AN ANALYSIS OF INNOVATION AND R&D ACTIVITIES OF FIRMS IN TURKISH MEDICAL DEVICES SECTOR

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ABSTRACT

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This thesis aims to explore the challenges of Medical Devices sector in their innovative activities with the use of qualitative and quantitative methods. The specific subject of analysis is the Turkish Medical Device industry. Throughout the thesis the convergence of Medical Devices with pharmacy and its role in healthcare is mentioned in addition to the institutional regulations of the sector due to their effect on the firms innovative activities. The main focus of this thesis is the innovation in medical devices as vital components of healthcare supply with an important share in health expenditures. Even though Medical Devices are considered to be heterogeneous and classified in many other sectors such as chemicals, textiles and electronics, they have common features sufficient to be considered as a special product group and being an important part of the healthcare system, they are subject to common regulations. Sectoral Systems of Innovation approach is used to investigate Medical Devices Sector in Turkey. Medical devices sector also suffer from regulations that put cost on innovative activities, reimbursement policies that aim at cost containment, lower degrees of consumer support (in terms of user-producer relationship), high marketing costs due to the specific market they act in, in addition to the general obstacles such as scarce finance and human resources. Nonetheless, the ambiguity in entrance and allowance to reimbursement lists is also found to be a blocking factor on innovation.The studies on this aspect of the medical devices sector are limited and this thesis aims to fulfil the gap in this respect.

Keywords: Medical Devices, Sectoral Systems of Innovation, Turkish Medical Devices Industry, Convergent Medical Technologies

öz

TÜRKİYE'DE TIBBİ CİHAZ SEKTÖRÜNÜN
YENİLEŞİM VE AR-GE AKTİVİTELERİNİN ANALİZİ

EREN, İlke
Yüksek Lisans, Bilim ve Teknoloji Politikası Çalışmaları Bölümü
Tez Yöneticisi : Doç. Dr. Mehmet Teoman PAMUKÇU

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Bu tez nicel ve nitel yöntemler kullanarak Tıbbi Cihaz sektörünün yenilikçi faaliyetlerini incelemeyi amaçlamaktadır. Bu tezin ana analiz konusu tıbbi cihazlardır. Sağlık harcamalarında önemli bir payı olan ve sağlık hizmet sunucularının vazgeçilmez bir bileşeni olan tıbbi cihazların inovasyonu incelenmektedir. Tez boyunca Tıbbi cihazların ilaç ile yakınsaması ve sağlık sistemindeki yerinin yanı sıra sektörü ilgilendiren düzenlemelerin şirketlerin inovatif faaliyetlerine olan etkileri bağlamında yer verilecektir. Tıbbi cihazlar çok heterojendir ve kimya, tekstil ve elektronik gibi diğer birçok sektörde tıbbi cihaz tanımlarına uyan cihazlara rastlamak mümkündür ancak bu dağınıklığa rağmen tıbbi cihazlar sağlık hizmet sunumunun önemli bir parçasıdır ve tek bir sektör olarak ele alınacak kadar çok ortak özelliğe sahiptir. Tezin kapsamı Türkiye ile sınırlı tutulmuş ve sektörel inovasyon sistemleri çerçevesinde tıbbi cihaz sektörü incelenmiştir. Finansal sıkıntılar ve insan kaynakları gibi tüm sektöreler tarafından paylaşılan sıkınıtların yanı sıra Tıbbi cihaz sektörü, üretimin sektöre özgü yükleri, inovasyonu baskılayan düzenlemeler ve geri ödeme listelerine giriş belirsizliği gibi sektöre özgü sıkıntılar yaşamaktadır. Tıbbi cihazları bu yönüyle inceleyen çalışma sayısı çok azdır ve bu tez ile bu boşluk giderilmeye çalışılmıştır.

Anahtar Kelimeler: Tıbbi Cihazlar, Sektör İnavosyon Sistemleri, Türkiye Tıbbi Cihaz Sektörü, Yakınsayan Tıbbi Teknolojiler

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TABLE OF CONTENTS

LIST OF TABLES

TABLES

LIST OF FIGURES

FIGURES

LIST OF APPENDICES

APPENDICES

CHAPTER 1

INTRODUCTION

1.1 Prologue

Today, ICT Nanotechnology and Biotechnologies are admitted as revolutionary technologies in the sense that Perez put it, they have clearly low relative costs, unlimited supply for all practical purposes, potential all-pervasiveness and capacity to reduce the costs of capital, labour, product as well as changing them qualitatively (Freeman and Perez, 1988) . Medical Devices is a sector where we can observe increased use of these three revolutionary technologies however, medical devices are not under focus and have not fully studied. Moreover, they are an essential part of healthcare supply, more active than pharmaceuticals in their extensive role in the diagnosis, testing and measurement and therapeutics as well. The rapid change medical devices are subject to, plus ever increasing health costs linked with the innovations of medical technology on the one hand, and on the other, the growth potential with the value added they create, medical devices is a challenging sector to analyze.

This thesis proposed many questions that rise with medical devices sector and had pointed relevant knowledge base, agents and institutions in their relation with this sector in the context of Sectoral Systems of Innovation concept. (Malerba, 2004) However, due to the complexity and heterogeneity of the sector, all inclusive generalizations are not possible and a detailed investigation considering the differences in subsectors, with emphasis on their specific knowledge base and their purchase methods are seen necessary.

1.2 Conceptual Framework

This thesis examines medical devices sector, defines its scope and demonstrate its differences from pharmaceuticals and the convergence they experience. Even though the medical devices sector has many diverse products range and wide categories with approximately 10.000 products (EUCOMED) they share many common components which makes them a specific sector regulated under Medical Devices title. R&D potential and innovation of the firms in Medical

Devices has also sectoral communities. Even if the National Innovation System of Turkey provides an overall framework for manufacturers, Medical Devices experience difficulties in benefiting from these systems. Accordingly a sectoral approach to innovation is adopted in this thesis. Malerba (2004) has proposed building blocks of a Sectoral System of Innovation Perspective as, knowledge base, agents and institutions. The knowledge base medical devices also differ according to subsets, yet throughout the thesis, the state of art is taken into account and the nano-bio technologies were revised. When medical devices production in Turkey is considered, the use of nano or biotechnologies are evident, on the other hand most of the production Turkey is capable is based on mechanical, electronics and chemical knowledge. Recently material sciences and biotechnology is entering the scene as well.

The building blocks are not limited to knowledge base but include agents as well. Malerba, mentions agents as including but not limited to firms as suppliers, users etc, and comprise non-firm agents as well such as clusters, universities, hospitals, R&D centres, scientists and the relationships they are in. This aspect of the theory enables one to make network or linkage analysis however; the agents are only mentioned here to provide an understanding of the innovation environment.

The last building block Malerba (2004) suggests is the institutions that have regulatory, binding or supporting mechanisms that affect the innovation of the sector. In this respect, Ministry of Health (MoH), Social Security Institution (SGK), and Human Resources are covered in their affects on innovation.

By the help of these building blocks a comprehensive approach to medical devices as a sector is achieved. Further work should address the differences in subsectors.

1.3 Methodology

The research is done through both qualitative and quantitative methods. As a qualitative method for data gathering in-depth interviews were conducted as well as participant observation while working in the sector and as a quantitative method a survey analysis was employed in addition to library search. Besides, official sources regarding the sector and relevant literature were also used as

data sources of this study. The aim was collecting data as much representative as of the current situation of the health industry sector in Turkey.

From 1988 onward a global harmonised system to trace world trade has been developed by World Customs Organization named Harmonized Commodity Description System (HS). Throughout the study, values and statistics on medical devices are traced by HS codes, transferred into NACE or GMDN for practical use. The subgroup information is my own compilation based on TURKSTAT.

