Policy Recommendations Innovation Financing in the European Medical Device Sector

InJection Network

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Entrepreneurial innovation: Networking the players and users
Networking innovation actors in the medical device sector
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Introduction

The Policy Recommendations document outlines the knowledge obtained by the InJection network on innovation financing for the medical device industry and provide recommendations for potential actions, which can be implemented by the European Commission through instruments available. The challenges pertaining to the medical device industry are part of a wider complex of factors that influence the current challenges in the European medical device and health care industries. Consequently, the challenges described in this document alongside the concrete recommendations outlined, require action on several levels and are thus aimed at both short-term implementation and long-term inspiration on the level of European Policy development.

The recommendations have been prepared on the basis of the work by the InJection network in analysing the European medical device and health industry with in-depth analysis of European health care systems, medical device industry, entrepreneurial and innovation support systems, financing and venture capital systems in European member states, as well as the global markets and global value chains in the medical device sector. The recommendations have further been discussed and edited by European policy experts and from the public and private sector, as well as industry specialists and representatives from the financing sector from the major European regions for purposes of validating and testing the recommendations to ensure quality and comprehensiveness on a pan-European level.

The study conducted prior to the drafting of the policy recommendations indicated that a broader focus was required to understand and address the complexities of the medical device sector in relation to innovation financing. Hence, the policy recommendations reach across a broad spectrum of fields and instruments, which need to be addressed in order to fully understand the scope of changes possible to improve the conditions directly or indirectly related to innovation financing. These include innovation support programmes, entrepreneurship tools, health economics, public procurement, public-private partnerships and regulation. These issues influence, through various measures, the access to funding for innovative SMEs of the medical device sector and involve a large panel of actors, either from the supply or from the demand side. Hence, the drafting of proper policy recommendations had to consider these multiple levels of actors and

fields of activities in order to answer the objective of the INJECTION project and submit proposals to improve the access of innovative enterprises to funding in the medical device sector, at national and European level.

The policy recommendations have been drafted in correspondence with the European Commission guidelines for Acceptance of Policy Recommendations for purposes of applying with the requirements for clarity, testability and consistency.[i] Consequently, the recommendations are structured according to the problem statement, addressing the challenge at hand, followed by the objectives of the recommendations. Subsequently, the overall actions to be taken are discussed, as well as concrete recommendations addressing the short-term actions, which can be taken further by instruments available to the European Commission and related organisations. Finally, each recommendation has been addressed to a certain target audience, to underline the specific relationship between the recommendations and European groups of stakeholders.

The following themes are outlined in the policy recommendations, and have been chosen on the basis of their priority and relevance for the European medical device and health care agenda:

- Innovation Financing
- Entrepreneurial Support Tools
- Health Economics
- Public Procurement
- Public-Private Partnerships
- Regulatory Environment

Several of the proposed themes imply longer term actions with far-reaching consequences for the European communities, and it is suggested that the policy recommendations give rise to further initiatives with the European Commission, to broaden the implementation process to encompass action on the national and pan-European levels.

One particular theme of relevance is health economics. This conclusion is supported by the demographic and financial challenges associated with the provision of health care to European citizens in the future. Although this challenge points beyond the scope of this project, several sources from policy, industry and research refer to this area as being one of the primary challenges to European societies in the next ten to twenty years. Consequently, should one primary recommendation be put forward on the basis of the work in the InJection network it

would be to target directly the future structure of the health care systems of the European countries on the levels of health care per se, but also as integral part of European economics systems, innovation, research and education, and address the systemic challenges, which have been thoroughly described and which present the underlying evidence for the policy recommendations presented in this document.

Innovation Financing

Context

The analysis and interviews performed across Europe in order to identify drivers and barriers for innovation financing of medical device SMEs, underlined that there is no significant shortage of innovation financing in the medical device sector compared to other sectors, despite European innovation financing being far below the US level of financing. There are significant challenges related to the distribution of innovation financing across the European member states, as well as the distribution of innovation across the innovation financing value chain. However, the main challenge associated with European innovation financing is the lack of attractive deal flows as an underlying reason for the perceived lack of funding on the financing demand side.

