The impact of EU-Regulation on Innovation of European Industry

The impact of Single Market Regulation on Innovation: Regulatory Reform and Experiences of Firms in the Medical Device Industry

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Executive summary

The objective of this study is to gain a deeper insight into the impact of Single Market regulation on innovation in the medical devices industry. This study looks in particular at the influence of the European Single Market on innovation in the medical devices industry. In its analysis of the regulative framework, the study concentrates on the New Approach directives 90/385 EEC “Active implantable Devices” and 93/42 EEC “Medical Devices” (Chapters 1 and 2).

The aim of the Single Market is to create an area without internal frontiers in which, by the removal of technical barriers to trade, the free movement of goods, services, persons and capital is ensured, and to improve the EU’s capacity to generate economic growth (Chapter 3). The strategies to remove technical barriers within the European Union are:

1. The mutual recognition principle
2. Harmonisation of national regulations and standards:
   - Detailed harmonisation (old approach)
   - Regulation limited to essential requirements (new approach).

The Single Market has become a reality which has a definite impact on the European economy as a whole. Nevertheless, both the Single Market and its impact are still developing, and technical barriers to trade still exist.

The specific characteristics of the medical devices industry and the current state of the industry’s innovation system are examined in Chapter 4. In this context, the following issues are explained:

a) the regulative framework of Directives 90/385 and 93/42 EEC
b) the supply side and
c) the demand side of the medical devices cluster.

In analysing the regulatory framework, the following were shown to be potentially important factors:

a) The directives are limited to “essential requirements” to protect the safety and health of patients and users; they contain no specific technical rules. This means that regulation offers technological flexibility for innovation.
b) The use of harmonised standards is a possible instrument for assessing conformity with the Directives in an efficient way. In terms of innovation, it must be remembered that technological flexibility still exists because the application of standards is voluntary. This is particularly important as standards generally only represent the current state of the art technology.
c) The directives offer different conformity assessment procedures. The manufacturer is therefore offered a modular and flexible organisational framework for conformity assessment. He can choose the best procedure for the firm and the product. The application of a quality assurance system may be an efficient element for conformity assessment within that system.

The analysis of the **supply side** of the medical devices cluster shows that the innovatory activities of the European medical devices industry are affected by many factors. Particular issues are: the cost and qualification of human resources; the globalisation of markets, increasing international competition; trends towards the concentration of industries; the high importance of R&D and innovation and increasing technological dynamics. The analysis showed characteristics peculiar to the medical devices industry, such as:

- the relevance of a wide range of technologies
- the requirement to involve the demands of doctors and patients
- the price pressure for innovative systems arising from healthcare systems themselves
- the high relevance of co-operation between various players
- the character of the innovation process as a non-linear "production chain" for innovation
- the long duration of the innovation process
- the rapid dynamism in the field of technological and medical knowledge
- the high innovation risk and the problem of financing.

Furthermore the analysis showed that a number of more general overall trends and challenges originating on the **demand side** had also an effect on innovation. Some examples are:

- the rise in the average age of the population
- an increase in income
- awareness of healthcare issues
- an increase in healthcare expenditure (driven by technological developments and wrong incentives within the health system),
- cost containment policies and the need for higher efficiency in the production of healthcare products.

Although facing common challenges, the solutions put in place by EU Member States to reorganise the demand side vary greatly. Differences on the demand side can be found in all important elements of the national healthcare systems, which also exert an influence on the development and marketing of innovative medical devices. So, on the demand side, harmonisation within the Single Market has been achieved only to a minor extent. Furthermore the high degree of regulation in the healthcare system (on the demand side in particular) makes it clear that regulation by means of Directives 90/385 and 93/42 EEC represents only one of several important factors influencing the medical devices industry.

The presentation and analysis of the empirical results of a survey of companies makes up the largest part of this study. Companies active within the European medical devices industry were asked to
evaluate the effect of Single Market regulation on innovation; the results can be seen in Chapter 5. The hypothesis was put forward that the new institutional framework has improved conditions for innovation. The empirical analysis of the impact of harmonisation on several factors in the innovation chain is based on a survey investigation of 150 firms from the medical devices industry. Even though all the factors examined show effects in the same direction and do not vary greatly in the strength of their effects, a comparison of the individual factors is still worthwhile. The strongest effects were recorded for the following questions:

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

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

- Impact on innovation costs
- Impact on innovation risks.

Firms highlighted the following aspects as being the strongest and weakest factors: in terms of opportunities for entering new international markets in Europe, companies regarded it as a definite advantage that there is easier access to the European markets, since product launching 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 harmonisation in the explanation and application of the Directives at the level of individual countries was stressed. From the companies’ point of view, individual countries’ practice still varies greatly. With regard to the quality assurance system, it was emphasised 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.

This general picture of the quantitative evaluation and the additional commentaries is further supported by the “most important advantages/disadvantages of the Directives for companies’ innovation activities” listed by the companies assessed:

<table>
<thead>
<tr>
<th>Main Advantages</th>
<th>Main Disadvantages</th>
</tr>
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<tbody>
<tr>
<td>- Better market access in Europe</td>
<td>- Costs</td>
</tr>
<tr>
<td>- Impact on quality assurance system and internal proceedings</td>
<td>- Time for first market entry</td>
</tr>
<tr>
<td>- Product quality and safety</td>
<td>- Administrative and bureaucratic efforts (&quot;paperwork&quot;)</td>
</tr>
<tr>
<td>- Time to enter European Markets.</td>
<td>- Harmonisation and Single Market not yet completed – national differences still exist.</td>
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From the companies’ point of view, in order that the new institutional framework of the Single Market can develop the expected positive effects in the long term, further actions are required. This is clearest in terms of the application of the Directives, which is still inadequately harmonised, in the companies’ opinion. Furthermore, although many firms have taken time to adapt to the new system of accreditation, there is still the view that the new system is overly bureaucratic and therefore time and money consuming.

In addition, the firms have identified barriers to the Single Market which still exist and which fall outside the scope of the Directives but also influence their success. In this context, the fact that both different healthcare systems in Europe and a lack of harmonisation in this area continue to act as a barrier to Europe-wide marketing was particularly emphasised. Finally, the removal of technical barriers in the European economy is still not accompanied by similar actions aimed at harmonising accreditation systems on a global scale (such as in the US and the Far East).

The following can be seen to be the overall conclusion to this study: on the basis of the empirical study 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 Single Market regulation assessed here by means of different factors will result in positive effects on innovations in the medical devices industry. But, whilst the basic prerequisites for this are in place today, the positive effects have not yet developed to their full potential. At present, firms are still greatly influenced by the negative effects of transition. Further actions also appear to be necessary for the achievement at the level of Member States and other players of a comprehensive harmonisation in the interpretation and practical application of the new institutional framework and for the full realisation of the expected positive effects of the new institutional framework.

Finally, in Chapter 6, policy implications are indicated on the basis of the empirical results. These are aspects which could contribute to the improvement of the regulatory framework under analysis here and to the strengthening of innovatory forces within the medical devices industry. The following points were recommended in particular as further policy actions:

- Further development of the Single Market through complete and harmonised implementation of the Directives
- Inclusion of the demand side in harmonisation
- Expansion of harmonisation at a global level
- Support of the dissemination of the CE sign by marketing
- Reduction of the costs of implementing a new institutional framework
- Increased efficiency in the application of the Directives
- Support for innovation in medical technology through initiatives involving more than one policy area
- Promotion of the Single Market through permanent dialogue
- Continued analysis of the impact of regulation on innovation.
1 Introduction

The relation of regulation on innovation accounts for a large proportion of the current discussion on economic theory and innovation policy. The creation of an innovation-friendly framework is an important economic policy goal. In its Green Paper on Innovation the European Commission therefore describes one of its fundamental objectives as being "to foster a legal and regulatory environment favourable to innovation". The development of a "favourable legal and regulatory framework" is a complete route-of-action in itself, within the scope of the Green Paper on innovation.²

On the whole, intensive discussions take place in all manner of contexts as to which framework conditions can provide a positive climate for innovation. The underlying aim in all of these is, however, the same - to resolve social challenges by means of innovation and technological developments, and to increase the competitiveness of the industry. At the same time, society expects governments to develop regulations that help to reduce risks and damages (e.g. for health or environment) resulting from technological developments.

However, the discussion is not always objective and based on facts. It can often be seen for example that references to an "innovation friendly atmosphere" are used broadly to demand deregulation, liberalisation and more competition. Such all-encompassing statements do not adequately convey the complex relations between the individual players in the innovation process nor the way in which different private, social and state institutions act in combination. Similarly, the simple dismantling of regulation cannot be seen as a solution, as state monitoring and corresponding regulation provides a minimum level of security in certain fields. This is true in cases such as the defence against potential health or environmental risks.

In terms of regulation it is not therefore a question of simple alternatives or of a simple yes or no. It is much more a question of how regulation must be carried out, and what form this regulation must take in order to achieve the intended effects (for instance in terms security guarantees) and to have a positive impact on innovation at the same time. Despite the fact that a number of studies into the relationship between regulation and innovation have been carried out, as yet the issue has by no means been sufficiently recognised scientifically.³

The objective of this study is to gain a deeper insight into the impact of Single Market regulation and innovation in the medical device industry. In its analysis of the regulative framework, the study concentrates on the two directives 90/385 EEC “Active implantable Devices” and 93/42 EEC “Medical Devices”. The background of the study and the motivation to analyse the impact of Single Market Regulation on Innovation in the medical device industry is the fact that in the past there has been a barrier to free product circulation caused by the lack of a common European regulative framework and

² See European Commission, 1995; III, VI, 33, 44.
³ E.g. Kuhlmann et al. (1998).
the existence of a large variety of national regulations. To be marketed in European countries medical devices had to undergo procedures of conformity assessment in single European countries. Manufacturers were confronted with different regulative frameworks at the national level. In order to develop a common regulative framework and to remove these technical barriers to trade within the Single Market there has been EU wide technical harmonisation under the New Approach, namely the two directives 90/385 EEC and 93/42 EEC.

Broadly speaking, the New Approach to technical harmonisation is based on a division of responsibility between public authorities on the one hand and producers, testing and certification bodies and standardisers on the other. In detail the new regulative framework is characterised by the following features:

- Free circulation for CE marked medical devices
- A set of different certification procedures to assess conformity
- Limitation to essential product requirements
- Specification by harmonised standards

Considering these aspects this study analyses the impact of technical harmonisation within the Single Market and the impact of the design of the New Approach directives 90/385 EEC and 93/42 EEC on innovation in the medical device industry. The key questions for this study are:

1. How does the new institutional framework of the Single Market influence innovation in the European medical device industry?
2. In what direction innovation is influenced?

Following the introductory discussions in chapter 1, chapter 2 outlines fundamental conceptual aspects concerning the analysis of regulation and innovation. As this study examines the impact of Single Market regulation, the background and the main characteristics of the regulative framework of the Single Market programme along with its general economic impact are presented in chapter 3. Chapter 4 sets out the specific features of the innovation system in the medical devices industry. In this context, the following are highlighted: a) the features of the regulative framework of Directives 90/385 and 93/42 EEC and of b) the supply side and c) the demand side of the medical device cluster. Chapter 5 forms the major part of this study. It provides a presentation and analysis of the empirical results of a survey of companies active within the European medical device industry. These companies were asked to evaluate Single Market regulation on innovation. Policy implications resulting from this survey, which could contribute to the improvement of the regulatory framework under analysis here and to the strengthening of innovatory forces within the medical device industry are discussed in chapter 6.

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4 Chapter 3 outlines the fundamental characteristics of the Single Market programme. This chapter draws on background information provided by earlier studies and analyses. Readers who are already familiar with this information can focus on the summary at the end of chapter 3 or can move straight on to chapter 4.
Dealing with the question of the influence of the Single Market framework on innovation the current study can be classified as being in the area of new institutional economics. The fundamental characteristic of these is that they analyse the influence of institutions on the economic process. They are particularly concerned with the question of how institutions influence the behaviour of economic actors. Fundamental aspects which must be taken into consideration in the analysis of the impact of institutional frameworks and regulation on innovation are described below.

5 For a comprehensive overview of the branch of new institutional economics see for example Richter, Furobotn (1996).
2 Conceptual aspects

Conceptual aspects concerning characteristics and the analysis of regulation, innovation and the link between regulation have been presented in the study “Economic Evaluation of the Internal Market” (European Commission, 1996a pp. 59-61), by Kuhlmann et al. (1998), by Brousseau (1998) and by Becher, Kemp, Smith (1999). A selection of aspects that have to be considered when investigating the impact of the Single Market on innovation will be presented in the following chapter.

Regulation

Becher, Kemp, Smith (1999; pp.7, 9) point out that regulations are a part of the institutional matrix of a sector. Together with the prevailing cost and demand conditions, this matrix provides the incentives that stimulate the level and the kinds of innovations to be developed. This means that in the incentive system regulation is one but not the only incentive factor for innovations.6

Kuhlmann et al (1998) point to the variety of different regulation instruments which are implemented by players from the political and administrative system. These regulations are essentially legitimated by two types of arguments; firstly, defence against risks (for instance for the security and health of citizens) and secondly the securing of individual wellbeing, particularly in the reduction of social costs.7 Moreover Brousseau (1998) underlines that the Single Market regulative framework consists of a set of different rules which do not all automatically exert the same effects as a kind of homogenous block. This is even more the case as the single regulations within this set of rules affect industries with different characteristics.

Furthermore, it has to be considered that there are differences in the way in which community regulations are implemented and enforced in the various EU countries (because of e.g. differences in timing of implementation or in interpretation). The explanation for these differences can be found on the institutional level of national administration or courts of justice, for example.

Innovation

Becher, Kemp, Smith (1999, 1-3) describe innovation as a collective, explorative activity which is distributed between many agents and involves complex interactions between a firm and its environment. They therefore underline the importance of a systems approach to innovation. As for important environment conditions Kuhlmann et al. (1998, 9) highlight e.g. the importance of specific technological paradigms and the conditions of regional, national or sectoral innovation systems.

Moreover, Brousseau (1998) describes innovation as a multifaceted and dynamic process. Because of this characteristic, "innovation" should not be reduced to a single aspect or indicator. Innovation should

6 See also Kuhlmann (1998, 15).
rather be seen under different aspects (e.g. technological marketing and organisational changes). Furthermore, as the regulative framework of the Single Market is comparatively young the measurement of innovation should concentrate not only on output factors (such as patents) but also on structural factors (like links between actors or co-operative networks as "infrastructure for innovation") as these provide the prerequisites for innovation.

Linkage between regulation and innovation

In their analysis of the effect of regulation on innovation, Kuhlmann et al. (1998; 17,41) stress that regulation can develop a set of different effects on innovation. Regulations may limit possibilities in decision-making (for example in the choice between various technical options) and that corresponding testing and registration procedures may involve greater cost and time expenditures. However, if the product fulfils the necessary requirements, regulations can at the same time also lead to increased product and process security and reduce insecurities for the firm. As for different time-horizons regulation may burden firms with higher costs in the short term (such as making the related adjustments to production). In medium to long term, however, they offer a potential increase in efficiency and create new markets for innovations and exports. Furthermore, as for the aspect of time it has to be considered that the link between regulation and innovation evolves over time, especially as Single Market regulation has just recently come into force and delays in national implementation have to be taken into account (Brousseau, 1998).

In their analysis of the impact of regulation on innovation, Becher, Kemp, Smith (1999, 5-6) point out that "regulation acts as a filter and focusing device for technical change by setting certain performance standards". Regulation can be seen as a modulator of technical change, influencing directions and modes of innovation.

Brousseau (1998) points out that the regulatory framework that influences innovation consists of several single interacting regulations and other public policies. This is the case for health policy, for instance, as the principle of subsidiarity means that each member state can manage its own health policy. Furthermore, innovation is influenced by other factors over and beyond regulation alone (e.g. other aspects of public policies, the economic climate and specific sectoral features).

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Summary

- The regulatory framework of the Single Market is characterised by a high complexity. It is part of the institutional matrix that influences the decisions of economic actors. The harmonisation of regulation within the Single Market and its impact on innovation is still developing.

- Innovation is a multifaceted, collective and explorative process involving different actor groups. The analysis of the impact of regulation on innovation should consider different indicators.

- As for the link between regulation and innovation regulation can be understood as a modulator of technical change influencing directions of technological development. There can be different effects of regulation in short/medium and long term perspective. In addition to the impact of a selected institutional framework the influence of other policies and influence factors of the innovation system have to be taken into account.
3 The Single Market and its economic impact

In analysing the impact of the Single Market Programme on innovation in the medical device industry resulting from the two directives 90/385 EEC and 93/42 EEC, the specific impact of the two directives is embedded in the general economic impact of the Single Market Programme. Therefore, it is important to consider the characteristics and the impact of the Single Market programme in general. Before analysing the specific economic impact of the two directives, the following passages will describe:

- characteristics of the Single Market programme, esp. for the removal of technical barriers (3.1-3.2)
- its general economic impact of the Single Market and its impact on innovation (3.3).

3.1 Free movement of goods by the removal of technical barriers to trade

One aspect of the Single Market is the emphasis it laid on eliminating all remaining obstacles which had an effect equivalent to that of physical barriers, such as customs, duties and quantitative restrictions. The legal basis is the Treaty of Rome (EC Treaty) with the following two elements:

- Prohibition of charges having an effect equivalent to that of customs duties
- Prohibition of measures having an effect equivalent to quantitative restrictions

Because the second aspect here, the prohibition of measures having an effect equivalent to quantitative restrictions, is more relevant for this study, it is described in greater detail. It was put into effect by a directive in 1969 (70/50/EEC) that banned all measures imposing an additional cost or restriction on the imported goods. It has a list of 19 measures that constitute barriers, including aspects of technical specifications and testing requirements as well. In addition, the Court of Justice defines this concept of measures equivalent to quantitative restrictions in very broad terms. It takes the view that “all trading rules enacted by Member States which are capable of hindering, directly or indirectly, actually or potentially, intra Community trade are to be considered as measures having an effect equivalent to quantitative restrictions” (CJ Case 8/74, 11 July 1974). The measures in question are generally those which only affect imported goods. However, the Court ruled in the Cassis de Dijon judgement (CJ Case 120/78, 20 February 1979) that a measure could be deemed to have equivalent effects even without discrimination between imported and domestic products. In particular, imposing the technical rules of the importing country on products from another country can be seen as an equivalent measure since the imported products are penalised by being forced to undergo costly adjustments.

8 The main aim of this study is the analysis of the impact of the Single Market on innovation in the medical device industry. The analysis of the general impact is therefore based on secondary material (e.g. European Economy, Economic evaluation of the internal market, 1996a).
There are also exemptions to the prohibition of measures which have an effect equivalent to that of quantitative restrictions. The EC Treaty, however, allows Member States to take such measures when these are justified by general, non-economic considerations (e.g. public morality, public security or the protection of health and lives of humans, animals or plants). Such exceptions are limited to a list and are no longer justified if Community legislation has come into force in the same area.

In analysing the impact of the removal of technical barriers within the Single Market it is necessary firstly to define what these barriers actually consist of. Technical barriers to trade can arise in particular whenever an EU producer is forced either to change his product (which is legally manufactured in accordance with domestic regulations and standards) in order to comply with industrial standards or legal regulations for commercialisation in other EU countries, or the product is to be tested and certified by the importing country (for reasons other than the customer’s legitimate contractual or quality requirements). Generally, the two main reasons for technical barriers to trade are:

1. Technical regulations: national regulations that result from government or other legal obligations and that impose (mandatory) technical specifications or requirements for testing and certification on goods and services put on the market. National governments impose these regulations particularly because of health concerns, consumer safety or environmental protection.

2. Non-regulatory barriers: other technical barriers arise from standards that are voluntary or from testing requirements imposed by consumers, industry bodies, trade associations, institutions or insurance companies etc., or by non-mandatory government advice or guidelines.

In either case, these barriers may impose requirements for the use of technical specifications or standards defining some technical aspect of the product, which may lead to changes or adaptations of the product or testing and certification of the products or the suppliers. This implies multiple testing and certification which is not technically necessary.

### 3.2 EU-Policy approaches to remove technical barriers

EU-Policy within the Single Market Programme follows two strategies for removing technical barriers:

1. Mutual Recognition Principle

2. Harmonisation of national regulations and standards
   
   a) Detailed harmonisation (Old Approach)
   
   b) The New Approach

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9 Regarding the following section, see also European Commission (1998), pp.13-20

10 The harmonisation of national regulations and standards in general means that directives have been adopted which require Member States to replace national regulations with harmonised procedures and standards.
The following chapters describe these policy approaches.

The Mutual Recognition Principle

The Mutual Recognition Principle states that products which are manufactured legally and put on the market in one Member State must be allowed to enter the market freely in other Member States as well. An exception to this rule are measures under Article 36 such as for reasons of public morality or security, the protection of humans, animals, the environment, or the national heritage. This situation arises in particular if a Member State refuses to recognise the equivalence of the objectives and levels of security and protection given by the regulation system of the exporting country. To make sure that this principle functions, mutual recognition has to exist at different levels, as e.g.:

1. the level of protection
2. between the accreditation systems, so that the competence of the bodies is accepted
3. for each specific product, so that procedures and tests are accepted

Problems with the Mutual Recognition Principle can arise in particular in cases where consumers and enforcement authorities in the importing country do not accept either the regulations and standards or the system under which these regulations and standards are tested and certified. This therefore highlights the need for accreditation of bodies for testing and certification, and a mutual recognition arrangement concerning bodies testing and certifying a particular product. In order to facilitate this, the “global approach” to testing and certification has been developed.[11]

In terms of its importance and effect on the Single Market, the Mutual Recognition Principle can be seen as a basic defence against technical barriers in the regulated, non-harmonised sphere. As for its importance in practice, however, in most of the product areas in which technical regulations are important, there is no mutual recognition, but harmonisation of regulation. In general the Mutual Recognition Principle works particularly well in fields that are either not highly sensitive in terms of security or protection, or if the system for testing and guaranteeing security and protection is not contentious. If there are serious concerns regarding potential health and safety hazards and the institutions and the procedures which guarantee protection from these, there tends to be divergent approaches on the national level, and the possibility to apply the Mutual Recognition Principle is limited.

Detailed harmonisation (“Old Approach”)

Harmonisation of national regulations is performed by directives that substitute the existing regulations on the national level by detailed EU-Specifications applying to specific products and testing requirements. The disadvantage of this approach is that the design of regulation is very time consuming and inflexible, as achieving consensus is a very complicated procedure. Once regulations

[11] A more detailed description of the “Global approach” can be found under the chapter describing the New Approach.
have been developed, they “freeze” technical specifications and do not take into account the technical progress. The adaptation of these very specific directives (which implies complicated and time-consuming institutional procedures) can hardly keep pace with the technological development. Therefore this approach is only suitable for certain products. It e.g. applies to narrow product groups and only harmonises certain aspects of the product which can be clearly defined (e.g. specific health, safety and environmental characteristics).

The New Approach to technical harmonisation and standards

The New Approach to technical harmonisation and standards applies to groups of products that have sufficiently similar characteristics, or a set of health, safety of environmental phenomena, that essential requirements can be devised for all the products and where there has been divergent technical regulation in the Member States. The New Approach is characterised by the following features:

1. The regulation is limited to essential requirements (especially in order to protect health and safety).
2. A more detailed technical specification by harmonised standards is developed by standardisation bodies.
3. The use of standards is voluntary. National authorities are obliged to recognise that products manufactured with harmonised standards are presumed to conform to the “essential requirements” established by the Directive.
4. The directives define different “Conformity assessment procedures” (Global Approach). These procedures are used by the manufacturer to establish that they meet the legal requirements. In these procedures also Notified Bodies have to be involved (depending on the kind of product and the kind of procedure).
5. The CE-marking certifies that a product conforms with all relevant requirements. CE-marked products are allowed to circulate freely within the Single Market.

3.3 General economic impact of the Single Market

Depending on the time scale under consideration, the Single Market programme is expected to have different effects:

- Allocation effects: Impact of integration on the short-run efficient allocation of resources.
- Accumulation effects: Impact on the accumulation of productive factors and their long-run growth effects.

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12 Among the New Approach also fall the Directives 90/385 EEC and 93/42 EEC. The New Approach to technical harmonisation and standards was initiated by the Council resolution 85/C136/01. For the fundamental principles on which the New Approach is based, see in particular Council Resolution of 7 May 1985, 85/C/136/01, Annex II. Furthermore for the following section see esp. European Commission (1994a), (1998a) and European Commission, DG III.D.2, Howes.
13 As for a more detailed description of the regulative framework of the New Approach see also chapter 4.
14 For this section see e.g. European Commission (1996a), esp. pp. 1-13; 175 ff.
3.3.1 Allocation effects of the Single Market

The analysis of the allocation effects can be based on classical analysis of comparative advantage combined with economies of scale. Here the removal of barriers by the Single Market is expected to improve the allocation and the use of resources in the European economies through specialisation and better exploitation of their comparative advantages. Specialisation in the allocation of resources along with the possibility to market products in a larger market can lead to better exploitation of scale economies. Furthermore, the Single Market will have an impact on competition, as it is expected that the removal of barriers will increase competition. As a result of both increased competition and the exploitation of scale economies, the Single Market is expected to improve efficiency in the production of goods. This improvement in production efficiency combined with higher competition can also lead to lower prices of the final goods.

Achieving the potential efficiency gains require a reallocation of resources within the European economy, both within and between firms, sectors and regions or Member States. This also implies transitional adjustment costs, depending on the area of change and on the flexibility of markets. These transitional cost-effects are also stressed in the Ceccini report (1988): "..the (Single Market programme) is a medium term therapy; it will take time for its benefits to become apparent."

3.3.2 Accumulation effects of the Single Market

The Single Market programme can stimulate accumulation and investment and thereby contribute to higher growth rates in two ways: Firstly, short-term efficiency gains will result in higher incomes over time, leading to higher savings and investments, which in turn will lead to higher growth rates. Secondly, the Single Market is expected to have a positive impact on innovation through factors like greater competition and the enlarged market. The combined effect of these two points is expected to result in higher growth within the Single Market. As this study is concerned with the question of the impact of the Single market on innovation, this aspect will be elaborated to a greater detail.

Following a neo-classical approach (e.g. Solow, 1956), which is based on the assumption of decreasing returns to capital and free access to a stationary technology, growth cannot be sustained permanently. This approach states that in the absence of technological progress, decreasing returns imply that the marginal product of capital will decrease with the accumulated stock. This reduces both the growth effects of a given amount of investment and the incentive to invest. As a result, growth will gradually slow down and under the above assumptions ultimately stop. Altering the assumptions, the introduction of exogenous technological progress into this model does allow for sustained growth.

However, the traditional neo-classical model suffers from its inability to explain technological progress.

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15 If policy is combined with Community competition policy.
16 The Cecchini report was published as an ex-ante assessment of the costs of the non-existence of a Single Market. A first empirical evaluation of the economic impact of the Single Market on the macro-level (see European Commission, 1996a, pp. 2-11) came to the conclusion that the Single Market started to develop these effects.
17 For the following section see European Commission, 1996a, p.177ff., or Fenkel, M., Hemmer, H.R. (1999).
It deals with technology as an exogenous factor “(Solow-Residual)” whose development cannot be explained within its framework.

As an alternative to traditional neo-classicism, endogenous growth approaches have analysed the implications of increasing return and the determinants of technical progress. In addition, endogenous growth models focus in particular on the micro-foundations of the accumulation process, i.e. on the private and social costs and benefits of investing in physical or human capital or in technological progress. This approach is characterised by spill-over effects. With increasing returns to scale the return on investment is an increasing function of the accumulated stock. Here the rate of technical progress is determined endogenously, as it reflects private investment decisions in human and technological capital (as long as they are not subject to decreasing returns to scale).

Within this framework of endogenous growth, Single Market integration can provide a stimulus for growth if it changes the private cost and benefits of investments in new technologies and innovations. There are several “channels” by which the participation in a more integrated economy can result in innovation and growth effects:

- An enlarged or more integrated market may be helpful in entering new markets with innovative products, by expanding the size of the potential customer base and thereby stimulating innovation. This would also provide better possibilities to write off fixed costs for research and product development.
- A higher degree of integration reduces the time, risks and costs needed to reach the market and customers with innovative new products, which may stimulate innovation.
- Economic actors can profit from a higher degree of free access to technical knowledge (e.g. by better conditions for co-operation or by lower barriers to trade) which can stimulate technological dissemination.
- These advantages may be an incentive for investment of resources (human or financial) in industrial research and product development which exerts a positive influence on innovation.
- A higher degree of competition may be an incentive for industrial research. A firm manufacturing in a more protected market innovates to a lesser extent and when it does, it uses technologies already common elsewhere, and which are only innovative in terms of the home market. Competition on an international level on the other hand forces the generation of innovations that have a higher quality, that is, they are innovative on a global scale.
- Competition can furthermore force domestic innovators to choose either to quicken their pace of innovation and to reduce the “time to market” or to be displaced by foreign innovators. Although some of the innovators may be forced out of the market, the total rate of innovation and therefore the growth-rate increases.