On the other hand, industry statistics in Appendix mostly depend on NACE (Rev. 1) 33.1, which reports data on "Manufacture of medical and surgical equipment and orthopaedic appliances". Considering the survey, the HDS codes are chosen to match NACE1.1 Section D, 33.10 as far as they could. However, these codes do not cover the high tech product groups which are mostly under chemicals.

For in depth interviews the project owners and their matching producers and the CEO of the firm established to fund innovative projects were considered if reached. Personal observations drawn from 3 years of experience in the sector were also useful in understanding the sector.

In accordance with the Sectoral Systems of Innovation Perspective, the above mentioned building blocks of the medical devices sector have been put forward. Even the sectoral systems are dynamic; the thesis provides a snapshot of current situation.

1.4 Definitions Used

Medical Devices are considered as a vital part of health industry together with pharmaceuticals. Both are restrained by specific regulations since the output is directly related to human health. Pharmaceuticals are more easily defined, categorized, also widely used at home and accordingly recognized more easily. However, medical devices are not easy to categorize, mostly used in hospitals, and defined to include nearly all products other than pharmaceuticals. Pharmaceuticals are classified simply under chemical production, yet medical devices are spread under many sectors including textiles, plastic, electrical and electronic devices, optical devices and metal production. Even disposables made of latex or chemicals used in laboratory are included in the definitions of medical devices. Turkish legislation is harmonized with EU, and refers medical devices

with the same definitions used in the European Union Medical Devices Directive (93/42/ECC). However, pharmaceuticals and medical devices sectors are reported as converging in industry surveys as the life sciences progress.

Banta and Luce (1993) suggested that the life cycle of a technology consists of five stages:

- Future: not yet developed
- Emerging: prior to adoption
- New: in the phase of adoption
- Accepted: in general use
- Obsolete: should be taken out of use.

Emerging technologies are technologies just about to be introduced to clinical practice. They comprise those technologies in the applied research stage. New technologies are technologies that have only recently been introduced to clinical practice. They comprise those technologies that should have passed the stage of clinical trials but are not yet extensively used.

Alternatively, the following definitions are provided by Euroscan as in the KCE report mentions:

Emerging technologies are technologies that are not yet adopted by the health care system. Pharmaceuticals will usually be in phase II or phase III clinical trials or perhaps pre-launch. Medical devices will be prior to marketing, or within 6 months of marketing or marketed but less than 10% diffused or localised to a few centres. (KCE reports vol. 44A)

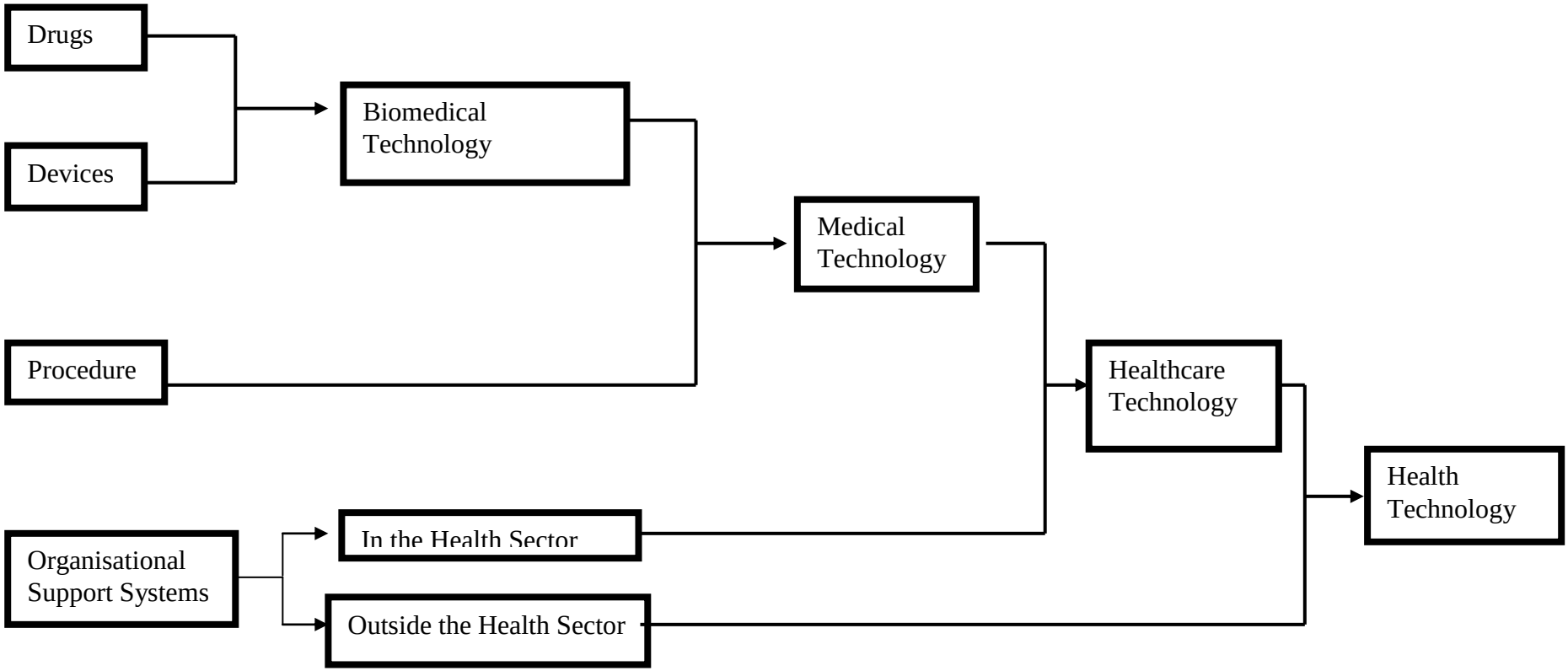


Figure 1.1 – Outline of the categories in the health technology
Source: KCE Reports vol. 44A, 2006

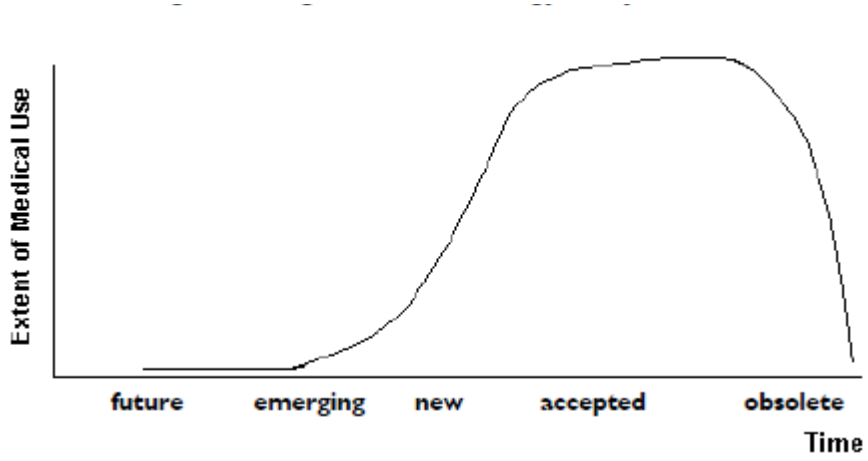


Figure 1.2 – Stages in the technology life cycle in Medical Devices
Source: KCE Reports vol. 44A, 2006

1.5 Outline of the Chapters

The study is organized as follows. First, the introduction chapter provided the overall outline of the thesis. It included a prologue which mentioned the main reason and peculiarity of the thesis. Introduction chapter also includes the conceptual framework, methodology and definitions used that refer to medical devices and clarify the scope.

The next chapter discusses the sectoral systems of innovation (SSI) perspective. The framework of the thesis and the building blocks of sectoral systems of analysis are put forward. Accordingly, the knowledge base, agents, institutions and demand is discussed. This discussion is further expanded to include the developing countries and a perspective on the framework is provided to include medical devices sector.

