand, there are indications that the establishment of a systematic regulatory foresight process to identify future standardization needs is gaining relevance. With such a toolkit, the likelihood can be reduced that the market launch of highly innovative medical products will be unnecessarily delayed due to the lack of, or inadequate, regulatory framework.

SMEs in the medical technology field: opportunities via cooperation

SMEs are a particular feature of the German medical technology branch. At the same time, they are acting in a dynamically changing environment, which presents them with considerable challenges. Among these developments the internationalization of production and marketing structures, the increased requirements of interdisciplinarity and R&D processes, as well as the growing significance of new marketing and financing models are particularly challenging.

Particularly problematic appears to be the situation that many SMEs could be »left behind« technologically. The growing R&D gap between large and small companies seems to indicate this development already. One possibility for SMEs to overcome the high entry costs for R&D is to cooperate with research institutions. The chance to combat the low R&D intensity of many SMEs through cooperation was recognized by the political actors and numerous initiatives were launched to promote cross-sectoral collaborations. These activities are fundamentally to be welcomed, but they could be further optimized in places.

But the conditions in the markets for medical products, in particular the stagnating domestic investments, have led to the development of alternative financing models. Increasingly, purchases of new equipment are not being financed by own funds or by the house bank, but to a greater extent by the producer himself (operator or transfer models). Admittedly, only between 5 to 10% of the domestic turnover of medical-technical capital goods are presently being handled using these new financing models. However, it is anticipated that this trend will be intensified in the coming years – a development which will once again pose challenges for SMEs in particular, due to their lower capitalization and personnel resources.

MAIN RESULTS AND ACTION OPTIONS

The positive message of this study is that no striking obstacles for innovative medical products were identified. The fundamental promotional policy approach of the federal government, as pursued particularly by the BMBF and BMWi in the High-Tech Strategy, as well as by the numerous activities supporting SMEs, has no basic deficits or gaps. Despite this overall positive assessment, which is largely supported in its general tendency by other independent studies of the German medical technology sector, improvements in the design of funding policy, in the area of regulatory framework setting and in particular, the inter-departmental decision-making and coordination processes are possible and desirable.

For the three areas which were analyzed in depth, the following starting points for the public sector emerged, which could contribute to further strengthening the German medical technology industry:

Research promotion and innovation policy

- > Consistently continue to pursue the High-Tech Strategy: The sector- and department-overarching approach of the High-Tech Strategy has undoubtedly had positive effects on German innovation policy. Effects which not least benefitted medical technology. In the implementation and further development of the High-Tech Strategy, the findings of strategic intelligence, and here in particular of foresight processes, should be more systematically taken up and realized in future. Also in future the fund allocations within the departments should be made more transparent, in order to ensure their better compliance with the strategic innovation policy goals. Ultimately, the successful realization of the High-Tech Strategy depends on the dedicated support of the political hierarchy.
- > Strengthen and stabilize coordination (processes): The interministerial coordination of decisions and measures which are relevant for medical technology could be significantly improved. A stabilization and systematization of the exchange processes between the responsible departments (BMBF, BMWi, and BMG) could be achieved by creating a competent coordination body. The specific design of such an institutional solution would have to be jointly developed and decided on by the ministries concerned.
- > More transparency, more information, more leeway: The publicly funded promotion on offer for the various phases in the medical-technical innovation cycle is mainly praised. Also the decision-making processes – and here particularly those instigated by the BMBF – which lead to the design of the various funding programs for medical technology, are considered exemplary with regard to



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the integration of stakeholders and the application of systemic instruments, such as roadmaps. In an international comparison, however, it stands out that the promotional policy decision-making processes could be made considerably more transparent, which again would positively impact their acceptance by the groups of actors concerned. Also an improved and integrated offer of information about the numerous funding activities, which are open to researchers and enterprises actively engaged in research, would facilitate the application procedure for inexperienced researcher groups – a task in which, for example, the industrial associations of the medical technology industry could participate much more intensively than they do now. Finally, more leeway and better conditions, especially in the form of time resources, should be created for (medical-technical) research in clinics.

- > Timely consideration of market introduction conditions: As the market entry conditions for medical devices are characterized by particularly complex rules and market conditions, it should be examined, as in the case of R&D funding by the BMBF, whether already early on – even for projects which are still relatively far from application – the market entry conditions for innovative medical devices can be taken into consideration (for example by obliging recipients of research funding to formulate business strategies).

Market approval

- > Strengthen innovation management: Many SMEs and inexperienced researcher groups are inadequately informed about the requirements for the approval procedure for medical products. Admittedly, the existing promotional measures of the BMBF already contribute towards preparing the applicants for the application procedure. However, it would be possible to give the pro-active handling of the market approval conditions greater importance in the assessment of grant applications. Also expanding and improving the consulting offered to beneficiaries of sponsorship regarding approval procedures should be examined.
- > Take into account the growing significance of clinical trials: The significance of clinical trials and the requirements of the quality of clinical studies will increase in the coming years. As the manufacturers of medical products have hardly any experience in conducting clinical trials compared with the pharmaceutical industry, it should be examined which measures could be undertaken to support the manufacturers. Thus existing infrastructures (e. g. coordination centers for clinical trials) could be utilized more frequently also for medical technology. In addition, methods for clinical trials need to be (further) developed to meet the requirements of medical technology. Moreover, a consensus should be reached with IQWiG (Institute for Quality and Efficiency in Health Care) and G-BA (Federal Joint Committee) about the methodological requirements for these studies.

- > Develop the regulatory framework further: Standardization processes are of enormous significance for the medical technology industry. This could be expressed in a stronger integration of standardization in the funding programs relevant for medical technology. At the same time, it could also be explored to what extent regulatory foresight could assist in systematically identifying research and technology fields which are in need of regulation and standardization. Establishing systematic processes of regulatory foresight could contribute on the whole towards a timely identification of future standardization needs, in order to prepare the existing set of rules and regulations for the introduction of innovative medical technology developments in time.

Cooperation capacity of SMEs

- > Continue and intensify promotion of R&D cooperations: R&D cooperation between SMEs and research facilities are an important approach to maintaining, respectively strengthening, the technological competitiveness of SMEs. The efficiency of the manifold measures on the part of the federal government and the states to sponsor cross-sectoral collaboration could be increased through a better fine tuning of content and coordination, particularly between the federal government and the Länder. Furthermore, an improved range of information material about potential cooperation partners may help to pave the way for joint R&D projects. Publicly funded research facilities for their part should improve the framework conditions for collaborations with companies.
- > Better framework conditions for SMEs in new financing models: In the medical-technical investment market a trend to new financing models has been observed for a few years (e.g. operator and transfer models), which are a special challenge for SMEs. The BMWi and the BMBF should examine which additional initiatives could help to pave the way for SMEs to exploit the new cooperation and business models. At the same time, the procurement rules for the public sector should be examined to see whether they hamper the new financing models.

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