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 whole1. 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.

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1 See the Communication from the European Commission to the European Parliament and Council of 30 October 1996.
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>
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<tr>
<th>Main Advantages</th>
<th>Main Disadvantages</th>
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<tr>
<td>Better market access in Europe</td>
<td>Costs</td>
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<tr>
<td>Impact on quality assurance system and internal proceedings</td>
<td>Time for first market entry</td>
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<td>Product quality and safety</td>
<td>Administrative and bureaucratic efforts (“paperwork”)</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.