Problem Statement

With reference to statistics from European Venture Capital Association and the European Investment Fund, European seed- and early stage venture funding amounts to less than 50% of the US level. European SME's experience funding gaps in the early stage of their investment phase, especially related to seed capital, business angel capital, and funding in the pre-commercial phases. Furthermore, few countries in Europe other than Germany and the UK have the necessary market size for medical device companies and the financing instruments covering the full innovation financing value chain from the seed phase to IPO. Beyond the advantages of market size, the publicly-backed venture financing systems of the United Kingdom and Germany are designed around strong public-private partnerships in the pre-commercial phase, with public financing of up to 70% of active investments.

However, in the majority of European member states one or more structural challenges create barriers for the development of efficient systems for early-stage financing. High taxation lowers the incentives of the private sector to take risks by reducing the potential gain. The tax regimes and punitive commercial laws also inhibit the development entrepreneurial culture and create widespread risk aversion of researchers. Inadequate incentive to commercialise innovations out of universities or and the general limited success of European technology transfer initiatives further limits the number of innovation maturing from research to commercialisation. Finally, the

intransparent and fragmented European markets for the medical devices limits the attractiveness of European ventures, further undermining the estimated value of European-oriented ventures.

Objectives

Improving the conditions for European innovation financing in the medical device industry requires targeted actions to change the conditions for the main factors affecting the current situation. These factors include improving conditions for cross-border investments and closing existing funding gaps, improve incentives for entrepreneurs, improve the availability of entrepreneurial, and most importantly improve the market conditions for medical devices on the European markets, as this will be mirrored in the attractiveness of European medical device ventures, thus improving the deal flow to potential investors.

Proposed Actions

Reaching the desired objectives require several actions to address the complex interaction of factors influencing the conditions for innovation financing in the European medical device industry. First, the conditions across the European member states should be addressed by creating what resembles an inner market for investments, through harmonisation of commercial laws, improve conditions for the flow of capital, and potentially supporting gaps in the financing value chains across European member states through targeted actions such as increased use of public-private partnerships in innovation financing, improve incentives for early-stage investments and improve conditions for capital flow across borders. Secondly, there is a massive need for supporting entrepreneurial culture by ensuring the necessary base of competences and skills, developing entrepreneurial talent and sharing best practices and successful models across European member states. Finally, there is a significant challenge in improving European market conditions for the medical device industry through targeted, long-term efforts to create transparency and improve the conditions for marketing products and services across European countries through measures such as a massive combined overhaul of the European public health care procurement systems.

Recommendations

1. Design measures to promote the set-up of national public-private seed funds in order to bridge early-stage funding gaps. These funds could be sourced from existing match-funding systems found in a number of European countries such as the Netherlands, Germany, France and in Scandinavia. A second step, which favours the close interaction and

underpinning of such funds at European level in order to create a critical mass for investment and the investment potential for high 'added value' start-ups involved in multiplication emerging technologies. It is paramount that such funds be earmarked for a) high technology or high value-added venture, b) carries a willingness to take risks, and c) be operated by commercial venture financing managers on commercial basis.

2. Promotion of local business angels' networks within European member states through exchange of best practices (e.g. Region of knowledge programme). Such support policy should be coupled with tax incentive measures to encourage private investments. Moreover, as business angels tend to invest on a local scale, they should be supported to gather within thematic networks at national and European level and thus create pan-European connected investment funds.

3. Specific attention should be paid to funding schemes supporting early proof-of-concept. Funding these and similar central R&D activities are both beneficial for the innovation development and the raising of funds in subsequent stages. Usually, neither academia nor SMEs have budgets to dedicate at this crucial stage. Consequently, public support must be organised through specific programs including an external assessment phase and, for example, closer partnerships with clinicians. SME's within this sector which embed further RTD investment should be incentivised.