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18 See e.g. Romer (1986); Lucas (1988).
Nevertheless there are also possible negative effects, particularly for countries or firms which are relatively less developed in terms of innovation capabilities. One reason for these effects could be that at the firm level, the greater competition could lead to less competitive firms regarding the anticipated profitability of their innovative capacities as less attractive, as they expect that they can not compete with other firms entering the market. This reduces the overall investments made in innovation by the less competitive firms. At the country level, the removal of trade barriers and the intensification of trade with technologically advanced countries may force less advanced countries to reduce their investment in innovation. Countries with lower skilled labour resources may be forced by market integration to specialise in goods that are lower in technological content.

However, these negative effects may not necessarily arise. The extent to which less developed firms, regions or countries reduce their innovation activities depends largely on the level of the differences in competitiveness. A complete halting of production and innovation activities in a particular product area would only come about when there were marked differences in competitive strength, which are important factors for the success of price competitiveness and simple quality parameters and when personal contacts along with the physical proximity to the customer are however less important issues in this respect. These would also need to be combined with the inability to specialise within a technology-oriented industry neither in its related product areas on the basis of available abilities. Specialisation can occur for instance in certain industries that are less technologically sophisticated, which however also allow for and even demand further development.

Whether or not a reduction of incentives for innovation in highly developed countries will occur also depends to a large extent on the level of competition between technologically advanced firms, regions and countries, and also therefore on competition policy. The level to which the integrated market is exposed to competition from competitors located outside the integrated market must also be taken into consideration. If a high level of competition continues to exist within the common market and this is combined with further pressure from external competition, then a continued innovation dynamic is to be expected. The following figure shows the general economic impact of the Single Market being described in this chapter:
New institutional framework

**Single Market**
(removal of barriers)

- Efficiency in allocation of resources by
  - specialisation on comparative advantages (supply-side)
  - enlarged market (demand side)

- Possibility for cooperation and networks

- Competition

- Production efficiency

- Economies of scale

- Diffusion of Knowledge

- Income, savings, investments

- Capital stock (human or physical)

**Innovation**

**Economic growth**

**Fig.1: Link between institutional change (Single Market) and innovation.**
3.3.3 General economic impact of the Single Market - empirical evidence

Several studies have tried to estimate econometrically the growth effects of European integration on the macro level. These studies suggest that European integration has exerted positive effects on European growth. However, so far the specific impacts are not quite clear. No clear evidence could be found for instance to suggest that integration had stimulated investment and growth so far. Evaluation of the further long-term growth effects of the Single Market on the basis of statistical data is currently possible only to a very minor degree. This is due to the fact that these are primarily long-run effects which would be unable to develop to their full potential within the relatively short period since the European Single Market came into existence. Another problem is the specific historical framework within which the Single Market came into being. The 1990’s saw for instance German unification, a huge increase in the pressures of globalisation as well as fundamental technological changes (e.g. ICT). The complexity of this environment makes it almost impossible to attribute certain change of growth trends directly to the Single Market.

In contrast to the rather weak empirical evidence on the macro level a better empirical evidence as for the general economic impact of the Single Market can be found on the firm level. This has been analysed in the context of the Single Market Review.

Summarising the results of the business survey of the Single Market Review four aspects shall be pointed out:

1. The Single Market seems to have started to meet its basic objectives for a significant percentage of companies. It has led to a removal of barriers to trade, an integration of the European economies and an increase in competition and efficiency in Europe. This shows that the Single Market has started to exert influences in the expected direction.

2. Among the analysed Single Market measures the highest positive impact was exerted by the removal of physical barriers. Nevertheless the removal of technical barriers to trade has a significant positive impact from the firms point of view. The positive impact is even higher in sectors like machinery and equipment or electrical and optical machinery.

3. The Single Market’s importance to development of strategies in research and development is comparatively high. This especially applies for high-tech sectors.

4. The Single Market is still developing its economic impact. A high fraction of firms in the Business Survey so far did not assess any impact, considered the Single Market not to be important or had no opinion about its impact.

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19 See e.g. studies listed in European Commission (1996a) pp. 179 ff.
20 A more comprehensively substantiated interpretation of the above facts would demand a complete and differentiated depiction and interpretation. This is however inappropriate in the context of this study.
21 See European Commission, 1997 a. For results of the survey see also annex I. As for the valuation of the results it has to be considered that this survey has been collected in 1995.
3.3.4 Economic impact of technical harmonisation

3.3.4.1 Long term impact
In addition to the general economic impact of the Single Market the EU approaches to technical harmonisation had an important impact by setting up a new institutional structure. These institutional changes encompassed amongst other things the development of New Approach directives, radical changes in the responsibilities and functioning of the European and national standards bodies, a global approach for testing and certification. The main advantage of technical harmonisation results from the removal of an inefficient market structure within Europe. The inefficiency of the non-harmonised technical regulation can be seen on different levels:

“In terms of the economic importance of technical barriers to trade, the Single Market Review and its analysis of technical barriers to trade came to the conclusion that 79% of intra-EU trade in products is potentially affected by technical barriers (including those sectors where the Single Market barriers have already been removed by harmonisation) and 55% of trade is also subject to non-regulatory barriers” (European Commission, 1998, 5). This underlines the importance of measures to remove these barriers in the completion of the Single Market.

The economic relevance of technical barriers to trade arises from the fact that they impose additional costs for traded goods which are not imposed on goods being produced domestically. Furthermore, the costs are not only financial, but also cause disadvantages through time-delays resulting for example from additional testing of technical barriers. In detail these costs and time-delays may result from the following factors:

- Research and development, design, technical documentation, retooling, etc to produce different variants of the product to meet differing national standards and regulations.
- Multiple testing and certification. In some cases the actual costs for testing and certification may be even higher for a non-resident firm, for instance, should the testing body of the importing country have to send its experts to visit the supplier and to inspect its plant and procedures or to take random samples.
- The requirement to be informed about and experienced in the target market procedures.
- The need for local representation or at least visits to the importing country. These serve not only to address customer and marketing needs but also deal with testing and certification.
- Re-labelling, either to meet labelling regulations, to comply with a quality labelling scheme or to make reference to national standards.
- Diseconomies of scale in production of several variants. Although the economies of scale arising from the total production volume may still enable the exporting foreign company to be cost competitive when measured against domestic companies serving only the home market,

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22 Consider that this analysis reflects the situation at the end of the year 1996.

the technical barriers will reduce the gains from trade and consequently levels of trades as well.

- Inventory and spares costs which result from the wide range of product variants.

In terms of the importance of single factors the Single Market Review (European Commission 1998, 20) comes to the conclusion that the most significant factors are

- the lack of information and experience of the target country’s procedures. This factor is a barrier to entering new markets because of e.g. constraints of management time and language abilities, and
- the time delays in obtaining additional testing and certification approvals. In the case of high-tech products where the competitive advantage by product innovation is important, the time-delay can prevent the supplier from gaining their competitive advantage and market-share.

3.3.4.2 Transitional costs

This change in the institutional infrastructure for harmonised technical regulation on the EU level has been developed mainly within a short period from 1989 to 1995. As regards the transposition on national level and the full implementation into the behaviour of the economic actors the new institutional infrastructure is still under development. This rapid change and the ongoing development have overthrown routines of the established system which firms had become used to. The Single Market Review (1998) analysing technical barriers to trade therefore states that firms complain about the transition costs and the difficulties of adapting to the new system, uncertainties and the lack of information and understanding of the needs of the new directives. Beyond the more general requirement for each firm to adapt to the new institutional environment transitional costs and further problems result especially from the following factors, which have been reported by firms:

Problems of European standardisation

- Slow production and in some instances lack of harmonised standards.
- Uncertainty and risk of liability if harmonised standards are not available to assess conformity with essential requirements.
- Higher cost for testing if standards needed are not available (e.g. as specific test procedures have to be developed).
- Limitation of testing capacity in selected countries (which can lead to higher prices and time delays for testing).

Industry’s reservations about CE-marking

- Possibility that the CE-marking is seen as a quality mark by customers.
- Some manufacturers want to use the CE-marking to promote their products.
- If misinterpreted or not used properly, competition between products by quality is undermined as both low and high quality products which fulfil the essential requirements carry the CE-mark.

Co-ordination of notified bodies and conformity assessment

- The quality of work of Notified Bodies varies widely. This can result from an inadequate co-ordination and monitoring or discrepancies in interpretation of the essential requirements according to traditional national practices.
- Notified Bodies refuse to carry out type-examination because of lack of standards.
- Notified Bodies re-test and certify products that have already been refused. Firms try to find the Notified Body that provides fastest, cheapest and least strict attestation.

Market surveillance
- Weak enforcement of directives requirements in some Member States.

3.4 Summary

It is the aim of the Single Market to create "an area without internal frontiers in which by the removal of technical barriers to trade the free movement of goods, persons and capital is ensured" and to implement structural changes designed to improve the EU's capacity to generate economic growth.

The general effect of the technical barriers to trade can be summarised as follows: Considering the additional cost and time expenditures brought about by technical barriers to trade and given the limited resources (e.g. management, capital to invest, specialist machinery) and the requirements for their efficient use, technical barriers and the resulting cost and time expenditures can themselves become an effective barrier to entering other markets. This means that trade between different countries without market integration does not reach its optimal level (considering their advantages in competition) because of the technical barriers to trade and the inefficient institutional structure of the market caused by these barriers. In terms of the general economic impact of the removal of technical barriers to trade by technical harmonisation the following effects can be identified:
• **Reduction of additional costs** for traded goods (on different levels on the production chain)
• **Reduction of time-delays** for trade goods (on different levels on the production chain)
• **Transitional costs** because of institutional change

EU-Policy approaches to create a Single Market, to remove technical barriers and to ensure the free movement of goods by the removal of technical barriers to trade are the Mutual Recognition Principle and the Harmonisation of national regulations and standards by detailed harmonisation (“Old Approach”) or by the New Approach.

In summary, the New Approach can be described as a harmonisation of technical regulations, standards and testing and certification requirements which is achieved by the directives that set out essential requirements. These cover all mandatory aspects of the product and provide a choice between different routes leading to the assessment and attestation of conformity of products to these essential requirements. The directives allow manufacturers and certification bodies to refer to harmonised standards which are developed by the European standard bodies under mandate from the European Community.

In addition to the advantages of the Single Market and the removal of technical barriers the regulative framework of the New Approach to technical harmonisation and standards offers the following advantages:

• **Flexibility in choosing different technological options** as regulation is limited to essential requirements and the application of harmonised standards is voluntary.
• **Organisational flexibility** to choose between different conformity assessment procedures.

As for the present situation of the Single Market it can be stated that on the one hand it has become a reality which has a definite impact on the European economy as a whole. On the other hand it has to be pointed out that both the Single Market itself and its impact are still developing and technical barriers to trade still exist.
4 The medical device innovation system

The findings of research into innovation show that the very existence of technical advances as well as their scope, direction and quality, develops within the context of certain historical paradigms, on which they are also dependent (see for instance Dosi, 1988, Grupp, 1997, 81ff). Within this context, individual players in innovation, such as companies and research institutes, establish innovation systems at the regional, national and in particular at the sectoral level (Lundvall 1992, 2ff). The shape of these innovation systems thereby defines the starting point for innovation and the external conditions which affect innovation in that field. The characteristics of a particular innovation system are therefore crucial to innovation and must be taken into account in analyses. For this reason, this study focuses on the impact of Single Market Regulation on innovation in one selected sector - here, the medical devices industry.

Innovation in the medical device industry is not determined by Single Market regulation alone. Innovation in the medical technology industry is, rather, influenced by a range of different factors from both the demand and the supply side. A particular feature e.g. of the medical device market, which is of course part of the wider healthcare market as a whole, is that by and large, it is particularly strongly influenced by public authorities and health policy. Regulation refers therefore not only to questions relating to product licensing but also to its financing and various other elements on both the supply and the demand side. As for the impact of Single Market Regulation it has to be considered that not only the general design of the Single Market and the general economic impact has to be taken into account but furthermore the characteristics of the specific directives. This means that in this analysis not only an isolated view of the impact of regulation on innovation or single features of the supply side which must be taken into account. An empirical analysis demands an integrated approach, in order to take these issues fully into account.

- Characteristics of the supply side, namely the European medical device industry
- Characteristics of the demand side for medical devices.

The following chapters discuss these points in greater detail. The following reports, which concentrate on medical devices, provide a second fundamental pillar of this analysis, in addition to the general comments on the Single Market.

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25 See also Kuhlmann et al. (1998, 9)
26 On characteristics of the healthcare market and the influence of different factors, particularly the influence of healthcare policies see e.g. Zdrowomyslaw, Dürig (1999, pp. 136 ff, 255 ff), European Commission (1996f, pp.105 ff), Bundesministerium für Bildung und Forschung (1999, 32).
27 The demand side is often neglected in analytical studies dealing with innovation. This study does not follow this approach.

The fundamental aim of a product, particularly in the medical technology industry, must be to contribute to the preservation, indeed the improvement of the consumer's health. Furthermore, the demand side has to be considered as the level of demand is for instance important for economies of scale, amongst other things. Moreover, the specifics of the quality of the demand side stimulate and influence the behaviour of the suppliers in e.g. developing new products.
4.1 Regulative framework: The Medical devices directives under the New Approach

4.1.1 General aspects

It is the aim of this study to analyse the impact of Single Market regulation on innovation. In this context, it looks in particular at the impact of regulatory reform and asks companies in the medical device industry to assess their experiences.28

Differing regulations and product standards in Member States proved to be a significant technical barrier to trade in the medical device industry, too. These therefore also impeded the free flow of goods throughout the Community also in this sector. Member States were found to have different ways of controlling the safety and marketing of medical devices. Manufacturers had to comply with different sets of rules and requirements and differing testing and certification procedures in each Member State in which the medical device product would be marketed. This meant increased expense in checking the compliance with national regulations.

The medical device Directives are primarily intended to remove these technical barriers to trade and complete the Single Market in the medical device industry in Europe. This should be achieved by both introducing harmonised and statutorily based control to regulate the safety of medical device products throughout the European Single Market and by replacing the different existing national systems. Under the harmonised regulation the manufacturers need not submit devices to time- and cost-consuming schemes for product approval or registration each time export to any other country in the Single Market is intended. This applies particularly to innovative medical devices entering the market.

Furthermore, the Directives shall provide the patients and users in the Single Market with a high level of protection. It is the aim of the Directives that necessary safety requirements are reached effectively all over Europe by harmonisation of essential requirements and certification and inspection procedures. The Medical Device Vigilance System shall make sure that devices are continually monitored to protect patients and users and incidents are reported to appropriate Member State health officials or competent authorities.29

So far the following three directives have been developed under the New Approach:

- Directive on active implantable Devices (90/385/EEC)
- Medical devices Directive (93/42)


29 It has to be noted that this study is not analysing this aspect, namely the impact of the Single Market Directives on quality and the level of protection of patients and users.
As for the Directive on in-vitro-diagnostic medical devices the phase of transposition by Member ends in December 1999. Therefore the analysis of this study concentrates on the two directives that have already come into effect:


Amended by:

Latest date of transposition by Member States: before 1 July 1992
Date of application: 1 January 1993
Transitional period: from 1 January 1993 to 31 December 1994


Date of adoption: before 1 July 1994
Date of application: 1 January 1995
Transitional period:
- from 1 January 1995 to 14 June 1998
- from 1 July 1994 to 30 June 2004 for thermometers subject to EEC pattern approval

Source: European Commission, DG III, Howes.

In the following section elements analytical framework that are important for the further analysis will be explained more detailed.

### 4.1.2 Definition of key terms

The Directives apply to medical devices (and their accessories) and to active implantable devices. The Active Implantable Medical Device Directive (90/385) covers all powered implants or partial implants that are left in the human body. Heart pacemakers are the most common example. The definition of active implantable devices is based on the definition of medical devices and is defined as follows (Directive 90/385/EEC, Article 1):

> ‘Active medical device’ means any medical device relying for its functioning on a source of electrical energy or any source of power other than that directly generated by the human body or gravity.

> ‘Active implantable medical device’ means any active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure.

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30 Regarding the implementation of the Directives into national law see European Commission, DG III, MedDev 2.14/1; 11/98 (1998c) and European Commission, DG III, MedDev 2.14/2; 11/98 (1998d).
The Medical Device Directive (93/42/EEC) covers most other medical devices, such as first aid bandages, hip prostheses and x-ray equipment for instance. An exact definition of “medical devices” is given in Directive 93/42/EEC, Article 1.31

'Medical device' means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

These definitions expressly state that a medical device is to be used for medical purposes. This medical purpose is reflected in the labelling, in the instructions for use and/or in promotional materials related to the device. The “manufacturer” assigns it to the product.

A “manufacturer” is defined as follows (Directive 93/42/EEC, Article 1):

'Manufacturer' means the natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party.

4.1.3 Limitation of regulation to essential requirements

General aspects of the New Approach

Legislative harmonisation is limited to the adoption of essential safety requirements (or other requirements in the general interest) which products marketed must conform with. These essential requirements are obligatory in all Member States. Conformity with these essential requirements entitles a product to free movement within the Single Market. The essential requirements are expressed in rather general terms that have to be met by products in order to protect important public interests (especially in the area of health and safety). As the New Approach directives are limited to essential requirements, they offer more flexibility for the design and the production of goods than detailed harmonisation directives.

Specifics of Directives 90/385 EEC and 93/42 EEC

31 As for the definition of important terms see also European Commission (1994b).
Besides fulfilling its function according to the definition (see Directive 90/385, Directive 93/42, Article 1) a medical device has to comply with the requirements of the relevant Directive before being allowed to be marketed in and circulate freely throughout the Single Market. Of particular importance is its adherence to essential requirements on health and safety (see Directive 90/385 and Directive 93/42; Article 3, Annex I). These essential requirements make clear that the devices must not compromise the health or the safety of a patient, a user or any other person. Furthermore it is made clear that any risks associated with the device are compatible with patient health and protection. Thus an important element of these essential requirements is the documented carrying out of a risk analysis by the manufacturer. Finally, any side effect must be acceptable when weighed against the intended performance. Devices that meet the requirements are allowed to carry the “CE” mark to demonstrate that they comply with the essential requirements.

In general the essential requirements refer to the following aspects of the medical device:

- security
- technical performance
- medical performance

More detailed information regarding which essential requirements have to be fulfilled is given in the Directives. The essential requirements are listed in Annex I of the Directives and address both general requirements and specific requirements.

In general, in addressing the essential requirements the manufacturer must apply the following principles in the following order:

1. eliminate or reduce risks as far as possible (inherently safe design and construction);
2. where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated;
3. inform users of the residual risks due to any shortcomings of the protection measures adopted.

More specific requirements regarding design and construction refer to e.g. chemical, physical and biological properties, infection and contamination, biocompatibility, construction and environmental properties, protection against radiation, the connection with an energy source and aspects concerned with the combination and interfaces between different devices.

In terms of the impact of these essential requirements on innovation it is important to point out that these contain no specific technical rules for the design of the product. It is largely up to the manufacturers themselves how they choose to fulfil the requirements. Meeting the requirements is itself much more important than the manner in which this is done, such as the technical design of the device. The manufacturer is therefore offered a large degree of technological flexibility, which enhances the possibility of innovative product development.
4.1.4 Technical specification by standardisation bodies and the role of standards

General aspects of the New Approach

The task of both drawing up the technical specifications needed for production and then placing them on the market is entrusted to organisations competent in the standardisation area. The technical specifications are provided through the development of harmonised standards. The European Standards bodies CEN and CENELEC are responsible for ensuring that further technical expression of the essential requirements is given by harmonised European standards.

Because of the volume of mandated work for the NEW Approach directives, the European Standards bodies are facing great challenges. Another challenge is the increasing dynamic of technological progress. In response to these challenges, the Standards bodies are aiming to reduce the production period for standards.

Under the New Approach the application of the technical specifications by harmonised standards is not mandatory. But national authorities are obliged to recognise that products manufactured according to harmonised standards are presumed to conform to the “essential requirements” established by the Directive. In general, industrial standards that are voluntary in nature are intended to facilitate trade. This is done for instance by simplifying the design process, simplifying the process of specification for procurement purposes; or perhaps by enabling a comparison of prices and quality, making markets work more efficiently; or by ensuring that separate parts work together in a modular system. The need for European standards arising from the New Approach has led to the development of the European standardisation system in which the Commission allocates standardisation mandated to the standardisation bodies (CEN, CENELEC).

Specifics of Directives 90/385 EEC and 93/42 EEC

Standards play an important role in the field of medical devices. Product safety is of high importance for manufacturers and users, and technology becomes more complex. In this situation standards may help to reassure that a medical device is reliable and can meet expectations in terms of safety, performance and other criteria.

Since the Directives 90/385/EEC and 93/42/EEC cover a wide range of products and involve many types of technology, the essential requirements of the directives can only provide a broad approach in setting the targets which the manufacturer must meet. The use of Standards may assist the manufacturer in demonstrating compliance with the essential requirements in an efficient way. They may help by, for instance, setting out objective definitions of what the necessary requirements are for particular medical devices and practical means for manufacturers to show that the products comply

[32 For this section see also Global harmonisation task force (1999)]
with the essential requirements. Thus article 5 of the Directive 90/385 EEC and Directive 93/42 EEC express:

*Member States shall presume compliance with the essential requirements referred to in Article 3 in respect of devices which are in conformity with the relevant national standards adopted pursuant to the harmonised standards the references of which have been publishes in the Official Journal of the European Communities; Member States shall publish the references of such national standards.*

Differing standards in single Member States would act as a technical barrier. To ensure the development and the application of harmonised standards, the European Commission has mandated the European standards organisations (i.e. the European Committee for Standardisation (CEN) and the European Committee for Electrotechnical Standardisation (CENELEC) to develop European standards to address the essential requirements. Once a European standard has been agreed it becomes binding on all national standards bodies in Europe and any conflicting national standard has to be withdrawn.  

In a kind of hierarchical approach there are different types of standards:  

1. Horizontal standards, which cover common requirements for all or a wide range of medical devices (e.g. for risk analysis, labelling, and sterilisation methods)  
2. Semi-horizontal standards, which cover requirements for a related family of medical devices, where such requirements are typical for a number of devices (e.g. safety of medical electrical equipment).  
3. Product standards, which cover requirements for a specific type of medical device (e.g. operating tables, infusion pumps).

Moreover, other harmonised standards define the characteristics of the manufacturers’ quality management systems. These are relied on to ensure the correct design and production of the medical devices. If the quality management system complies with the relevant harmonised standards there is the presumption that compliance with the essential requirements is given. These standards are the EN 29000 and EN 46000 series of standards. The EN 29000 series of standards specifies the components needed in order to set up and manage a quality system, regardless of the product or production technology.

- **EN 29000**: basis for the entire series, it deals with the general philosophy underlying quality system standards;

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33 See European Commission, DG III, list of European Harmonized standards under Directives 90/385 EEC and 93/42 EEC, MedDev 2.3/1, Rev 5, 11/98; 1998e
34 This hierarchical approach is also important with respect to an efficient production of standards and a transparent standard system.
35 For the following description see Medical Devices Agency (1995), Conformity assessment procedures, bulletin no.13.
EN 29001: deals with the most complete quality system, the components of which cover all aspects including design/development, production, installation and servicing;

EN 29002: covers production and installation;

EN 29003: deals with final inspection and testing;

EN 29004: intended to assist managers in designing, developing and setting up the quality system that is most suited by the company.

Particular requirements for quality systems relating specifically to medical devices are defined by the EN 46000 series of standards. It can only be used in combination with the EN 29000 series of standards. The EN 46000 series of standards embraces all the principles of quality systems management widely used in the manufacture of these products. It is also supported by other harmonised standards (e.g. covering such aspects as sterilisation).

As regards innovation, it is important to note that the use of standards is voluntary. This is particularly important for innovation, as standards are based on experience; they are in other words retrospective and may represent the current state of the art in a technological field. However, innovation may present unanticipated challenges to experience and not all medical devices or elements important for device safety and/or performance may be addressed by harmonised standards. This applies particularly for new types of devices and emerging technologies. If manufacturers were forced to follow a rigid and mandatory application of standards, innovation might be influenced negatively. However, this is not the case, as manufacturers are free to select alternative solutions to demonstrate that their product meets the relevant essential requirements. Such alternative means of demonstrating compliance with essential requirements may include for instance:

- national and international standards that have not been given the status of a “recognised (or harmonised) standard by the Regulatory Authority
- industry standards
- internal manufacturer standard operating procedures developed by an individual manufacturer and not related to an international standard
- current state of the art techniques related to performance, material, design, methods, processes or practices.

As standards are therefore not mandatory and manufacturers can choose among different methods to demonstrate compliance with the essential requirements, they are offered a technological flexibility that is particularly important for innovative products.

Nevertheless as standards are an efficient way of demonstrating conformity they should reflect the current, broadly applicable technology and should not discourage the use of new technologies. Considering the volume of harmonised standards, the dynamics of technological development and the

36 Except in those particular cases where by the Regulatory Authority certain standards have been deemed mandatory.
heterogeneity of the field of medical devices, this presents a great challenge to European standards organisations.

4.1.5 The modular system of the Global Approach for conformity assessment

General aspects of the New Approach

To ensure a successful implementation of the New Approach, the systems and means of certifying products used by a single Member State need to be automatically recognised by other Member States. This was the aim behind the Commission communication on a Global Approach to certification and testing. The central goal of the Global Approach is to accompany the New Approach with an European policy on the harmonised assessment of conformity. It assures in particular the conditions under which the requirements of the directives are tested, as it lays down the conditions for conformity assessment. It also sets out criteria for the functioning and technical evaluation of the testing laboratories and certification bodies in order to achieve confidence in conformity testing systems and institutions.

Since the adoption of the Global Approach to testing and certification, these routes are now selected from a clear set of optional modules that apply separately to the design phase and the production phase in product development. A key feature of the Global Approach is that it offers a system with different procedures for conformity assessment from which the manufacturer can then choose according to their product requirements. Thus, the Global Approach offers a flexible framework for testing and certification at the European level. One particular advantage of this approach is that the modular system allows companies to choose a solution method which is tailored to the individual situation in order to assess conformity. The system distinguishes between the design and production phases. It also takes other specific industrial requirements into consideration such as whether or not a complete quality management system is available (module H) or whether a type examination (Module B) refers to the quality assurance of either product or production (Module D or E). Furthermore the Global Approach and the modular system established the use of ISO EN 29000 for quality assurance systems and EN 45000 for accreditation.

Specifics of Directives 90/385 EEC and 93/42 EEC

The assessment of conformity with the essential requirements and with requirements relating to the design and production of medical devices is carried out using different “conformity assessment procedures”. The “conformity assessment procedures” of the Directives 90/385 EEC (Article 9) and 93/42 EEC (Article 11) offer an organisational flexibility within a “modular system”. This allows companies to chose a method appropriate to the risk level of their product and the characteristics of

37For the Global Approach to Conformity Assessment see Commission Communication 89/C267/03; Council resolution 90/C10/01 and Council decision 93/465/EEC.
their company, such as the existence and coverage of a quality system. This modular system is based on the Council Directive 90/683/EEC concerning the modules for the various phases of the conformity assessment procedures (European Commission, 1990c).

The modular and flexible character of the conformity assessment procedures, which is important for innovation, is based on the fact that the Directives cover a wide range of medical device products. The use of different products within the heterogeneous field of medical devices therefore implies different levels of risks for the patient. To apply the most strict control levels to all products would imply additional, costly and unnecessary procedures for a lot of manufacturers. It is therefore important that the level of control is in accordance with the degree of risk inherent in the device ("principle of proportionality").

The risk classes for medical devices are grouped into 4 classes as follows:

- **Class I:** Generally regarded as low risk (e.g. corrective glasses)
- **Class IIa:** Generally regarded as medium risk (e.g. dental filling materials, hearing aids)
- **Class IIb:** Generally regarded as medium risk (e.g. X-ray equipment, anaesthesia machines)
- **Class III:** Generally regarded as high risk (e.g. heart valves)

The classification of medical device products follows criteria outlined in Annex IX of Directive 93/42 EEC. It contains definitions and 18 rules that are a set of broad statements relating to product properties, functions and intended purpose rather than a list of products. This has the advantage of being more flexible and better able to take new technological developments into consideration. A list of products would only require constant updating.

The different procedures open to the medical devices manufacturer for assessing conformity in different risk classes are along the following lines:

**CLASS I**

The manufacturer is responsible for declaration of conformity with the provisions of the Directive, including compliance of the product with all relevant Essential Requirements. This means that the manufacturer is legally obliged to meet those Essential Requirements (Module A).

In addition, the production of sterile products and measuring devices is expected to be subject to a limited degree of Notified Body intervention. It is intended that this should be limited to those aspects of manufacture relating to sterility and/or metrology (Modules D,E,F).