Chapter 3 introduces the medical devices sector with the emphasis of the specific knowledge, actors and institutions exist in the sector. Main points addressed in knowledge base are the convergent medical technologies including nano and biotechnologies, and the economic aspects of convergent medical technologies, and the current situation in Turkey in medical devices production. Considering agents, the trade structure and the non firm actors in the sector are mentioned. The chapter also includes the institutions that are important for the sector which

are Ministry of Health and Social Security Institution. The last institutional factor was Human Capital in Chapter 3.

Chapter 4 presents the methodology of the qualitative and quantitative data and then provides the findings concerning Medical Devices Industry in Turkey. The survey conducted is examined and conclusions on the survey are drawn. Later, the interviews and survey data are interpreted concurrently with a broader perspective relying on the sectoral systems approach.

Finally Chapter 5 is a brief conclusion on the analysis of the innovation and R&D activities in medical devices sector in Turkey and provides a policy recommendation.

CHAPTER 2

SECTORAL SYSTEMS OF INNOVATION PERSPECTIVE

The thesis is essentially based on the dynamic concept of Sectoral Systems of Innovation (SSI) framework propounded by Malerba (2004). Accordingly the firms in a sector have more commonalities even though they can be easily seen heterogeneous, likewise the innovation and R&D potential of these firms have a sectoral aspect. Throughout the thesis, the sectoral system of innovation (SSI) is used to understand the medical devices sector in Turkey as a framework. The sectoral systems approach is a dynamic approach where time also makes difference yet the thesis is attempting to take a snapshot of the medical devices sector and its innovation capabilities in Turkey. The Sectoral Systems of Innovation proposes that a system is composed of various agents in market and non-market relations for creation, production and sale of products in a sector. Malerba mentions three basic building blocks of a sectoral system, Knowledge and technologies, Agents and Networks and Institutions. In his approach, the sectoral systems have a knowledge base, technologies, input and (potential or existing) demand where "the agents are individuals and organizations at various levels of aggregation with specific learning processes, competencies, organizational structure, beliefs, objectives and behaviours." (pg 10)The agents are interacting by "exchange, cooperation, competition or command" and there are institutions that shape and regulate these interactions. The flux in these elements results a change and transformation in the system. Thus the SSI is a dynamic approach. However for practical reasons, the dynamic essence of the Sectoral Systems of Innovation approach is not reflected in the thesis. Rather a snapshot of existing conditions is positioned.

A sector in Malerba's terms is "a set of activities unified by some linked product groups for a given or emerging demand and characterized by a common knowledge base." (2004, 16). The actors are the firms with common features which are shaped by similar structural relations at the same time reacting in a variety of types even in similar conditions. In a sectoral system of innovation a set of new and established products of a particular system exists together with the agents that carry out relevant activities in (market or non market)

interactions including demand, creation of technologies, inputs or regulations. The agents may be individuals such as consumers, entrepreneurs or scientists or organisations as firms like users, suppliers, producers or non-firm organisations such as universities, financial institutions, government agencies, trade unions or technical associations. They may also be parts of bigger organizations or groups of smaller organizations as in R&D department of a unit or an association of firms etc. The sectoral approach emphasises the learning processes, competencies, beliefs, objectives, organizational structures and behaviours specific to the sector.

One of the classical approach underlining the sectoral differences in innovation used by Organization for Economic Co-operation and Development (OECD), European Union or other such bodies classifying the sectors as "high R&D-intensive" (such as electronics and drugs) and " low R&D-intensive" (such as shoes). Another such distinction among sectors famous is the the Schumpeterian legacy where some sectors are marked with "creative destruction," and others with "creative accumulation" Creative destruction is relevant for the sectors where one can observe the technological ease of entry, important role for entrepreneurs and new firms in innovative activities. On the other hand "creative accumulation" is valid for the sectors where large established firms prevail through cumulative technological advancements and there are to some degree barriers to entry for new innovators where there are large established firms and limited new ones.

Sectors are differentiated as net suppliers and users of technology in Scherer's study. In 1982, Scherer identified computers and instruments sectors as "net suppliers" and textiles and machinery like sectors were identified as "users technology". Later it was conventional that some sectors were "core" and generated most of the innovation and some were secondary and used technology. (qt. in Malerba, 2004)

Another important taxonomy is that of (Pavitt, 1984)where sectors are differentiated by the sources of innovation and appropriability mechanisms. Accordingly, the first category is "supplier dominated sectors" where the new technology is embodied in new components and equipment and new technology is learnt by doing and using. The second category is scale intensive sectors, and process innovation is important while internal (R&D) and external sources

(equipment producers) of innovation are used. Secrecy or patents are effective in appropriability. Specialized suppliers are mentioned as a third category and innovation is focused on performance improvement and customization. Innovation is internal (technicians etc) and external (user-producer interaction). Appropriability is based on local an interactive basis of knowledge. Forth is the science based sectors where the rate of innovation is high and innovations, internal R&D and scientific research done at universities and public research laboratories. Appropriability has various tools such as patents, secrecy, lead times, and learning curves.

Malerba in his concept of Sectoral Systems of Innovation proposes on these concepts and further asserts three building blocks of sector specific analyisis of innovation and production. These three building blocks are Knowledge and technologies, Actors and networks, and Institutions. Accordingly knowledge and technologies are the specific knowledge base, technology and inputs that are required by the sector. This knowledge is the source of sectoral boundries and it is dynamic and change over time rather than to be fixed. Actors and networks are the heterogenous agents composed of individuals or organizations and their interactions. They can interact through communication, exchange, cooperation, competition or command and they can be in market or non-market relationships. Wide varieties of actors are understood involving in generation and dissemination of knowledge. The wide conceptualization of this term enables one to go beyond the market for technological licensing and knowledge, inter-firm alliances, and formal network of firms. Institutions are shaping the cognitive domain as well as the actions and interactions of the agents. They are the norms, routines, common habits, established practices, standards etc. They may have loose impacts or binding enforcements on agents. They may be formal or informal. They may be sector specific as in sector specific funds or regulations or more frequent they may be national as in many laws (labor, patent, competition etc...)

2.1 Knowledge Base

Consistent with the the evolutionary literature (Dosi, 1997) (Nelson R. , 1995) knowledge is a key factor in determining technological change and it is essential for innovation. Tacit knowledge idiosyncratic at the firm level doesn’t permit easy diffusion among firms nor freely available to firms. The absorbtive capacityof the

firm and national capabilities matter in firms' abilities in their responses to the technological change. (Lall S. , 1992)

Accesibility of the knowledge in different sectors create a difference between sectors in their innovative activities. Opportunity of scientific state and cumulative character of knowledge also provide a basis for the sectoral differences as well. (Malerba, 2004)

Knowledge can be accessed by firms in different degrees. The ways of gaining knowledge can be internal or external to the sector for the firms. The greater accessibility of knowledge decreases industrial concentration. If greater accessibility exists in the sector then one can observe lower appropriability of that knowledge. Competitors are rapid to gain knowledge on the new products and processes and may imitate them more easily. If the accessibility of knowledge is external to the sector, it may be related to scientific and technological opportunities, in terms of level and sources. The external environment in the form of human capital may affect firms in this group. Human capital may have a certain level and type of knowledge, or hold relevant scientific and technological knowledge developed in non-firm organizations like R&D labs or universities.

As Freeman & Soete (1997) among others put forward that some sectors are related to the breakthrough developments occurring in universities and these sectors hold better opportunities. These sectors need close interaction with universities and R&D laboratories. Other sectors appropriate knowledge by the help of the R&D conducted by firms, equipment and instrumentation. Some other sectors may make use of external sources of knowledge related to suppliers or users. If external knowledge is easily accessible, transformable into new artifacts and exposed to a number of actors (such as customers or suppliers), then innovative entry may take place (Winter, 1984).On the other hand, if advanced integration capabilities are necessary (Cohen & Levinthal, 1989), the industry may be concentrated and formed by large established firms.

