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SINGLE-MARKET REGULATION AND INNOVATION IN EUROPE'S MEDICAL DEVICES INDUSTRY

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Abstract

In this article we analyze the influence of the legal regulatory framework in Europe, established by the two directives on medical devices and active implantable devices, on the performance of innovation in a single European market. First, we describe in general the possible influence of a single European market on innovation and the institutional features of the particular harmonization approach ("New Approach") we are looking at here. The empirical results presented derive from a survey investigation involving 150 firms that we defined as best innovators in the European medical devices industry from a pre-survey. The results confirm that the total impact of the New Approach regulation on firms' innovation in the long term is positive. However, it also becomes clear that the impact of regulation on innovation is limited if the factors are looked at individually and that there is a clear difference regarding short-term effects. To improve the regulatory framework, several policy actions are recommended.

Keywords: European single market regulation, New Approach regulation, Institutions, Innovation, Medical devices

The impact of regulation on innovation is discussed widely, but it is rarely analyzed. The debate has been characterized by an inadequate level of information and has lacked a good, systematic, empirical foundation. An innovation-friendly framework is an important economic policy goal since it influences the decisions of economic actors, it guides the direction of technological development, and it stimulates economic growth (10). In its Green Paper on Innovation, the European Commission describes one of its fundamental objectives as "to foster a legal and regulatory environment favourable to innovation" (2).

The objective of this article is to gain a deeper insight into the impact of regulation in the European single market (single market regulation) on innovation in the medical devices industry. The European dimension of health care is frequently discussed, but the importance of the European single market for health care has hardly been studied (8). The

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European Commission recently developed Europe-wide regulation in this sector by means of two directives, 90/385 EEC Active Implantable Devices and 93/42 EEC Medical Devices. These two directives aim to construct a Europe-wide harmonized system for the safety approval and control of medical devices. The directives replace the different regulation systems on the national level and thus remove technical barriers within the European single market.

In particular, this study asks: a) how does the new institutional framework of the two single-market directives influence innovation in the European medical devices industry; and b) in what direction is innovation influenced?

In order to ascertain the effect of regulation on innovation, features of both the institutional framework and of the industry in question are taken into account. Therefore, the most important features of Directives 90/385 EEC and 93/42 EEC and of the supply and the demand side of the innovation system of the medical devices industry are included in the analysis. The most recent directive, 98/79 EEC (*in vitro* diagnostics), has only been in force for a short time and it would be too early to estimate its impact on innovation. That is why it is not taken into consideration in this article. The empirical results presented here are based on a survey investigation involving 150 European firms from the medical devices industry. Finally, several policy recommendations are deducted from the analysis.

SINGLE-MARKET REGULATION IN THE EUROPEAN UNION

The European Single Market and Its General Effects on Innovation

The aim of the Single Market Programme of the European Union (EU) is to create an area without internal frontiers and to implement structural changes designed to improve the EU's capacity to generate economic growth. With the removal of technical barriers to trade, the free movement of goods, persons, and capital are ensured (3;5).

The relationship between harmonization in the European single market and the development of healthcare markets, differentiating the potential effects on national healthcare systems, has already been analyzed by Maynard (12) and Wismar and Busse (13). For the medical devices industry, the new institutional framework of the European single market has the potential to affect innovation on two levels. First, the single market creates a more integrated economy in general; and second, the two single-market directives, Active Implantable Devices (90/385 EEC) and Medical Devices (93/42 EEC), create further effects.

The effects on innovation deriving from a more integrated economy within a single market are outlined below.

- An enlarged and more integrated market expands the size of the potential customer base, thus helping firms to enter new markets with innovative products, and thereby stimulating innovation (e.g., products with improved safety features can find better marketing conditions since all customers in the single market are offered the same level of safety).
- An enlarged or more integrated market also creates better possibilities to write off fixed costs for research and product development through higher production volumes.
- A higher degree of integration reduces the time, risks, and costs needed to reach the market and customers with innovative new products. This also means that safety improvements can diffuse more quickly within the single market.
- Technology diffusion is stimulated by a higher degree of free access to technical knowledge (e.g., by better conditions for cooperation or by lower barriers to trade).