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39 As for guidelines for classification of medical devices see European Commission 1996e.
40 For the following description see Medical Devices Agency(1995), Conformity assessment procedures, bulletin no.4.
CLASS IIA
In terms of design, the manufacturer is responsible for conformity assessment (Module A). In terms of production, however, a Notified Body must back up the declaration of conformity in all cases with a conformity assessment. This assessment may, at the manufacturer's choice, consist of:
- audit of the production quality assurance system (Module D)
- audit of final inspection and testing (Module E)
- examination and testing of sample products (Module F)
Alternatively, the manufacturer may follow the full quality assurance route as for Class IIb devices (Module H)

CLASS IIb/III
One possibility of assessing conformity for design and production is the operation of a full quality assurance system that has been audited by a Notified Body (Module H). Alternatively the manufacturer uses module B for design. For module B the manufacturer submits type and technical documentation to a Notified Body, which ascertains conformity (eventually with type testing). In addition to module B, modules D,E or F have to be used for production.

CLASS III
Class III controls are broadly equivalent to the controls applied under Directive 90/385 EEC for active implantable devices. The conformity assessment procedure is similar to those for Class IIb devices but also requires the manufacturer to submit the design dossier to the Notified Body for approval.

An overview of the total “modular system” for the conformity assessment is given by the figure on the following page (= figure 2).
### Module A: Internal control of production
**ANNEX VII**
- Manufacturer
- Keeps technical documentation at the disposal of national authorities
- Aa
- Intervention of notified body

---

### Module B: Type examination
**ANNEX III**
- Manufacturer submits to notified body
  - Technical documentation
  - Type
- Notified Body
  - Ascertains conformity with essential requirements
  - Carries out tests, if necessary
  - Issues EC type-examination certificate

---

### Module C: Production quality assurance
**ANNEX V**
- Manufacturer
  - Declares conformity with essential requirements
  - Affixes the CE mark
- Notified Body
  - Approves the QS
  - Carries out surveillance of the QS

---

### Module D: Product verifications
**ANNEX IV**
- Manufacturer
  - Declares conformity with approved type or to essential requirements
  - Affixes the CE mark
- Notified Body
  - Verifies conformity
  - Issues certificate of conformity

---

### Module E: Product quality assurance
**ANNEX VI**
- Manufacturer
  - Declares conformity with approved type or to essential requirements
  - Affixes the CE mark
- Notified Body
  - Approves the QS
  - Carries out surveillance of the QS

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### Module F: Full quality assurance
**ANNEX II**
- Manufacturer
  - Operates an approved quality system (QS) for production and testing
  - Declares conformity
  - Affixes the CE mark
- Notified Body
  - Carries out surveillance of the QS
  - Verifies conformity of the design
  - Issues EC design examination certificate

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4.1.6 Notified Bodies

General aspects of the New Approach

Each of the New Approach directives requires that the Member States notify bodies that have the technical competence to carry out single elements of the attestation procedures within the Global Approach. There is no specific requirement for the procedure for accreditation or the responsibilities of the notifying body because the Member States have differing accreditation systems for testing and certification bodies. These differences in the approach to notification and accreditation on the national level can lead to differences in attestation of conformity. These differences make an European-wide co-operation between the different notified bodies important.

Specifics of Directives 90/385 EEC and 93/42 EEC

As described above, the Notified Bodies play an important role in the system and procedures of conformity assessment. The national authority (the Competent Authority) of a Member State designates these Notified Bodies.

The Notified Bodies have to be qualified to perform all the functions set out in any annex and the corresponding procedure it is designated for. The minimum criteria it has to fulfil are described in Directive 90/385 EEC, Annex VIII and Directive 93/42 EEC, Annex XI. Due to the wide and heterogeneous field of medical devices this designation may be restricted to specific types of devices, as certification organisations have to be sufficiently qualified to act as Notified Bodies. Furthermore, the designation can be limited to a defined range of conformity assessment procedures. To ensure that the expected criteria are still being met the Competent Authority may periodically audit the Notified Bodies after they have been appointed.

In their choice of Notified Body, manufacturers are free to apply to any Notified Body in the EC, regardless of which Member State the Notified Body is established in. Manufacturers cannot be forced to choose their national Notified Body. This would be against the principles of the Single Market. This means that a product whose conformity has been assessed by Notified Body in the EC can be sold within the whole Single Market. On the other hand, the idea of the Single Market also implies that the

41 For a list of Notified Bodies under Directive 90/385 EEC and Directive 93/42 EEC see European Commission (1998f). It is not necessary that a Notified Body carry out each part of the testing and auditing. Single aspects may be undertaken by subcontractors, for instance testing laboratories or other experts. But in all cases of subcontracting, the Notified Body must retain the final and overall responsibility.

42 The Competent Authority is the body that has the authority to act on behalf of the government of a Member State to ensure that the requirements of the Directives are carried out in that particular Member State.

43 This applies to regulated formal procedures. There is still a possibility that customers will have a particular preference for being assessed by a national Notified Body.
Competent Authorities perform an equal practice of designation, for instance in the interpretation of criteria the Notified Bodies have to meet. It also suggests an equal practice of auditing Notified Bodies and equal enforcement of the Directives in general in the individual Member States.

4.1.7 Free circulation within the Single Market for CE-market medical devices

General aspects of the New Approach

To certify that a product conforms to all the requirements of the relevant directives, a CE-marking is affixed to the product by the manufacturer or importer. The CE-marking may also show the identification number of the notified body involved in the conformity assessment (if this applies). Each Member State of the EEA has to accept the free circulation of CE marked products and is not allowed to ask for further approval procedures or confirmation.\footnote{44 Common rules for CE-marking of products which fall under any of the New Approach directives have been set by Directive 93/465/EEC.}

Specifics of Directives 90/385 EEC and 93/42 EEC

Medical devices carrying the CE-mark can be freely marketed anywhere in the Single Market without further control. This is expressed in Directive 93/42 EEC, Article 4 and Article 17.\footnote{45 With regards to Directive 90/385 EEC see Articles 4 and 13.}

\textit{Member States shall not create any obstacle to the placing on the market or the putting into service within their territory of devices bearing the CE marking provided for in Article 17 which indicate that they have been the subject of an assessment of their conformity in accordance with the provisions of Article 11 (Article 4/1).}

\textit{Devices, other than devices which are custom-made or intended for clinical investigations, considered to meet the essential requirements referred to in Article 3 must bear the CE marking of conformity when they are placed on the market (Article 17/1).}

Medical devices which are allowed to carry the CE mark conform with the essential requirements and have been assessed according to the corresponding procedures. This means that the CE mark is a declaration by the manufacturer that their product meets all the relevant provisions of the Directive which apply to that particular product and that it has been assessed in accordance with the regulations of the Directives. Hence the CE marking ought to indicate that the medical device is safe, but it should not be seen as an absolute guarantee of safety.

Medical devices bearing the CE marking are assumed to conform to the appropriate essential requirements unless there is reason to believe otherwise. If the Competent Authority becomes aware...
that a particular product bearing the CE mark does not conform to the requirements or is a risk to health it has to take appropriate measures to verify this and if necessary, withdraw the medical device from the market.

In every case, products that are not allowed to carry the CE-mark are Medical Devices intended exclusively for the purposes of clinical investigation (i.e. trial) of a device and custom-made devices specific to individual patient needs. For these cases a statement concerning the conformity with essential requirements according to Directive 90/385 EEC, Annex VI and Directive 93/42 EEC, Annex VIII has to be made.

As for its impact on innovation it has to be pointed out that therefore manufacturers need not submit devices to time- and resource-consuming national schemes for product approval or registration each time export to any other country in the Community is planned. This especially applied for innovative products as it shortens the time-to-market in Europe.

4.2 Characteristics of the supply-side of the medical device cluster

4.2.1 General characteristics and trends

The European medical devices industry is characterised by a large degree of variety and heterogeneity. It covers a wide range of different products on different technological levels and for various application fields. Every product requires a specific area of competence for its development, production and sales. A large number of small and medium-sized companies that concentrate on a particular product line can therefore be seen within this field. In addition, there is often a geographical limitation to their activities which is on occasion reinforced by the fact that in the medical devices industry, a close client relationship built on trust is important for innovation as for other things. In addition, there are also a few large companies that offer a broad range of products and have a global strategy. In Europe, the field has a total of around 5,500 companies.

The EU medical device industry covers c. 76% of EU-wide demand for medical devices. It therefore has a strong standing in the home market. Yet in other markets, products manufactured in Europe have to date only captured a relative small share of the market -7% of the US market and 10% of the Japanese. The reasons for these low values are for instance strict admissions requirements to entering overseas markets (such as the FDA), characteristic features of the sales system overseas or

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46 For the following section about the supply side see European Commission (1996f) and (1997c); Kaiser, G, Wappelhorst, M. (1997), Deutsches Institut für Wirtschaftsforschung (1999).
47 By comparison there are around 7,700 companies in the USA and around 2850 in Japan.
48 Value correct for 1993. It can be assumed that there has not since been a remarkable change to these values.
specific preferences for locally manufactured goods. On the whole, the general development of the European medical device industry is positive. The following table illustrates this point:

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<td>3.180</td>
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<td>-440.0</td>
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<td>Employment (x 1000)</td>
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<td>114.0</td>
<td>120.0</td>
<td>120.0</td>
<td>120.0</td>
</tr>
</tbody>
</table>

* Few countries reported estimated values for visible consumption, production and employment.
** Eurostat-estimation for EUR15
*** Rounded DRI-prognosis for EUR15
Main indicators at regular prices

Fig. 3: Economic development of the European medical device industry

The front-runner amongst manufacturing countries is Germany. Its proportion of the total EU net product amounted to well over 50% in the mid-1990s. Germany is followed by France with around 20% of the total EU net product, the UK, with around 15%, and Italy with around 8%. These countries together produce around 95% of the total EU net product in this sector (European Commission, 1997c, 16-10).

On closer examination of the individual countries within Europe, it is noticeable that the supply side of the medical devices industry portrays clear country-specific features. If individual EU countries are compared, differences can clearly be seen in, for instance, the level of R&D, technological areas of competence, the innovation culture and performance, production systems and also in the level of exports. These differences were highlighted in a recent study which looked at export success in the UK and the German medical equipment industries.49

Despite these individual country differences, the EU medical devices industry as a whole recognises that it faces shared challenges. These are in particular:

- costs and qualification of human resources
- globalisation of markets and increasing international competition
- trends towards concentration
- the high importance of R&D and innovation, increasing technological dynamics
- cost-containment policies on the demand-side

49 See Deutsches Institut für Wirtschaftsforschung (1999).
The following reports look at these challenges in greater detail. Due to the subject of this study, the aspect of innovation is dealt with to a greater extent. The issue of cost-containment policies will be discussed more extensively in the next chapter in the context of the demand side.

4.2.2 Costs and qualification of human resources

Comparatively high labour costs in the EU are an incentive for the manufacturing trade to transfer areas of their production to countries with lower wage levels. This affects in particular areas of the industry which have a lower technology component or a lower net product. In all, the question of high labour costs played a smaller role in the past due to the relatively high net product within the EU medical devices industry compared to other industries. However, there are still areas with a lower net product in which the EU has already lost ground compared to countries with a lower wage level. This is true for instance in the manufacture of medical dressings or in the production of simple reusable surgical instruments. It can be seen that the medical devices industry is not only following a strategy of producing innovative and technologically sophisticated products in order to distinguish itself from its competitors, but that it is clearly also increasing its productivity at the same time in order to maintain competitiveness. In the future it can be expected that the issue of work productivity will become even more important as a result of price pressure on the demand side. However, it is assumed that there are still reserves available which would improve productivity and increase the added value in the EU devices industry.

In addition to labour costs the qualification level of employees plays an ever more important role in competitiveness levels as a result of the increasing technical sophistication and complexity of the products. A recent study of the export success in the UK and German medical equipment industry (DIW, 1999,38) emphasised the importance of higher-skilled staff, as they develop their own ideas for products to a greater extent and are more responsive to the introduction and application of innovative technologies and new processes. It is only having employed staff with relevant knowledge that allows companies in the medical devices industry to develop high quality, technologically sophisticated products and then to manufacture and market these, thereby reaching the global market with technologically sophisticated, innovative products.

4.2.3 Globalisation of the markets - increasing competition

The globalisation of the markets has important consequences for EU-manufacturers in the medical devices industry. The majority of medical devices are tailored for specific illnesses and uses. Markets are therefore highly segmented and national markets are often too small for extensive R&D

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50 The gross value added per employed person totalled around 25 200 ECU in 1985, rising to 33 100 ECU in 1990 and to 43 900 ECU in 1995. The values for work-productivity in individual countries show an increase after 1995 as well. Source: Eurostat
investments to be worthwhile, for efficient, capital-intensive production techniques to be implemented and for the necessary turnovers to be achieved. This is especially true for fields with high technological dynamics. Companies must therefore orientate their marketing activities internationally.

A characteristic feature of globalisation is an increasing international interweaving of economic activities, particularly in trade and direct investment. With regard to the intensity of foreign trade, it is significant that at a figure of around 54%, the average level of exports as a proportion of the total production in Germany, the United Kingdom, France and Italy, clearly exceeds the values of that of the USA (23%) and Japan (27%). It can be seen that these EU countries are clearly more export-oriented. However, if internal trade within the EU is not taken into account, it can also be seen that EU countries, the USA and Japan demonstrate a fairly similar intensity of exports. Nevertheless, it is clear in this context that European medical device enterprises have to be export-oriented to a much greater degree and have to enter the foreign marketplace at a much earlier level of their company development or of their product development than their overseas competitors. The Single European Market ought to create positive impulses which enable an easier entry into the market. The fact that the internal community trade has also significantly increased in the medical devices industry can be seen in the following table, which depicts a summary of the volume of internal trade for important areas of medical technology. The table also shows the volume of exports for each of the listed countries into the EU.

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51 Please note that between 1995 and 1996 there is a jump due to the change in the basic product list. For an overview of the products included, see annex.
Export into EU from the following MEMBER States:

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<td>685016</td>
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</table>

Source: EUROSTAT; Unit: 1000 ECU

Fig.4: Intra-EU-trade in the medical device industry.

Despite a high degree of “self-sufficiency” in the USA, Japan and Europe, an increase in economic interdependence can also be observed here. The export of medical devices to the USA and Japan, however, continues to be costly, due particularly to country-specific testing and admissions procedures. A mutual recognition of harmonisation of the corresponding regulatory systems has not yet been achieved. Direct investment abroad is therefore very important for entering new markets. We can see for instance that US companies have opened production centres in Europe in order to reach the European market, and that in Europe there have also been a number of company take-overs by US firms in order to acquire market share in Europe. A study of the competitiveness of the European medical devices industry in 1997 showed that US companies control 26% of internal EU production. If we also take EU imports from the USA into account, at a level of around 17%, then in 1993 43% of the EU market for medical devices was already under the control of US companies (European Commission, 1997c, 138).

In addition to the increasing economic interdependence of the USA, Japan and Europe, it must also be noted that despite the recent crises, the “newly industrialising countries” of Asia and Latin America are becoming increasingly important both as producers of and as markets for selling medical devices. Countries on the threshold level of industrialisation, such as South East Asian countries will enter the world market as competitors.

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52 In the early 1990s around 75 –85 % of the relevant internal demand was met by internal production. See European Commission, 1997g, p. 133.
4.2.4 Trends towards concentration – the need for flexibility

The trend towards larger company units and towards concentration is very important in the medical device industry. This is true on the one hand particularly as a result of the high proportion of SMEs which continue to exist within the industry today. As a result of the high R&D expenditure and the substantial growth in the volume of process automation as well as the tendency towards globalisation of the market, a minimum company size is increasingly becoming a competitive advantage. In the last decade, a continuous process of concentration has been seen in the field. The development described here is noticeable for example in the fact that the world market share of the top 5 companies amounts to around 90% for pacemaker production and to around 75% in the area of imaging. The figures for the share of the world-wide market show that the 30 leading European and American companies were able to increase their aggregate market share between 1988-1993 from 49% to 56% (European Commission, 1997c, 137,139).

At the same time it must however be remembered that smaller and medium-sized firms generally tend to possess better prerequisites to adopt new technologies rapidly and to respond more flexibly to the demands of their clients. In this respect they also have a market advantage over large companies, which will in future allow them to remain in the market if they use these advantages purposefully. It is particularly important that small companies in particular occupy a position in the market early on, especially high yield market niches which do not generate the necessary number of pieces for large companies, and to hold on to this position with customer-oriented innovation.

4.2.5 High importance of R&D and innovation, increasing technological dynamics

One characteristic feature of the medical devices industry is its high R&D intensity. On average in the EU, 5% of turnover is used for R&D. The fact that the health service sector demands the latest treatment methods means that suppliers in the medical devices industry are constantly aiming to improve their products and methods. Hospitals and other clients make their purchases depending on whether it is a leading technological product which meets the highest demands of the quality of treatment. In addition to rising requirements of the quality of treatment there are also additional demands on innovation because medical technology products must increasingly satisfy the criteria of cost efficiency in addition to the demands on technology and function. The competitiveness of a company is therefore clearly dependent on whether they are providing a leading technological product that meets these demands. Innovation is therefore a substantial factor of competitiveness in the medical devices industry. Research and development in medical technology is characterised by the following:

53 The corresponding values for the USA and Japan are comparatively higher: USA: 6.7%, Japan: 6% (European Commission, 1997c, 135).
Medical technology is a multi-disciplinary field. It combines knowledge from various natural and engineering sciences as well as techniques for solving medical problems. It therefore fulfils a role as “intermediary” (point of transmission) between technology and medicine.

Due to the relevance of various technologies and the great importance of doctors in the development of new medical devices (such as the specification of demands or of licensing requirements for new markets), innovation in the medical device field is a multi-player process which demands a high degree of co-operation. Groups which participate in this co-operative process amongst various players are research institutes, enterprises and hospitals.

It is this co-operation with the medical field in particular which is a substantial factor for success, as innovative medical technological solutions must be defined in conjunction with competent doctors, must be clinically validated, proven in terms of medical progress and transferred into application. At the same time there are barriers to the co-operation and agreement of individual players in this network which hinders the innovation process. The following table depicts the main fields in which the particular groups of players are active and also barriers to co-operation.

A necessary condition of market success for innovation is moreover that it takes the framework conditions of the individual healthcare systems into account. Besides the highest standards, these demand medical devices that are affordable and that allow for efficient treatment techniques. Innovations in the medical device industry are therefore under an increasing price pressure resulting from the financial bottlenecks within health systems. This price pressure is increased further by global competition. At the same time, the
demand for cost-efficient treatment methods provides new opportunities for medical devices which meet these standards.

- In order that innovations in the medical devices industry are successful, they must be determined not only by what is technologically possible, rather they must primarily take the needs of the medical profession as the users and those of the patients into consideration.

- Innovation in the medical device industry presents itself as the process of a “production chain” for innovation. This consists of various phases involving various players. The innovation process here does not follow a straight line, but follows rather a recursive pattern which involves various “loops” (such as the inclusion of applications in problem definition within medical technology and the generation of product ideas). The following diagram provides an overview of this production chain of innovation in medical technology and the co-operation aspects.

Fig.6: The production-chain for innovations in the medical device industry, (Source: Berger et al.(1997)).

- Moreover, starting from specific areas of treatment, this innovation process rarely runs in the straight line of a specific technological solution. It is much more commonplace that different technologies will alternate in their support of medicine.

- Technology fields which are very important for medical technologies, such as IC-technologies, micro or laser technologies, are characterised by a rapid technological dynamism. A broad spectrum of new possibilities for products and treatments is presented by this technological dynamism, as well as opportunities to distinguish their products to those of competitors. At the same time, however, the intensity of technological competition also increases. In addition to the technological dynamism, a rapid dynamism in the creation
of medical knowledge can also be observed. Both these dynamics must be seen in relation to one another and are mutually reinforcing.

- The high technological and medical dynamism leads to shorter product life-cycles and to a more rapid price decay. The tendency towards a shortening of the depreciation period makes it necessary that innovative products reach the market quickly and in large enough quantities so that the high investments in R&D are profitable.

- At the same time experts point out that the dynamism from technology and medicine does not replicate itself to its full extent in a corresponding innovation dynamism. It takes many years for a medical technology innovation to run the course of its production chain for innovation and to reach the market. The rapid development and rapid arrival in the marketplace of high standard and highly innovative developments is less common in medical technology due to the complexity of the innovation process (such as the involvement of various groups of players or the need to meet regulatory requirements to guarantee safety). In comparison with other industries, the innovatory process is characterised by a longer duration.

- As a result of the more rapid technological dynamism, rising development costs and the long duration and complexity of the innovation process, there is a high innovation risk in attaining a satisfactory return on investment.

- As a result of the high R&D intensity, extensive initial investments are necessary for innovations in medical technology. The financing of innovations in the medical technology industry presents a great challenge as a result of long development cycles, the shortening of the length of amortisation and high innovation risks, for small companies in particular. Financing involving external capital is made more difficult by the fact that in the capital market medical technology stands in direct competition to other technologies, from which higher growth rates can often be expected.

- To complete the background to these issues the important aspect of the qualification of staff needs to be looked at further. The high technological level of the products, the implementation of various technologies and the close relationship between medical technology and its use in practice in medicine demands a wide range of competencies of staff.

4.3 Characteristics of the demand side

The primary aim of innovation is the successful satisfaction of the needs of both citizens and society. This is particularly true for medical devices. Its aim must be to contribute to improved healthcare. A factor of success for innovation is therefore not what is technically possible but rather making a concrete contribution to an affordable solution to medical problems.5

5 See e.g. Stehr, H. (1997).
It can also be seen that in the medial device industry, the demand side and technological development influence each other. A study published in 1995 by the Office of Technology Assessment (OTA) of the U.S. Congress ascertained that:

"Reimbursement schemes and other powerful incentives embodied in payment for health services underline the importance of the structure of the health care system and the nature of health policies on adoption and use of innovative technology."56

On the other hand Rutten et al. (1992) point out that the impact of medical technology goes far beyond its impact on selected patient groups that benefit directly from its application. They point out that technological developments in the healthcare sector have a variety of social, economic and ethical implications.57

In the analysis of the demand side of the European medical device industry, general, overall developments influencing innovation in the medical device industry which hold true for all of Europe can be observed. However, clear country-specific differences can also be seen to characterise the demand side. Both the general, overall trends and areas with country-specific differences will be discussed here in further detail.58

4.3.1 General trends and impact factors

Throughout all the European Union a demographic change can be noted, with the rise in the average age of the population and the simultaneous increase in average life expectancy. This can be put down to, amongst other things, better living conditions and improved healthcare. At the same time, these developments also bring about a growing need for treatment. In this respect, good healthcare has the effect of increasing and changing healthcare needs. This demographic development in particular will continue to be a fundamental determining factor for demand of medical devices in the future.

A further factor is the gradual increase in income throughout the EU. As both individuals and the economy as a whole have more resources in total at their disposal and as healthcare is one of the areas where both individuals and the economy prefer to spend their money, expenditures in this area increase accordingly. This is supported further by an increase in public awareness of healthcare issues.

Technological developments such as the implementation of IC-technologies or micro-technologies allow for the development of new applications, better availability and also a fundamentally improved level of user-friendliness of medical technology products. Tightly bound up with these is the new development that demand, which previously came almost exclusively from hospitals and care institutions, today comes to a much greater extent from private consumers and will continue to do so in the future as well.

In view of dynamic technological developments, suppliers of healthcare services, such as doctors for instance, are interested in making use of this sophisticated technological medical technology. This leads to problems particularly when a corresponding cost-efficiency incentive does not coexist at the decision-making level of these suppliers, for instance with doctors and that cost-efficiency is instead the concern solely of those who pay the costs, such as hospitals, local authorities and insurance companies.

However, on the basis of the above-mentioned development we can also note a simultaneous dramatic increase in healthcare expenditure. The fundamental reasons for this are in particular: the ageing of the population (with associated increasing rates of chronic diseases and disabling conditions) and implications of technological development (with unprecedented means for medical treatment and increasing expectations of consumers).

In this context it has to be pointed out at the same time that surprisingly little is known about the total impact of technologies on health care costs. Some attempts have been made to estimate the aggregate effects of all changes in medical techniques relative to the increase in real healthcare expenditure. But there is only little exact and detailed information about the role of technology and innovation in the health care expenditure. So far it has been estimated for instance that 75% of the health care budget is spent on wages whilst a mere 5% goes to investment in equipment. Furthermore, total costs of "high-ticket" technologies are estimated to account only for a few percent of the healthcare budget. The reverse is assumed to be true for "small-ticket" technology which is basically inexpensive in itself, but is often used and for many patients. However, irrespective of this unclear picture about the exact impact of technology on costs in the medical sector it can be noted that the healthcare policy climate is rather negative for technical innovation and technology.

As a response to the rising level of healthcare expenditure, EU Member States have adopted a set of cost containment policies. These efforts to control the increase of the total healthcare budgets have engendered a health policy issue around the control and management of technological change and innovation in the medical sector, which affect medical devices as well.

Thus, because of the high percentage of hospital treatment in the healthcare budget, all Member States have been taking measures to control the cost of healthcare. In general, there is significant

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pressure to make hospitals work more efficiently, to reduce the length of hospital stays or to close hospitals. Furthermore, most governments continue or have begun to shift the use of resources away from acute in-patient care towards primary and community care. These measures directly affect the budgets, financing mechanisms, hospital equipment and hospital working methods. As hospitals generally represent the largest consumer group of medical devices, this therefore also has extensive implications for the medical device industry. The following diagram reinforces this relationship further:

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**Legislator**

- cost reduction

- claim for economic procedure

**Hospitals**

- rationalization
  - reduction in hospital beds
  - specialization
- concentration of cost-intensive medical services (increased capacity utilization)
- formation of purchasing associations
- outsourcing of services
- increase in automation

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**Fig. 7: Impact of healthcare reforms on demand** (Source: Berger et al. (1997)).

There are two main strands of actions to deal with the problem of a rise in expenditures: Firstly, there are calls for public control and regulation in the organisation and funding of healthcare as well as calls for a strategy that defines precisely which healthcare services are to be covered by public funds. Secondly, there is a tendency to diminish the role of the government and to leave more decisions over resource allocation in healthcare to the players within the field such as insurance companies, health care providers and consumers. Therefore, because of the pressure of high costs there is a trend towards privatisation in the provision of healthcare in order to achieve greater efficiency. In essence, both of these tendencies have the same effect: The efficiency of a technology becomes more of a critical factor throughout the various phases during which an innovative technology in the medical device sector is introduced.61

Finally, it is becoming increasingly less likely that demand will be limited to a narrow geographical area. Instead, as in most other markets, we are witnessing a globalisation in medical technology

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markets. Clients are scattered throughout the world, as most medical technological devices cater for specific healthcare needs, whereas the majority of national markets are strongly segmented. In order that the high level of investment in R&D proves itself worthwhile and that the latest production techniques can be implemented, it is necessary that suppliers offer their products world-wide in order to achieve economies of scale.

4.3.2 Heterogeneous institutional frameworks in the national healthcare-systems

However, it has to be pointed out that the demand side in the Member States and the systems put in place by different EU countries to organise the delivery of healthcare vary widely. This mainly results from the fact that healthcare systems stem from specific political, historical, cultural and socio-economic traditions. Health policy making is guided by the principle of subsidiarity. Although the Member States have to face common challenges in delivering equal, efficient and high quality health services, the strategies employed by the Member states to meet those challenges differ widely. A comparative study of the health care systems in the EU points out that the "health care systems in the EU reflect a variety of different philosophies and approaches and retain their own peculiarities”. Differences between individual Member States can be observed at very different levels. These are influential factors for innovation in the Medical Device industry. Examples are:

- Demographic determinants (standard of living, health status, age structure), need for health care.
- Public or medical preferences in terms of certain forms of treatment.
- Preferences in terms of the technical level of those products which are in demand.
- Specific characteristics relating to safety and certification, such as preferences for certification by a familiar national notified body.
- Characteristics of the healthcare services on offer, such as the amount of healthcare located nearby (hospitals, specialists etc.) and the availability out-patient treatment, hospital treatment or home care.
- Approaches as to how providers of medical services (e.g. primary care) are employed and paid
- The mix between public and private sector healthcare services; competition between health-care providers.
- Sales channels and the marketing of medical technology products, such as distributors or sales agents.
- Purchasing procedures and systems (e.g. for medical devices in hospitals)
- Volume and rise of health care budget and expenditure.
- Allocation of health care budget to different health care providers and services.

62 For the following section see European Parliament (1998c) and European Commission (1996f, pp 105 ff.)
64 A discriminating representation of the specifics of medical technology markets in individual EU countries can be found in Bundesstelle für Außenhandelsinformation (1998). For further details on national differences on the demand side of the medical devices market, see European Commission (1996f, pp.82-93, 105-131) and European Parliament (1998c).
• Funding and financing mechanisms (e.g. mainly by taxation, mixture of social and private insurance, mainly social insurance with mixed public and private providers).
• Measures of cost-containment (e.g. indirect measures like improved cost measurement, encouragement of competition, direct measures like expenditure ceilings, alternatives to in-patient care, influence on authorising behaviour and other measures like cost sharing or creating of an internal market).
• Terms and habits of payment for medical devices (e.g. different payment terms of hospitals).