The cumulative character of the knowledge also creates a difference for sectors.The cumulativeness is the need for basis knowledge where one can build new knowledge upon existing one. For Malerba, there are three different sources of cumulativeness of knowledge that affect sectoral spesifities. There are three

aspects of cumulativeness, cognitive, firm's organizational capabilities and feedback from market. Cognitive aspect is related with the learning process and the stage of existing research shape and constrain current research while opening a space for new questions.

The second aspect of the cumulative knowledge is the firm capabilities. According to the evolutionary theories "technological knowledge is not shared equally among firms, nor is it easily imitated by or transferred across firms." Due to the tacit part of the technology, technology transfer is not costless but requires investment of the receiving firm. Since firms operating within a technology doesn't know much about dissimilar technologies of the same sector, they operate not on a production function but rather "localized" around a point which is determined by their technological efforts and skills. Lall quotes Dosi affirming evolutionary theories' success in explaining the "permanent existence of asymmetries among firms, in terms of their process technologies and quality of output". Considering Firm Level Technological Capabilities (FTC) Lall distinguishes between functions as investment capabilities, production capabilities and linkage capabilities and provides a matrix where complexity or difficulty is measured by the activity from which the capability arises (1992).

Another important source for cumulativeness is the feedback from the market for Malerba. He stresses the motto "success breeds success". He further develops these three dimensions of the knowledge and defines "*technological and learning regimes*" which has its basis back form (Nelson & Winter, 1982)and proposes that these regimes also differ among sectors as well.

2.2 Agents

In Sectoral System of Innovation perspective firms are suggested as key actors who involve in innovation, production, sales and they are active in generation, adaptation and use of the new technologies. Firms may be users, suppliers, service providers and their role and relationship with the innovation and production differs according to their position. Some sectors like Medical Devices as well, users are agents (evenif non-firm such as healthcare professionals) most important in diffusion and acceptance of the new technologies (Hippel, The Sources of Innovation, 1995 (first pub. 1988)). Malerba mentions the importance of the suppliers as one of "the components and subsystems also play major role

in affecting innovation, productivity increases and the competitiveness of downstream sectors. Suppliers are characterized by specific attributes, knowledge and competencies, with more or less close relationships with firms within a sector" (Malerba, 2004, p. 24)

Malerba underlines the importance of firm heterogeneity in sectoral systems.The degree of heterogeneity in terms of types, competencies, behaviour, and organizations may be resulted from the "characteristics of the knowledge base, experience and learning processes, firm-specific interactions with demand; the working of dynamic complementarities; firms' histories; and differential rates and trajectories of innovation and growth" (Malerba, 2004, p. 25)The agent heteregoneity is different sectorally.

Agents are not limited to the firms in the sectoral systems; non-firm organizations such as universities, financial organizations, government agencies, local authorities and many more can be mentioned in their relation and affect on sectoral systems as well. Malerba's own example for explaining sectorla differences in their relation to specific agents in specific sectors includes biotechnology and the role of venture capital compared to military in initial stem of semi-conductors. (Malerba, 2004, p. 25)

2.3 Institutions

The third building block of the sectoral system is the institutions. Institutions may have great impact on differentiating sectors from each other. Institutions are wide enough to include norms, routines, common habits, established practices, rules, laws, standards etc. Institutions hold a position that shape agents' knowledge base as well as interaction between agents. (Malerba, 2004, p. 27)

Even though many institutions like patent system cover national boundaries, they still have differences in their relations with different sectors. Formal education outputs, sectoral labor markets, sector specific R&D labs, incentives or financial institutions exist as well. Standards and regulations are more important for military or health related sectors. Malerba points out that "Sectoral institutions may emerge either as a result of deliberate planned decisions by firms or other organizations, or as the unpredicted consequence of agents' interaction. This

requires a careful examination of each specific case of sectoral system evolution." (Malerba, 2004, p. 27)

2.4 Demand

The role of demand in sectoral systems and in innovation process focuses on on users, customers, public procurement and regulations. Demand includes individual consumers, firms and public sector with specific knowledge, learning processes, competencies and they all are affected by institutions. In sectoral systems demand which is an important factor in shaping production and innovation is not seen as a group of similar buyers but instead it is shaped by the interaction of different actors and out of effects of various institutions. (Malerba 2004)

Malerba locates demand as a powerful tool in a sectoral system represented by the interaction of the agents and the results of institutional boundaries. Demand can be either a stimulus for or an obstacle in front of innovation. Demand is the determinant in technologies and thus it creates the problems that firms have to solve in relation to their productions. Demand shapes the incentives and constraints on organizations as well. Heterogeneous firms with different interactions and organizational behaviours create differences in production and innovation as well even in the same sectoral system. (2004)

2.5 Sectoral Systems of Innovation in Developing Countries

For Malerba, derived from various case studies, concludes some key points on sectoral systems of innovation in developing countries. Accordingly, for him, economic development and its realtion to innovation needs a detailed understanding of the relevant sectoral system. He suugessts that, "the awareness of the key differences existing across sectoral systems allows an understanding of why some factors affect innovation in some sector and not in others and why some policies have a big impact in some sectors and a weak one in others." (Malerba & Mani, 2009, p. 22)He further mentions the separation of research from development and production capabilities as a harmful factor for innovation and development. The case studies in developing countries refer to the need for public policy receptivity to both the positive feedbacks but also to the blocking role which may be caused by the links and interdependencies

between different sectors. Another key point is that institutions such as industrial associations may play a key role in coordination and networking mechanisms and depending on the instruments, timing and sectoral context, government can also be active as a facilitator or an obstacle for a sectoral system of innovation.

2.6 Perspective

The sectoral approach to innovation requires a comprehensive glance to many factors which are grouped in three building blocks – knowledge base, agents and institutions at the same time. The dynamic nature of the sectoral systems of innovation perspective also requires a historical evaluation of these factors as well. An all-inclusive analysis of medical devices sector would be a huge study thus, this thesis is limited to the current environment, with the emphasis on the knowledge base, main actors and institutions evident in medical devices sector in Turkey. The subsectors of medical devices which have their own spesifities in terms of purchasing methods, production methods, and relation to the knowledge base (proximity or distance) would be better to be analysed on their own. Throughout the thesis, the subsectors will be mentioned but not analysed broadly.

