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Personalised Medical Technology

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Personalised medicine is all the rage and has become a dominant guiding theme of health research. The focus is on the development of drugs that allow customised treatment. Based on the genetic individuality of each person, patient groups with certain characteristics are identified to receive specific medication. For this, molecular genetic tests are developed to determine in advance whether or to what extent a drug works for an individual patient. Only then is the drug administered. The goal is to make the drug more effective and to reduce systemic side effects that continue to pose a significant challenge in drug treatment.

The principle of personalisation or customisation is not only interesting for pharmaceuticals but also for medical devices. Firstly, medical devices are required to implement personalised medicine as a direct combination of diagnostics and therapeutics ('theranostics'). Imaging without technology is unthinkable, for example. Also suitable, possibly mobile, in vitro diagnostics and medication administration technologies are needed. Secondly, the general objective of rendering medical treatment more effective and reducing side effects through patient-specific adaptation can also be applied to the design of medical components, equipment and systems.

Innovative medical devices are characterised by significant benefits for the patient and should be safe, gentle and efficient to use. The personalisation of diagnostics and treatment can therefore be regarded as a significant optimisation strategy that provides an increasingly important role for medical technology. Unlike pharmacology, however, the biological individuality of a person from the perspective of medical technology is expressed less on the molecular genetic level and more on the anatomical, physiological and partly also on the cellular levels. There are a number of examples for this, such as autologous bio-implants, individualised methods and technologies for imageguided intervention and telemedical patient monitoring.

Background

The use of technical devices and aids is an indispensable part of modern medicine. In the areas of prevention, diagnostics, treatment, and rehabilitation, medical technology has a significant place in homes, private practices, and hospitals. The medical technology industry is a dynamic, innovative, and future-oriented industry that not only contributes to the creation of jobs and wealth but also makes significant contributions to better healthcare for the population and thus enjoys great social significance. Medical technology companies benefit from a diversified and

internationally recognised research community in many countries.

Medical technology is a highly complex technological field characterised by an equally complex stakeholder

structure and interaction. The environment is particularly marked by technological intensity, interdisciplinarity, regulation,

and competition, as well as by demographic change. While this complexity results in numerous opportunities it can also produce factors that may hamper innovation. This may lead to negative economic effects for both related companies and for the respective country as an industrial location. In the worst case, however, patients receive no access to new technologies with medical benefits. Overall, only a fraction of the continuously acquired medical technological knowledge ultimately trickles down to clinical care in the form of medical equipment, systems, and procedures.

Research and development are the basis for any medical technological innovation process. Conditions promoting innovation are thus of considerable importance for sustainable economic growth and employment in the medical technology industry. This is especially true for an export-oriented industry that must compete internationally primarily through technological leadership and quality.

Directions of Innovation

Five general directions of innovation can be identified:

Miniaturisation

Miniaturisation of technical components and systems, e.g., in instruments for minimally invasive surgery or portable sensor systems for monitoring vital parameters.

Biologisation

Integration of biological and technological components, e.g., in bioimplants such as cartilage and vascular implants.

Computerisation

Integration of information and communication technology into medical technological systems, e.g. computed tomography.

Personalisation

Adaptation of treatment to the individual case and medical history of a patient and hence the use of customised medical technological components, devices, and systems. This includes customised treatment by directly pairing diagnostics with treatment (theranostics), e.g., in theranostic implants.

Networking

Information technological integration of medical devices into existing data and communication networks, e.g., networking of various technical devices in the operating room.

The driving forces for these different directions are varied. At the core is a considerable medical need, which is mainly due to demographic developments that include a significant increase in the prevalence of chronic diseases (such as heart failure, diabetes, and neurodegenerative diseases) and a number of untreatable or inadequately treatable diseases. Innovative medical technology also possesses considerable potential to increase efficiency. Its combination with steadily growing technological capabilities and the increasing importance of the health industry and thus medical technology as a key catalysing element results in a significant technological and medical need-based innovation momentum.

The following technological areas have high potential for innovation with a continued high demand for research and development (R&D) and corresponding significant R&D risks:

- Diagnostic image procedures;
- Interventional techniques;
- In vitro technologies;
- Medical information systems and telemedicine;
- Prostheses and implants; and
- Therapy systems.

There are overlaps between the individual areas of technology so clear distinctions are not always possible. Furthermore, additional subtopics which exhibit considerable innovation activity, can be identified in the respective areas of technology.

There are interdisciplinary crosscutting issues that are important in view of all the aforementioned areas of technology and that significantly drive the research and development of innovative medical technology (e.g. patient safety in medical technology, usability and user acceptance of medical devices, human-technology interaction and human-machine interfaces, cross-sectoral medical technology, education and training in medical technology, standardisation in medical technology and medical technology in the context of society and ethics).

Clinical Research

Clinical research using new medical devices and systems has changed in recent years and has been influenced by new regulatory frameworks.