- The factors mentioned can create an incentive for investment of resources (human or financial) in industrial research and product development that exerts a positive influence on innovation.
- A higher degree of competition stimulates industrial research and innovation. Firms in less competitive markets tend to innovate less and to use already established technologies. On an international level, competition forces the generation of innovations of a higher quality that are also competitive on a global scale.
- Competition also forces domestic innovators to choose either to speed up their pace of innovation and reduce the time to market or be displaced by foreign innovators. Although some of the less competitive innovators may be forced out of the market, the total rate of innovation, and therefore the growth rate, increases.

The diagram in Figure 1 illustrates the various aspects of the relationships between regulation and innovation described above.

In addition to the effects of regulation caused by the removal of market barriers and a higher degree of economic integration in the single market in general, further effects arise from the specific features of individual policy approaches and the relevant directives.

EU Policy Approaches to Promote the Single Market

Single-market regulation uses two strategies to remove technical barriers and to ensure the free movement of goods in the EU (5):

1. The Mutual Recognition Principle; and
2. The harmonization of national regulations and standards:
   - Detailed harmonization (old approach); and
   - Regulation limited to essential requirements (the "New Approach").

For the medical devices industry, the New Approach regulation is relevant, since Directives 90/385 EEC and 93/42 EEC fall under this approach. In general the new approach to technical harmonization and standards applies to groups of products that have sufficiently similar characteristics or share a set of health and safety or environmental issues, so that essential requirements can be devised for all the products, and where there has been divergent technical regulation in the member states (Council Resolution of May 7, 1985, 85/C/136/01) (5).

The New Approach regulation is characterized by the following features:

1. The regulation is limited to essential requirements (especially in order to protect health and safety). Essential requirements contain no specific technical rules.
2. A more detailed technical specification by means of harmonized standards is developed by standardization bodies.
3. The use of standards is voluntary. National authorities are obliged to recognize that products manufactured according to harmonized standards are presumed to conform to the essential requirements established by the directive.
4. The directives define a modular system of different conformity assessment procedures. These procedures are used by the manufacturer to establish that they meet the legal requirements.
5. Notified bodies also have to be involved in these procedures (depending on the kind of product and procedure).
6. The CE marking certifies that a product conforms to all relevant requirements. Products with the CE mark are allowed to circulate freely within the single market.

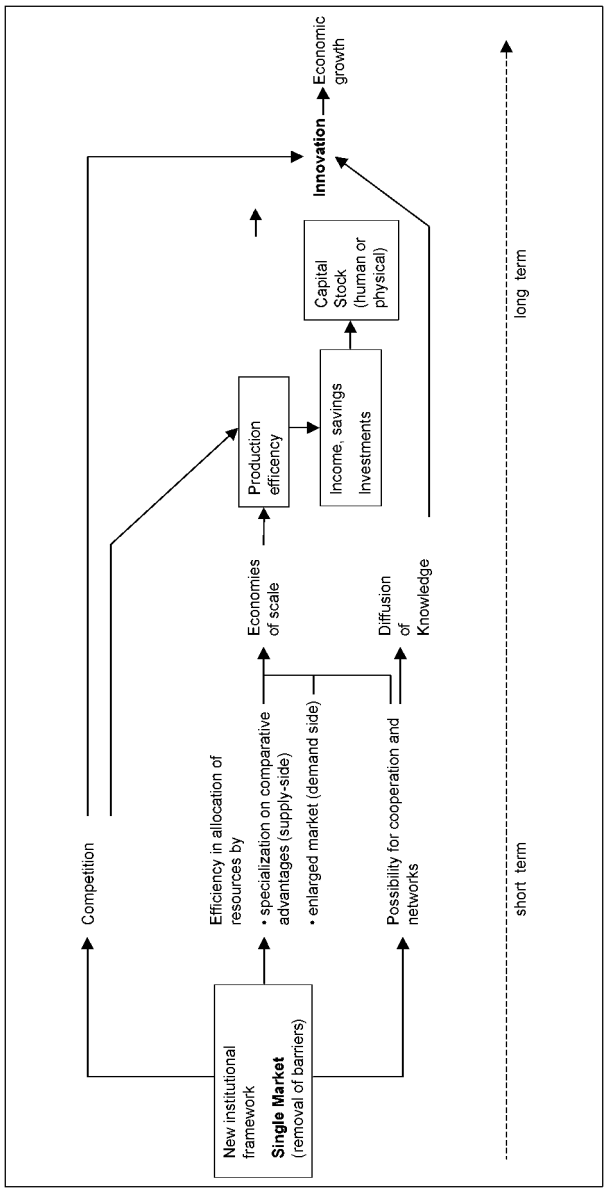

Figure 1. Link between single-market regulation and innovation.