However, the comparative study analysing the health systems in the EU also points out that irrespective of existing differences it can be observed that the fundamental division between the systems is weakening. Feeling the necessity of cost-containment, the EU countries have started to reform their systems. In this context a trend towards convergence and an attempt to retain the relative advantages of the own system as well as to take up advantages of other systems can be seen (European parliament, 1998, 5-6). Yet this convergence is still developing. Furthermore, the Member States still develop their own solutions to solving the problems of their health care systems.
4.4 Summary

The following box summarises important results of the analysis of chapter 4 considering the regulative framework of the Directive 90/385 EEC and 93/42 EEC and the supply and demand side of the medical device cluster.

Regulation
In addition to the general economic impacts of the Single Market there are additional impacts of the New Approach and the Medical Devices Directives 90/385 EEC and 93/42 EEC. Possible important impacts are:

- The directives are limited to “essential requirements” to protect safety and health of patients and users (93/42/EEC, Art.3/annex I and 90/385/EEC, Art.3/annex I). They contain no specific technical rules. This means that regulation offers technological flexibility for innovation.
- The use of harmonised standards is a possible instrument to assess conformity with the directives (93/42/EEC, Art.5 and 90/385/EEC,Art.5) in an efficient way. As for innovation it has to be considered that technological flexibility is still given as the application of standards is voluntary. This is esp. important as standards generally only represent the current state of the art technology.
- The directives offer different conformity assessment procedures (93/42/EEC, Art.11, annex II-VII and 90/385/EEC,Art.9, annex II-V). Thus the manufacturer is offered a modular and flexible organisational framework for conformity assessment. He can choose the best procedure for the firm and the product. The application of a quality assurance system may be an efficient element for conformity assessment within that system.

Supply side
The analysis above has shown that the European medical devices industry is faced with a range of different influential factors, which have an impact on its innovatory activities. On the supply side these are particularly issues relating to the cost and qualification of human resources, the globalisation of markets, increasing international competition, trends towards concentration of industries as well as the high importance of R&D and innovation and increasing technological dynamics.

The detailed analysis of the innovation process showed characteristics peculiar to technical development and innovation in the medical device industry. These are for instance: the relevance of a wide range of technologies, the requirement to involve the demands of doctors and patients, the price pressure for innovative systems arising from healthcare systems themselves, the high relevance of co-operation between various players, the character of the innovation process as a non-linear “production chain” for innovation, the long duration of the innovation process, the rapid dynamism in the field of technological and medical knowledge, the high innovation risk and the problem of financing.
Demand side

In addition to Single Market Regulation and both Directive 90/385 EEC and Directive 93/42 EEC there are a number of more general overall trends and challenges which the European medical device industry has to face originate from the demand side and which have an effect on innovation in the Medical Device industry. Examples for these general trends and challenges are e.g. the rise in the average age of population, an increase in income, awareness for healthcare issues and demand on the level of private households, an increase in healthcare expenditure (driven by technological developments and wrong incentives within the health system), cost containment policies and the need for higher efficiency in the production of healthcare products.

Although facing common challenges the solutions put in place by different EU countries to reorganise the demand side in the Member States vary very widely. Differences can be found in all important elements of the national health-systems, which also exert an important influence on the development and marketing of innovative medical device products. It can therefore be stated that with regard to the demand side of the European Medical Device cluster, a rather low level of harmonisation has been attained so far and that in this aspect, seen from the demand-side the harmonisation within the Single Market has been achieved only to a minor extent.

Furthermore the high degree of regulation in the healthcare system (esp. on the demand side) healthcare system makes also clear that the regulation by means of Directives 90/385 and 93/42 EEC represent only one important influencing factor amongst several others in terms of innovation in the medical device industry.
5 Empirical analysis

5.1 Framework and methodological approach for the empirical analysis

5.1.1 Analytical framework

Becher et al. (1999, 7) point out that regulations are part of the institutional matrix of a sector which, together with conditions of the demand and supply side, provide a specific range of incentives and opportunities. These then influence the kinds of knowledge, skills and innovations which are developed. The institutional framework therefore provides incentives and influences particular ranges of opportunities on several levels:

1. at the individual player level within innovations, such as the individual company level
2. at the innovation system level, by way of co-operation or competition

The channels through which Single Market regulation (particularly Directives 90/385 EEC and 93/42 EEC) establishes potential incentives for innovation have been discussed in earlier chapters. The Single Market programme, the Directives 90/385 EEC and 93/42 EEC (incl. their economic impact) and the characteristic of the medical device cluster have also been discussed in previous sections. Based on this analysis, the following hypothesis can be formulated for the further empirical research of this study:

“The New Approach has improved conditions for innovation”.

Examples for these improved conditions are for instance:

- Re-testing and adaptation in order to comply with national regulation is no longer necessary
- Reduction of costs, risks, time to market for innovations (especially for conformity assessment)
- Better conditions for export (especially to enter new markets) and high-volume production provide a better return on investment
- A higher rate of competition fosters product innovations
- The Single Market framework facilitates co-operation
- Regulation offers technological flexibility
- Regulation offers organisational flexibility
The following diagram shows the analytical framework for this study.

The aim of the following empirical analyses was to test this hypothesis, to define its scope more precisely and to describe the relationships between effects in greater detail.

5.1.2 Methodological approach

5.1.2.1 General implications from the conceptual and methodological requirements

In chapter 2 the conceptual aspects for the analysis of the Single Market impact on innovation has been worked out. Considering these aspects the following section will describe the structure and methodology of the following empirical analysis.

Empirical basis: The actual effect of regulation cannot be determined from the wording of the law itself. It is much more important to consider the law’s practical implementation and the effect it has on companies in order to gain an insight into the real effects of the regulation on the industry. This study therefore undertook a company survey in order to obtain an empirical basis for evaluation.

65 The question marks represent the impact of regulation on innovation to be analysed empirically.
**Combination of different research-methods:** In order to do justice to the complexity and the lack of defined research standards as for this research field, the study worked with a mixture of methods. The questionnaire for the postal survey combined quantitative or quantifiable data, such as the personal evaluation of effects on a pre-defined value scale, with qualitative data results, through providing the opportunity for respondents to expand upon their answers in the questionnaire. The questionnaires were supplemented by interviews. However, the main focal point of the data collection was placed on the questionnaires themselves.

**Understanding of innovation:** Innovations have been characterised as a multifaceted, collective and dynamic process which is difficult to conceptualise by means of a single indicator alone. This description is particularly relevant for the medical device industry. In view of the particular complexity and heterogeneity of innovations in the medical device industry along with the challenge of statistical measurements, this study did not focus on a few single indicators. In our collection of data the term ‘innovation’ was understood in very broad terms and open, general questions were asked regarding the effect of the new regulations on attitudes towards innovation.

**Complexity makes focus on a selected industry and regulations necessary:** The implementation and interpretation of particular elements of Single Market Regulation presents a high degree of heterogeneity for the internal market as a whole. It was necessary to reduce this heterogeneity in the first instance, in order to reach usable conclusions. The study concentrated therefore on one selected industry sector – the Medical Devices Industry.

In view of the complex relations between Single Market Regulation and innovation in general, the study concentrated on two chosen directives (90/385; 93/42). This allowed more accurate conclusions to be drawn, as these were put in place a longer time ago compared with other directives and the extent of their implementation therefore greater.

**Consideration of wider institutional framework and analysis of general mechanisms:** In addition, the analysis of the impact of the two chosen directives (90/385; 93/42) are viewed in the context of the general economic effects of the internal market. In order to be able to apply the results of this study into one particular branch of industry and certain specific EU directives in other areas, or even to use similar approaches, general questioning and effectiveness mechanisms were examined (e.g. characteristics of the New Approach), rather than purely individual characteristics.

**Different levels of analysis:** Various effectiveness levels were included in the analysis in order to gain a better understanding of the complexity of the linkages between innovation and regulation (see analytical framework). In this way, for the firm level, it was e.g. able to take the issue of efficient organisational structures and processes into consideration as well as on the system level the issue of co-operation in networks and the issue of competition.
**Time-horizon**: In view of the fact that Single Market Regulation was only recently developed and implemented and that its full results will as a result not be seen for some time, the main focal point of the analysis was placed specifically on the general effects which are to be expected in the future. Temporary or transitional effects have not been the main focus (esp. for postal survey). In order then to assess these general and long-term effects, the study enquired explicitly as to both current effects along with those expected to develop in future. Transitional impacts mainly have been worked out in additional comments and interviews.

**Integrated approach considering characteristics of the industry and the supply-side and aspects of the demand-side**: In order to consider factors of influence outside both the regulatory framework and the specific characteristics of the chosen industry, the study also considers the structures and developments important within the Medical Devices industry, such as its economic development and its pattern of innovation. The effects of regulation on innovation are seen not merely in terms of Single Market Regulation alone. Effects result further from other frameworks of regulation besides that of the Single Market Regulation. For this reason, health policy on a national level and conditions of the demand side was also taken into account in this study, as this provides a framework of great importance for the attractiveness and economic success of new medical devices (see chapter 4).

5.1.2.2 **Approach of the empirical analysis**

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

- **Step I**: Selection of „best-innovators“ in a pre-survey
  (postal survey among different expert groups of the medical device cluster)
- **Step II**: Researching the experiences of best-innovative firms with the New Approach
  (postal firm survey among best innovators selected in step I).

In addition to the postal survey telephone-interviews have been conducted to deepen the analysis.

Following the single steps of the empirical analysis are being explained more closely.

**Approach of the pre-survey (step I)**

The pre-survey was a postal survey among important expert-groups in the medical device cluster. Using the criterion of product-innovation the main goal of the pre-survey was to identify best-innovative firms. The analysis concentrated on this group as the analysis was concentrating on general-long term effects as it can be expected that this group has overcome transitional problems in between times better than less innovative firms. For identification of these firms there was the question as for the name and address (incl. person to contact for the survey if known) of best innovators. To get the right firms as best innovators only such firms should be named which have a „proven capability to reach the
market successfully with innovative products”. More defining criteria (e.g. quantitative firm data) had not been used because of the complexity of the aspect of innovation and to avoid an „overloading“ of the pre-survey.

To ensure a best choice of innovative firms and a selection of firms that is characterised by both a wide coverage and an objective selection of best-innovators experts belonging/being related to different groups have been contacted in a first postal survey.

The different expert groups have been:

| Research               | National and international research associations |
|                       | Centres of competence |
| Industry              | National and international industry federations of the medical device industry |
| Capital               | Venture capital funds (with concentration on biotechnology/ medical devices) |
| Regulation            | Notified bodies and their national/ international associations |
| Intermediaries        | International innovations networks |
|                       | Regional innovation initiatives with international networks |
|                       | Regional development agencies |
| Others                | E.g. users (national and international professional associations) |

Within these groups 608 experts have been identified to be questioned in an European wide survey to select “best innovators”. As a result of this expert survey 85 experts answered. They have nominated 428 firms as “best innovators” in the European medical device industry. These have been contacted in step II.

Approach of the firm-survey (step II):

The research of the experiences of best-innovative firms with the New Approach has been organised as a postal firm survey. The survey among the 428 firms being nominated in step I has been sent out mid May 1999 (week 19/1999). The firms have been asked to sent back the survey until 18 June 1999. To increase the response rate a reminding letter has been sent out at the beginning of June (week 23/1999). Finally, the survey has been answered by 150 firms. Thus a response rate of 35 % could be reached.

The questionnaire contained 15 concise questions about the impact of the Directives 90/385 EEC and 93/42 EEC on innovation and 6 questions for firm-classification (relevance of directives, firm size, firm location, market segment, risk class, location of markets). As for the questions about the impact of regulation the firms should state their assessment on a scale from –2 = very negative (“bad”) impact, 0 = no impact, +2 = very positive (“good”) impact. In addition to this assessment the firms were asked to give more detailed comments. According to the analytical framework the questionnaire had the following structure:
I) Impact of direct access to the Single Market on ...
⇒ ...investment
⇒ ...time to market
⇒ ...innovation costs
⇒ ...innovation risks
⇒ ...the opportunity to enter new international markets in Europe, overseas in general and in the USA

II) Impact of technological and organisational flexibility on innovation:
⇒ Impact of technological flexibility by limitation to essential requirements
⇒ Impact of harmonised standards
⇒ Impact of organisational flexibility by different conformity assessment procedures
⇒ Impact on quality assurance system

III) General impacts of the directives ...
⇒ ...on co-operation with the following actor groups: medical research and clinical testing, other scientists / laboratories, companies, national or international notified bodies
⇒ ...on competition within Single Market
⇒ ...on competitiveness of EU manufacturers
⇒ Total impact of the directives in the long term
⇒ Transitional impact of the directives

Additional telephone interviews

In order to obtain a differentiated picture of the way in which Directive 90/385 EEC and Directive 93/42 EEC work, telephone interviews were conducted with certain companies, in addition to the written questionnaires. These companies were selected from those already contacted with the written questionnaire. Companies whose answers had shown a more thorough reflection on the issues raised by this study were chosen, for example, if they had provided extensive additional information. It was expected that these companies would provide a deeper insight into the relationships between regulation and innovation from the perspective of medical device companies.

In the interviews it became clear that although the transition period for the inclusion of the directives into the national legislation of each individual EU Member State has now been completed and the new legislation is in place, many companies are still experiencing and accommodating the effects that the changes have introduced. As the firms continue to be confronted with challenges in adapting to the new systems, their statements concentrated more on short term effects and their problems in adapting to the new systems than on the long-term effect of the medical device directives on innovation. In the interviews, the firms were as yet unable to explain the overall effects that the directives will have on the medical devices sector, and particularly their impact on innovation in the longer-term.
5.2 Empirical results

5.2.1 Impact of the direct access to the Single Market

5.2.1.1 Impact on investment

By comparison, with a mean value of 0.58, the effect on investment is comparatively positive. The following diagram gives an overview of the results of the survey:

Fig. 9: Impact of the direct access to the Single Market on investment (B.1.1). n=144.

In the postal-survey only a few of the additional commentaries referred to the influence of regulation on investment. These particular statements mainly pointed out negative aspects. It has been emphasised that investments cannot be used for innovation (especially in the short term), as it has to be invested in the implementation of certification and quality management systems and processes.

The following aspects were regarded as possible positive impacts:
- there are better opportunities and chances to find investors.
- that there is potential to increase the return on investment.

The telephone interviews pointed out that investment in the development of new products is closely related to changes in innovation costs. Wherever the directives have led to a decrease or little change in the costs of innovation, there has been little or no change in investment so far. Those companies that have experienced an increase in the costs of bringing a product to market stated that they will have to consider more carefully investing in new products in the future.
5.2.1.2 Impact on „time to market“

The positive effect on “time to market” is comparatively weak, with a mean value of 0.34. The mean variation is 1.22 and is the highest value recorded for all questions. Opinions on “time to market” are therefore extremely varied.

In their additional comments in the postal-survey firms mentioned the negative impacts on the “time to market” and delays in the innovation process above all else. The length of time needed to translate manuals and the time taken for administrative work was noted particularly frequently in this context. However, the reduced “time to market” when entering the market in another EU country was regarded positively. All together the following negative factors were mentioned specifically:

- The obligation to translate manuals, technical documentation, maintenance instructions into different EU languages is a very time consuming task.
- Formal procedures, extra testing and documentation seriously delay innovation.
- Minor product developments are influenced negatively (alteration of existing products). The technical solution is sometimes realised faster than the paperwork.
- Time delays result from the obligation to obtain CE signs for prototypes and clinical samples.
- Some negative impacts for those medical devices where clinical investigation is needed.
- More stringent technical requirements (e.g. EMC requirements) need more time.
- A delay in reaching the foreign market as firms are still confronted with specific national requirements.
- Limited benefit on "time to market" because of proliferation of "quality marks" in addition to the CE signs at the national level.
- Negative impacts for products only being marketed at the national level.

Evaluation of the time factor was more evenly balanced in assessing most important advantages/disadvantages. Here, about as many companies said the time factor was the most
important advantage as disadvantage (advantage as for time to reach European markets, disadvantage as for first market entry). Furthermore, in their positive comments, the firms have pointed out:

- When comparing the possibility of extending exports to all EU countries to beforehand there are clear gains.
- Positive impact on “time to market” for products marketed internationally
- As introduction takes place EU-wide, competition is more efficient, since local competitors have fewer time-related advantages
- Time reduction particularly for in-house conformity assessment
- Reduction in time needed for re-designing
- Important decisions are made earlier in the design and innovation process
- The new regulation has improved the time to market in general

In the telephone interviews firms additionally pointed out, that so far directives do not appear to have had a major impact one way or another on the time that it takes products to reach the market. Those firms that did not have quality assurance systems in place argued that ongoing developments were held up whilst QA systems were introduced, but found that times to market returned to normal subsequently. Furthermore, also in the interviews, it has been mentioned that one aspect of the new directive which has added to development times is the requirement to have user manuals and other product documentation translated into all the languages of the member state countries. Some firms have indicated that they would not pursue a new product if it became clear that the accreditation process would require a clinical trial. Trials are costly and can delay the time it takes to bring a product to market. This procedure can be avoided in many situations by gaining accreditation by proving the safety of the product through academic papers.

5.2.1.3 Impact on innovation costs

This question attained the lowest value for all factors with a positive effect, with a mean value of 0.04

66 Over one third of all companies suppose that the new regulative framework has had a negative impact on costs. For no other question (other than that on transitional impact) is the proportion of companies with a negative evaluation as high. A group-specific examination reveals that small companies in particular evaluate the cost effects as being highly critical.67 However, in the general opinion of all companies there is almost as high a proportion who have a positive assessment (which leads to a comparatively high mean variation of 1.01). This relatively heterogeneous set of opinions with similar levels of positive and negative evaluations is shown in the following diagram:

66 The only lower value recorded was that for “transitional impacts” (-0.23).
67 See the corresponding tables in the annex.
In their additional comments relating to the individual questions, companies primarily mentioned negative aspects. This was seen in their choice of the most important advantages/disadvantages as well. Costs associated with the implementation of new regulation and the resultant operational procedures were mentioned particularly often. The high level of administrative effort required and the use of resources were also regarded as particularly important here. In addition, several companies stressed that the translation of documents such as user manuals into different EU languages not only results in longer “time to market” but also in higher costs. As positive has been mainly seen the rationalisation effect and the rise in efficiency due to better structuring of innovation processes. The following factors were mentioned specifically:

Positive impacts:
- Overall costs for R&D have been reduced by having a single set of technical requirements
- The directives allowed activities to be rationalised and streamlined
- Positive impacts are expected particularly in the long term initial difficulties have been overcome

Negative impacts:
- Language requirements (e.g. the translation of manuals into different EU languages is very costly)
- Increased test requirements and requirements for technical documentation.
- Collecting different papers and certificates requires more common resources.
- Costs did increase due to the application of the harmonised conformity assessment to a wider range of medical devices (including low risk products).
- Costs have gone up as regulations are now much more demanding, more investigation and evaluation processes have to be carried out
- High cost of installing certified quality management systems
- More expensive clinical investigation
- Increased fixed-costs mean that new products with a limited potential market are now less likely to be developed.
The results of the additional telephone-interviews have underlined that the impact of the directives on innovation costs has been mixed. Despite the positive fact that the new directives were intended to be flexible by not imposing set technical standards and by allowing firms to chose the way in which they conform to the new systems of conformity assessment, the overall impression given by the firms interviewed is that the directives are more bureaucratic. Having said this, also the firms’ responses to the directives are not uniform and the new emphasis on quality has affected not only different parts of the sector in different ways but also the impact on different sizes of firms has been varied.

The requirement that the directives have placed on firms to prove that quality is embedded within the design and production processes has increased the administrative costs of developing new products for many firms. Although it is difficult to predict the long-term effects of the directives on innovation costs. Many firms said that they are now more cautious and consider more carefully the development of new products due to the increased costs associated with the new accreditation process. Small firms who had either no quality system previously in place or who have limited human resources to dedicate to these requirements have been especially affected.

Also in the telephone interviews it has been mentioned that one element of the new directives that has had a large impact on the costs of innovation is the introduction of language requirements. Firms now have to translate the user manuals into member state languages to ensure that the product is being used properly (previously UK firms e.g. were able to export in English). The cost of translating product guidelines is also set to increase as the European Union enlarges and central and east European languages are added to the regulations.

Furthermore, the telephone interviews revealed that a number of companies being interviewed that are involved in medical trials mentioned that the insurance costs had increased as they were now responsible for any problems that could occur during the clinical trials, not just those that could be directly traced to a fault with the product. If a problem occurs during the trials then there is the risk that the producer has to carry the cost even if the hospital was at fault and not the product itself. Larger companies can afford to pay the higher insurance costs or, as has been the case in the past, pay compensation themselves.

5.2.1.4  Impact on innovation risks

The results of the quantitative evaluation show that the effect on innovation risks is, by comparison, only marginally positive (mean = 0.06). Company opinion is relatively unanimous. This is clear in the following diagram as well. It shows that according to the quantitative results, a high proportion of companies suppose there are no effects on innovation risks.
Fig. 12: Impact of the direct access to the Single Market on innovation risks (B1.4).

A slightly different picture is given by the evaluation of the additional comments. These can mainly be seen by the results of important advantages/disadvantages. The evaluation here was largely positive. The reduction of risks by means of a better structuring, planning and management of the innovation process were emphasised in particular. It was also often pointed out that product risks are reduced by checking the safety of medical devices and that safety was therefore increased for patients and hence also for firms. Specific comments on the positive or negative impacts were as follows:

**Positive impacts:**
- More security that a product meets the required standards
- Proof of quality makes it easier to place the product on a new market
- Complying with regulatory requirements improves patient safety
- More uniform approach within Europe in terms of successive risks

**Negative aspects:**
- Large volume of administrative and formal requirements lead to uncertainty
- Varyied interpretations of Directives, for instance by different notified bodies, increase uncertainty and the risk of errors
5.2.1.5 Impact on the opportunity to enter new international markets

The results of the written questionnaire clearly confirm the positive effect of the Directives on the entry into European markets. Almost three quarters of all companies suppose that there has been a positive effect in this respect. No other factor attained a higher value (mean = 1.01)\(^{68}\). It is also clear that in particular small companies and companies which were previously only active on the national market suppose there has been a particularly strong positive effect.

However, positive effects were seen not only on the entry into markets within Europe but also into those outside Europe (“overseas in general”). With a mean value of 0.60 the result for this question was clearly under the result of that for Europe; however, it is still among the highest values recorded for the factors assessed. The effect on entry into the US market is much weaker. The mean value of 0.13 is still in the positive range for results, yet it is at the lower end. Companies’ evaluation of market entry “overseas in general” and into the US market is relatively unanimous. The lowest standard deviation of all the questions is seen here, where values of 0.68 are recorded. The clear differences in the effect on market entry can be seen in the following diagram:

![Fig. 13: Impact of the direct access to the Single Market on the opportunity to enter new international markets with an innovative product in Europe (B.1.5.1) n=142, overseas in general (B1.5.2) n=140, in the USA (B.1.5.3) n=134.](image)

Also the additional comments in terms of opportunities to enter new markets were definitely positive, (both in responses to the individual questions and when listing the most important advantages/disadvantages). In the comments the fact that access to the European market is easier was particularly emphasised. The fact that market introduction is now possible in all EU countries simultaneously and that no multiple national registrations are necessary was highlighted as a clear advantage.

\[^{68}\text{Only the mean value for “impact on quality assurance system” is as high.}\]
However, in this context, the fact that European harmonisation has not yet been completely realised was also heavily criticised. There are still differences between individual countries in their application of the guidelines. The reasons for this include for example differences in the interpretation of the Directives by notified bodies. It was also noted that in addition to national differences in the practice of the guidelines for Directive 90/385 and 93/42 EEC, further national features and country-specific requirements are responsible for the Single Market not yet having been fully attained in the field of medical devices. These are for instance particular features of the individual national healthcare systems, national characteristics in terms of demand (such as hospitals) or in the design of or demand for additional quality guarantee seals. France was frequently cited as an example of a country whose own national features make it particularly stand out.

The effect of the CE sign on entry into non-EU markets was interpreted in various ways. Firms repeatedly stressed that the CE sign is recognised in these markets or that it makes entering the market there easier. However, companies also point out that more steps have to be taken towards greater harmonisation or mutual recognition on the global marketplace. Whilst European harmonisation has brought about improvements in entering the US market, in certain circumstances the strongest criticisms made in relation to this question referred to problems in entering the US market.

The individual factors for impact on market access were listed as:

Positive aspects:
- Due to regulatory convergence it is easier to access foreign markets in Europe.
- Market introduction to all European countries simultaneously.
- CE sign has a positive reputation in non-European countries as well.
- An increasing number of countries outside Europe recognise the CE sign (sometimes in spite of their own regulations).
- The CE sign helps new customers from abroad have confidence in the product.
- Easier to apply for FDA approval with CE sign; European harmonisation will also improve access to the US market.
- If the globalisation effort succeeds there will be a major positive impact.

Negative impacts:
- Still necessary to comply with other countries regulation schemes outside Europe, even though the CE sign exists.
- Although some harmonisation with the US has brought about certain improvements there is still a lack of mutual recognition between the EU and the US. The FDA does not accept the CE sign. Every product has to be registered separately. Documents have to be issued additionally.

Also in the telephone interviews the majority of firms stated that it has now become easier to access other European markets where previously the national regulation system was a barrier. Firms have welcomed the ability to market their products much more easily as this national system has been abolished with the introduction of the directives.
Those firms which were already adept at working with the old national systems have found the new system to be beneficial to a lower degree. They claim that the Single Market does not function as efficiently as was originally envisaged. Also in the interviews it has been pointed out that some national requirements remain in place and the health care systems in each country have their own preferences for certain products and processes that cannot be removed simply through introducing new regulation. Many companies mentioned that their customers have special safety preferences and still required extra standards (e.g. such as in Germany specific preferences as for the TÜV). Even though a single accreditation system has been introduced the health services in the EU member states in their health systems have different rules and different ways of controlling their budgets that will have an effect on how they acquire medical devices. Other examples of how the Single Market does not yet function to its full extent on the customer side were also raised. Even though standards have been harmonised and national regulation largely abolished practices within health services and hospital can still create barriers to market entry.

The firms being interviewed also pointed out that the CE mark has given customers in overseas markets extra confidence in European products. However, as more countries introduce their own regulatory systems it is becoming increasingly difficult to have access to all Far Eastern markets. Many companies are active in East Asian countries and have experienced that over the past few years, as Europe deregulates, each of these markets is introducing new legislation As for the ability to access the US market it has been confirmed in the interviews too that the introduction of the directives has made little difference. Many of the companies claimed that there had been no change in the accessibility of this market.

5.2.2 Impact of technological and organisational flexibility on innovation

For factors relating to technological flexibility” (B.2.1) and “organisational flexibility” (B.2.3) as well as to the effect of harmonised standards (B.2.2), a comparative picture is seen. The results lie clearly in the positive range (technological flexibility, mean = 0.41; organisational flexibility = mean 0.44, impact of standards, mean = 0.37). In comparison to other factors, these three factors therefore lie in the middle of the range. The mean deviation of the individual responses, with values between 0.87 and 0.96, also ranges on the same scale.
The following chart shows a comparable answer pattern for these issues:

![Chart showing impact of technological flexibility, standards, and organisational flexibility](chart.png)

**Fig. 14**: Impact of **technological flexibility** (B.2.1). n=145. Impact of **standards** (B.2.2). n=145. Impact of **organisational flexibility** (B.2.3). n=147

The different questions meant of course that commentaries given and the results of the interviews varied greatly. They are therefore presented separately in the following section.

### 5.2.2.1 Impact of technological flexibility

In terms of technological flexibility, companies on the whole acknowledge the positive effect on the development of new products, both in the additional commentaries provided on individual questions and when listing the most important advantages/disadvantages. The voluntary use of standards is emphasised.

Occasional criticisms were raised relating to the following issues: technological flexibility only exists formally and in the companies’ experience standards are in practice “virtually obligatory” (for example, as standards are widely accepted). A high level of flexibility also leads to uncertainty and to possible mistakes in the interpretation and implementation of Directives. A list of the most important comments:

**Positive impacts:**
- Limitation to essential requirements is positive. If there are too many specific rules there is no room for innovation. The flexibility to use different problem solutions is essential for novel products.
- It is possible to pursue conformity assessment with or without standards, allowing more innovative products to reach markets which were formerly heavily controlled by standards.
- As the use of standards is voluntary there is a higher level of technological flexibility and there are therefore better opportunities for product differentiation and product competition.
- Increased flexibility in the application of standards.
- Technological flexibility provides the ability to rationalise product design for a large European market.
- Increased flexibility means that a technological development can be made according to the “nature of the product” and the market requirements.