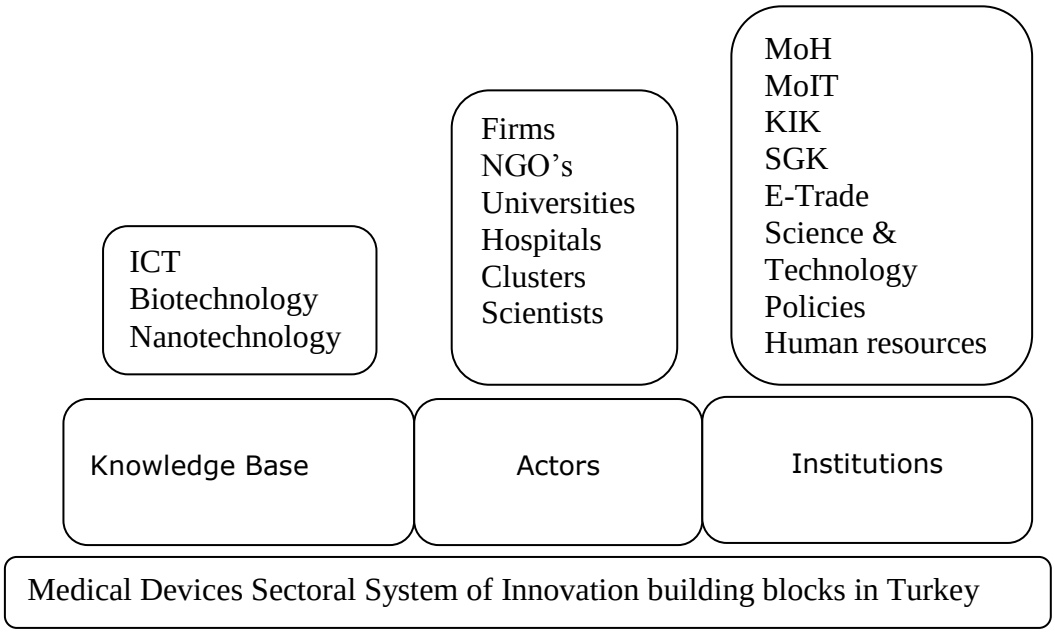


Figure 2.1. Source: Own compilation

CHAPTER 3

KNOWLEDGE, INSTITUTIONS AND ACTORS IN MEDICAL DEVICES SECTOR IN TURKEY

Medical Devices sector is a high technology multi-disciplinary sector whose components are medicine, engineering, information technologies at the simplest. It is in close relation with pharmacy and has been reported to converge with pharmacy as well. This chapter aims to put forward the main building blocks of the medical devices sector in Turkey. Whlie doing so, pharmaceuticals are taken as a reference point at times since medical devices and pharmaceuticals are two relevant components of a healthcare supply and pharmaceuticals are subject to more variety and number of studies than medical devices.

The wide scope of medical devices was introduced in Introduction. This chapter focuses on the knowledge base, actors and institutions in Medical Devices Sector in Turkey.

3.1 Pharmacy and Medical Devices: Similarities and Diversification

Pharmaceuticals and medical devices are both indispensible components of health-care providing. Healthcare professionals utilize the devices and pharmacy in order to cure or alleviate any health problem. The major similarity between pharmaceuticals and medical devices are that they are both essentials of healthcare and thus they are needed extensively in large geographical areas and they have to be available for all in equity (as far as the universal health care limits suggest). This availability is offered via local pharmacies in pharmaceuticals. On the other hand, medical devices, with their wide range in diversity and difference in use, cannot be offered in pharmacy like single shops. Yet, all healthcare providers still use at least some of the devices according to their scale. Furthermore the devices are also significant in determining the patient potential and variety in a hospital since the availability of a specific device results in increased diagnosis range. To be more explicit, having urology related devices in a hospital attracts the patients with the related problems and vice-versa. Accordingly, hospitals mostly opt for capable devices. The geographic distribution of devices require their disperse repair and maintenance

services as well as a nation-wide sales network. Thus pharmaceuticals can be considered to have low distribution costs compared to devices' distribution costs. Moreover the service and maintenance requirements are essential in devices with rigid liabilities whereas pharmaceuticals lack this input cost. The service requirements and even the montage of a device may be considered to be undertaken by highly skilled personnel. This people mostly having a degree in an engineering or technical program have to attend various on the job trainings whenever a new product is developed. The working place is mostly a hospital that makes their training more expensive than other vocational education programmes.

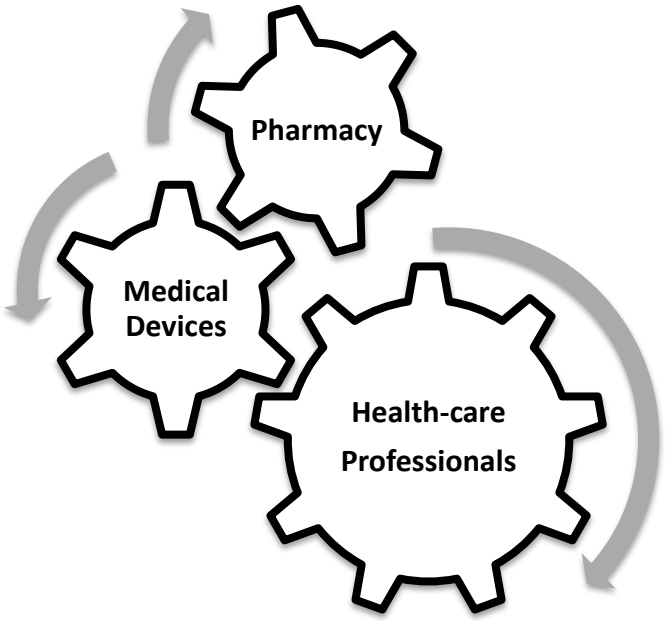


Figure 3.1 Sectoral Relations in Healthcare Soruce: Own compilation

To compare pharmaceuticals and medical devices first we should mention their function in healthcare. Pharmaceuticals are therapeutics and used after a diagnosis or at least a suspicious projection like in vaccines. On the other hand, Medical Devices can be used for diagnostic, therapeutic, monitoring purposes. Their use in diagnostic and monitoring purposes makes them active in preventative healthcare or early diagnosis. The improved dimensions in medical devices with their convergence in pharmacy also enable them to be better therapeutics in some cases. Pharmaceuticals are developed in pharmacology, chemistry, (nano)biotechnology, and genetic engineering but medical devices are

developed mostly in mechanical, electrical and/or materials engineering and converge with pharmaceuticals and in given situations medical devices may include pharmaceuticals as well (ie. drug eluting stents). As can be found in Table 3.1, pharmaceuticals are biologically active and effective when absorbed by the body on the other hand only active implantable devices are "active" in the body, other medical devices act on physical means in contrast to metabolical means.

In pharmacy the number of products is limited and they are developed by trial and selection on the basis of quality, safety and efficacy. On the other hand in Medical Devices there are over 10.000 devices and this may increase to millions if we consider the size and model differences. Medical devices are designed specially to perform definite functions based on quality, safety and performance. The innovations in both are continuous and improvements on products are effected from biotechnology and nanotechnology. However, in pharmaceuticals innovation is a result of a laboratory work yet in medical devices innovation is the result of insights from clinicians. Furthermore, in pharmaceuticals the trials are simple to perform and drugs either work or don't work and accordingly the efficacy and efficiency easy to prove. In contrast, randomized control trials[1] are difficult to perform in medical devices. Besides, their efficacy and efficiency, which cannot be proved before product is used, also relies on other agents in the system like the experience of the physician, the quality of the hospital etc. Operator skill has been mentioned as a factor below in Table 3.1

The products in pharmacy have long product lifecycles. The innovations in drugs are mostly radical innovations that are more substantial compared to the innovations in medical devices. On the other hand medical devices have short product lifestyle and investment recovery period as long as 18 months (the KCE report mentions 2 to 4 years in Table 3.1) and new devices bring added functions and clinical value based on incremental improvements. (Eucomed, 2007, Medical Technology Brief)

[1] Randsomized Control Trials are a scientific experiment method used commonly in heathcare to test efficacy and efficiency. The distinctive feature of the usual Randsomized Control Trials is that subjects, after assessment of eligibility and recruitment, but before the intervention begins, are randomly allocated to receive one or other of the alternative treatments under study usually without knowing which treatments they are recieving.

Table 3.1: Differences between medical devices and pharmaceuticals

	Medical Devices	**Pharmaceuticals**
Therapeutic effect	Effective by mechanical and/or electrical action	Effective when absorbed and metabolised by the body
Operator skill	Outcomes often depend on surgical skill	Rarely relevant
Product life cycle	Relatively s*h*ort (2 – 4 years) [a]	Longer (10 – 20 years)
Physical infrastructure	Often necessary for delivery of treatment	Usually not required
Delivery environment	Often delivered in hospitals (public and private)	Usually administered in community settings
HTA processes	Recently established processes	Long-established processes
Evidence base	Good quality scientific data often not available	Good quality scientific data usually available

a The Therapeutic Goods Administration observed that there are some devices (such as syringes, bandages, condoms and surgical instruments) which have changed little over the past 10 – 20 years (DoHA , sub. PR56)

Source: Henry, DA., Hi**l**l SR. Assessing new health technologies: lessons to be learned from drugs. Medical Journal of Australia. 1999; 171(10):554–6. Qt.in KCE reports vol. 44, 2006

3.2 Knowledge Base in Medical Devices

ICT, Nanotechnology and Biotechnologies are admitted as revolutionary technologies in the sense that Perez put it, they have clearly low relative costs, unlimited supply for all practical purposes, potential all-pervasiveness and capacity to reduce the costs of capital, labour, product as well as changing them qualitatively (Freeman and Perez, 1988) Medical Devices is a sector where we can observe increased use of these three revolutionary technologies The rapid change medical devices are subject to, plus ever increasing health costs linked with the innovations of medical technology on the one hand, and on the other, the growth potential with the value added they create, medical devices is a challenging sector to analyze.