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CHARACTERISTICS OF THE MEDICAL DEVICES INNOVATION SYSTEM

An analysis of the effect of regulation on innovation in the medical devices industry involves more than merely the examination of different policy approaches and the directives themselves. Indeed, it is highly important to take into consideration the specific features of the innovation system in which the regulation is effective. The following paragraphs present important factors in the medical devices innovation system (1;4;6;7;9;11).

The European medical devices industry is faced with a range of influences on its innovatory activities. On the supply side, in particular, these influences are issues relating to the cost and qualification of human resources, the safety of products, the globalization of markets, increasing international competition, trends toward concentration of industries, and the high importance of research and development, innovation, and increasing technological dynamics.

Furthermore, the innovation process shows sector-specific characteristics of technical development and innovation. The knowledge base develops dynamically and consists of a wide range of technologies and medical knowledge. This requires cooperation between the various players necessarily involved in the innovation process (e.g., the requirement to involve the demands of doctors). Further specific characteristics of the process are its long duration, its nonlinear dynamics, and its high risk.

There are several more general trends and challenges that the European medical devices industry has to face that originate from the demand side and which have an effect on innovation in the industry. Examples of these general trends and challenges are the aging population, an increase in income, awareness of healthcare issues and demand at the level of private households, an increase in healthcare expenditure (e.g., the wrong kind of incentives within the healthcare system), cost-containment policies in healthcare systems, and the need for higher efficiency in the production of healthcare products.

The high degree of regulation in healthcare systems (in particular on the demand side) in general also makes clear that the regulation by means of Directives 90/385 and 93/42 EEC represents only one important influence among several in terms of innovation in the industry. Although facing common challenges, the institutional solutions put in place by different EU countries to reorganize the demand side in the member states vary widely. Differences can be found in all important elements of national health systems, which also exert an important influence on the development and marketing of innovative medical devices products. On the demand side of the European medical devices cluster, a rather low level of harmonization has been attained so far as seen within the single market.

EMPIRICAL ANALYSIS

Methodology

The empirical work of the study was structured in a two-step postal survey:

- *Step 1*: Selection of the best innovators in the European medical devices industry via a pre-survey (postal survey among different expert groups of the medical devices cluster); and
- *Step 2*: Researching the experiences of the most innovative firms in the medical devices industry with the New Approach regulation (postal firm survey and additional telephone interviews among the best innovators selected in step 1).

Approach of the Pre-survey (Step 1). The pre-survey was a postal survey among important expert groups in the medical devices cluster. Using the criterion of product

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innovation, the main goal of the pre-survey was to identify the most innovative firms. Best innovators were requested by name and address (including person to contact for the survey, if known). The definition of *best innovators* was firms that have a proven capability to reach the market successfully with innovative products. The wide coverage of consulted experts (608) from different European countries was thought likely to ensure good coverage of innovators. Finally, 85 experts answered and nominated 428 firms as best innovators in the European medical devices industry.

Approach of the Firm Survey (Step 2). All 428 identified firms from the pre-survey were contacted. Some 35% (150 firms) answered the final questionnaire on which the following analysis is based.

This questionnaire contained 15 concise questions about the impact of Directives 90/385 EEC and 93/42 EEC on innovation and six questions for firm classification (relevance of directives, firm size, firm location, market segment, risk class, location of markets). As regards the questions about the impact of regulation, the firms were asked to provide their assessment on a scale ranging from -2 = very negative ("bad") impact, to 0 = no impact, and 2 = very positive ("good") impact. In addition to this assessment, the firms were asked to give more detailed comments. The survey concentrated on the following factors that could be influenced by the New Approach regulation in the area of medical devices:

1. Impact of direct access to the single market on:
   - Investment;
   - Time to market;
   - Innovation costs;
   - Innovation risks; and
   - The opportunity to enter new international markets in Europe, overseas in general, and in the United States.
2. Impact of technological and organizational flexibility on innovation:
   - Impact of technological flexibility by limitation to essential requirements;
   - Impact of harmonized standards;
   - Impact of organizational flexibility by different conformity assessment procedures; and
   - Impact on the quality assurance system.
3. General impacts of the directives:
   - On cooperation with the following actor groups: medical research and clinical testing, other scientists/laboratories, companies, and national or international notified bodies;
   - On competition within the single market;
   - On competitiveness of EU manufacturers;
   - Total impact of the directives in the long term; and
   - Transitional impact of the directives.