4. In the growth stage, support measures have to be developed to adapt and structure existing or new funds to investment in the innovative medical device sector. As the time-to-market in the medical device sector is linked to market access procedures, the funding chain should be adapted to this time frame. This would pre-suppose better sourcing possibilities from the public-private partnership venture environment as well as focussed and incentivised investment capital at European level, which could be further enhanced through the gathering and development of thematic venture capital funds at European level.

5. Initiation of European and national support schemes for developing entrepreneurial talent on the basis of leading programs and models from countries such as Germany, United Kingdom and Denmark. Such support schemes could include sharing of best practices, initiation of education and training, collaboration with universities to create talent labs and small-scale venturing, and ensuring the availability of the condition for small-scale venturing

such as mini-incubators, available funding for prototyping, and encouragement to develop ventures from universities, public organisations and research organisations.

6. Incentives for the development of management skills within research organisations would create capable and motivated entrepreneurs and would therefore improve technology transfer of research IP by making it easier to attract seed or venture capital.
7. As the intellectual property (IP) is a crucial point for investors, measures to standardize the rules for the transfer of the IP from research institutes/universities to entrepreneurs willing to create a start-up could be developed in Europe.

Target Audiences

1. European regions to influence and encourage policy changes at local level
2. Business angel networks at regional and national level
3. Local and national seed funds
4. Venture capital funds
5. Universities and research organisations

Entrepreneurial Support Tools

Context

Beyond the requirements for targeted actions in relation to innovation financing, European entrepreneurs can benefit from exchanging knowledge about existing tools aimed at supporting entrepreneurs to successfully obtain investments and commercialize innovations and ideas. Today, significant numbers of projects fail to raise funding due to a lack of knowledge about investor requirements among entrepreneurs in European member states.

Problem Statement

Major European medical device clusters such as London/Cambridge (United Kingdom), Paris (France) and the Oresund Region (Denmark-Sweden) have managed to develop significant entrepreneurial activity through establishing venture financing ecosystems. These results have been achieved by ensuring the availability of the key factors for developing and maintaining an entrepreneurship culture and on the basis of a high degree of knowledge exchange concerning the requirements for developing ventures with an adequate level of attractiveness to potential investors. However, looking across the European Union there is a significant shortage of the equivalent knowledge on how to develop attractive ventures as according to the standards of professional investors, resulting in limited quality of deal flows and entrepreneurs investing significant time in essentially hopeless business cases.

Objectives

Improving the knowledge base and competences of European entrepreneurs for the purpose of improving the quality of deal flows, require that existing knowhow and expertise can be gathered and distributed throughout European medical device clusters. Existing knowhow and expertise needs to be codified and structured in formats which can efficiently be distributed and assessed across different levels of competence, cultures and possible language barriers in the European member states.

Recommendations

1. Implement programs to support the training of professionals, support the establishment of systems for efficient handing of the pre-commercial gap, and support regional programmes to support smaller business in the transition period, potentially as part of current innovation support systems or as integrated in innovation financing support.
2. Encourage the development of private-sector service companies to allow agglomeration of knowledge and expertise, and improve availability of competences on market conditions.
3. Implement Regional investor readiness Facilities (RIRF) in European Regions. The primary objective of RIRF is to ensure the quality of the SME/entrepreneur projects through targeted training and advisory services.
4. The services should be implemented in regions by embedding it into existing business support actors or regional development agencies. The RIRF facility should be equipped with a comprehensive toolbox with e.g. business plan self-assessment tools, guidelines, innovation management tools – e.g. the large number of tools developed through European partnerships (projects like Injection and IMPROVE) and based on existing best practise in Europe. Furthermore the regional support services should receive targeted training sessions e.g. in the format of the Master Class developed by InvestorNet under the European initiative Gate2Growth.
5. Organizing regional networking events, where different types of investors could highlight their expectations and requirements for the management team.
6. Organize and raise the visibility of networks of experts and service providers within investment readiness to improve availability at market conditions.
7. Provide access to state-of-the-art online self-assessment tools in European language versions, where SMEs and entrepreneurs can gain insight into their 'investor-readiness' (e.g. the Gate2Growth SATMED DEV-tool)
8. Science-based incubators and tech transfer offices have in many regions proved well-equipped to support university spin-outs and high-tech SMEs with support in the IPR protection process. However in some cases, the processes in these organisations are very focused on technology and less on commercialization. This can lead to an over-emphasis