Negative impacts:
- Some flexibility (technical and organisational) leads to a degree of flexibility of interpretation and therefore possibly to confusion.
- A high level of freedom can lead to problems in proving compliance with essential requirements due to the range of possible options on standards to refer to and decisions to take.
- Because of regulatory requirements spontaneous activities have gone.
- The application of standards in practice is not always voluntary as firms point out they feel forced by the notified bodies to use standards. The standards remain and must be observed.

5.2.2.2 Impact of standards

Companies’ evaluation shows varied effects of standards on innovation, both positive and negative. One particularly positive aspect is that the use of standards is voluntary and that standards offer an efficient form of conformity assessment and product security. (Semi-) horizontal standards, which cover common requirements for all or a wide range of medical devices or requirements for a related family of medical devices were particularly welcomed. The fact that standards only represent the current state of technology and are not aligned with innovative technologies was most strongly criticised. The following factors were mentioned in relation to the effects of standards:

Positive impacts:
- Harmonised standards guarantee the safety and credibility of innovative products.
- The harmonisation of standards improves market access.
- Standards are not a barrier to innovation as their use is voluntary.
- Higher efficiency and transparency as a result of uniform horizontal standards for general requirements, as these do not refer to a specific product or technology.
- Strictly high standards offer the chance of remaining competitive.
- Standards offer a reference point for comparison of products and for improve them if necessary.

Negative:
- Standards hinder innovative technology and limit innovation in that the products are tested with very obsolete standards representing only existing technologies, the current state of technology or state of the art technology of several years before.
- Standards lower technological variety and moreover, can reduce competition in terms of product variety.
- Compliance with standards is often necessary, but is not sufficient; in these cases additional higher internal standards (or other methods of conformity assessment) have to be applied.
- The influence exerted by particular companies is not equal - large companies have a better chance of directly influencing standards.
5.2.2.3 Impact of organisational flexibility

In the companies’ commentaries their assessment of the effect of organisational flexibility is largely positive, both in their responses to individual questions and in the listing of the most important advantages/disadvantages. The opinions were generally global and were differentiated only to a very minor extent.

Positive
- Flexibility and liberal regulation is a benefit - it encourages innovation and makes work easier.
- Especially positive for small enterprises, as this flexibility permits slower adaptation and participation, depending on financial and human resources disposable.
- Allows the sourcing from different factories that operate under different parts of the ISO 9000 series (and EN 46000).

Negative impact:
- Flexibility causes confusion.
- Obstacle to founding a new company for CE signed products (evaluation during the production) due to the fact that CE approval is necessary for production, but you need production in order to get CE approval.
- No opportunity for switching procedures between products. Procedures are dictated by the highest class product at a particular site.

5.2.2.4 Impact on quality assurance system

With a mean of 1,01 the impact of the directives on the implementation of a quality assurance system reaches the highest positive result of all factors being analysed (together with Market access to Europe). About 70% of the companies see a positive impact. This is also shown by the following chart.69

69 The standard deviation of 0,88 lies in the middle of the range. On the whole there is an almost identical pattern of answers as the other very positive impact factor „market access in Europe“ (B.1.5.1).
The additional commentaries support the clearly positive relationship between regulation and the introduction of a quality assurance system, too. A clearly positive assessment predominated both in the commentaries on individual questions and in the listing of the most important advantages/disadvantages. This is emphasised further by the fact that companies which stated that regulation had “no impact” in this instance generally already had such system in place. In particular, the clearer structuring of operational processes, the more extensive documentation of work done and a generally stimulating effect for the implementation of a QA system were emphasised as positive effects. The expected positive effect on the quality and safety of products was also stressed. On the negative side, however, was the fact that some firms did not regard the quality assurance system as a voluntary choice, but rather as an obligation in order to obtain a CE sign. The following factors were mentioned specifically:

Positive impacts
- Quality assurance system was clearly promoted by the regulation.
- Clarity of operational processes, better structured development process.
- Better documentation.
- ISO serves as a (necessary) basis for the CE sign.
- Regulation has stimulated the improvement of the in-house quality system (also in non European plants, particularly US headquarters).
- Installation requires a large initial effort, but once installed it will very much help in ensuring quality and identifying eventual errors or non-conformities.
- Safer devices, the end-users have a means by which they can rely on the product.

Negative impacts:
- Lack of choice of other options.
- The installation of a quality assurance system increases costs.
The results of the telephone interviews showed that many interviewees had already implemented quality assessment systems before the directives were introduced. For those that had not, the interviews confirmed that directives have undoubtedly stimulated them to put these in place. Although the directives do not stipulate the need for a quality system, such a system allows for easier and quicker accreditation. If such a system is not in place then assessing the firms compliance with the “essential requirements" with regard to quality can take longer.

5.2.3 General impacts of the directives

5.2.3.1 Impact on co-operation

On the whole the results for co-operation lie in the middle of the range of the factors being analysed. Among all potential co-operation partners assessed the strongest effects of the Directives can be seen in terms of “other companies" (mean 0.58) and “notified bodies at the national level" (mean = 0.69). Co-operation is becoming more intense at a slower rate among other groups, as the following tables show.

Fig. 16: Impact on co-operation with medical research/clinical testing (B.3.1.1) n=145, with other scientists/laboratories (B.3.1.2) n=144, with other companies (B.3.1.3) n=140.

Fig. 17: Impact on notified bodies in your country (B.3.1.4) n=145, on international level (B.3.1.5) n=145.
The values for the standard deviation among all potential co-operation partners range from 0.68 to 0.87. Companies’ opinion is therefore relatively homogenous. It is, however, noticeable that companies which previously only produced for the national market expect to see a markedly more positive effect of the Directives on their co-operation with all named groups\(^71\). The intensification of co-operation with “medical research/clinical testing” and “other scientists” is clearly above the average for those companies who previously produced only in risk class I.

Contrary to the quantitative results, in the additional comments on the issue of co-operation, companies' opinion tended to be rather negative, both in their responses to individual questions and in the listing of the most important advantages/disadvantages. Most of the additional commentaries related to the field of clinical tests and co-operation with the notified bodies. Improvements were regarded as particularly necessary in the following areas: costs and the strong commercial behaviour of the notified bodies, a lack of international agreement between the notified bodies and the increasing level of regulation in clinical tests.

In addition, one aspect was highlighted as being particularly important for co-operation along the “production chain for innovation”: In order to guarantee efficient co-operation among different companies along the net-product chain (such as suppliers or system producers) it is essential that all partners meet the relevant requirements and take the requirements of regulation into account in their work. Problems for co-operation can arise in particular when certain companies are less far advanced in the implementation of quality assurance in their procedures or when individual partners pay less attention to the demands of certification in their work. However, when all partners meet the necessary prerequisites, co-operation is made easier by the new common regulative framework. As for the different groups the following factors were mentioned specifically:

**Medical research and clinical testing:**

Positive impact:
- Clinical feedback has become important in assessing safety.

Negative impact:
- There is more clinical testing and lab testing carried out, clinical investigations are much more extensive under administrative aspects.
- Clinical trials are more regulated, there is additional paperwork, the cost of testing (clinical trials) have increased.
- Lack of understanding in the clinical arena of the significance of these directives and even of their existence.
- It is difficult to incorporate clinical trials in the development process.

\(^71\)The mean value here falls in the range of 0.6 (international notified bodies) to 1.0 (national notified bodies).
Other companies (positive impacts):

Positive impacts:
- Closer co-operation is now required with other prospective OEM companies.
- CE sign important along the supply-chain.
- Directives make co-operation with other companies easier.

Negative impact:
- Notified bodies interpret the directives in different ways.

Notified bodies (national/international):

Negative impacts:
- Differing behaviour of the notified bodies in individual countries. Particularly different degree of stringency with which regulations are interpreted.
- The costs for conformity assessment and support by notified bodies are very high. Small companies in particular cannot afford the comprehensive support of a notified body.
- Increased business opportunities and commercial behaviour of notified bodies.
- Design of “own quality brand labels” by notified bodies.

Positive impacts:
- Knowledge of different regulation aspects was increased. Notified bodies are a source of information.
- Pro-active support by notified body, dialogue with notified bodies.

From the interviews as a general result it became clear that from the firms point of view the directives alone are not the most important impact on co-operation with other companies. Most of the smaller companies interviewed did not feel under any pressure to co-operate with larger organisations as a direct result of changes brought about by the directive. Some of the smaller, specialised companies have begun co-operation, e.g. the begun to use larger companies to market and sell their products. But this is driven by more general, global economic pressures and not mainly by directives.
5.2.3.2 Impact on competition within the Single Market

The effect of harmonisation on competition is regarded as an important issue. Companies’ commentaries clearly point to an intensification of competition. This also corresponds to the result of the quantitative analysis: the majority of firms expect an intensification of competition (53.4%; mean = 0.55). The mean deviation is, at 0.96, comparatively high. Company opinion is therefore generally very heterogeneous and this is made even more clear by their commentaries (see below). In this context it is surprising that companies with less than 20 employees expect to see an intensification of competition only to a much lower extent (mean = 0.29)\(^\text{72}\). For firms with upwards of 20 employees, there are much stronger expectations in terms of an intensification of competition (mean = 0.63 to 0.78).

The following diagram chart provides an overview of the quantitative results:

![Diagram](image)

**Fig. 18:** Impact on competition within the Single Market (B.3.2). n=146.

In their comments firms regard as positive the fact that harmonisation of registration requirements led to fairer framework for competition as, formally speaking, the same rules apply to all companies. They also regard as positive the fact that regulation means it is not just producers who have the capacity to fulfil safety requirements who can assert themselves in the marketplace. However, at the same time companies also criticise the fact that in practice, a harmonised implementation and application of the requirements is not always guaranteed.

In relation to the increased competition intensity, firms also repeatedly point out that it will be harder in future for small firms to assert themselves in competitive terms. In this context, the possibility of worse competitive conditions for small companies was the most commonly raised criticism. From the

\(^{72}\)However, in the additional commentaries, including those of the larger companies, the fact that conditions of competition could become more difficult for smaller firms in the future was noted.
companies’ perspective, this may result in disadvantages for functioning competition in the long term if
the continued existence or establishing of new smaller companies is thereby made more difficult and if
the market is shaped by individual large companies. On the basis of the experiences related here, no
judgement can yet be made as to whether this will result in a lower or higher level of competition (for
example if a narrow oligopoly would result in there being “less competitors but more competition”). This
holds true particularly as it is expected that globalisation and EU-harmonisation will in future lead to
non-EU producers (particularly American companies) being represented in European markets to a
greater extent. Firms stressed that this desired intensified competition within Europe will only come
about if there is more harmonisation in the implementation and application of regulation and if
competitive distortions are avoided. The following factors were mentioned specifically:

Positive impacts:
- Higher competition, easier for competitors to enter new markets.
- Competition is more efficient as local competitors have less timing advantages.
- Small companies are also able to assert themselves in terms of competition.
- Elimination of unsafe devices; only serious companies left on the market.
- The use of standards is voluntary; the resultant greater level of technological flexibility allows for more
  opportunities for product differentiation and product competition.

Negative impacts:
- Intensification of competition and the structuring of the regulation and competition requirements makes it
  more difficult for smaller companies (particularly for those that were only active on national markets
  beforehand or also for newly-established companies to assert themselves in the marketplace or to establish
  themselves)
- Competition conditions within Europe are not yet harmonised (varying levels of stringency in the
  interpretation of Directives by notified bodies in individual countries, additional regulation), therefore
  continued distortion of competition
- Regulation in general favourable to large companies (e.g. fewer suffer as a result of the cost of certification,
  better influence on the setting of standards)
- continued variation in the market conditions - policy action is needed, agreement between the notified bodies
- Potential competition distortions are possible if conformity assessment is not accompanied by the
  establishment of an independent regulatory agency

Also the results of the telephone interviews showed that the impact of the directives on competition is
not yet clear. On the one hand, there is an expectation, particularly among larger firms, that the
smaller companies will find it increasingly hard to compete (esp. For SMES) and this will lead to the
European medical devices market becoming dominated by a few very large companies. Not all of the
small firms interviewed agreed with this viewpoint. Many felt that they had successfully adapted to the
new regulations, and these now see a significant role for themselves in the future. They believe that
their small size and flexibility gives them the ability to react more quickly to changes in the market.
From their point of view their quality assurance systems are less complicated and are easier to modify
to accommodate new products.
5.2.3.3 Impact on competitiveness of EU manufacturers

The quantitative results show that in terms of the effect of the Directives on competitiveness, positive expectations clearly predominate. With a mean value of 0.60, this question is clearly in the upper range of all factors examined. Company opinion is, however, comparatively heterogeneous, with a standard deviation of 0.97. The following diagram gives an overview of the quantitative results:

![Diagram showing impact on competitiveness of EU manufacturers](image)

**Fig. 19:** Impact on **competitiveness** of EU manufacturers (B.3.3). n=146.

In companies’ commentaries as well the effect on long-term competitiveness tended to be regarded positively. However, they also pointed out that this increased level of competitiveness has not yet been reached. In listing the causes, issues were generally raised that had already been mentioned in the context of other individual questions and will not be reiterated here.

On the whole, it is interesting to note that the additional commentaries on this point referred less to the effect on their own company. They related much more to the competitive position of EU-suppliers as a result of external market conditions. The fact that EU harmonisation also creates better conditions for US or Japanese companies to enter the European market is regarded as being particularly critical for the competitive standing of European medical device companies. At the same time they note on the positive side that it is also easier for European companies to enter markets outside the EU as a result of the CE sign.

Positive Impacts:

- CE signing is now well known in most parts of the world - EU regulation makes the world-wide marketing of European medical devices easier compared to the past.

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73 For instance, the 13 exporting companies whose market is concentrated on the EU (not overseas or in the US) expect to see a lower level of effects (mean = 0.23).
- Additional improvement of international competitiveness is expected from mutual recognition agreements between the EU/USA and EU/Canada, EU/Japan etc. currently under development.
- Better chances to face US market.

Negative Impacts:

- Easier entry into the EU market for non-EU producers as a result of EU-harmonisation. This perhaps weakens the competitive position of EU producers.
- The continuing high level of effort needed to meet the bureaucratic demands of the directives creates costs, leading to a weakening of competitive strength.

5.2.3.4 Total impact in the long term

The total long-term impact of the directives on innovation is evaluated extremely positively. Almost 75% of all companies expect to see a positive effect here. These results, with a mean value of 0.72 are among the highest values recorded for a question in this study. If a company which previously only produced for the national market is studied, the expectations are even higher (mean=1.09). The following diagram illustrates the clearly positive expectations of companies on the issue of total long-term impacts:

![Fig. 20: Total impact in the long term (B.3.4). n=146.](image)

The commentaries relating to the total long-term impact showed which factors are particularly important from the point of view of companies and repeatedly emphasised the sustained effects and directions of the Directives. In this context, greater flexibility, reduced conformity assessment, easier market access, product/patient safety and performance, drive towards global harmonisation were seen as particularly positive.

According to most of the firms interviewed, the directives have succeeded in breaking down many of the barriers associated with national accreditation systems. This relates to the overall objective of the
new directive – the introduction of a European-wide single accreditation process which would obviate the need for firms to negotiate separate national systems. Many also felt that in the longer-term some aspects of the new directive will lead to an improvement in the quality and safety of the devices produced.

At the same time, however, other conditions were mentioned in the comments which need to be met in order that the positive effect can be fully realised. A clearer and simpler structuring of the Directives at all levels and successful negotiations on global harmonisation were mentioned in particular. Furthermore, the high level of bureaucracy and an overburdening of administrative requirements were raised as particularly negative aspects. The background to this assessment is that from companies’ perspective, innovation cannot entirely be planned in advance; rather, it is an evolutionary process which takes place outside of strictly regulated procedures. For the long term effect, it was regarded as crucial that the CE sign on a medical device may become the lowest common denominator for the market. To stimulate innovation customers may ask a level of quality over and above this sign.

Although the majority of firms have stated that by the introduction of a European-wide single accreditation process the main objective has been realised, it has been pointed out in the interviews as well that not all barriers have been removed (see comments above). The removal of these barriers and problems is seen as a condition to make the Single Market exert its full positive impact which is expected on the long run. Furthermore in the interviews firms have identified barriers to innovation which the directive has not been able to address:

1) The first barrier that firms mentioned concerned the fact that although a single accreditation system had now been introduced, the different health care systems in Europe still acted as a barrier to firms attempting to market their products on a Europe-wide basis.

2) Moreover, barriers to the development of the medical devices sector in the European Union are not only affected by European legislation. Many firms stated that they found barriers to the development of the European medical devices industry lay equally outside European legislation as within. The USA and markets in the Far East all have their own accreditation systems which many firms stated were barriers to the development of their own company.

3) Additionally, the interviews have shown that innovation in the medical device industry is influenced by a complex set of different factors. Many companies interviewed found that they were unable to distinguish the causes of changes experienced by the sector over the last five years. There are many global factors that are currently shaping the sector and that must be taken into account (like e.g. the increasing international competition, technological developments).

5.2.3.5 Transitional impact

The evaluation of the transitional impact has a much more negative result than the other factors examined. This was the only question to achieve a negative evaluation (mean = - 0.23). Fewer than one third of all firms state that a positive effect has come about during the phase of transition. On the
other hand, almost half of all companies evaluated the question negatively. With the standard deviation of 1.03, company opinion was relatively heterogeneous. The results for transitional impact is shown by the following diagram:

Additional comments on the transitional impacts referred almost exclusively to factors with negative effects. From the companies’ point of view, administrative efforts associated with the implementation of new regulations within companies were particularly criticised. It was emphasised that adapting company structures and processes on various levels involved costs, without any direct effect on innovation or the safety or quality of the products. Examples given for concrete knock-on effects are the temporary reduction of innovatory activities (for instance on account of the resources tied up in the adjustment processes), longer time to market or that new devices were being sold to limited EU countries as a result of language requirements.

The uncertainty regarding the implementation of formal conditions in practice caused during a transitory period was also seen as negative. Some specific criticisms were made that in this case, the marketing of the Directives is missing and that missing or divergent information about the new directive was given. As several groups are involved in the innovation and certification process, lack of clarity leads to more difficult agreement procedures (for example with clinics, customers or notified bodies). The fact that the length of transitional periods tends to increase this uncertainty was also mentioned.

In the telephone interviews it became clear that although the transition period for the inclusion of the directives into the national legislation of each individual EU member state has now been completed

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74 It can therefore be ascertained for instance that the following groups of companies gave a positive response to this question: companies which previously produced for the national market (mean = 0.40; 14 companies), producers of disposable devices (mean = 0.22, 22 companies); companies from Sweden (mean = 0.19, 16 companies).
and the new legislation is in place, many companies are still experiencing and accommodating the effects that the changes have introduced. As for the medical device directives themselves firms in the interviews pointed out that they have introduced elements that from their experience so far had the opposite effect on innovation than had been envisaged. Although many firms have taken time to adjust to the new system of accreditation, there is still the view that the new system is overly bureaucratic and therefore time and money consuming. Many firms find elements of the new regulation unnecessarily strict. They claim that all firms in this sector depend on high levels of quality and the new directives merely enforce systems that most already had in place before hand whilst at the same time increasing the paper work and inevitably the costs associated with accrediting new devices. Some firms do not see the need to comply with such strict regulation (this applies especially to those branches of the sector where there was previously little regulation). Firms who are active in the medium and high-risk devices sector the new system entails applying to a Notified Body to carry out a conformity assessment process. The firms being interviewed point out that there is now more paper work and stricter accreditation processes for these products which often include a clinical trial.

Furthermore, another feature associated with the new directives firms still have to adapt to are changes to the mechanisms by which companies gain accreditation for their products under the new regime, and in particular the fact that the new directives are based around the quality of the design and production process rather than technical standards associated with the final product. Some of the firms so far have found the transition easy, are happy with the new accreditation system, and believe that the impacts of the directive on innovation will be positive. Others have found the changes difficult to adjust to.
The following chart shows the general picture obtained by the quantitative survey, relating to this differentiated overview to the results for each individual factor assessed:

<table>
<thead>
<tr>
<th>B.1 Impact of direct access to the Single Market on ...</th>
<th>Total</th>
<th>-2</th>
<th>-1</th>
<th>0</th>
<th>+1</th>
<th>+2</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 ...investment</td>
<td>mean 0.58</td>
<td>1.4%</td>
<td>11.1%</td>
<td>32.6%</td>
<td>38.2%</td>
<td>16.7%</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>144</td>
<td></td>
<td>16</td>
<td>47</td>
<td></td>
</tr>
<tr>
<td>2 ...time to market</td>
<td>mean 0.34</td>
<td>8.9%</td>
<td>17.8%</td>
<td>21.9%</td>
<td>32.9%</td>
<td>18.5%</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>146</td>
<td></td>
<td>26</td>
<td>32</td>
<td>48</td>
</tr>
<tr>
<td>3 ...innovation costs</td>
<td>mean 0.04</td>
<td>4.1%</td>
<td>30.3%</td>
<td>29.0%</td>
<td>30.3%</td>
<td>6.2%</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>145</td>
<td></td>
<td>44</td>
<td>42</td>
<td>44</td>
</tr>
<tr>
<td>4 ...innovation risks</td>
<td>mean 0.06</td>
<td>2.1%</td>
<td>14.9%</td>
<td>63.8%</td>
<td>13.5%</td>
<td>5.7%</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>145</td>
<td></td>
<td>21</td>
<td>90</td>
<td>19</td>
</tr>
<tr>
<td>5 ... the opportunity to enter new international markets ...</td>
<td>mean 1.01</td>
<td>0.7%</td>
<td>4.2%</td>
<td>22.5%</td>
<td>38.7%</td>
<td>33.8%</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>142</td>
<td></td>
<td>6</td>
<td>32</td>
<td>55</td>
</tr>
<tr>
<td>B.2 Impact of technological and organisational flexibility on innovation: Impact of ...</td>
<td>mean 0.41</td>
<td>2.8%</td>
<td>10.3%</td>
<td>37.9%</td>
<td>40.7%</td>
<td>8.3%</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>145</td>
<td></td>
<td>4</td>
<td>15</td>
<td>55</td>
</tr>
<tr>
<td></td>
<td>mean 0.37</td>
<td>2.8%</td>
<td>15.2%</td>
<td>35.9%</td>
<td>35.2%</td>
<td>11.0%</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>145</td>
<td></td>
<td>12</td>
<td>52</td>
<td>51</td>
</tr>
<tr>
<td></td>
<td>mean 0.44</td>
<td>2.0%</td>
<td>7.5%</td>
<td>46.9%</td>
<td>32.0%</td>
<td>11.6%</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>147</td>
<td></td>
<td>11</td>
<td>69</td>
<td>47</td>
</tr>
<tr>
<td>B.3 General impacts of the directives on ...</td>
<td>mean 1.01</td>
<td>1.4%</td>
<td>0.7%</td>
<td>28.1%</td>
<td>35.6%</td>
<td>34.2%</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>146</td>
<td></td>
<td>2</td>
<td>41</td>
<td>52</td>
</tr>
<tr>
<td></td>
<td>mean 0.39</td>
<td>1.4%</td>
<td>6.9%</td>
<td>51.7%</td>
<td>31.7%</td>
<td>8.3%</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>145</td>
<td></td>
<td>2</td>
<td>10</td>
<td>75</td>
</tr>
<tr>
<td></td>
<td>mean 0.36</td>
<td>0.0%</td>
<td>3.5%</td>
<td>64.6%</td>
<td>24.3%</td>
<td>7.6%</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>144</td>
<td></td>
<td>5</td>
<td>93</td>
<td>35</td>
</tr>
<tr>
<td></td>
<td>mean 0.58</td>
<td>0.0%</td>
<td>4.3%</td>
<td>43.6%</td>
<td>42.1%</td>
<td>10.0%</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>144</td>
<td></td>
<td>6</td>
<td>61</td>
<td>39</td>
</tr>
<tr>
<td></td>
<td>mean 0.69</td>
<td>1.4%</td>
<td>7.0%</td>
<td>28.2%</td>
<td>47.9%</td>
<td>15.5%</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>142</td>
<td></td>
<td>10</td>
<td>40</td>
<td>68</td>
</tr>
<tr>
<td></td>
<td>mean 0.38</td>
<td>2.1%</td>
<td>5.7%</td>
<td>52.5%</td>
<td>31.2%</td>
<td>8.5%</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>141</td>
<td></td>
<td>3</td>
<td>74</td>
<td>44</td>
</tr>
<tr>
<td>2 Competition within Single Market</td>
<td>mean 0.55</td>
<td>2.7%</td>
<td>8.9%</td>
<td>34.9%</td>
<td>37.0%</td>
<td>16.4%</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>146</td>
<td></td>
<td>13</td>
<td>51</td>
<td>54</td>
</tr>
<tr>
<td>3 Competitiveness of EU manufacturers</td>
<td>mean 0.60</td>
<td>4.1%</td>
<td>7.5%</td>
<td>27.4%</td>
<td>45.9%</td>
<td>15.1%</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>146</td>
<td></td>
<td>11</td>
<td>40</td>
<td>67</td>
</tr>
<tr>
<td>4 Total impact in the long term</td>
<td>mean 0.72</td>
<td>2.1%</td>
<td>10.3%</td>
<td>13.0%</td>
<td>63.0%</td>
<td>11.6%</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>146</td>
<td></td>
<td>15</td>
<td>19</td>
<td>92</td>
</tr>
<tr>
<td>5 Transitional impact</td>
<td>mean -0.23</td>
<td>7.6%</td>
<td>40.3%</td>
<td>22.9%</td>
<td>25.7%</td>
<td>3.5%</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>144</td>
<td></td>
<td>11</td>
<td>58</td>
<td>33</td>
</tr>
</tbody>
</table>

Fig.22 Empirical results, total overview (σ = Standard deviation)
5.2.4 Summary of empirical results

Directives 90/385 EEC and 93/42 EEC laid the foundations for the fact that medical devices marked with a CE sign can be freely marketed within the Single Market. The results of the empirical analysis clearly show that this institutional change plays a part in developing positive effects in the European medical device industry. In answer to the question as to what long-term effects are expected after the transition period (which is necessary for firms to adapt to the new regulation), positive values were recorded for all individual factors assessed. The result relating to the total impact on firms’ innovation in the long term is also clearly in the positive range, with a mean value of 0.72. Only the question relating to the transitional impact recorded a negative value, at -0.23. The following chart shows the generally positive effect of the Directives on innovation by means of the various individual factors:

On the whole, the results of the written questionnaires listed above also show that the impact of regulation on innovation is limited if only individual factors are looked at in turn. The innovative effect of
the Directives occurs essentially by means not of individual dominating factors but rather much more by means of a broad range of various channels of effect. The major proportion of the results lies however in the range of “0” (no impact) to “+1” (positive impact). Both front-runners (“opportunity to enter new markets in Europe”, “impact on quality assurance system”) only marginally exceed the “+1” mark. This result (many different factors yet each having only a weakly positive effect) is underlined by the additional company commentaries on the question regarding the overall effect. In this context a broad set of different influence factors having an effect are listed, such as more flexibility, reduced conformity assessment, easier market access, product/patient safety and performance and a drive towards global harmonisation.

Clear differences in the effect of regulation can be seen by means of a dynamic assessment. It was evident that on the long-term positive impacts on innovation are expected. However, on the short term from the companies’ perspective negative factors dominate. The response to the question on the “transitional impact” is the only one to lie in the negative range (see also above diagram). Yet companies’ additional commentaries also make it clear that in the short term they expect to experience disadvantages, particularly as a result of the new institutional framework arising from the requirement to adjust their operational processes and procedures.

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

- Impact on the opportunity to enter new international markets in Europe (+1.01)
- Impact on quality assurance system (+1.01)
- Total long term impact on innovation (+0.72)

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

- Impact on innovation costs (+0.04)
- Impact on innovation risks (+0.06)

As for the strongest/weakest factors the firms have pointed out the following aspects: In terms of opportunities for entering new international markets in Europe, companies regarded it as a definite advantage that there is easier access to the European markets, 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 harmonisation in the explanation and application of the Directives at the level of individual countries was stressed. From the companies’ point of view, individual countries’ practice still varies greatly. With regard to the quality assurance system, it was emphasised 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 as well as faster and more efficient conformity assessment (after the QA system has been implemented) were particularly regarded as advantages of a QA system.

75 The values in parentheses are the mean values.
The weak positive value regarding the question of innovation costs corresponds with a large number of critical commentaries regarding this point given by companies. Firstly, the costs involved in implementing new structures and processes for meeting the demands of the new institutional framework were mentioned. Secondly, the expectation that the ongoing application of the Directives will increase costs (e.g. because of administrative requirements) in the long term was also criticised. 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 assessed positively. According to the quantitative results, from 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 the reduction in risks this has brought about), companies regard regulation as highly important.