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In direct comparison with established clinical research in the pharmaceutical sector, innovations in medical technology are usually aimed at smaller groups of patients. Therefore, the identification of a suitable clinical partner for research and establishment of an innovation is often challenging for both the manufacturer and the research institution. A suitable clinical research partner must exhibit an appropriate skills profile in combination with an appropriate patient population and a sufficient number of cases.

Another difficulty arises from the requirements for proof of clinical benefit. In Germany for example, suitable methods and specifications for proving clinical benefit are missing on the part of the Federal Joint Committee (GBA) and the Institute for Quality and Efficiency in Health Care with respect to biologised medical technologies and/or medical technologies with combined active ingredients, the complexity of requirements for clinical research was also significantly increased by the introduction of Advanced Therapy Medicinal Products (ATMP). In addition, there are problems of demarcation between medical devices and pharmaceuticals. In this increasingly complex regulatory environment, the interactions between manufacturers, research institutes, hospitals, university centres, and government agencies appear to be poorly developed and in need of improvement.

Again, compared to the pharmaceutical sector, medical-clinical research has been established less systematically, both on the part of hospitals and on the part of manufacturers, such that there appears to be room for overall expertise development. A further complication on the part of hospitals is the still relatively low level of interest of doctors in medical technological clinical research. One major reason for this is the higher impact factors of journals in the fields of medicine, molecular biology, and pharmacology. Added to this is an a priori lack of interest of researching physicians in medical technology, which is not least due to medical degree programmes focusing on biomedicine instead of technology.

Medical Device Approval

Medical devices may be marketed or used in Europe if they have a CE mark. This mark may be affixed if the essential requirements' are met and the mandatory conformity assessment has been carried out. The conditions of approval of medical devices are subject to constant changes. The EU Commission is currently working on the reorganisation of the standards, including more binding and detailed requirements for notified bodies and stricter monitoring of conformity assessments. The changes will also be aimed at better coordination of market observation and vigilance activities of national authorities at the EU level. In addition, the requirements for clinical trials are to be adapted to the pharmaceutical law.

Overall, it should be noted that the approval process for medical devices is adapting to the regulations in the pharmaceutical sector and is therefore becoming more complex, timeconsuming and costly. This results in an increasing burden and a higher risk, in particular for manufacturers of medical devices. Especially for small and medium-size enterprises (SMEs), this is increasingly difficult to deal with due to their limited financial capacity. It is also becoming increasingly difficult for research facilities, which supply companies with R&D results in the wake of the technology transfer, to integrate into the research process aspects geared toward the future approval of medical devices. A particular difficulty arises in the respective delineations of medical devices and pharmaceuticals in terms of the applicable approval guidelines and responsibilities.

On the other hand, internationally harmonised standards that adequately reflect the increasing technological complexity are of great importance for the future economic success of medical devices. They can be an important basis for quality assurance, safety, compatibility, and technical communication for medical device manufacturers, as well as support the global acceptance of components, devices, and systems. They thus serve to protect investments in hardware and software and are an important tool for maintaining competitiveness and sustainability.

Reimbursement

Reimbursement by statutory health insurance (SHI) is crucial for successful marketing of a medical device. In general, reimbursement of medical technological innovations by SHI is fraught with hurdles and often proves to be a bottleneck in the medical technology innovation process.

Usually, the path of a medical technological innovation to reimbursability is long and fraught with risk. Unlike many pharmaceutical products, medical devices often cannot be fully protected by patents. This means that imitations that can be supplied much cheaper, without the high added cost for the reimbursement approval, quickly enter the market. This increases the economic risk, especially for SMEs. This is aggravated by a general lack of information with regard to detailed questions on reimbursement, which can also have a negative effect, again particularly affecting SMEs. Research institutions usually do not deal with reimbursement issues and the corresponding framework conditions are practically irrelevant in the phase of applied research.

From a business perspective, these hurdles result in an increase in the overall risk of medical device development and can lead to ideas or concepts being abandoned. The potential innovation will then never reach the patient. To make matters worse, the industry is not allowed to request inclusion of an innovation into the reimbursement catalogue and no direct involvement of the industry in the decision-making process is currently projected, as only patient initiatives and doctors can request inclusion.

From a methodological perspective, the proof of the clinical benefit of innovations has proven to be a major problem. In particular, demonstrating the long-term benefit of medical devices by means of the gold standard of the RCT (Randomised Controlled Trial) is problematic and costly. There are no suitable methods and requirements for RCTs of medical devices, especially with regard to the definition of appropriate clinical

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endpoints. Small businesses often have no adequate expertise to carve out the benefits of innovation in this way. The financial expenditure for this is usually not feasible and is associated with considerable risk. In addition, RCTs cannot answer all the important questions of those that bear the costs, as the impact on healthcare services and thus the impact on reimbursement cannot be represented.

Conclusion

Medical device technology for personalised medicine is an exciting and promising area for development, which has immense potential for innovation. However, the costs and risks of investment in clinical research within current regulatory frameworks and the difficult path to medical device approval and reimbursement may hamper development. There is room for improvement given that research in medical device technology currently lags behind pharmaceutical research.

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