on patenting – and too little focus on generating commercial value for the company. Therefore the Injection consortium recommends that regions establish incubators and tech transfer facilities, but that they build into these incentive structures that focus on the 'investor-readiness' and commercialization of businesses and the creation of growth – and not solely on the number of patents.

Target Audiences

1. Inward investment agencies
2. Regional councils
3. Incubators

Health Economics

Context

Currently national reimbursement processes, health technology assessment systems and procurement policies and practices provide insufficient support to the introduction of innovative technology on the European markets. Encouraging a shift away from the current emphasis on costs of procurement to a more comprehensive view on health economics and total cost of care could ideally be developed within the European member states in order to benefit innovative technology as well as individual patients and social welfare in broader terms.

Problem Statement

Across the European member states strategies for curbing the rising costs of the public healthcare systems effectively works counter to ambitions of the innovation support policies, by deteriorating market conditions and destroying profits to be invested in research into new technologies. Economic competitiveness and innovation strategies is currently not part of the strategies of the public healthcare systems, and the national reimbursement systems are often detrimental to the introduction of new and innovative products and therapies in national healthcare systems. Furthermore, procedures for obtaining inclusion in the reimbursement lists for new products appear to be complex and slow, thus favouring existing products and therapies to the extend where European medical device markets are increasingly seen as low cost and low technology. The current conditions effectively create a European innovation dilemma, in which the ageing society creates rising costs of healthcare result in budgets being cut. The result is deteriorating conditions for innovation in a situation where innovation is needed to create new and efficient products and services that can cope with the increasing requirements for healthcare in the ageing European society.

Objectives

Breaking the European innovation dilemma requires a rethinking of the European public healthcare systems from the current compartmentalised cost-based thinking, to understanding the public healthcare systems as innovation systems integrated with industry supply chains working under economic conditions with European-wide implications. Consequently, new strategies must be

implemented to ensure that European healthcare systems become more efficient and that such efficiency gains are measured against the total economic impact across the healthcare systems and the associated industry supply chains. Such far-reaching objectives require not only the implementation of ambitious strategies for the future European healthcare systems, but also the implementation of successful models and methodologies from private industries in relation to quality management, process redesign and information technology to harvest similar gains in efficiency and productivity.

Proposed Actions

Implementing health economics on a European level is a long-term programme designed to significantly change how the public health care systems work. In the short and medium term, procedures for agreement on strategies and plans for the transformation should be devised and pilots for large-scale testing and development of new programmes should be initiated to understand the practical implications. Furthermore, education of health care professionals, managers and consultants or professionals must be undertaken to ensure adequate levels of competence, and to initiate the gradual transformation of current systems in collaboration with stakeholders from the health care sector. In the long-term, the transformation must be supported through continuous research into health economics including the development of the models for care, new technologies as well as new models for management and organisational design to ensure the long-term sustainability and continuous improvement.

Recommendations

1. Leverage existing initiatives across Europe by supporting cross-border knowledge exchange between national and regional reimbursement decision makers and industry representatives in order to facilitate the design and proliferation of new models and methodologies for applying health economics.
2. Support the design of new incentive systems to encourage public procurement agencies to purchase innovative technologies and consider factors beyond simply cost, especially quality of care. Instead of a single treatment reimbursement within hospitals, the hospital could be given a budget per in-patient in order to have a free choice to treat the patient in whatever way it decides. This might include treatment with innovative technology if such was perceived to be more effective than conventional treatments. If the hospital operates very efficiently and spends less than the budgeted amount, it should be entitled to use the

money for its own purposes, such as attracting patients, training its staff and purchasing new technologies.