This general picture of the quantitative evaluation and the additional commentaries is further supported by the “most important advantages/disadvantages of the Directives for companies’ innovation activities” listed by the companies assessed.

<table>
<thead>
<tr>
<th>Main Advantages</th>
<th>Main Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Better market access in Europe</td>
<td>• Costs</td>
</tr>
<tr>
<td>• Impact on quality assurance system and internal proceedings</td>
<td>• Time for first market entry</td>
</tr>
<tr>
<td>• Product quality and safety</td>
<td>• Administrative and bureaucratic efforts (“paperwork”)</td>
</tr>
<tr>
<td>• Time to European Markets</td>
<td>• Harmonisation and Single Market not yet completed – national differences still exist</td>
</tr>
</tbody>
</table>

Fig. 24: Main advantages/disadvantages for the firms innovation activities.

The issue on which companies’ opinion diverged most widely was that of the effect of regulation on “time to market” for innovative products. On the one hand, companies value as positive 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 criticised. Companies’ opinions gave a further differentiated picture on the issue of innovation costs and on questions relating to more fundamental issues (competition within the Single Market, competitiveness of EU manufacturers and of transitional impacts).

The examination of company groups showed for instance that the assessment of companies which had previously only produced for the national market were clearly above average. However, the assessment of companies which already produce for the EU market (however not for overseas and the US) was below average. Companies from the ‘disposable devices’ market segment also returned

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76 The standard deviation recorded for this question was the highest value among all questions.
positive assessments above the average level, as did firms from Sweden and Italy. However, a lower than average assessment was returned by the market segment ‘imaging’ as from the individual firms in Austria.

From the companies’ point of view, in order that the new institutional framework of the Single Market can develop the expected positive effects in the long term, further actions are required. This is clearest in terms of the application of the Directives, which is still inadequately harmonised in the companies’ opinion. They continue to observe marked differences in the practice of the new institutional framework both on the national level and on the level of individual players. This shows that the process of harmonising the institutional framework with its formal adoption and the formal end of the phase of transition for national regulations has not yet been completed. Rather, a comprehensive harmonisation is required, particularly a harmonisation in the interpretation and the practical application of institutional rules by the various players in the innovation system.

Furthermore, although many firms have taken time to adapt to the new system of accreditation there is still the view that the new system is overly bureaucratic and therefore time and money consuming. 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 have identified barriers to the Single Market which still exist and which fall outside the scope of the directives but also influence their success. In this context, the fact that different healthcare systems in Europe and a lack of harmonisation in this area continue to act as a barrier to Europe-wide marketing was particularly emphasised.

Finally, it is pointed out that the removal of technical barriers in the European economy is still not accompanied by similar actions aimed at harmonising accreditation systems on a global scale (such as in the US and the Far East).

77 For the evaluation of this group related statement, it must be remembered that as only a few cases were actually studied, this must be seen only as a first pointer towards possible deviations from the overall picture. These ought to be more closely studied.
Summary

In conclusion, the following can be ascertained as a result of this study:

It was the aim of this study to find out how the new institutional framework of the Single Market and the New Approach Directives 90/385 EEC and 93/42 EEC influence innovation in the European medical device industry and in what direction innovation is influenced. The hypothesis was put forwards that the new institutional framework has improved conditions for innovation. It could be shown on the basis of the empirical study that this hypothesis can fundamentally be upheld. It can be expected that the Single Market regulation assessed here by means of different factors will result in positive effects on innovations in the medical device industry in the longer term. However, it must be noted that whilst the basic prerequisites for this are in place today, the positive effects have not yet developed to their full potential. Presently, firms are still greatly affected by the negative transitional impact effects. Further actions also appear to be necessary in order that a comprehensive harmonisation in the interpretation and the practical application of the new institutional framework on the level of different Member States and players can be achieved and that the expected positive effects of the new institutional framework can fully be realised.
6 Policy implications

⇒ Further development of the Single Market through complete and harmonised implementation of the Directives: Steps should be taken towards the complete and uniform implementation in all Member States of the rules laid down in Directives 90/385 EEC and 93/42 EEC or towards the uniform interpretation and realisation of their scope. Differences continue to exist in the explanation and application of this regulative framework in different countries and among individual players. These should be eliminated. More extensive action, such as further controls or monitoring appears to be necessary, particularly in terms of achieving a higher degree of harmonisation among notified bodies and competent authorities in the Single Member States. Attention should also be paid to ensuring that in future, the standardised Europe-wide quality assessment for medical devices and the mutual institutional framework which goes along with this, does not become weakened again by additional country-specific quality-seals.

⇒ Inclusion of the demand side in harmonisation: Within the Single Market, healthcare systems are in place in each Member State which reflect a variety of different philosophies and approaches and retain their own peculiarities. In this field, which is important for innovation in medical devices, the level of harmonisation is as yet inadequately developed. However, further harmonisation of the conditions on the demand-side of the European medical device market is required if the Single Market in the medical device industry is to develop its full potential. As a first step the healthcare systems in Europe needed to be evaluated to establish what the differences are, if the different systems were leading to different conditions for innovation and to barriers within the Single Market. The exchange of opinions and level of agreements between the individual Member States about how innovative medical technology can be implemented as fully as possible in the individual healthcare systems should be intensified. In this context, it must be considered that the individual Member States have specific political, historical, cultural and socio-economic traditions and that health policy is guided by the principle of subsidiarity.

⇒ Expansion of harmonisation at a global level: Innovations in the medical devices sector in the European Union are not only affected by European legislation. Influencing regulations lie outside European legislation as well. The USA and markets in the Far East all have their own accreditation systems which act as a barrier to the development and the marketing of innovative European medical devices. Activities already underway and negotiations aimed at increasing global harmonisation in the area of medical devices should be intensified in order to expand international trade in the area of medical devices and to allow products carrying the CE sign a better access to non-EU markets as well (e.g. by means of mutual recognition agreements).

⇒ Support of the dissemination of the CE mark by marketing: Closely related to this is the need to increase the level of recognition of the CE mark and trust in it as a reliable indicator of uniform quality across all Member States through active marketing of the CE sign. European producers are not the only actors who need to be considered here. In order to guarantee efficient and effective co-operative relationships in the innovation process, other groups must
also be included. The understanding and implementation of the medical devices Directives should be improved along the entire ‘production chain for innovation’ in the medical device industry (for example, in the field of medical research). Furthermore, the CE sign should be actively marketed outside the European Single Market, in order to improve the business opportunities for the European medical device industry.

⇒ **Reduction of the costs of implementing a new institutional framework:** Companies associate introduction of the new institutional framework of the Directives with the costs involved in adapting their operational processes and structures in terms of information, re-direction and change. Even though these effects are only temporary, the objective must be to limit their extent during the phase of transition. It is therefore important that clarity regarding the requirements which need to be met in the introduction of a new institutional framework is achieved rapidly and comprehensively. Where there is room for interpretation, an equally rapid and comprehensive agreement between those responsible for registration needs to be achieved in order to avoid uncertainty amongst companies. In addition, “good practice solutions” should also be disseminated which show exemplary ways of implementing the regulatory requirements both efficiently and effectively. Furthermore, the aim should be to create a long-term stability of the institutional framework so as to reduce further costs involved in adaptation and in order to offer companies a more secure basis on which to plan their innovation activities.

⇒ **Increase efficiency in the application of the Directives:** Companies criticise the high level of formal administrative work involved in the registration of innovative medical devices and the use of valuable resources which this involves. How the registration of innovative medical technology products could as far as possible be freed of formal administrative tasks and how regulative requirements could be clarified should be checked. Measures which 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 would not result in restrictions on product safety. At the same time, the advantages of the use of a quality assessment system must be demonstrated as after its implementation the innovation process is more clearly structured and the registration of products is organised more efficiently.

⇒ **Support innovation in medical device industry through initiatives involving more than one policy area:** Regulation by means of Directives 90/385 EEC and 93/42 EEC is an important factor of influence in the field of medical devices, but it is not the only one. Rather, a number of other areas of politics play a deciding role. The structure of healthcare systems and the rules of health policy also have a decisive influence on the development and use of innovative medical technology. Trade policy, market structure and competition policy along with technology and innovative policy also have an important effect. The issue of innovation-supporting regulation should therefore be seen as a more general inter-departmental challenge for all political departments.
Promotion of the Single Market through permanent dialogue: Single Market regulation and innovation as well as their interaction are characterised by a high degree of complexity and a lasting dynamic development. Regulation should therefore not be constructed solely as a top-down codification of a general framework for action which is then occasionally amended. Regulation ought rather to be constructed as a continuous process of technological and political interaction. A permanent and intensive dialogue between all relevant groups of players appears particularly useful in this context in order to guarantee a regulation design which fits to the socio-economic conditions for implementation and application. This dialogue should also check that the development of standards by the European standardisation bodies meets the requirements of dynamic technological development and the demands of companies.

Continue analysis about the impact of regulation on innovation: This study concentrated on examining the impact of regulation on innovation in the medical device industry. This task meant that the long term impacts expected on the firm level were necessarily at the centre of the investigation. Important questions concerning the impact of regulation on innovation in the medical device industry that could not be dealt with in this study are e.g. a) how regulation affects different levels of players and their collaboration (e.g. by surveying players from research institutes and medicine), b) the short-term adaptation processes on the firm level and “good-practice” in managing this structural change, c) how quality of medical devices and medical provision in Europe is influenced by the Single Market. Future studies should consider these questions and look at these particular aspects in greater depth.

The suggested areas for policy action can be summarised as follows:

- Further development of the Single Market through complete and harmonised implementation of the Directives
- Inclusion of the demand side in harmonisation
- Expansion of harmonisation at a global level
- Support of the dissemination of the CE sign by marketing
- Reduction of the costs of implementing a new institutional framework
- Increase efficiency in the application of the Directives
- Support innovation in medical technology through initiatives involving more than one policy area
- Promotion of the Single Market through permanent dialogue
- Continue analysis about the impact of regulation on innovation
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The impact of EU-Regulation on Innovation of European Industry

The Impact of Single Market Regulation on Innovation: Regulatory Reform and Experiences of Firms in the Medical Device Industry

Annex

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April, 2000
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The economic impact of the Single Market -
Results of the EUROSTAT business survey
To work out the impact of the Single Market on firm level, the following section deals with important empirical results of that business survey given by manufacturing companies as for the following aspects:

- General economic impact of the SMP and its impact of companies’ short term operations
- Impact on competitiveness and efficiency
- Impact on strategies and innovation

The Single Market and specific SMP-measures – general economic impact and impact on companies short-term operations

Analysing the business perception of the Single Market it can be seen that European businesses largely agree that the SMP has achieved its main objective. Among the manufacturing companies 41 % consider that the SMP has been successful in the removal of obstacles to trade in their sector (20 % disagree, 39 % no opinion). Furthermore asked about the Single Market’s impact on the company’s operations for the category “sales to other EU countries” the most important positive effect can be found compared with other effects.

Nevertheless in the firms point of view a genuine Single Market has not been reached yet. Only 23 % of the firms state that the SMP has been successful so far in creating a genuine Single Market in the firm’s sector (43 % no opinion, 35 % disagree). Consequently the fraction of firms (25 %) which agree that additional measures are needed to create a genuine Single Market (in the firm’s sector) is high compared to the fraction (14 %) that disagrees to that question (61 % no opinion). Similar to this result 27 % agree that additional measures are needed to eliminate obstacles to EU trade (12 % disagree, 61 % no opinion). (see tab.1, tab.3).

A general trend in the responses is that large firms have perceived the SMP impact more positively. E.g. 46 % of firms with 1000 employees and more and 38 % of the firm with 500-999 employees state that the SMP has been a success for the firm, whereas this statement is supported only by 30 % of the firms with 20-49 employees. On the average of total Europe (Eur-12) 33 % agree that the SMP has been a success for the firm (40 % no opinion, 27 % disagree) (see tab.2).

Asked about the impact of the SMP on the companies’ operations on the one hand it can be seen that the SMP exerts an influence in the expected direction. The most important effects are the impact on sales to other EU countries, on productivity and profitability. Furthermore especially for sales to other EU-countries and productivity the fraction of firms perceiving a positive impact clearly is higher than the fraction perceiving a negative impact. On the other hand it also can be realized that this impact is still developing as the percentage of firm perceiving these positive impacts is rather low (sales to other EU

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1 See European Commission, 1997 a. As for the valuation of the results it has to be considered that this survey has been collected in 1995.
countries 28 %, productivity 16 %, profitability 16 %). Still a high fraction (about 2/3) of firms perceives no impact of the SMP on the analyses operations (see tab.3).

As for the effectiveness of individual SMP measures designed to deal with the removal of barriers within the Single Market it can be seen that the measures aimed at removing physical barriers within the Single Market had the strongest positive impact on the firms (e.g. elimination of customs documentation, elimination of delays at frontiers, deregulation of freight transport). Still among the important SMP measures, but less important than the removal of physical barriers, has been the removal of technical barriers (e.g. harmonisation or mutual recognition of technical regulation and/or standards, conformity assessment procedures). Furthermore for the removal of technical barriers it can be seen that they have an overall positive impact on the firms. About three to four times as many companies have been affected rather positively than negatively. This positive impact of technical harmonization is even higher in high-tech sectors, such as e.g. machinery and equipment or electrical and optical machinery (see tab.4).

Impact on competition and efficiency

By the elimination of trade barriers and the creation of a larger Single Market, one goal was to stimulate competition and to encourage firms to improve their efficiency and to lower their production costs. Analysing the survey results on the one hand again it can be seen that the SMP again so far has not developed its full influence as the majority of firms still does not feel any change in competition levels in the domestic market (see tab. 5).

On the other hand one of the most visible consequences of the SMP has been an increase in competition. As for Single Market’s impact on the company operations the results for category “sales on the domestic market” indicate a higher degree of competition on the companies domestic markets, as companies here see comparatively negative impacts of the Single Market (see tab.3). An increase in competition was most apparent as for competitors coming from other EU countries (39 % increase) and as for price competition (both among domestically (44 % increase) and other EU-owned enterprises (41 % increase). Comparing competition on the basis of price with competition on the basis of quality it can be seen that the increase of price competition is higher than the increase of quality competition. E.g. an increase in price competition is stated by 41 % whereas an increase of quality competition is stated by 29 % (as for increase of competition from other EU-owned enterprises) (see tab.5). An increase of competition with impacts on prices also is indicated by the development of the firms’ strategies. Here the survey results show that the SMP (compared with other strategies) is most important to pricing strategies (see tab. 8).

As for the SMP effects on average unit costs the majority of firms perceive that the implementation of the SMP has not affected their unit costs. However, size-weighted results indicate that when firms felt an impact, average unit cost decreases clearly prevailed over increases. This is even more the case the larger the companies are. E.g. Only 12 % of the firms having 20-49 employees feel a reduction whereas 21 % (500-999 employees) and 26 % (1000 and more employees) have registered a
reduction. This is a sign that large firms benefited most from economies of scale to reduce their costs. The survey results suggest that, where changes in unit costs have taken place, this reduction has been mainly due to changing cost of raw materials (30% of firms state importance), more efficient production processes (22%), lower distribution costs (21%) and testing and certification (19%) (see tab.6 and tab.7).

**Impact on strategies and innovation**

An assessment of the Single Market impact on business strategy shows that at a very aggregated level, the SMP has been more important to product and pricing related strategies than production and acquisition related strategies.

In detail the fields the SMP exerts the highest impact on companies’ strategies (with the percentage of enterprises expressing an important impact of the SMP as for these strategies) are:

- Pricing (36%)
- Research and development of new products (34%)
- Purchase of raw materials from other EU markets (34%)
- Penetration of markets in other EU states (32%)
- Product specialization (31%)

In general the SMP was perceived as having relatively low importance so far as across border purchase of services (both financial and business service) and (direct) investments in and/or from other companies are concerned (see tab.8).

As for the strategy relevance of the Single Market the survey results point out two general features: First of all as for different sectors slight differences can be assessed. Globally speaking, export intensive sectors like the chemical industry, the machinery and equipment sector and the electrical and optical machinery were the manufacturing sectors that showed above-average perceptions. Furthermore it seems that for larger firms and their strategies the SMP has a higher degree of importance than for smaller firms.

In the business survey of the Single Market Review 19 different strategies have been analysed The result concerning the impact of the SMP on the companies’ R&D strategies is especially important to mention as for the underlying question of that study. Therefore among other strategies it is fruitful to explain these results to a greater detail (see tab.9). The strategy “Research and development of new products” in the manufacturing sector reaches the second highest level of importance among these 19 strategies. Analysing the question of the SMP importance to research and development of new products by distinguishing among the classification criteria the following results can be seen:
Classification by different sectors: The SMP is perceived as being even more important to the research and the development of new products in high-tech sectors like machinery and equipment NEC industries, electrical and optical machinery and chemicals, rubber and plastics.

Classification by member-states: Higher degrees of importance for R&D are attributed by southern countries (Greece, Spain, Italy), Belgium and Ireland.

Classification by employment size class: For larger firms the SMP seem to be (slightly) more important as for their R&D strategies. Whereas smaller companies express a higher uncertainty about the importance of the Single Market as for their R&D strategies.
Tab.1: Single Market legislation as it affects your own firm or sector

<table>
<thead>
<tr>
<th>Category</th>
<th>Percentage of enterprises expressing opinion</th>
<th>Agree</th>
<th>No opinion</th>
<th>Disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>The SMP has been successful in eliminating obstacles to EU trade in your sector</td>
<td></td>
<td>41</td>
<td>39</td>
<td>20</td>
</tr>
<tr>
<td>The SMP has been successful in creating a genuine single market in your sector¹</td>
<td></td>
<td>23</td>
<td>43</td>
<td>35</td>
</tr>
<tr>
<td>Additional measures are needed to eliminate obstacles to EU trade</td>
<td></td>
<td>27</td>
<td>61</td>
<td>12</td>
</tr>
<tr>
<td>Additional measures are needed in this sector to create a genuine single market¹</td>
<td></td>
<td>25</td>
<td>61</td>
<td>14</td>
</tr>
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</table>

¹EUR-11=EUR-12 excluding Ireland.

Tab.2: The SMP has been a success for your firm

<table>
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<tr>
<th>Size class</th>
<th>Manufacturing sector</th>
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<tbody>
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<td></td>
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<td>20-49</td>
<td>30</td>
</tr>
<tr>
<td>50-199</td>
<td>36</td>
</tr>
<tr>
<td>200-499</td>
<td>40</td>
</tr>
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<td>500-999</td>
<td>38</td>
</tr>
<tr>
<td>≥1,000</td>
<td>46</td>
</tr>
<tr>
<td>EUR-12</td>
<td>33</td>
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</tbody>
</table>

### Tab.3: Single Market’s impact on your company’s operations

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<tr>
<th>Category</th>
<th>Percentage of enterprises expressing opinion</th>
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</thead>
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<td></td>
<td>Positive impact</td>
</tr>
<tr>
<td>Sales to the domestic market</td>
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</tr>
<tr>
<td>Sales to other EU countries</td>
<td>28</td>
</tr>
<tr>
<td>Sales to non-EU countries</td>
<td>9</td>
</tr>
<tr>
<td>Productivity</td>
<td>16</td>
</tr>
<tr>
<td>Profitability</td>
<td>16</td>
</tr>
<tr>
<td>Employment</td>
<td>12</td>
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<table>
<thead>
<tr>
<th>Category</th>
<th>Percentage of enterprises expressing opinion</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Positive impact</td>
</tr>
<tr>
<td>Harmonization of technical regulations and/or standards</td>
<td>31</td>
</tr>
<tr>
<td>Mutual recognition of technical regulations and/or standards</td>
<td>32</td>
</tr>
<tr>
<td>Conformity assessment procedures</td>
<td>23</td>
</tr>
<tr>
<td>Simplified patenting procedures</td>
<td>13</td>
</tr>
<tr>
<td>The opening-up of public procurement</td>
<td>9</td>
</tr>
<tr>
<td>The elimination of customs documentation</td>
<td>60</td>
</tr>
<tr>
<td>Deregulation of freight transport</td>
<td>43</td>
</tr>
<tr>
<td>The elimination of delays at frontiers</td>
<td>56</td>
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<tr>
<td>The change in VAT procedures for intra-EU sales</td>
<td>32</td>
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<tr>
<td>The liberation of capital movements</td>
<td>23</td>
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<tr>
<td>Double-taxation agreements</td>
<td>17</td>
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</table>

Tab.5: Any change in competition levels in the domestic market

<table>
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<tr>
<th>Category</th>
<th>Percentage of enterprises expressing opinion</th>
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<tbody>
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<td></td>
<td>Increase</td>
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<td>Competitors: domestically owned enterprises</td>
<td>25</td>
</tr>
<tr>
<td>Competitors: other EU-owned enterprises</td>
<td>39</td>
</tr>
<tr>
<td>Competitors: non-EU-owned enterprises</td>
<td>25</td>
</tr>
<tr>
<td>Price competition: domestically owned enterprises</td>
<td>44</td>
</tr>
<tr>
<td>Price competition: other EU-owned enterprises</td>
<td>41</td>
</tr>
<tr>
<td>Price competition: non-EU-owned enterprises</td>
<td>29</td>
</tr>
<tr>
<td>Quality competition: domestically owned enterprises</td>
<td>33</td>
</tr>
<tr>
<td>Quality competition: other EU-owned enterprises</td>
<td>29</td>
</tr>
<tr>
<td>Quality competition: non-EU-owned enterprises</td>
<td>18</td>
</tr>
</tbody>
</table>

Tab.6: The extent to which the implementation of the SMP has affected unit cost of typical or average product

<table>
<thead>
<tr>
<th>Classification by Employment Size Class</th>
<th>Percentage of enterprises expressing opinion</th>
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<tbody>
<tr>
<td></td>
<td>All reduction</td>
</tr>
<tr>
<td>20-49</td>
<td>12</td>
</tr>
<tr>
<td>50-199</td>
<td>16</td>
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<tr>
<td>200-499</td>
<td>22</td>
</tr>
<tr>
<td>500-999</td>
<td>21</td>
</tr>
<tr>
<td>≥ 1,000</td>
<td>26</td>
</tr>
<tr>
<td>EUR-12</td>
<td>15</td>
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</table>

### Tab.7: Importance in changing unit costs

<table>
<thead>
<tr>
<th>Category</th>
<th>Percentage of enterprises expressing opinion</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Important*</td>
</tr>
<tr>
<td>Production process</td>
<td>22</td>
</tr>
<tr>
<td>Testing and certification</td>
<td>19</td>
</tr>
<tr>
<td>Distribution costs</td>
<td>21</td>
</tr>
<tr>
<td>Marketing costs</td>
<td>15</td>
</tr>
<tr>
<td>Costs of raw materials</td>
<td>30</td>
</tr>
<tr>
<td>Banking costs</td>
<td>17</td>
</tr>
<tr>
<td>Insurance costs</td>
<td>14</td>
</tr>
<tr>
<td>Other cost sources</td>
<td>4</td>
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</table>

## Tab.8: Single Market’s importance to development of strategy

<table>
<thead>
<tr>
<th>Category</th>
<th>Percentage of enterprises expressing opinion</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Important*</td>
</tr>
<tr>
<td>Products standardization</td>
<td>29</td>
</tr>
<tr>
<td>Products specialization</td>
<td>31</td>
</tr>
<tr>
<td>Pricing</td>
<td>36</td>
</tr>
<tr>
<td>Research and development of new products</td>
<td>34</td>
</tr>
<tr>
<td>Capacity of existing national production</td>
<td>28</td>
</tr>
<tr>
<td>Number of existing production plants</td>
<td>14</td>
</tr>
<tr>
<td>Establishment of plants in other EU states</td>
<td>9</td>
</tr>
<tr>
<td>Lean production methods</td>
<td>22</td>
</tr>
<tr>
<td>Penetration of markets in other EU states</td>
<td>32</td>
</tr>
<tr>
<td>Advertising in other EU states</td>
<td>19</td>
</tr>
<tr>
<td>Distribution networks in other EU markets</td>
<td>22</td>
</tr>
<tr>
<td>Pan-European labelling</td>
<td>22</td>
</tr>
<tr>
<td>Purchase of raw materials from other EU markets</td>
<td>34</td>
</tr>
<tr>
<td>Purchase of components from other EU markets</td>
<td>25</td>
</tr>
<tr>
<td>Purchase of business services from other EU markets</td>
<td>9</td>
</tr>
<tr>
<td>Purchase of financial services from other EU markets</td>
<td>7</td>
</tr>
<tr>
<td>(Direct) Investment in other companies</td>
<td>9</td>
</tr>
<tr>
<td>(Direct) Investment from other companies</td>
<td>8</td>
</tr>
<tr>
<td>Co-operation agreements with other companies</td>
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</tbody>
</table>

## Tab.9: Single Market's importance to development of strategy.
Research and development of new products

<table>
<thead>
<tr>
<th>Classification</th>
<th>Percentage of enterprises expressing opinion</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Important*</td>
</tr>
<tr>
<td>EUR-12</td>
<td>34</td>
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**By Member state**

<table>
<thead>
<tr>
<th>Country</th>
<th>Important*</th>
<th>Not important</th>
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<tbody>
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<td>45</td>
<td>28</td>
<td>27</td>
</tr>
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<td>Denmark</td>
<td>25</td>
<td>56</td>
<td>19</td>
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<td>BR Deutschland</td>
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<td>55</td>
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<td>Greece</td>
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**By Manufacturing Sector**

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<th>Sector</th>
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<th>Not important</th>
<th>Don't Know</th>
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</thead>
<tbody>
<tr>
<td>Food, beverages and tobacco</td>
<td>34</td>
<td>39</td>
<td>27</td>
</tr>
<tr>
<td>Textiles, leather and furniture</td>
<td>36</td>
<td>44</td>
<td>21</td>
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<tr>
<td>Wood, paper and printing/publishing</td>
<td>21</td>
<td>47</td>
<td>32</td>
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<tr>
<td>Chemicals, rubber and plastics</td>
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<td>40</td>
<td>21</td>
</tr>
<tr>
<td>Non-metallic mineral products</td>
<td>29</td>
<td>45</td>
<td>25</td>
</tr>
<tr>
<td>Metals and metal products</td>
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<td>44</td>
<td>26</td>
</tr>
<tr>
<td>Machinery and equipment NEC</td>
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<td>Electrical and optical machinery</td>
<td>37</td>
<td>48</td>
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<td>Transport equipment</td>
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**By Employment Size Class**

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<td>500-999</td>
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<td>18</td>
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<tr>
<td>≥ 1,000</td>
<td>37</td>
<td>52</td>
<td>11</td>
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Annex II:

Directive 90/385 EEC and Directive 93/42 EEC (overview)
DIRECTIVE 90/385/EEC
on active implantable medical devices

(OJ L 189 of 20 July 1990)

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Article 8 Information on incidents occurring following placing of devices on the market
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Annex XII CE MARKING OF CONFORMITY

Source: Medical Devices Net (1998)
Annex III:

Medical device cluster (selected data)
### Intra-EU-Trade

#### Export into EU

<table>
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Source: EUROSTAT; Unit: 1000 ECU

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Source: EUROSTAT; Unit: 1000 ECU
Product description - valid from 1998-1995

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+902140+902150+902190+902211+902221+902229+902230+902290+940210+940290