Some 12 firms providing detailed information and showing a special interest were interviewed by telephone in addition to the written survey.

Empirical Results

With Directives 90/385 EEC and 93/42 EEC, the foundations were laid so that medical devices marked with a CE sign can be freely marketed within the single market. The results of the empirical analysis demonstrated that this institutional change plays a part in developing positive effects in the European medical devices industry. Asked about what long-term effects are expected after the transition period (which is necessary for firms to adapt to the new regulation), the companies answered with positive values on the value scale for all individual factors assessed. The total impact of the New Approach regulation

Figure 2. Comparative overview of results—mean of individual factors, values: −2 = very negative (bad) impact, to 0 = no impact, and 2 = very positive (good) impact.

on the firms' innovation in the long term is confirmed clearly by a positive mean value of 0.72 (scale: −2 to 2). Among all factors, only the transitional impact was assessed to be low, with a negative value. Companies' additional remarks also make clear that short-term disadvantages are expected, since operational processes and procedures have to be adjusted to the new institutional framework.

Figure 2 shows the generally positive effect of the Directives on innovation by means of the various individual factors.

Altogether, the results of the written questionnaires show that the impact of regulation on innovation is limited if only individual factors are examined. The innovative effect of the directives works essentially not by means of individual dominating factors but rather by means of a broad spectrum of various channels. In terms of the given value scale, most results lie in the range of zero (no impact) to 1 (positive impact). Also, the strongest factors, "opportunity to enter new markets in Europe" and "impact on quality assurance system," only marginally exceed 1. This result (many different factors, yet each having only a weakly positive effect) is underlined by the additional comments of companies regarding the overall effect on innovation. These companies list a broad set of influences such as more flexibility, reduced conformity assessment, easier market access, product/patient safety and performance, and a drive toward global harmonization.

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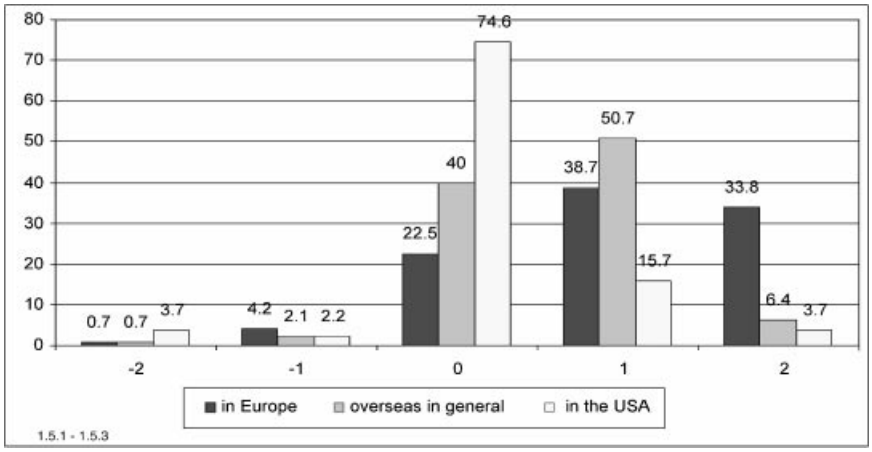

Figure 3. Impact of the direct access to the single market on the opportunity to enter new international markets with an innovative product in Europe, n = 142; overseas in general, n = 140; in the United States, n = 134.

Even though all the factors examined show an influence in the same direction from a long-term perspective and do not vary greatly in the strength of their effects, a comparison of the individual factors is worthwhile. The strongest effects were recorded for the following questions:

- Impact on the opportunity to enter new international markets in Europe;
- Impact on the quality assurance system; and
- Total long-term impact on innovation.

The weakest factors (which did however still have a positive effect) were:

- Impact on innovation costs; and
- Impact on innovation risks.

In respect of these factors that exert the strongest/weakest effects, the companies pointed out that in terms of opportunities for entering new international markets in Europe, easier access to the European markets is a definite advantage, since market introduction is now possible in all European countries at the same time and there is no longer a need for multiple national testing and registration. In this context, the need for more harmonization in the explanation and application of the directives at a national level was stressed. From the companies' point of view, individual countries' practices still vary greatly.