3. Develop specific support programmes to enterprises in the technology assessment phase to demonstrate to regional or national authorities the benefits of the products in connection to healthcare economics would foster the integration of innovative technology in the reimbursement lists. This could be specifically done through a targeted financing or technical support for enterprises or through incubators and technology transfer offices.
4. Support the implementation and use of information technology in the public healthcare systems combined with standardised information management systems implying a stronger exchange of information between stakeholders in the medical device sector. Considerable amounts of treatment data, know-how, expertise and ideas are being kept internally and rarely exploited. This information could be publicised to provide data for health economics, although necessary measures must be installed to protect the privacy of individual citizens.
5. Design of special bodies to assess and prioritise the outcomes of the use of innovative technology within public healthcare services in terms of care benefits to the patient and costs for the hospital and the patient. Such systematic assessment of public policy inputs would be a part of increased transparency and would thus secure investments in new technologies.

Target Audiences

1. National policy makers
2. Healthcare service
3. Industry representatives
4. Private health insurance providers
5. Universities

Public Procurement

Context

Public procurement to the European healthcare systems constitutes the major European mechanism influencing the markets for innovative products and services for the European medical device industry. Changing the current procurement practices directly influences the innovation and product development strategies of European medical device companies, and is thus the primary instrument through which new strategies for supporting innovation can be implemented. However, since the current medical device industry in Europe has built processes and technologies around the existing procurement systems, abrupt changes to public procurement can create severe shocks to the medical device industry unless carefully devised.

Problem Statement

Public procurement practices across European countries vary significantly and are subject to significant challenges in relation to creating efficient market conditions. Current challenges of the procurement systems are bias on local procurement, local languages, special procedures for approval, national safety regulations and dominant suppliers on national markets. In addition, national procurement systems are often complex, bureaucratic and pose a significant challenge for smaller medical devices companies wishing to address the European markets beyond the immediate regional or national markets. The lack of transparency makes it difficult and costly for medical device companies to obtain critical mass in Europe, leading many companies to prioritise the US markets for introduction of new products and services. Additional adverse effects of the complexities of the procurement systems are the difficulties in introducing new products or therapies that are not already on the procurement lists or that require approval of new qualities to justify changes in costs or implementation. Besides, large distributors often dominate value chains and client relationships, and there is limited influence on procurement policies by the actors concerned. Finally, it is often difficult for SMEs to take part in calls for tenders since they often do not have the resources to answer tenders beyond the local region, and often do not have the capacities to deliver sufficient quantities or deliver the required product portfolio.

Objectives

The complexity of the procurement situation in the European medical device sector currently leaves the industry and the health care sector with significant information gaps and challenges in managing public tenders. Specific measures should be implemented to improve transparency and efficiency of procurement policies and practices, as well as improve access to tenders beyond the local regions for the purpose of improving market access conditions for SMEs and start-ups.

Proposed Actions

Ensuring efficient access to national and regional procurement systems, and supporting the increased uptake of innovation products and services require measures directly target the lack of transparency in the European reimbursement systems. Measures should include harmonizing procurement systems, or alternatively provide standardised information about procurement list, and create efficient processes for answering tenders across European regions. Furthermore, in order to increase the uptake of innovation technologies new procedures for prioritising innovation technologies in the public procurement systems must be developed.