Products 84192088-: MEDICAL, SURGICAL OR LABORATORY STERILIZERS
Products 90181988-: ELECTRO-CARDIOGRAPH

Products 90182088-: ULTRA-VIOLET OR INFRA-RED APPARATUS USED IN MEDICAL, SURGICAL, DENTAL OR VETERINARY SCIENCES
Products 90183188-: SYRINGES, WHETHER OR NOT WITH NEEDLES, USED IN MEDICAL, SURGICAL, DENTAL OR VETERINARY SCIENCES
Products 90183988-: NEEDLES, CATHETERS, CANNULAE AND THE LIKE, USED IN MEDICAL, SURGICAL, DENTAL OR VETERINARY SCIENCES (EXCL. SYRINGES, TUBULAR METAL NEEDLES AND NEEDLES FOR SUTURES)
Products 90184188-: DENTAL DRILL ENGINES, WHETHER OR NOT COMBINED ON A SINGLE BASE WITH OTHER DENTAL EQUIPMENT
Products 90184988-: INSTRUMENTS AND APPLIANCES USED IN DENTAL SCIENCES N.E.S.
Products 90185088-: OPHTHALMIC INSTRUMENTS AND APPLIANCES N.E.S.
Products 90189088-: INSTRUMENTS AND APPLIANCES USED IN MEDICAL, SURGICAL, DENTAL OR VETERINARY SCIENCES N.E.S.
Products 90190188-: MECHANO-THERAPY APPLIANCES, MASSAGE APPARATUS AND PSYCHOLOGICAL APTITUDE-TESTING APPARATUS
Products 90192088-: OZONE THERAPY, OXYGEN THERAPY, AEROSOL THERAPY, ARTIFICIAL RESPIRATION OR OTHER THERAPEUTIC RESPIRATION APPARATUS
Products 90200088-: BREATHING APPLIANCES AND GAS MASKS (EXCL. PROTECTIVE MASKS HAVING NEITHER MECHANICAL PARTS NOR REPLACEABLE FILTERS, AND ARTIFICIAL RESPIRATION OR OTHER THERAPEUTIC RESPIRATION APPARATUS)
Products 90211188-: ARTIFICIAL JOINTS, FOR ORTHOPAEDIC PURPOSES
Products 90211988-: ORTHOPAEDIC APPLIANCES AND FRACTURE APPLIANCES (EXCL. ARTIFICIAL JOINTS)
Products 90212188-: ARTIFICIAL TEETH
Products 90212988-: DENTAL FITTINGS (EXCL. ARTIFICIAL TEETH)
Products 90213088-: ARTIFICIAL PARTS OF THE BODY (EXCL. ARTIFICIAL TEETH)
Products 90214088-: HEARING AIDS (EXCL. PARTS AND ACCESSORIES)
Products 90215088-: PACEMAKERS FOR STIMULATING HEART MUSCLES (EXCL. PARTS AND ACCESSORIES)
Products 90219088-: ARTICLES AND APPLIANCES, WHICH ARE WORN OR CARRIED, OR IMPLANTED IN THE BODY, TO COMPENSATE FOR A DEFECT OR DISABILITY (EXCL. ARTIFICIAL PARTS OF THE BODY, COMPLETE HEARING AIDS AND COMPLETE PACEMAKERS FOR STIMULATING HEART MUSCLES)
Products 90221188-95 : APPARATUS BASED ON THE USE OF X-RAYS FOR MEDICAL, SURGICAL, DENTAL OR VETERINARY USES
Products 90221988- : APPARATUS BASED ON THE USE OF X-RAYS FOR OTHER USES
Products 90222188- : APPARATUS BASED ON THE USE OF ALPHA, BETA, OR GAMMA RADIATIONS, FOR MEDICAL, SURGICAL, DENTAL OR VETERINARY USES
Products 90222988- : APPARATUS BASED ON THE USE OF ALPHA, BETA, OR GAMMA RADIATIONS, FOR OTHER USES
Products 90223088- : X-RAY TUBES
Products 90229088- : X-RAY GENERATORS OTHER THAN X-RAY TUBES, HIGH TENSION GENERATORS, CONTROL PANELS AND DESKS, SCREENS, EXAMINATION OR TREATMENT TABLES, CHAIRS AND THE LIKE, AND GENERAL PARTS AND ACCESSORIES FOR APPARATUS OF HEADING 9022, N.E.S.
Products 94021088- : DENTISTS’, BARBERS’ OR SIMILAR CHAIRS HAVING ROTATING AS WELL AS BOTH RECLINING AND ELEVATING MOVEMENT, AND PARTS THEREOF N.E.S.
Products 94029088- : OPERATING TABLES, EXAMINATION TABLES, AND OTHER MEDICAL, DENTAL, SURGICAL OR VETERINARY FURNITURE (EXCL. DENTISTS’ OR SIMILAR CHAIRS, SPECIAL TABLES FOR X-RAY EXAMINATION, AND STRETCHERS AND LITTERS, INCL. TROLLEY-STRETCHERS)
Product description - valid since 1996

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Products 84192088- : MEDICAL, SURGICAL OR LABORATORY STERILIZERS
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Products 90181396- : MAGNETIC RESONANCE IMAGING APPARATUS
Products 90181496- : SCINTIGRAPHIC APPARATUS
Products 90181988- : ELECTRO-DIAGNOSTIC APPARATUS, INCL. APPARATUS FOR FUNCTIONAL EXPLORATORY
EXAMINATION OR FOR CHECKING PHYSIOLOGICAL PARAMETERS (EXCL. ELECTRO-CARDIOGRAPHS, ULTRASONIC SCANNING APPARATUS, MAGNETIC RESONANCE IMAGING APPARATUS AND SCINTIGRAPHIC APPARATUS)
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Products 90183188- : SYRINGES, WHETHER OR NOT WITH NEEDLES, USED IN MEDICAL, SURGICAL, DENTAL OR VETERINARY SCIENCES
Products 90183288- : TUBULAR METAL NEEDLES AND NEEDLES FOR SUTURES, USED IN MEDICAL, SURGICAL, DENTAL OR VETERINARY SCIENCES
Products 90183988- : NEEDLES, CATHETERS, CANNULAE AND THE LIKE, USED IN MEDICAL, SURGICAL, DENTAL OR VETERINARY SCIENCES (EXCL. SYRINGES, TUBULAR METAL NEEDLES AND NEEDLES FOR SUTURES)
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Products 90189088- : INSTRUMENTS AND APPLIANCES USED IN MEDICAL, SURGICAL, DENTAL OR VETERINARY SCIENCES N.E.S.
Products 90191088- : MECHANO-THERAPY APPLIANCES, MASSAGE APPARATUS AND PSYCHOLOGICAL APTITUDE-TESTING APPARATUS
Products 90192088- : OZONE THERAPY, OXYGEN THERAPY, AEROSOL THERAPY, ARTIFICIAL RESPIRATION OR OTHER THERAPEUTIC RESPIRATION APPARATUS
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## Health care systems in Europe

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<td>Mandatory, comprehensive health insurance</td>
<td>Health indicators are typically close to EU norms</td>
<td>Expenditure is high in absolute terms and average as a % of GDP (7.7%)*</td>
<td>The health insurance scheme is the dominant feature, but substantial private insurance contribution</td>
<td>High bed capacity with most beds in public ownership and control</td>
<td>Provided by independent practitioners in hospitals and specialised clinics</td>
<td>Mostly in private practice but contracted to insurance agencies</td>
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<td><strong>BELGIUM</strong></td>
<td>Compulsory health insurance for all major risks</td>
<td>Most health indicators are close to EU average values</td>
<td>Expenditure is high, both per capita and as % of GDP (8%)</td>
<td>Compulsory health insurance with significant state subsidy</td>
<td>Mainly private or independent non-profit hospitals</td>
<td>GPs mostly in single practices with fee-for-service payments</td>
<td>Mainly independent - high level of supply</td>
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<td><strong>DENMARK</strong></td>
<td>A national health service mainly funded from general taxation</td>
<td>Indicators for women below EU levels</td>
<td>A high per capita level but low % of GDP (6.5%)</td>
<td>85% from general taxation with the remainder from copayments</td>
<td>Almost all hospitals under close municipal (or local) control</td>
<td>Independent GPs in single and group practices</td>
<td>Some independent but a high number of salaried specialists</td>
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<td><strong>FINLAND</strong></td>
<td>A national health service with a shift of decision making from state to local level</td>
<td>Some health indicators unfavourable by EU standards. Cardiovascular disease remains a problem</td>
<td>Expenditure is high in absolute terms, but moderate as % of GDP (7.5%)</td>
<td>An almost even balance of state and local taxation with some national insurance and some private payments</td>
<td>High level of supply of beds, a high admission rate and a relatively low length of stay</td>
<td>A renowned comprehensive system of local health centres with a strong emphasis on preventive health care</td>
<td>Although most doctors are salaried public employees there is significant private practice</td>
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<td><strong>FRANCE</strong></td>
<td>Compulsory health insurance covers almost all the population</td>
<td>High life expectancy especially for women. Low heart disease incidence. Possibly due to dietary factors</td>
<td>Expenditure high, both in absolute terms (ECU 1,999 per head) and relative to the GDP (9.3%)</td>
<td>Mostly statutory sickness funds but some direct payments</td>
<td>A mix of public and private, but public dominates</td>
<td>Independent GPs, except for health centres in towns</td>
<td>Mainly independent with average supply</td>
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<td>GERMANY</td>
<td>Numerous insurance funds and a significant private sector</td>
<td>High proportion of elderly. Low infant and perinatal mortality</td>
<td>Very high – ECU 2,362 per head and 10.4% of GDP</td>
<td>A complex mixture of sources with only 21% from general taxation</td>
<td>Over 50% are private or independent non-profit hospitals</td>
<td>A wide range of services from independent single practitioners, strictly separated from hospital care</td>
<td>High levels of supply with medical unemployment</td>
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<td>GREECE</td>
<td>Compulsory health insurance, national health service and a significant private sector</td>
<td>High infant mortality – otherwise high life expectancy</td>
<td>Low by EU standards at ECU 483 per capita and 5.8% of GDP</td>
<td>The private sector is substantial and there is a high degree of unofficial „additional payments”</td>
<td>Many private hospitals but only around 20% of admissions are private</td>
<td>State owned health centres co-exist with private GPs</td>
<td>A very high level of supply - salaried in the public sector</td>
</tr>
<tr>
<td>IRELAND</td>
<td>A national health service and some co-payment insurance</td>
<td>A young population with relatively low life expectancy</td>
<td>Average percentage of GDP but only ECU 733 per head</td>
<td>Mainly from general taxation with a small proportion from insurance</td>
<td>Mainly public hospitals but with some moves to greater independence</td>
<td>Independent GPs in single or group practices</td>
<td>Salaried in public hospitals with a low level of supply</td>
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<tr>
<td>ITALY</td>
<td>A national health service based on compulsory health insurance</td>
<td>High life expectancy and low heart disease incidence. Possibly due to dietary factors</td>
<td>Average levels by EU standards at 8.3% of GDP-ECU 1340 per head</td>
<td>A mixture of general taxation and compulsory contributions</td>
<td>Mainly public hospitals but a sizeable private sector especially in south</td>
<td>GPs are either independent or employees of local health boards</td>
<td>Controversial data - low level of supply by EU standards</td>
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<td>LUXEMBOURG</td>
<td>Compulsory health insurance</td>
<td>Overall indicators often worse than EU norms - especially for men</td>
<td>High per capita expenditure and close to EU average % of GDP</td>
<td>Mostly from the sickness funds with 27% from state subsidies</td>
<td>Mainly a balance of public and independent non-profit units</td>
<td>Mainly single independent practitioners</td>
<td>Almost all doctors are independent contractors</td>
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<td>Country</td>
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<td>Health Status</td>
<td>Expenditure</td>
<td>Funding</td>
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<td>Netherland</td>
<td>Complex system of public and private insurance but moving to a national scheme</td>
<td>Relatively small proportion of elderly. Overall health generally favourable</td>
<td>Slightly above EU average levels - ECU 1,711 per head and 8.6% of GDP</td>
<td>Mostly from compulsory insurance schemes with some voluntary or private</td>
<td>Mostly private non-profit hospitals</td>
<td>Independent GPs with many working in group practices and health centres</td>
<td>Mainly independent</td>
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<tr>
<td>Portugal</td>
<td>A national health service based on compulsory health insurance</td>
<td>High infant mortality and relatively low life expectancy</td>
<td>Above EU average proportion of GDP, but low in absolute terms</td>
<td>A small private sector - main funding from the national insurance scheme</td>
<td>Mainly public hospitals. Rather low bed supply</td>
<td>Mainly state run health centres with salaried doctors</td>
<td>Overall good levels of supply but not in some specialities</td>
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<td>Spain</td>
<td>An embryonic national health service. A mix of general taxation and compulsory insurance</td>
<td>Health indicators are generally favourable especially for women. Again, diet may be a factor</td>
<td>Around EU average at 7.6% of GDP but this is a low ECU 894 per capita</td>
<td>Dominated by general taxation but some compulsory insurance</td>
<td>Over 50% are independent non-profit hospitals</td>
<td>GPs mainly work within health centres serving defined geographical areas</td>
<td>Salaried doctors. An above average supply in most areas</td>
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<td>Sweden</td>
<td>A comprehensive public sector health system with strong local democratic control</td>
<td>High life expectancy and very good health status apart from cardiovascular disease which is nearer the EU norm: very high proportion of elderly</td>
<td>Recent shift of expenditure between sectors and decrease of expenditure as a share of GDP (7.2%)</td>
<td>Local taxation is the key element supplemented by state funds and national insurance</td>
<td>A relatively good supply of hospital beds with a high admission rates and low length of stay</td>
<td>A weaker element of the system provided mainly from health centres, but growing in recent times</td>
<td>Mostly salaried public sectors employees: the majority are specialists with GPs in short supply</td>
</tr>
<tr>
<td>U.K.</td>
<td>A national health service mainly funded from taxation</td>
<td>A high proportion of elderly. Some health indicators worse than EU norms, possibly due to dietary factors.</td>
<td>Below the EU average at ECU 1,005 and 6.3% of GDP</td>
<td>Mainly from general taxation. A small private sector</td>
<td>A move from public to more independent Hospital Trusts</td>
<td>GPs are independent contractors working mainly in group practices</td>
<td>Salaried doctors in the hospitals. A below EU average level of supply</td>
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</table>

Source: European Parliament (1998). *= Change of interpretation because of reasons of consistency with other countries. (Original wording: „Expenditure is high, both in absolute terms and as a % of GDP (7,7%)“).
Annex IV:

Empirical analysis
Musterinstitut
Musterstraße 11
12345 Musterhausen

29 January 1999

Impact of EU-Regulation on Innovation in the Medical Devices Industry

Dear Mr. Mustermann,

We are writing to you with regard to the preparation of an important study for the European medical devices industry and the European Commission. We are from the European Commission’s Institute for Prospective Technological Studies (IPTS) based in Seville in Spain, and have asked VDI/VDE-IT and Technopolis Ltd. to analyse the impact of Single Market regulation on innovation in the medical devices sector.

The study will consist of a survey of experiences of firms in the medical devices sector. It will be based on a short list of questions to the best innovating firms. Therefore it is necessary to know these best innovating companies which we would define as „companies that have a proven capability to reach the market successfully with innovative products“. The focus of the study is on innovation concerning products in the medical devices sector falling under the directives "Active implantable medical devices" (90/385) and "Medical devices" (93/42).

We would be grateful if you could name the firms you would think of as best innovators in the medical devices sector. The one-page yellow form annexed which is anonymous and confidential should be returned in the reply paid envelope or by fax +49 3328 435-216 until 26 February 1999.

Our contractors, VDI/VDE-IT and Technopolis Ltd., and ourselves will be careful to treat your information as being strictly confidential, will not quote your answers or refer to you in any manner in contacts with firms or people you mention, or use your information for any other purpose than this study. Your co-operation is appreciated and is an important key to the success of this study.

In return for your response, we will be happy to send you the report for free when it will be finalised in October. The report will offer interesting new insights into the interaction between innovation and regulation. If you are interested please enclose the reply form with your address.

For any further questions please contact Mr. Horst Steg at VDI/VDE-IT, phone +49-3328-435-117; Ms. Karen Henderson at Technopolis, phone +44-1273-204-320 or Mr. Nikolaus Thumm at the Institute for Prospective Technological Studies, phone +34-95-4488-333.

Yours sincerely,

P. Sørup
Head of Unit (acting)
Best innovating firms in the medical devices industry

Please indicate below “best innovating” firms in the medical device industry i.e. which have a proven capability to successfully reach the market with innovative products.

We wish to identify companies across EC Member States and EEA Countries. So please consider nominations in Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, United Kingdom.

Please list name and address of the firm. In addition we shall be grateful for further information about a suitable person to contact and telephone or fax. If you want to nominate more than 5 firms please just copy the form.

<table>
<thead>
<tr>
<th>Firm’s name</th>
<th>Address (with country)</th>
<th>Contact person</th>
<th>Telephone/ Fax</th>
</tr>
</thead>
<tbody>
<tr>
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</tbody>
</table>

⇒ Please send back this form in the postage paid green envelope or by fax +49-3328-435-216 until 26 February 1999.
Reply form for receiving your free copy of the report

⇒ Please indicate the name and address where the final report should be sent to:

name:

institution/firm:

postal address:
Impact of EU-Regulation on Innovation in the Medical Device Industry

Dear «Anrede»,

The European Commission’s Institute for Prospective Technological Studies (IPTS) in Seville, Spain is currently undertaking an important study on the European medical device sector. The study focuses on innovation in the medical device sector and the impact of two European directives “Active implantable medical devices” (90/385) and “Medical devices” (93/42). The study will survey the experiences of the “best innovating firms”. Your firm has been suggested as one of the 400 best leading innovators operating in the European Economic Area by a number of medical device experts.

We would be grateful if you could take the time to answer some questions on the impact of the above mentioned regulations on the innovation activities of your firm. Could you complete the yellow survey form attached to this letter and return it using the pre-paid envelope enclosed or fax +49-3328-435-216 before 18 June 1999.

Our contractors, VDI/VDE-IT and Technopolis Ltd., and IPTS will treat all information as strictly confidential and use the information supplied for this study, only.

In return for your help, we would be happy to send you a copy of the final report in October in which we expect to be able to offer a deeper analysis of the relationship between innovation and regulation in the medical device industry. If you would like to receive a copy of the report please fill in the reply form with your address.

If you have any further enquiries please contact Mr. Horst Steg at VDI/VDE-IT, phone +49-3328-435-117; Ms. Catherine Whitelegg at Technopolis, phone +44-1273-204-320 or Mr. Nikolaus Thumm at the Institute for Prospective Technological Studies, phone +34-95-4488-333.

Yours sincerely,

P. Sørup
Institute for Prospective Technological Studies (Seville)
Head of Unit (acting)
Innovation and regulation in the medical device industry

- The aim of the study is to analyse the relationship between innovation in the European medical device industry and Single Market Regulation in the form of the following directives: “Medical devices” (93/42) and “Active implantable medical devices” (90/385).
- We are interested in more general, long-term effects and are therefore concentrating on impacts that have happened or that you might expect to happen after the transition period necessary for firms to adapt to the new regulation.
- The following questions focus on A) firm classification and B) various factors influencing innovation in the medical device industry. In B), in addition to the questions concerning the quantitative data, you have the option of providing more detailed comments. We would welcome any such comments or examples.

Thank you very much for your help

⇒ Please send back the completed questionnaire

in the postage paid envelope

until 18 June 1999
A) Firm classification:

A 1) Is your firm affected by the following directives and their translation into national law?

- Directive 90/385 “Active implantable medical devices”
- Directive 93/42 “Medical devices”

A 2) Firm size (number of employees)?

A 3) Firm location (country)? (only state the main location of the firm if located in more than one country)

A 4) Your market segments within the medical device sector?
(See attached list with 13 segments. Please fill in the appropriate code number 1,2,...,13. If there are more than one please state the most important)

A 5) Risk classes of your products (Please state all risk classes of your major products)

- Class I
- Class IIa
- Class IIb/Class III

A 6) Location of your markets (Please state the appropriate level)

- Only national level
- National and export on European level
- National level and export: Europe and overseas, but not US-market
- National level and export: Europe and overseas including US-market
B) Interaction between Regulation and Innovation

B.1 Impact of direct access to the Single Market for CE-marked medical device innovations

A CE-marked medical device can be marketed freely within the whole Single Market of the European Community without further testing and conformity assessment on the national level (93/42/EEC, Art.4 and 90/385/EEC,Art.4).

What is/will be the impact of this direct access to the Single Market on the following factors?

⇒ Please fill in questions B.1.1 to B.1.5 stating the appropriate level on a scale from

-2 = very negative ("bad") impact, 0 = no impact, +2 = very positive ("good") impact.

| B 1.1) Impact of the direct access to the Single Market on the investment of monetary and/or human resources in the development of innovative medical devices. |
|-------|-------|-------|-------|-------|
| very negative | no impact | very positive |
| -2 | -1 | 0 | +1 | +2 |
| ☐ | ☐ | ☐ | ☐ | ☐ |

Further comments:

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B 1.2) Impact of the direct access to the Single Market on „time to market“: Duration of the whole innovation process to the point at which the product reaches the targeted markets on national and international level (incl. R&D, clinical investigation, conformity assessment, market entry )

| B 1.2) Impact of the direct access to the Single Market on „time to market“. |
|-------|-------|-------|-------|-------|
| very negative | no impact | very positive |
| -2 | -1 | 0 | +1 | +2 |
| ☐ | ☐ | ☐ | ☐ | ☐ |

Further comments:

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B 1.3) Impact of the direct access to the Single Market on innovation costs for R&D, clinical investigation, conformity assessment, market entry.

<table>
<thead>
<tr>
<th>very negative</th>
<th>no impact</th>
<th>very positive</th>
</tr>
</thead>
<tbody>
<tr>
<td>-2</td>
<td>-1</td>
<td>+1</td>
</tr>
<tr>
<td>+2</td>
<td></td>
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</tbody>
</table>

Further comments:..............................................................................................................
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B.2 Impact of technological and organisational flexibility on innovation

B 2.1) Impact of technological flexibility: The directives are limited to “essential requirements” to protect safety and health of patients and users (93/42/EEC, Art.3/annex I and 90/385/EEC, Art.3/annex I). They contain no specific technical rules. The application of standards is voluntary.

What has been/will be the impact of this “technological flexibility” on your firms innovation activities?

Further comments:.............................................................................................................. .....................................................
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B 2.2) Impact of standards: The use of harmonised standards is a possible instrument to assess conformity with the directives (93/42/EEC, Art.5 and 90/385/EEC,Art.5). But generally, standards only represent the current state of the art technology.

In the case of medical device innovations: What has been/will be the impact of the existing system of harmonised standards on the development of innovative technology?

Further comments:.............................................................................................................. .....................................................
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What has been/will be the impact of this organisational flexibility on your innovation activities?

Further comments:.............................................................................................................. .....................................................
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B 2.4) Impact on quality assurance system: How have the directives stimulated/will stimulate your firm to install a quality assurance system (e.g. DIN EN ISO 9001-9003) ?

<table>
<thead>
<tr>
<th>Impact on q. assurance system</th>
<th>very negative</th>
<th>no impact</th>
<th>very positive</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>-2</td>
<td>-1</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>+1</td>
<td>+2</td>
<td></td>
</tr>
</tbody>
</table>

Further comments:........................................................................................................................................
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B.3 General impacts of the directives

B 3.1) Impact on co-operation: What has been/will be the impact of the directives on co-operation between your firm and the following groups:

1) medical research and clinical testing
2) other scientists, laboratories (e.g. ICT, materials, biomedical engineering)
3) other companies (e.g. medical devices and other industries)
4) notified bodies in your country
5) notified bodies on international level

<table>
<thead>
<tr>
<th>Impact on co-operation</th>
<th>very negative</th>
<th>no impact</th>
<th>very positive</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>-2</td>
<td>-1</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>+1</td>
<td>+2</td>
<td></td>
</tr>
</tbody>
</table>

Further comments:........................................................................................................................................
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B 3.2) Impact on competition within the Single Market: How will the directives influence competition within the Single Market ?

<table>
<thead>
<tr>
<th>Impact on competition</th>
<th>much lower</th>
<th>no impact</th>
<th>much higher</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>-2</td>
<td>-1</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>+1</td>
<td>+2</td>
<td></td>
</tr>
</tbody>
</table>

⇒ Please fill in the most appropriate level on a scale from −2 = much lower competition, 0 = no impact, +2 = much higher competition

Further comments:........................................................................................................................................
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36
B 3.3) Impact on competitiveness of EU manufacturers: How will the directives stimulate world-wide competitiveness of the medical device manufacturers based in the EU?

<table>
<thead>
<tr>
<th>very negative</th>
<th>no impact</th>
<th>very positive</th>
</tr>
</thead>
<tbody>
<tr>
<td>-2</td>
<td>-1</td>
<td>+1</td>
</tr>
</tbody>
</table>

Further comments: ........................................................................................................................................................................

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B 3.4) Total impact in the long term: Taking all positive and negative impacts of the directives on your firms innovation activities. What is/will be the total impact in the long term?

<table>
<thead>
<tr>
<th>very negative</th>
<th>no impact</th>
<th>very positive</th>
</tr>
</thead>
<tbody>
<tr>
<td>-2</td>
<td>-1</td>
<td>+1</td>
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</tbody>
</table>

Further comments: ........................................................................................................................................................................

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B 3.5) Transitional impact: What is/will be the total impact of the directives during the transition phase necessary for firms to adapt to the new regulation?

<table>
<thead>
<tr>
<th>very negative</th>
<th>no impact</th>
<th>very positive</th>
</tr>
</thead>
<tbody>
<tr>
<td>-2</td>
<td>-1</td>
<td>+1</td>
</tr>
</tbody>
</table>

Further comments: ........................................................................................................................................................................

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B 3.6) Main impacts: What are the most important advantages / disadvantages of the directives for your firms innovation activities?

Advantages: ........................................................................................................................................................................

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Disadvantages: ........................................................................................................................................................................

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Reply for receiving your free copy of the report

⇒ Please indicate the name and address where the final report should be sent to:

name:

institution/firm:

postal address:
A) Firm classification

A.1) Affected by the following Directives

<table>
<thead>
<tr>
<th>Directive</th>
<th>Affected Firms</th>
<th>Total</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Directive 90/385</td>
<td>n=110</td>
<td>12</td>
<td>10.9%</td>
</tr>
<tr>
<td>Directive 93/42</td>
<td>n=144</td>
<td>139</td>
<td>96.5%</td>
</tr>
</tbody>
</table>

A.2) Firm Size

<table>
<thead>
<tr>
<th>Firm Size</th>
<th>Firms</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-19</td>
<td>38</td>
<td>26.4%</td>
</tr>
<tr>
<td>20-49</td>
<td>26</td>
<td>18.1%</td>
</tr>
<tr>
<td>50-199</td>
<td>32</td>
<td>22.2%</td>
</tr>
<tr>
<td>200-499</td>
<td>20</td>
<td>13.9%</td>
</tr>
<tr>
<td>500-999</td>
<td>9</td>
<td>6.3%</td>
</tr>
<tr>
<td>1000 and more</td>
<td>19</td>
<td>13.2%</td>
</tr>
<tr>
<td>Total</td>
<td>144</td>
<td></td>
</tr>
</tbody>
</table>
### A.3) Firm location (country)

<table>
<thead>
<tr>
<th>Country</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Austria</td>
<td>6</td>
<td>4.1%</td>
</tr>
<tr>
<td>Belgium</td>
<td>7</td>
<td>4.7%</td>
</tr>
<tr>
<td>Denmark</td>
<td>5</td>
<td>3.4%</td>
</tr>
<tr>
<td>Finland</td>
<td>4</td>
<td>2.7%</td>
</tr>
<tr>
<td>France</td>
<td>11</td>
<td>7.4%</td>
</tr>
<tr>
<td>Germany</td>
<td>37</td>
<td>25.0%</td>
</tr>
<tr>
<td>Ireland</td>
<td>7</td>
<td>4.7%</td>
</tr>
<tr>
<td>Italy</td>
<td>11</td>
<td>7.4%</td>
</tr>
<tr>
<td>Netherlands</td>
<td>2</td>
<td>1.4%</td>
</tr>
<tr>
<td>Norway</td>
<td>2</td>
<td>1.4%</td>
</tr>
<tr>
<td>Portugal</td>
<td>4</td>
<td>2.7%</td>
</tr>
<tr>
<td>Spain</td>
<td>9</td>
<td>6.1%</td>
</tr>
<tr>
<td>Sweden</td>
<td>17</td>
<td>11.5%</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>26</td>
<td>17.6%</td>
</tr>
</tbody>
</table>