Figure 3 shows a more detailed analysis of the answers to the question about the opportunities to enter into European markets and those outside Europe (overseas in general) as well as the U.S. market. The impact on the opportunity to enter overseas markets in general (mean value, 0.60) and the impact on the U.S. market (mean value, 0.13) are given a much lower rating than the impact on the opportunity to enter new European markets (mean value, 1.01).

On the one hand, firms underlined that the CE sign is recognized in these markets and that it makes entering markets much easier. On the other hand, companies pointed out that further steps toward harmonization or mutual recognition in the global marketplace are necessary.

The individual factors explaining the firms' statements about impact on access to international markets are listed in Table 1.

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Table 1. Factors Explaining the Firms' Statements Regarding Impact on Access to International Markets

Positive aspects	Negative impacts
Due to regulatory convergence it is easier to access foreign markets in Europe.	Still necessary to comply with other countries, regulation schemes outside Europe, even though the CE sign exists.
Market introduction to all European countries simultaneously.	Although some harmonization with the United States has brought about certain improvements, there is still a lack of mutual recognition between the EU and the United States. The FDA does not accept the CE sign.
CE sign has a positive reputation in non-European countries as well.	
An increasing number of countries outside Europe recognize the CE sign (sometimes in spite of their own regulations).	
The CE sign helps new customers from abroad to have confidence in the product.	
Easier to apply for FDA approval with CE sign; European harmonization will also improve access to the U.S. market.	
If the global harmonization effort succeeds, there will be a major positive impact.	

With regard to the quality assurance (QA) system, the firms emphasized that regulation provides a generally stimulating effect for the implementation of a QA system. The clear structuring of operational innovatory processes, improved product quality and safety, and faster and more efficient conformity assessment (after the QA system has been implemented) were particularly regarded as advantages of a QA system.

The low positive value regarding the question of innovation costs corresponds with a large number of critical remarks on this point. First, the costs involved in implementing new structures and processes for meeting the demands of the new institutional framework were mentioned. Second, there was criticism that the ongoing application of the directives will increase costs (e.g., because of administrative requirements) in the long term. Nevertheless, in terms of the costs related to quality assessment, the fact that the cessation of certification requirements and barriers for market entry in individual member states has created cost advantages in the innovation process was evaluated positively. From the companies' point of view, regulation has only a slight effect on the risk of the innovation process in general. But in terms of product safety and corresponding risk reduction, companies regard regulation as highly important.

The issue on which companies' opinions diverged most widely was that of the effect of regulation on time to market for innovative products (the standard deviation recorded for this question was higher than any other). On the one hand, companies estimate positively the clear time advantage in terms of access to other European markets. On the other hand, the time delay arising from formal and administrative demands and additional steps involved in quality assurance were criticized. In the examination of different company groups, companies that had previously only produced for the national market gave a value above the mean value in the assessment. However, the assessment of companies already producing for the EU market (though not for overseas and the United States) was below average. Companies from the disposable devices market segment also returned positive assessments above the average level, as did firms from Sweden and Italy.

This general picture of the quantitative evaluation is further supported by the most important advantages and disadvantages of the directives that the companies assessed in their additional comments, as shown in Table 2.

Table 2. Main Advantages/Disadvantages of the Directives

Main advantages	Main disadvantages
Better market access in Europe	Costs
Impact on quality assurance system and internal proceedings	Time for first market entry
Product quality and safety	Administrative and bureaucratic efforts (paperwork)
Time to European markets	Harmonization and single market not yet completed—national differences still exist

From the companies' point of view, further actions are required to attain the expected positive effects from the new institutional framework of the single market in the long term. This is clearest in terms of the application of the directives, which is still inadequately harmonized in the companies' opinion. They continue to observe marked differences in the practice of the new institutional framework both at the national level and at the level of individual players and the need for consistent enforcement systems. This shows that the process of harmonizing the institutional framework, with its formal adoption and the formal end of the transition phase for national regulations, has not yet been completed. Rather, a comprehensive harmonization is required, and in particular a harmonization of the interpretation and practical application of institutional rules and their enforcement by the various players in the innovation system (e.g., the notified bodies).

Although many firms have taken time to adapt to the new system of accreditation, the statements of the companies still reflect the view that the new system is overly bureaucratic and that it consumes a great deal of time and money. To make the new institutional framework exert its full positive impact in the long run, the firms ask for a more efficient and less bureaucratic regulation.