The ICT use in medical devices is spread in nearly all subgroups possible, and the networking of medical devices, tele-consultancy, broadband use for education purposes, and distance patient monitoring are available technologies. The revolutionary character of ICT is not questioned in healthcare technologies.

On the other hand, as Miles (1997) puts it, Biotechnology has revolutionary characteristics in the sense that it is based on fundamental discoveries of life sciences, and especially DNA as a molecular carrier of genetic material storing information. The technology it suggests includes techniques to manipulate, alter, and synthesize the genetic material in addition to techniques for plant cell and tissue culture for accelerated propagation of useful plants or other organisms. It is marked with the downstream processing techniques for extraction, treatment, purification and conversion of useful materials following the biomass production stage.

Again Miles (1997) foresaw nanotechnologies as revolutionary in their advanced material changes where the question is neither a new material finding nor even applying a particular technique or set of instruments or producing but the allowance for new processes to be applied to the production of materials with the help of detailed manipulation of material in atomic or molecular levels. Miles mentions a %5-10 percent output increase as well as %40 decrease in cost of manufacture by the help of nanotechnology. The key features of nanotechnology that Miles mentions are, the complexity and multidisciplinary knowledge inputs necessary, integration of function which is more performance characteristics

packed into smaller areas and volumes, reduced steps in manufacturing process. Additionally the nanotechnologies promise an added value due to high unit prices related to information content and level of processing required and an increased variety with broad range of materials adapted to user requirements. The new materials science has effects on all sectors of manufacturing industry (and most of the subsectors of medical devices as well) and likely to have multiplier effect. Even the traditional materials with saturated markets show rapid market growth with the use of nanotechnology and the life cycle of new materials are suggested to have short cycles explained through the competition among continually evolving materials and shorter life cycles. (Miles, 1997)

3.2.1 Convergence in Medical Technologies

The use of interdisciplinary knowledge in Life Sciences is mentioned sometimes as Convergent Medical Technologies[2] as well, includes mainly Biotechnology, Nanotechnology and Information Technologies. Venn diagram below shows the use of each scientific "area" in medical technologies. Medical devices being an important part of medical technologies also experience interdisciplinary convergence.

Factors behind the growth of convergent medical technologies are

- Advances in minimally invasive surgery (MIS)
- Miniaturization of electronics
- Closing the loop between diagnostics, therapeutics – also known as theranostics. (convergence of pharmaceuticals with medical technologies
- The rise of personalized medicine including pharmacogenomics.
- Increasing demand for convenience
- Growing importance of safety

FDA (Food and Drug Administration, USA) distinguishes between medical products as biologic, chemical or as device. The first being a result of biotechnology, the second is a pharmaceutical product and the third is neither chemical nor biological but a device using electronics and information /

[2] The interdisciplinary aspect has been focused on in some Conferences like BioDevice Partnering (June 2007, by Eucomed, EU), BioMedDevice (October 1997, BayBio, USA) PharmaMed Device (April 2007 by MDMA, USA) , Convergent Medical Technologies, (November 2005, MEDEC, Canada)

communication technology. Yet, the convergence in medical technologies results in different combinations of these; such as: orthopaedic implants with biotech support or drug eluting stents, PET imaging using radiopharmaceuticals. Products using wireless or distant communication tools are under their way to enable home diagnostics and monitoring. IT use in hospital management systems and for patient medical records are increasingly available.

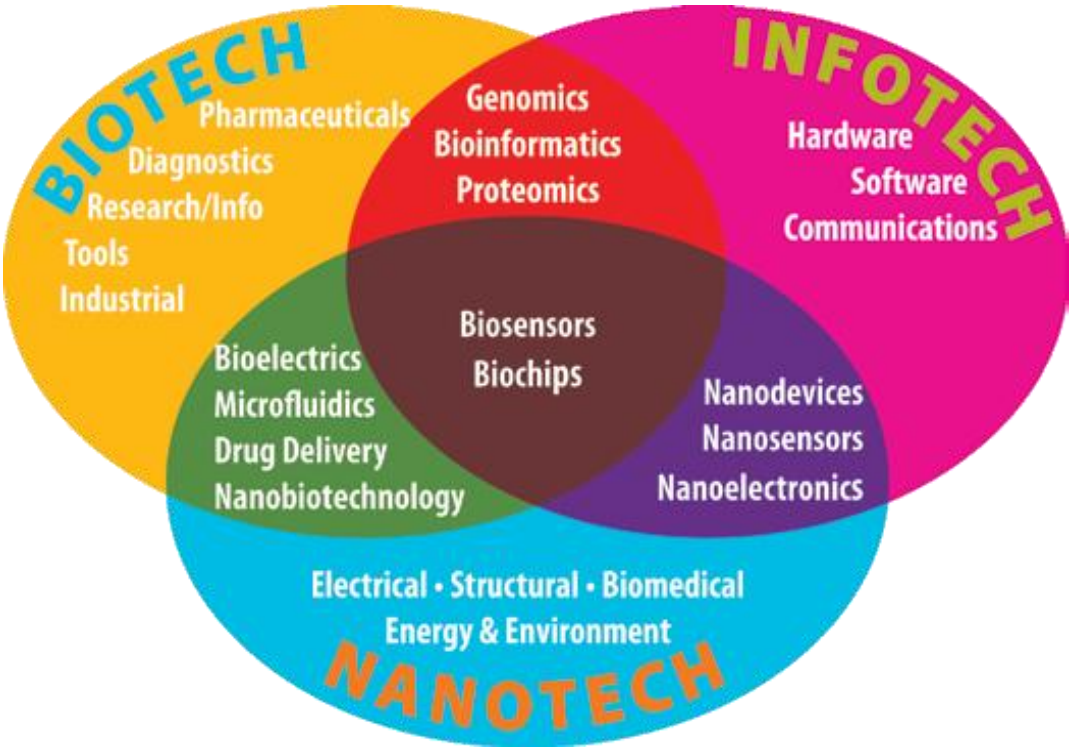


Figure 3.2

Convergent Medical Technologies [Adapted from: Biology, Bioconvergence, Information and Enterprise: Taking the Broad View, May 20, 2004, Allan Barrel]

Source: Qt in (Preliminary Business Plan North Caroline Advanced Medical Technologies Center, 2010)

The North Caroline Advance Medical Technologies Center mentionsin their strategic plan the interdisciplinary aspect of the area as a challenge for medical devices producers since the upcoming technology requires physicians, engineers, biologists, material scientists, nanotech experts, IT specialists, optical knowledge, as well as biotechnology, genomics and data expertise that reflects not only on R&D but also on the production techniques and processes. In other

words, not only R&D but also production techniques and processes require multidisciplinary human capital.

3.2.1.1 The Use of Biotechnology in Medical Devices:

After the discovery of DNA in 1953, the biological investigation of the DNA has reached a point where human beings play on the structure of it. Biotechnology can provide new materials like Bio-Steel having a spider net gene contained in goat milk. In 2001 the Human Genom Project has been successfully completed and genetics started to speak of 500 years of life-spans for human. (Yerebakan & Karakuş, 2009). For now, bio-technology has a great use in pharmacy especially in drugs of cancer or hepatitis. Some of the bio-sensors produced can be implanted into human body and communicate/ report the change or activate some mechanisms. To produce biotechnological material, micro-level mechanisms are suggested to be sufficient. However, with the progress of nanotechnologies, biotechnology seems to converge and make use of nanotechnologies as well.