Recommendations

1. Support the design of European common standards for procurement and tendering processes in order to encourage enterprises to grow on the European Single Market. For instance, an increased exchange of information between European public procurers, healthcare authorities and industry representatives could be the first step for harmonization or at least for dissemination of procurement information to enterprises.
2. Create programmes to develop roadmaps of care delivery, against which innovators could target product development, could be achieved by employing process models of disease management. Therefore a stronger link should be developed between industry, reimbursement and health technology assessment in order to design care evaluation criteria spanning the entire health care value chain and patient care cycle.
3. Develop fast track approval mechanisms for national reimbursement lists targeting innovative products, to speed up the adoption of new technologies in line with medical roadmaps.
4. Support the lifting of limits on diagnostics related group-based (DRG) reimbursements for hospital treatments. The imposition of maximum reimbursement payments for any given

treatment in any given period has an adverse effect on the use of innovative treatments. In particular, if the reimbursement limit for any given period has been reached, no further treatments of this kind will be reimbursement in this period, meaning that no such treatments will be carried out anymore during this period. The result is inefficient usage of hospital equipments and more importantly a loss of patient value as embodied in longer waiting times for treatments. Lifting such reimbursement limits would mean more treatments could be carried out by efficient providers, which would attract more patients, enabling further economies of scale and scope to be realized by these providers. Rising revenues of such hospitals would allow the purchase of even more innovative technologies resulting in even better service and patient value.

5. Support for the creation of medical device critical mass through networking and cooperation of companies, large groups and SMEs within dedicated technology clusters, at national and European level in order to foster dissemination of information on tenders, improve market access conditions, and build up joint projects.
6. Creation of specific incentives to increase competition between enterprises could be considered as a better solution to foster the involvement of SMEs in public tenders and thus benefit innovation, e.g. generalisation of a European small business act adapted to public procurement; or limit the size of public tenders to create better opportunities for SMEs to get market access, thus also limiting monopoly or exclusivity contracts.
7. Creation of incentives in order to ensure competition among purchasers to avoid monopoly-purchaser situations. For instance, a centralised purchasing structure has been proved to favour monopoly or exclusivity contracts whereas decentralised buying systems are more appropriate for innovative efforts of manufacturers.

Target Audiences

1. National policy makers
2. Healthcare services
3. Industry representatives

Public-Private Partnerships

Context

Public-private partnerships have proven to a successful model for bridging commercialisation gaps between universities and industry and between industry and hospitals or clinics. Supporting public-private partnerships is thus an indirect model of providing support for innovation, that carries several advantages in terms of access to knowledge, understanding of demands and requirements of the public sector markets, and closer collaboration between actors in the market.

Problem Statement

Regional and national healthcare systems are the largest buyers of products and services and are thus the main sources of demand-driven innovation. Hence, the regional and national healthcare systems are unique innovation systems to be leveraged in collaboration with industry in public-private partnerships. However, it appears that in the current procurement practices, information exchange between the health care sector and industry is not systematized, thus resulting in limited use of knowledge and experience from the health care sector in the innovation processes of the European medical device sector. Health care systems in the United Kingdom, Belgium and the Netherlands have experimented with new models for procurement such as tendering out research contracts with guaranteed purchases of the resulting products or therapies, as long as that certain criteria are met. Such models allow companies to seek innovation financing or investments on the basis of future contracts, thus improving their business case and improving the prospects of attracting investments. Despite successes in some European countries, public-private partnerships are not systematically used across the European member states.

Objectives

For European member states to systematically use and benefit from public-private partnerships, knowhow and expertise from regions with advanced use of such partnerships must be shared with regions across Europe. Furthermore, research into the implementation of public-private partnerships should be systematised, and emerging models promising to target specific areas such as the commercialisation of innovation, as seen with for example pre-commercial procurement in

the United Kingdom, should be given special priority for large scale testing across European member states.

Proposed Actions

To support the wider uptake of public-private partnerships in Europe, actions should be taken to support knowledge exchange of existing experience with public-private partnerships in advanced regions such as the United Kingdom, the Netherlands and Scandinavia. Furthermore, public-private partnerships should be supported through European research funding, which could extend into funding European networks or special interest groups concerned with public-private partnerships. Finally, special models such as pre-commercial procurement, which promises solutions to specifically urgent problems should be given special priority to ensure that research in these models are prioritised and that successful implementation can subsequently be diffused with minimal delay across other European member states.