In addition, the firms identified barriers to the single market that still exist and fall outside the scope of the directives but also influence their success. It was emphasized in particular that the different healthcare systems in Europe and a lack of harmonization in this area continue to act as a barrier to Europe-wide marketing. Finally, it was pointed out that the removal of technical barriers in the European economy is still not accompanied by enough similar actions aimed at harmonizing accreditation systems requiring similar procedures and safety standards on a global scale (such as in the United States and the Far East).

CONCLUSION AND POLICY IMPLICATIONS

The overall conclusion is that, on the basis of the empirical study, it was shown that the initial hypothesis—that the new institutional framework of Directives 90/385 EEC and 93/42 EEC has improved conditions for innovation—can fundamentally be upheld. In the longer term, it can be expected that the European single-market regulation assessed here by means of different factors will result in positive effects on innovations in the medical devices industry. However, it must be noted that while the basic prerequisites are in place today, the positive effects have not yet developed to their full potential. At present, companies are still greatly influenced by the negative effects of transition. Further actions appear to be necessary so that a comprehensive harmonization of the interpretation, practical application, and enforcement of the new institutional framework at the level of different member states and players can be achieved and that the expected positive effects of the new institutional framework can be realized fully.

The empirical analysis suggests a number of policy recommendations to improve the regulatory framework and to strengthen innovatory forces within the European medical devices industry. Based on the empirical results, the authors recommend the following policy actions:

1. *Further development of the single market through complete and harmonized implementation and enforcement of the directives*. Between countries and among individual players, the explanation and application of the regulatory framework is still different. The complete and uniform implementation of Directives 90/385 EEC and 93/42 EEC in all member states should be the final objective.
2. *Inclusion of the demand side in harmonization and harmonization of healthcare systems in the single market*. Within the single market, healthcare systems are in place in each member state that represent a variety of different approaches, each with its own peculiarities. Further harmonization of the conditions on the demand side of the European medical devices market is required if the single market in the industry is to develop its full potential.
3. *Expansion of harmonization at a global level*. Activities already under way and negotiations aimed at increasing global harmonization in the area of medical devices should be intensified in order to expand international trade in this sector and to allow products carrying the CE sign better access to non-EU markets as well (e.g., by means of mutual recognition agreements).
4. *Support of the dissemination of the CE sign by marketing*. The understanding and implementation of the medical devices directives should be improved along the entire production chain for innovation in the medical devices industry (e.g., in the field of medical research). Furthermore, the CE sign should be actively marketed outside the European single market.
5. *Reduction of the costs of implementing a new institutional framework*. Companies introducing the new institutional framework of the directives are confronted with uncertainty and high costs in adapting their operational processes and structures in terms of information, re-direction, and change. Therefore, the aim should be to create a high degree of clarity and guidance regarding the interpretation of requirements and to offer long-term stability of the institutional framework.
6. *Increased efficiency in the application of the directives*. A study should be conducted on how far the registration of innovative medical technology products could be freed of formal administrative tasks. Measures that would help to make the registration process for products more efficient, and thereby save valuable resources in the innovation process, ought to be developed and introduced immediately, providing this does not impinge on product safety.
7. *Support for innovation in medical technology not only by single-market regulation but also through initiatives involving other policy areas*. Regulation by means of directives 90/385 EEC and 93/42 EEC is an important policy factor in the field of medical devices, but it is not the only one. A number of other policies play a deciding role (e.g., the national health policy, trade and competition policy) that should be considered as well.
8. *Promotion of the single market through permanent dialogue between relevant groups in the medical devices innovation system*. Regulation ought to be constructed as a continuous process of technological and policy interaction. A permanent and intensive dialogue between all relevant groups of players appears particularly useful in this context in order to guarantee that regulations are designed that fit the socioeconomic conditions for implementation and application. The needs of users and patients (e.g., safety requirements) should be given an active voice in this dialogue as well.
9. *Internationalization of technology assessment*. Regulation for conformity assessment no longer takes place at the national level, and the medical devices industry is becoming increasingly global. Technology assessment in the field of health care should therefore be more transnational. This involves the exchange of information and experiences across national borders or transnational institutions in the field of technology assessment.
10. *Continued and deepened evaluation of the impact of regulation on innovation*. This study has concentrated on specific questions and has chosen a specific methodologic approach. The objective of future analysis could be the short-term adaptation processes at the business level, the behavior of

different players in the medical devices innovation system and their cooperation, and the impact on product quality and safety of innovative medical devices.

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