Total respondents: 148
### A.4) Market segments within the medical device sector

<table>
<thead>
<tr>
<th>Category</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Imaging</td>
<td>23</td>
<td>15.3%</td>
</tr>
<tr>
<td>Elektromedical/Mechanical devices</td>
<td>21</td>
<td>14.0%</td>
</tr>
<tr>
<td>Anaesthetic/Respiratory and supply devices</td>
<td>6</td>
<td>4.0%</td>
</tr>
<tr>
<td>Surgical reusable instruments</td>
<td>2</td>
<td>1.3%</td>
</tr>
<tr>
<td>Active implantable devices</td>
<td>2</td>
<td>1.3%</td>
</tr>
<tr>
<td>Non-Active implantable devices</td>
<td>25</td>
<td>16.7%</td>
</tr>
<tr>
<td>Disposable devices</td>
<td>23</td>
<td>15.3%</td>
</tr>
<tr>
<td>Aids for disabled persons</td>
<td>10</td>
<td>6.7%</td>
</tr>
<tr>
<td>Hospital and medical hardware</td>
<td>4</td>
<td>2.7%</td>
</tr>
<tr>
<td>Dental devices</td>
<td>11</td>
<td>7.3%</td>
</tr>
<tr>
<td>Ophthalmic and optical devices</td>
<td>2</td>
<td>1.3%</td>
</tr>
<tr>
<td>In Vitro Diagnostic (instruments and reagents)</td>
<td>6</td>
<td>4.0%</td>
</tr>
<tr>
<td>Others</td>
<td>12</td>
<td>8.0%</td>
</tr>
</tbody>
</table>

n=150
A.5) Risk classes of major products

<table>
<thead>
<tr>
<th>Risk Class</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class I (and others)</td>
<td>74</td>
<td>49.3%</td>
</tr>
<tr>
<td>Class Iia (and others)</td>
<td>89</td>
<td>59.3%</td>
</tr>
<tr>
<td>Class IIb / Class III (and others)</td>
<td>86</td>
<td>57.3%</td>
</tr>
<tr>
<td>Class I (only)</td>
<td>14</td>
<td>9.3%</td>
</tr>
<tr>
<td>Class Iia (only)</td>
<td>20</td>
<td>13.3%</td>
</tr>
<tr>
<td>Class IIb / Class III (only)</td>
<td>28</td>
<td>18.7%</td>
</tr>
</tbody>
</table>

n=150

A.6) Market location

<table>
<thead>
<tr>
<th>Market Location</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Only national level</td>
<td>12</td>
<td>8.0%</td>
</tr>
<tr>
<td>National and export on European level</td>
<td>15</td>
<td>10.0%</td>
</tr>
<tr>
<td>National level and export (but not USA)</td>
<td>41</td>
<td>27.3%</td>
</tr>
<tr>
<td>National level and export (including USA)</td>
<td>82</td>
<td>54.7%</td>
</tr>
</tbody>
</table>

n=150
**B) Interaction between regulation and innovation**

<table>
<thead>
<tr>
<th>B.1 Impact of direct access to the Single Market on ...</th>
<th>Total</th>
<th>-2</th>
<th>-1</th>
<th>0</th>
<th>+1</th>
<th>+2</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 ...investment</td>
<td>mean 0,58</td>
<td>1,4%</td>
<td>11,1%</td>
<td>32,6%</td>
<td>38,2%</td>
<td>16,7%</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>n 0,94</td>
<td>144</td>
<td>2</td>
<td>16</td>
<td>47</td>
</tr>
<tr>
<td>2 ...time to market</td>
<td>mean 0,34</td>
<td>8,9%</td>
<td>17,8%</td>
<td>21,9%</td>
<td>32,9%</td>
<td>18,5%</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>n 1,22</td>
<td>146</td>
<td>13</td>
<td>28</td>
<td>32</td>
</tr>
<tr>
<td>3 ...innovation costs</td>
<td>mean 0,04</td>
<td>4,1%</td>
<td>30,3%</td>
<td>29,0%</td>
<td>30,3%</td>
<td>6,2%</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>n 1,01</td>
<td>145</td>
<td>6</td>
<td>44</td>
<td>42</td>
</tr>
<tr>
<td>4 ...innovation risks</td>
<td>mean 0,06</td>
<td>2,1%</td>
<td>14,9%</td>
<td>63,8%</td>
<td>13,5%</td>
<td>5,7%</td>
</tr>
<tr>
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<td>141</td>
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<td>90</td>
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<td>mean 1,01</td>
<td>0,7%</td>
<td>4,2%</td>
<td>22,5%</td>
<td>38,7%</td>
<td>33,8%</td>
</tr>
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<td>mean 0,13</td>
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<td>2,2%</td>
<td>74,6%</td>
<td>15,7%</td>
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<td>40,7%</td>
<td>8,3%</td>
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<td>35,9%</td>
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<td>11</td>
<td>69</td>
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<td>mean 1,01</td>
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<td>35,6%</td>
<td>34,2%</td>
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<td>n 0,88</td>
<td>146</td>
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<td>10,0%</td>
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<td>n 0,73</td>
<td>140</td>
<td>0</td>
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<td>61</td>
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<td>52,5%</td>
<td>31,2%</td>
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<td>11,6%</td>
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<td>15</td>
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<td>4 Total impact in the long term</td>
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<td>3,5%</td>
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<td>144</td>
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**44**
| 1.1 Investment                        | 0.68 |
| 1.2 Time to market                   | 0.34 |
| 1.3 Innovation costs                 | 0.04 |
| 1.4 Innovation risks                 | 0.06 |
| 1.5 Opportunity to enter new markets |       |
|   ...in Europe                       | 1.91 |
|   ...overseas in general             | 0.60 |
|   ...in the USA                      | 0.13 |
| 2.1 Impact of technological flexibility |     |
| 2.2 Impact of standards              | 0.41 |
| 2.3 Impact of organisational flexibility |   |
| 2.4 Impact on quality assurance system |   |
| 3.1 General impacts of the directives on cooperation with the following groups |     |
|   ...medical research/clinical testing | 0.39 |
|   ...other scientists/laboratories   | 0.36 |
|   ...other companies                 | 0.58 |
|   ...notified bodies (national)      | 0.69 |
|   ...notified bodies (international) | 0.38 |
| 3.2 Competition within Single Market |     |
| 3.3 Competitiveness of EU manufacturers |   |
| 3.4 Total Impact in the long term    |     |
| 3.5 Transitional Impact              | 0.72 |
## B.1 Impact of direct access to the Single Market on ...  

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<tr>
<th></th>
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<th>Innovation Costs</th>
<th>Innovation Risks</th>
<th>In the Opportunity to Enter New International Markets</th>
<th>In Europe</th>
<th>Overseas in General</th>
<th>In the USA</th>
<th>Total Impact in the Long Term</th>
<th>Transitional Impact</th>
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<td>-0.21</td>
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<td>1.10</td>
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<td>-0.19</td>
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<td>1.00</td>
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<td>-0.22</td>
<td>-0.22</td>
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<tr>
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<td>...and more</td>
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<td>0.26</td>
<td>0.74</td>
<td>0.44</td>
<td>0.16</td>
<td>0.09</td>
<td>0.09</td>
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<td>0.40</td>
<td>...National and Export on European Level</td>
<td>0.68</td>
<td>...National and Export (but not USA)</td>
<td>0.43</td>
<td>...National Level and Export (including USA)</td>
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<td>...Total Impact in the Long Term</td>
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<td>...500-999</td>
<td>0.68</td>
<td>...1000</td>
<td>0.68</td>
<td>...and more</td>
<td>0.68</td>
<td>...Only National Level</td>
<td>0.57</td>
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## B.2 Impact of technological and organisational flexibility on innovation: Impact of ...  

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<th>Technological Flexibility</th>
<th>Harmonised Standards</th>
<th>Organisational Flexibility</th>
<th>Impact on Quality Assurance System</th>
<th>Co-operation with ...</th>
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<td>146</td>
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<td>0.27</td>
<td>0.34</td>
<td>0.51</td>
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<td>0.43</td>
<td>0.35</td>
<td>0.68</td>
</tr>
<tr>
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<td>...50-199</td>
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<td>0.63</td>
<td>0.61</td>
<td>0.61</td>
</tr>
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<td>...1000</td>
<td>1.00</td>
<td>0.55</td>
<td>0.55</td>
<td>0.67</td>
</tr>
<tr>
<td>6</td>
<td>...and more</td>
<td>1.00</td>
<td>1.00</td>
<td>0.67</td>
<td>1.00</td>
</tr>
<tr>
<td>7</td>
<td>...Only National Level</td>
<td>0.47</td>
<td>0.53</td>
<td>0.56</td>
<td>0.78</td>
</tr>
<tr>
<td>8</td>
<td>...National and Export on European Level</td>
<td>0.73</td>
<td>...National and Export (but not USA)</td>
<td>0.74</td>
<td>...National Level and Export (including USA)</td>
</tr>
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<td>0.90</td>
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## B.3 General impacts of the directives on ...  

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<th>Competitiveness of EU Manufacturers</th>
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<th>Transitional Impact</th>
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<td>0.73</td>
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<td>...National and Export (but not USA)</td>
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<td>0.63</td>
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</table>

## Notes:  
- The table above represents the impact of direct access to the Single Market on various aspects of business operations.  
- The data includes mean values and sample sizes for different firm sizes and market locations.  
- The impact is measured on a scale from -2 to 2, with positive values indicating a positive impact and negative values indicating a negative impact.  
- The table includes data for investment, time to market, innovation costs, innovation risks, and the opportunity to enter new international markets.
### By market segments

<table>
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<th>Market Segment</th>
<th>Total</th>
<th>Imaging</th>
<th>Elektromedical/Mechanical devices</th>
<th>Anaesthetic/Respiratory</th>
<th>Surgical reusable instruments</th>
<th>Active devices</th>
<th>Non-Active implantable devices</th>
<th>Disposable devices</th>
<th>Aids for disabled persons</th>
<th>Hospital and medical hardware</th>
<th>Dental devices</th>
<th>Ophthalmic and optical devices</th>
<th>In Vitro diagnostic</th>
<th>Others</th>
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### B.1 Impact of direct access to the Single Market on innovation: Impact of ...

<table>
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<th>Mean</th>
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<th>2) ... overseas in general</th>
<th>3) ... in the USA</th>
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</thead>
<tbody>
<tr>
<td>...investment</td>
<td>1.01</td>
<td>0.73</td>
<td>1.00</td>
<td>1.00</td>
</tr>
<tr>
<td>n</td>
<td>142</td>
<td>22</td>
<td>23</td>
<td>6</td>
</tr>
<tr>
<td>...time to market</td>
<td>0.60</td>
<td>0.48</td>
<td>0.52</td>
<td>0.50</td>
</tr>
<tr>
<td>n</td>
<td>140</td>
<td>23</td>
<td>23</td>
<td>7</td>
</tr>
<tr>
<td>...innovation costs</td>
<td>0.13</td>
<td>0.05</td>
<td>0.32</td>
<td>0.00</td>
</tr>
<tr>
<td>n</td>
<td>134</td>
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<td>22</td>
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</table>

### B.2 Impact of technological and organisational flexibility on innovation: Impact of ...

<table>
<thead>
<tr>
<th>Flexibility</th>
<th>Mean</th>
<th>1) ... in Europe</th>
<th>2) ... overseas in general</th>
<th>3) ... in the USA</th>
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</thead>
<tbody>
<tr>
<td>...technological flexibility</td>
<td>0.41</td>
<td>0.43</td>
<td>0.64</td>
<td>0.71</td>
</tr>
<tr>
<td>n</td>
<td>145</td>
<td>23</td>
<td>23</td>
<td>7</td>
</tr>
<tr>
<td>...harmonised standards</td>
<td>0.37</td>
<td>0.35</td>
<td>0.39</td>
<td>0.71</td>
</tr>
<tr>
<td>n</td>
<td>143</td>
<td>23</td>
<td>23</td>
<td>7</td>
</tr>
<tr>
<td>...organisational flexibility</td>
<td>0.44</td>
<td>0.26</td>
<td>0.43</td>
<td>0.43</td>
</tr>
<tr>
<td>n</td>
<td>147</td>
<td>23</td>
<td>23</td>
<td>7</td>
</tr>
<tr>
<td>Impact on quality assurance system</td>
<td>1.01</td>
<td>0.87</td>
<td>1.13</td>
<td>0.57</td>
</tr>
<tr>
<td>n</td>
<td>146</td>
<td>23</td>
<td>23</td>
<td>7</td>
</tr>
</tbody>
</table>

### B.3 General impacts of the directives on ...

<table>
<thead>
<tr>
<th>Impact</th>
<th>Mean</th>
<th>1) ... in Europe</th>
<th>2) ... overseas in general</th>
<th>3) ... in the USA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Co-operation with medical research and clinical testing</td>
<td>0.39</td>
<td>0.30</td>
<td>0.09</td>
<td>0.00</td>
</tr>
<tr>
<td>n</td>
<td>145</td>
<td>23</td>
<td>23</td>
<td>7</td>
</tr>
<tr>
<td>...other scientists laboratories</td>
<td>0.36</td>
<td>0.13</td>
<td>0.04</td>
<td>0.14</td>
</tr>
<tr>
<td>n</td>
<td>144</td>
<td>23</td>
<td>23</td>
<td>7</td>
</tr>
<tr>
<td>...other companies</td>
<td>0.58</td>
<td>0.52</td>
<td>0.55</td>
<td>0.86</td>
</tr>
<tr>
<td>n</td>
<td>140</td>
<td>23</td>
<td>22</td>
<td>7</td>
</tr>
<tr>
<td>...notified bodies in your country</td>
<td>0.69</td>
<td>0.74</td>
<td>0.50</td>
<td>0.57</td>
</tr>
<tr>
<td>n</td>
<td>142</td>
<td>23</td>
<td>22</td>
<td>7</td>
</tr>
<tr>
<td>...notified bodies on international level</td>
<td>0.38</td>
<td>0.48</td>
<td>0.13</td>
<td>0.43</td>
</tr>
<tr>
<td>n</td>
<td>141</td>
<td>23</td>
<td>23</td>
<td>7</td>
</tr>
<tr>
<td>Competition within Single Market</td>
<td>0.55</td>
<td>0.17</td>
<td>0.48</td>
<td>1.00</td>
</tr>
<tr>
<td>n</td>
<td>146</td>
<td>23</td>
<td>23</td>
<td>7</td>
</tr>
<tr>
<td>Competitiveness of EU manufacturers</td>
<td>0.60</td>
<td>0.43</td>
<td>0.74</td>
<td>1.14</td>
</tr>
<tr>
<td>n</td>
<td>146</td>
<td>23</td>
<td>23</td>
<td>7</td>
</tr>
<tr>
<td>Total impact in the long term</td>
<td>0.72</td>
<td>0.39</td>
<td>0.78</td>
<td>1.00</td>
</tr>
<tr>
<td>n</td>
<td>146</td>
<td>23</td>
<td>23</td>
<td>7</td>
</tr>
<tr>
<td>Transitional impact</td>
<td>-0.23</td>
<td>-0.43</td>
<td>-0.26</td>
<td>0.43</td>
</tr>
<tr>
<td>n</td>
<td>144</td>
<td>23</td>
<td>23</td>
<td>7</td>
</tr>
</tbody>
</table>
### B.1 Impact of direct access to the Single Market on ...  

#### Table: Impact of direct access to the Single Market on various indicators by country

<table>
<thead>
<tr>
<th>Indicator</th>
<th>MW</th>
<th>Austria</th>
<th>Belgium</th>
<th>Denmark</th>
<th>Finland</th>
<th>France</th>
<th>Germany</th>
<th>Ireland</th>
<th>Italy</th>
<th>Netherlands</th>
<th>Norway</th>
<th>Portugal</th>
<th>Spain</th>
<th>Sweden</th>
<th>United Kingdom</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Investment</strong></td>
<td>0.58</td>
<td>-0.33</td>
<td>1.00</td>
<td>0.50</td>
<td>1.25</td>
<td>0.55</td>
<td>0.43</td>
<td>0.86</td>
<td>0.67</td>
<td>0.00</td>
<td>0.50</td>
<td>1.50</td>
<td>0.22</td>
<td>0.81</td>
<td>0.54</td>
</tr>
<tr>
<td><strong>Time to market</strong></td>
<td>0.34</td>
<td>-1.00</td>
<td>0.17</td>
<td>0.00</td>
<td>1.25</td>
<td>0.00</td>
<td>0.27</td>
<td>0.43</td>
<td>0.73</td>
<td>0.00</td>
<td>0.00</td>
<td>0.75</td>
<td>0.22</td>
<td>0.94</td>
<td>0.27</td>
</tr>
<tr>
<td><strong>Innovation costs</strong></td>
<td>0.04</td>
<td>-0.67</td>
<td>-0.17</td>
<td>-0.40</td>
<td>0.00</td>
<td>-0.55</td>
<td>0.17</td>
<td>0.14</td>
<td>0.55</td>
<td>-0.50</td>
<td>-0.50</td>
<td>0.00</td>
<td>0.56</td>
<td>0.04</td>
<td>0.58</td>
</tr>
<tr>
<td><strong>Innovation risks</strong></td>
<td>0.06</td>
<td>-0.67</td>
<td>0.00</td>
<td>0.00</td>
<td>0.25</td>
<td>0.00</td>
<td>0.06</td>
<td>0.00</td>
<td>0.36</td>
<td>0.00</td>
<td>-0.50</td>
<td>0.25</td>
<td>0.44</td>
<td>0.06</td>
<td>0.00</td>
</tr>
<tr>
<td><strong>... the opportunity to enter new international markets</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1) ... in Europe</td>
<td>1.01</td>
<td>-0.17</td>
<td>1.50</td>
<td>0.25</td>
<td>1.50</td>
<td>0.91</td>
<td>1.03</td>
<td>1.14</td>
<td>1.27</td>
<td>0.00</td>
<td>0.50</td>
<td>1.00</td>
<td>1.25</td>
<td>1.38</td>
<td>0.84</td>
</tr>
<tr>
<td>2) ... overseas in general</td>
<td>0.60</td>
<td>-0.33</td>
<td>0.83</td>
<td>0.00</td>
<td>0.75</td>
<td>0.91</td>
<td>0.46</td>
<td>0.29</td>
<td>0.70</td>
<td>0.50</td>
<td>0.00</td>
<td>0.75</td>
<td>0.89</td>
<td>0.93</td>
<td>0.72</td>
</tr>
<tr>
<td>3) ... in the USA</td>
<td>0.13</td>
<td>-0.50</td>
<td>0.40</td>
<td>0.25</td>
<td>0.75</td>
<td>0.10</td>
<td>0.09</td>
<td>0.17</td>
<td>0.11</td>
<td>-1.00</td>
<td>0.00</td>
<td>0.25</td>
<td>0.38</td>
<td>0.43</td>
<td>0.04</td>
</tr>
</tbody>
</table>

### B.2 Impact of technological and organisational flexibility on innovation: Impact of ...  

#### Table: Impact of technological and organisational flexibility on innovation

<table>
<thead>
<tr>
<th>Indicator</th>
<th>MW</th>
<th>Austria</th>
<th>Belgium</th>
<th>Denmark</th>
<th>Finland</th>
<th>France</th>
<th>Germany</th>
<th>Ireland</th>
<th>Italy</th>
<th>Netherlands</th>
<th>Norway</th>
<th>Portugal</th>
<th>Spain</th>
<th>Sweden</th>
<th>United Kingdom</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Technological flexibility</strong></td>
<td>0.41</td>
<td>-0.67</td>
<td>0.17</td>
<td>0.20</td>
<td>0.75</td>
<td>0.45</td>
<td>0.41</td>
<td>0.29</td>
<td>0.64</td>
<td>0.00</td>
<td>1.50</td>
<td>0.75</td>
<td>0.67</td>
<td>0.60</td>
<td>0.32</td>
</tr>
<tr>
<td><strong>Harmonised standards</strong></td>
<td>0.37</td>
<td>-0.33</td>
<td>-0.50</td>
<td>-0.60</td>
<td>1.00</td>
<td>0.00</td>
<td>0.35</td>
<td>0.86</td>
<td>0.60</td>
<td>-0.50</td>
<td>0.00</td>
<td>0.50</td>
<td>0.78</td>
<td>0.50</td>
<td>0.58</td>
</tr>
<tr>
<td><strong>Organisational flexibility</strong></td>
<td>0.44</td>
<td>-0.50</td>
<td>0.33</td>
<td>0.20</td>
<td>0.75</td>
<td>0.36</td>
<td>0.35</td>
<td>0.29</td>
<td>1.36</td>
<td>-1.00</td>
<td>1.00</td>
<td>0.50</td>
<td>0.56</td>
<td>0.38</td>
<td>0.46</td>
</tr>
<tr>
<td><strong>Impact on quality assurance system</strong></td>
<td>1.01</td>
<td>-0.17</td>
<td>0.33</td>
<td>1.60</td>
<td>1.75</td>
<td>1.09</td>
<td>0.92</td>
<td>1.29</td>
<td>1.45</td>
<td>0.00</td>
<td>1.00</td>
<td>1.75</td>
<td>0.89</td>
<td>1.38</td>
<td>0.76</td>
</tr>
</tbody>
</table>

### B.3 General impacts of the directives on ...  

#### Table: General impacts of the directives on various indicators

<table>
<thead>
<tr>
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<th>MW</th>
<th>Austria</th>
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<th>Denmark</th>
<th>Finland</th>
<th>France</th>
<th>Germany</th>
<th>Ireland</th>
<th>Italy</th>
<th>Netherlands</th>
<th>Norway</th>
<th>Portugal</th>
<th>Spain</th>
<th>Sweden</th>
<th>United Kingdom</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Co-operation with ...</strong></td>
<td>mean</td>
<td>0.39</td>
<td>0.60</td>
<td>0.33</td>
<td>0.20</td>
<td>0.75</td>
<td>0.55</td>
<td>0.16</td>
<td>0.14</td>
<td>0.80</td>
<td>-0.50</td>
<td>1.00</td>
<td>0.75</td>
<td>1.11</td>
<td>0.50</td>
</tr>
<tr>
<td><strong>Medical research and clinical testing</strong></td>
<td>mean</td>
<td>0.36</td>
<td>0.20</td>
<td>0.33</td>
<td>0.00</td>
<td>0.25</td>
<td>0.60</td>
<td>0.16</td>
<td>0.43</td>
<td>0.80</td>
<td>-0.50</td>
<td>1.00</td>
<td>0.89</td>
<td>0.38</td>
<td>0.19</td>
</tr>
<tr>
<td><strong>Other scientists / laboratories</strong></td>
<td>mean</td>
<td>0.58</td>
<td>-0.20</td>
<td>0.33</td>
<td>0.50</td>
<td>1.00</td>
<td>0.60</td>
<td>0.39</td>
<td>0.57</td>
<td>1.33</td>
<td>0.50</td>
<td>1.00</td>
<td>0.89</td>
<td>0.50</td>
<td>0.60</td>
</tr>
<tr>
<td><strong>Other companies</strong></td>
<td>mean</td>
<td>0.69</td>
<td>0.00</td>
<td>0.17</td>
<td>0.75</td>
<td>1.00</td>
<td>0.90</td>
<td>0.41</td>
<td>1.00</td>
<td>1.20</td>
<td>0.00</td>
<td>1.50</td>
<td>1.00</td>
<td>0.75</td>
<td>0.81</td>
</tr>
<tr>
<td><strong>Notified bodies in your country</strong></td>
<td>mean</td>
<td>0.38</td>
<td>-0.60</td>
<td>0.50</td>
<td>0.50</td>
<td>0.75</td>
<td>0.44</td>
<td>0.08</td>
<td>0.43</td>
<td>1.00</td>
<td>-0.50</td>
<td>1.50</td>
<td>0.50</td>
<td>0.67</td>
<td>0.19</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Indicator</th>
<th>MW</th>
<th>Austria</th>
<th>Belgium</th>
<th>Denmark</th>
<th>Finland</th>
<th>France</th>
<th>Germany</th>
<th>Ireland</th>
<th>Italy</th>
<th>Netherlands</th>
<th>Norway</th>
<th>Portugal</th>
<th>Spain</th>
<th>Sweden</th>
<th>United Kingdom</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Competition within Single Market</strong></td>
<td>mean</td>
<td>0.55</td>
<td>0.33</td>
<td>0.67</td>
<td>0.25</td>
<td>0.75</td>
<td>0.55</td>
<td>0.46</td>
<td>1.00</td>
<td>0.82</td>
<td>0.00</td>
<td>0.50</td>
<td>0.75</td>
<td>1.00</td>
<td>0.38</td>
</tr>
<tr>
<td><strong>Competitiveness of EU manufacturers</strong></td>
<td>mean</td>
<td>0.60</td>
<td>-0.50</td>
<td>0.67</td>
<td>1.00</td>
<td>1.00</td>
<td>0.45</td>
<td>0.28</td>
<td>0.71</td>
<td>1.27</td>
<td>-0.50</td>
<td>1.00</td>
<td>1.00</td>
<td>1.00</td>
<td>0.65</td>
</tr>
<tr>
<td><strong>Total impact in the long term</strong></td>
<td>mean</td>
<td>0.72</td>
<td>-0.33</td>
<td>0.67</td>
<td>0.40</td>
<td>1.25</td>
<td>0.55</td>
<td>0.58</td>
<td>0.71</td>
<td>1.18</td>
<td>-0.50</td>
<td>1.00</td>
<td>1.25</td>
<td>1.06</td>
<td>0.69</td>
</tr>
<tr>
<td><strong>Transitional impact</strong></td>
<td>mean</td>
<td>-0.23</td>
<td>-1.33</td>
<td>-0.33</td>
<td>-0.25</td>
<td>0.00</td>
<td>-0.27</td>
<td>-0.39</td>
<td>0.00</td>
<td>0.20</td>
<td>-0.50</td>
<td>0.00</td>
<td>-0.75</td>
<td>0.00</td>
<td>-0.19</td>
</tr>
</tbody>
</table>

### 48
## B.1 Impact of direct access to the Single Market on ...

<table>
<thead>
<tr>
<th></th>
<th>By relevant directives</th>
<th>By risk classes</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Total affected by 90/385</td>
<td>Affected by 93/42</td>
</tr>
<tr>
<td>1</td>
<td>Mean</td>
<td>Class I</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Class II a</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Class II b / Class III</td>
</tr>
<tr>
<td></td>
<td>n</td>
<td>Class I (only)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Class II a (only)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Class II b / Class III (only)</td>
</tr>
</tbody>
</table>

### 1 ...investment
mean 0.58 0.83 0.54 0.46 0.49 0.39 0.92 0.75 0.68
n 144 12 134 71 88 83 13 20 28

### 2 ...time to market
mean 0.34 0.75 0.35 0.28 0.28 0.24 0.46 0.30 0.39
n 146 12 136 72 88 85 13 20 28

### 3 ...innovation costs
mean 0.04 0.08 0.07 -0.06 0.02 -0.06 -0.08 0.05 0.11
n 145 12 135 72 88 84 13 20 27

### 4 ...innovation risks
mean 0.06 0.10 0.09 -0.01 0.01 0.02 0.00 0.10 0.27
n 141 10 131 70 86 81 13 20 26

### 5 ... the opportunity to enter new international markets ...

#### 1) ... in Europe
mean 1.01 1.08 1.01 0.96 0.95 1.00 1.08 0.90 1.15
n 142 12 133 70 87 84 12 20 27

#### 2) ... overseas in general
mean 0.60 0.45 0.60 0.65 0.60 0.62 0.50 0.45 0.59
n 140 11 136 68 85 84 12 20 27

#### 3) ... in the USA
mean 0.13 -0.27 0.12 0.23 0.18 0.07 0.25 0.15 0.08
n 134 10 125 65 82 81 12 20 25

## B.2 Impact of technological and organisational flexibility on innovation: Impact of ...

<table>
<thead>
<tr>
<th></th>
<th>By relevant directives</th>
<th>By risk classes</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>Class I (only)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Class II a (only)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Class II b / Class III (only)</td>
</tr>
</tbody>
</table>

### 1 ...technological flexibility
mean 0.41 -0.17 0.44 0.44 0.41 0.42 0.54 0.40 0.48
n 145 12 135 72 88 85 13 20 27

### 2 ...harmmonised standards
mean 0.37 0.50 0.39 0.31 0.33 0.32 0.31 0.45 0.50
n 145 11 137 69 88 84 13 20 28

### 3 ...organisational flexibility
mean 0.44 0.25 0.45 0.42 0.29 0.42 0.54 0.25 0.75
n 147 12 137 73 89 86 13 20 28

### 4 Impact on quality assurance system
mean 1.01 0.58 1.01 0.93 1.06 1.07 0.85 1.25 1.26
n 146 12 136 73 89 85 13 20 27

## B.3 General impacts of the directives on ...

<table>
<thead>
<tr>
<th></th>
<th>By risk classes</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Class I (only)</td>
</tr>
<tr>
<td></td>
<td>Class II a (only)</td>
</tr>
<tr>
<td></td>
<td>Class II b / Class III (only)</td>
</tr>
</tbody>
</table>

### 1 Co-operation with ...

#### ... medical research and clinical testing
mean 0.39 0.42 0.40 0.37 0.28 0.36 0.62 0.30 0.52
n 145 12 136 73 89 85 13 20 27

#### ... other scientists /laboratories
mean 0.36 0.08 0.38 0.33 0.33 0.35 0.54 0.30 0.37
n 144 12 135 72 88 84 13 20 27

#### ... other companies
mean 0.58 0.64 0.61 0.57 0.65 0.62 0.31 0.75 0.73
n 140 11 131 69 85 81 13 20 26

#### ...notified bodies in your country
mean 0.69 0.25 0.72 0.77 0.84 0.72 0.69 0.74 0.48
n 142 12 133 71 88 83 13 19 27

#### ...notified bodies on international level
mean 0.38 0.33 0.39 0.41 0.36 0.42 0.31 0.20 0.50
n 141 12 132 70 87 81 13 20 26

### 2 Competition within Single Market
mean 0.55 0.83 0.55 0.57 0.69 0.49 0.15 0.45 0.25
n 146 12 136 72 88 85 13 20 27

### 3 Competitiveness of EU manufacturers
mean 0.60 0.67 0.60 0.61 0.63 0.56 0.46 0.65 0.54
n 146 12 136 72 88 86 13 20 28

### 4 Total impact in the long term
mean 0.72 0.58 0.73 0.82 0.77 0.65 0.69 0.75 0.61
n 146 12 136 72 88 86 13 20 28

### 5 Transitional impact
mean -0.23 -0.09 -0.22 -0.26 -0.28 -0.26 -0.31 -0.10 -0.21
n 144 11 134 70 86 85 13 20 28