Biochips

The first bio-chip is produced to allow early diagnosis of liver diseases especially of cancer. Another biochip allocates pathogens that cause epidemic infections. Green-chip is a considerably new bio-chip having 30.000 spores of viruses, bacteria, parasite and fungi. When the potential carrier blood contacts the chip, it alerts the active spores and helps categorizing the organism. Life-sciences and Genetics are provided significant budgets in EU FP6 and 7. A new generation Eliza test and some cancer kits are being developed by these funds. Use of nanotechnology in biochips is a promising technology and set goals with (European Commission, 2010)document.

Re-combinant DNA & protein engineering and biotechnology promise variety of new methods in diagnosis and treatment.

Purification and production technologies for proteins cheaply and easily in order to use in human health has started to be realized. Enzyme and particularly monoclonal antibodies in cancer treatment promising to produce cheaper and better quality facilities emerged. Producing steroid hormones, antibiotics and

vitamins with increased efficacy, decreased side-effects decreased costs can be possible.

The hardware and machinery needed to exploit biotechnology is expensive compared to nanotechnology and include high definition microscopes, to monitor and measure ecological tocsins, optoelectronic laser technology needed to analyze molecules and patient monitoring, fiberoptic sensors, otomation systems that eases the process of purification of biological molecules, analysis and sterilization, automated computer aided laboratory systems, image processing and analysing systems specialized on medicine and biotechnology, gene sensors, laser lithography etc. (Yerebakan & Karakuş, 2009)

3.2.1.2 The use of nanotechnology in Medical Devices:

The improved ability of manipulation of materials at nano level across many disciplines like physics, chemistry and biology enables human-being to have an increased control over the material and thus the product. The word nanotechnology implies the technological field where one deliberately creates nanostructures for manufacturing functional nan0*systems or entities with at least one nanoscale dimension. Nanotechnology with its application to material science, has been diffused to many areas of human life including agriculture & food to computer, textiles and also healthcare and medical technologies.

Concerning medical technologies the effect of nanotechnology is not limited to the improved materials and devices but also it has the potential in creating smart devices and technologies. It is expected to increase the scientific and economic activities in medical development. The devices that already adopted nanotechnology can be mentioned as; contrast agents incorporating nanoparticles for greatly improved imaging, bone replacement materials incorporating nanostructured materials allowing better integration in the body, nanostructured biomaterials for use in scaffolds for regenerative medicine, wound dressings incorporating antibacterial nanoparticles, orthopaedic implants with nanocontoured surfaces to improve fixation in bone. (EUCOMED, 2008)

The suggested benefits of these new technologies in the healthcare are "early diagnosis, perhaps even at the stage of initial onset of a disease, more effective treatments and therapies, better prognosis, earlier recovery of the patient and return to a contributive role in society." (Wilkinson, 2009)

The main goal of the nanodiagnostics is to facilitate early diagnosis of the diseases, if possible as a single cell. Therefore, the effectiveness of both in vivo and in vitro activities are needed to be improved through research and development activities in the area of nanotechnology which provides sensitive and specific, thus the reliable diagnostic materials such as these and further. Also, nanomaterials enable to take different measures at a time and fills different needs of different phases, from sample preparation to detection, with a device. Last but not the least; such nanomaterials are powerfully built and well-developed to be used by patients themselves, easily.

Drug Delivery Systems

The basic objective of the drug delivery systems is that the pharmaceuticals target and affect selected cells and receptors of the body. Newly developing drug delivery systems aim to find better ways to deliver the pharmaceuticals, to better target the selected cells and receptors, to increase acceptability, and to increase the access to pharmaceuticals by reducing the costs. Nanotechnology helps the development of such new drug delivery systems through drug delivery microchip technologies which are the products of the electronic industry and release and production techniques. If pharmaceuticals that are not easily soluable be properly encapsulated, that is as nanoparticles, this enables the delivery to be managed and prevents the pharmaceuticals to be solved too early, as a result, increases affectivity and decreases the risks and side effects of the pharmaceuticals. Thus, such nanoparticle delivery systems are significant to be used especially for the delivery of the pharmaceuticals that are highly affective but that have heavy side effects. This newly developing drug delivery systems promises to be able to further target the selected cells and receptors of the body. It is foreseen that nanoparticles can be developed in a way to carry to the diseased cells or receptors the needed content, even genetic contents, which further maximizes the affectivity and minimizes the risks and side effects of the pharmaceuticals. Further, nanoparticles are expected to be able to manage the dosage of the drug, besides the timing and locale, which would prevent the drug-related poisoning.

Another significant advantage of the use of nanotechnology in medicine is that it supports regenerative medicine. Regenerative medicine facilitates body’s own repair mechanisms to prevent and treat diseases. With nanotechnology, body’s

own repair mechanisms can be stimulated at the cellular and molecular level, to seek remedy of chronic conditions, rather than delaying its progress or easing its symptoms. It helps the development of disease modifying therapies and tissue regenerative processes. Also, nano-assited technologies trigger the development of biomimetic materials which again helps the development of tissue regenerative processes.

Regarding these, nanotechnology is expected to contribute especially to the treatment of common and severe diseases like cancer, cardiovascular system diseases, neurological diseases, blood diseases, lung diseases, inflammatory or infectious diseases, diabetics, and orthopaedic problems.

Better targeting diseased cells, nanoparticulated pharmaceuticals aims directly and more effectively the cancer cells, with accurate timing and dosage, and with minimum risks and side effects. Nanotechnological devices helps to better monitor the cardiac patients and cardiovascular diseases which serves both their diagnosis and treatment. In the same way, nanomedicine, nanodevices and artificial nanostructures serve to improve the diagnosis and treatment of neurological diseases which one of the most complex areas of medicine. Basically, nanotechnology is significant for the improvement of, every single area of medicine, from the most basic to the most complex, from inflammatory diseases or orthopaedic problems, to diabetics, blood diseases or to the most complex surgical operations.

The miniaturization of electronics which has enabled other areas of technology convergence such as cell phones and the like also enable such implanted devices to have increased capabilities – thus enabling the field of "smart devices." The growth of personalized medicine goes hand-in-hand with the convergent medical technologies. "Personalized" medicine, by definition, includes not only a therapeutic component but also a corresponding diagnostic aspect. To "personalize" a medical treatment for a particular patient requires a more personalized and specific diagnosis which has led to the growing field of pharmacogenomics and a tighter link between diagnostics and therapeutics which has led to the concept of theranostics. Another feature of the personalized medicine is not just a higher degree of specificity from the genomic perspective (e.g. pharmacogenomics) but also a better personalization and specificity from an anatomic perspective. The example of drug-eluting stents is certainly

illustrative as the powerfully toxic drugs used in such stents could not at all be administered systemically at the therapeutically relevant doses. Putting them directly on a stent at the localized site for their action is what makes the entire thing work. That's the increased effect of drug-device combinations with increased safety.

Such use of convergent medical technologies also brings new technological paradigms with itself and serves to the contemporary sensitivities of the modern medicine. The rise of theranostics – the closer link between diagnostics and therapeutics – is as much a new technological paradigm as well as a payment of homage to the increasing demand for rapid information delivery and convenience by our society.

Nanotechnology has a wide range of use in Medical Technologies one of which is in Surgery. Minimally invasive surgical techniques (such as the catheter techniques that have enabled drug-eluting stents and stenting more generally) make it possible to implant devices in patients with less risk. As it becomes easier and more accepted for patients to have these devices implanted, new markets, new capabilities and new indications arise for biotech/IT/device combinations of a nearly infinite variety.