Recommendations

1. Encourage the design of models for public-private partnerships and risk-sharing models such pre-commercial procurement contracts in the medical device sector in order to improve European market access conditions. For instance, make available funding for government agencies and health insurance providers to offer financial and structural support for the necessary clinical trials or demand-driven innovation programs.
2. Allocate 7th framework funding for regional projects focused on developing public-private partnerships in the medical device sector. Such projects could subsequently be coordinated through coordination actions, developing networks across regions involved with developing public-private-partnerships for purposes of sharing knowledge and experiences, and sharing these with regions across Europe.
3. Develop proposals for special legislation on European tendering rules for pre-commercial procurement for the medical device sector to ensure that investments carried out by companies in pre-commercial procurement projects are not jeopardised by subsequent tenders for specified amounts of time.
4. Support education and training of public managers to properly handle public-private partnerships, in terms of developing sustainable strategies, understand legal conditions and

provide the necessary knowledge of how to develop value for both the private and public sector stakeholders.

Target Audiences

1. National decision policy makers
2. Research organisations
3. Healthcare services
4. Industry

Regulatory Environment

Context

The European medical device sector is heavily regulated both at national and European level. The existing European regulation is shaping the market conditions through requiring certain levels of safety and product quality. Consequently, the regulatory environment is protecting the interests of European companies by ensuring that certain standards must be met for products to enter the European markets, but are also working as a barrier for efficient market conditions since especially SMEs not always have the time and the resources to handle it.

Problem Statement

European member states impose high quality standards for European medical device products as a result of the strong emphasis of consumer protection. However, the requirements for testing, safety and quality assurance also install significant demands on smaller businesses and raise the production costs for European-produced products putting European manufacturers at a significant disadvantage in relation to products from low-quality producers. Also, differences in consumer protection regulations across European countries currently work as a detriment to supporting synergies across the markets for healthcare products, therapies and services in the European economic zone. By for example imposing different technical specifications in each member states, safety regulations prevent enterprises from a complete free circulation of goods and services. In addition, some European member states, such as Germany, have parallel quality approval systems managed by the industry associations, which effectively create barriers for SMEs in other European countries to enter the German markets, if they do not have the resources to obtain the necessary quality certificates.

Objectives

To address the challenges with the European regulatory environment for the medical device industry, the requirements of SMEs to operate freely across the European markets must be addressed through a) ensuring transparency across different national product standards and private industry quality control systems b) protect European products from unfair competition from foreign manufacturers c) ensure the necessary level of competences for SMEs to navigate the

European regulations for medical devices, in order for them to access European markets and protect their investments.

Proposed Actions

To overcome the barriers of the European regulatory environment, the transparency of the national and European health technology assessment and reimbursement requirements and methods used by authorities should be improved, to give more flexibility to enterprises to find suitable investments. Specific support should also be considered to help innovative SMEs to successfully comply with regulation requirements and thus secure their investment strategy.

Recommendations

1. Implement systems for sharing and dissemination of information on the approval procedures and conformity for purposes of transparency. Supporting the dissemination of standards at European level such as rating systems and other features could offer more visibility on processes to enable enterprise to develop at the international level. In this regard, pan-European cooperation between medical device clusters should be supported.
2. Dedicated financial and technical support to SMEs to overcome complex regulation requirements. For instance, education and training programmes to support SMEs to efficiently manage safety regulations could be provided within incubators, technology transfer offices and universities to enable skilled quality engineers and other professionals to handle such regulation. Clusters could also support specific cooperation schemes and exchange of good practises between large groups and SMEs on these issues.
3. Support new measures to control counterfeit imports or improper quality assurance from countries with less reliable control systems and control cultures than the European benchmarks.

Target Audiences

1. SMEs
2. European and national regulatory bodies
3. Inward investment agencies

Literature

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2 Professor Terry YOUNG, Chair of Healthcare Systems Brunel University, United Kingdom

3 Mr Rob GERAERDTS, Managing Director, Roche Diagnostics, Belgium

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Endnotes

[i] European Commission (2007)