The use of nanotechnology in medical diagnostics, in "in vitro" applications with biosensors and integrated devices and in "in vivo" applications with implantable devices and medical imaging, has its roots from the 19th century, from the idea that cell is the core of the health and disease. Therefore, a comprehensive understanding of the structure and working of a cell was needed. Here, nanotechnology comes into the scene.

Imaging, in-vivo Diagnosis and Theranostics

Nanotechnology is set to play a massive role in the development of more specific, accurate and less invasive diagnosis of diseases and metabolic states. The size range enabled by new tracing and imaging agents based on nanotechnology allows for imaging down to the cellular, or even molecular, level. The most promising areas for imaging using nanotech-based agents are magnetic resonance imaging (MRI), ultrasonic imaging and optical imaging. These technologies offer the possibility of safer, less invasive and much more targeted and precise imaging and diagnosis. Combined with suitable targeting

molecules and either drugs or other nanoparticulate or encapsulated materials, e.g. semimetallics, this opens up also the possibility of combining, possibly very early, diagnosis with treatment, so-called theranostics.

New imaging techniques provided new opportunities for in vivo applications. Imaging techniques and implantable devices are in vivo diagnostic tools. In principle imaging techniques are based on the idea that the tracers and contrast agents are injected into the body and colour the diseased cells. Such imaging techniques involve optical imaging, X-ray imaging, spectroscopy, nuclear imaging, Magnetic Resonance Imaging and ultrasound. It is foreseen that nanoparticles might be used as tracers and contrast agents to colour the diseased cells, and that is even at the molecular level. This way, nanotechnology helps imaging techniques by allowing targeted molecular imaging. Quantum dots are such nanoparticles, fluorescent nanocrystals that can target a single specific cell and fluoresce it. Targeted molecular imaging also allows to control the drug release and to be able to see unwanted accumulation of drug. Yet, the main benefit of such nanoimaging techniques is that they enable earlier diagnosis and help to detect and follow the disease stages.

In-vitro Diagnostics

Before the use of nanotechnology, in vitro diagnosis was based on laboratory tasks, which had its disadvantages. The laboratory based diagnosis was reached through testing of samples from the body, such as samples from blood, tissues, or body fluids. These procedures, procedures to collect and test the samples had its disadvantages, as the tests required long time which was a much significant disadvantage for urgent cases, and which increased the cost of the tests, as small samples might lead to inaccurate results, as labour intensive sample collection led into poor standardization, and as it was difficult to integrate different parameters of the tests and reach accurate conclusions. Electronic industry provided solutions to these short comings of the traditional laboratory based diagnosis with nanotechnology. Nanotechnology enhanced the standards and more importantly the reliability of the medical diagnostics. Nanotechnological devices improved the sample collection and testing, standardized sample collection techniques, enabled much faster and effective testing of even smaller samples, and made it possible to integrate different parameters and to reach dependable results. Nanotechnological devices made it

possible to work on a single sample for the diagnosis of different diseases and to work on different samples for the diagnosis of a disease. These advances in the medical diagnostics made it even possible to produce personally tailored pharmaceuticals. And yet, the most interesting and unforeseen outcome if the nanotechnology based medical diagnostics techniques is that, these techniques found also place in nonmedical areas such as environmental monitoring and safety. Convergent nanotechnologies, especially the convergence of nanotechnology and medical imaging, provided new possibilities, such as the detection of a single cell in any complex biological environment, through biosensors.

Biosensors are in vitro diagnostic tools, which are sensors with biological elements to detect and signal the presence, concentration and activity of a single specific biological cell or molecule. Biosensors detect a single biomolecule by following the biochemical changes. Then this biochemical signal is transferred into a quantifiable signal. This way, nanoanalytical tools provided new opportunities for in vitro applications (European Commission European Technology Platform on NanoMedicine). The area of in-vitro diagnostic medical devices is one of great growth and potential for nanotechnology. The development of micro- and nano-fluidic systems allows for the use of tiny amounts of analyte and the degree of miniaturisation possible will allow for the development of true "lab-on-a-chip" devices capable of simultaneously carrying out dozens, or even hundreds, of analyses in virtually real time. Linked to other devices, this will allow for continuous monitoring of the patient's condition and variations in treatment, e.g. drug delivery, to take account of the patient's actual needs.

3.2.1.3 Economic Aspects of Nano-Bio Technologies

The European Technology Platform on NanoMedicine Nanotechnology for Health Vision Paper and Basis for a Strategic Research Agenda for NanoMedicine (2005) suggests that the nano-medicine as an important technology in both creating a value in social welfare but also creating economic value as well. The definition suggested is as: 'systems and technologies for healthcare, aimed at prevention, diagnosis or therapy'. Market data is not readily available on Nanomedicine nor nano-bio technologies in health-care. However, the Vision Paper mentions medical devices and drugs aer represented in 2003 with an end-user value of €

535 billion, with drugs holding € 390 billion of this value. Globally this market has been growing at a 7 to 9% annual rate, with variations according to country, technologies and market segments. The introduction of novel nanotechnologies can be expected to give rise to a much higher rate, by providing innovative solutions and more precise care and new information for preventive medicine.

The market can be further segmented into areas where NanoMedicine might have the highest potential of penetration, such as in-vitro diagnostic products, patient monitoring systems imaging systems or imaging contrast agents. In a medical devices market of € 145 billion in 2003, in-vitro diagnostic systems represented € 18 billion, or 13% of the total. It is expected that nanotechnology will have a growing impact on the growth of this segment with the reason mentioned in the previous section. According to the Vision Paper, Medical imaging systems represent € 14.5 billion, or 8% of the total devices market. Imaging tools and imaging agents (including contrast media and radiopharmaceuticals) represent € 4 billion, or 3%. (2005). Nanoscale imaging techniques mentioned in the previous section can refer to a potential growth of this segment as well. As the Vision Paper puts it, "the sale of tools dedicated to molecular clinical and preclinical imaging represents € 0.8 billion out of the € 14.5 billion total, and the patient monitoring market represents € 1.5 billion."

NanoMedicine have the potentiality to affect all segments of medical devices, such asnew materials for surgical implants, nanometric systems for monitoring cardiac activities or minimally invasive surgery sensors.

The worldwide market for pharmaceutical drugs has been growing at a rate of 7% in 2004. When the drug market is segmented, the global market for advanced drug delivery systems accounts for € 42.9 billion which is 11% of the total. To the Vision Paper,

"Approximately half of this market is in controlled release systems, with needle-less injection, injectable/implantable polymer systems, transmucosal, rectal, liposomal drug delivery and cell/gene therapy responsible for the rest, and is estimated to reach € 75 billion in 2005. Developments in this market are rapid; especially in the sector of alternatives to injected macromolecules, as drug

formulations seek to cash in on the € 6.2 billion worldwide market for engineered protein andpeptide drugs and other biological therapeutics." (2005)

Commenting on the economic potential of Nanomedicine, one should approach all the biotech companies as they are directly involved in the development of new molecules, and also in the development of new tools for accelerating the discovery of appropriate molecules. According to the Vision Paper of European Technology Platform, in 2005 half of the new molecules discovered worldwide are by biotech companies and the number of companies active in US are over 300 and more than 4000 worldwide which work on developing drug-delivery platforms, including therapies targeted to the site of the disease, as well as drug-containing implants, patches and gels (European Commission European Technology Platform on NanoMedicine, 2005).

As evident in Figure 3.3, from all medical technologies (drugs and medical devices) medical devices market is 145 billion € and pharmaceutical drug market is 390 billion €. Among these the share of medical devices other than imaging remains considerably low in share as 4 billion €. To give concrete numbers, of 145 billion €'s market, 126,5 billion is the category of " other medical imaging systems" while, molecular pre-clinical and clinical imaging has 12,20 billion € market, patient monitoring market is 0,80 billion €, imaging tools and imaging agents has a 1.50 billion € market.

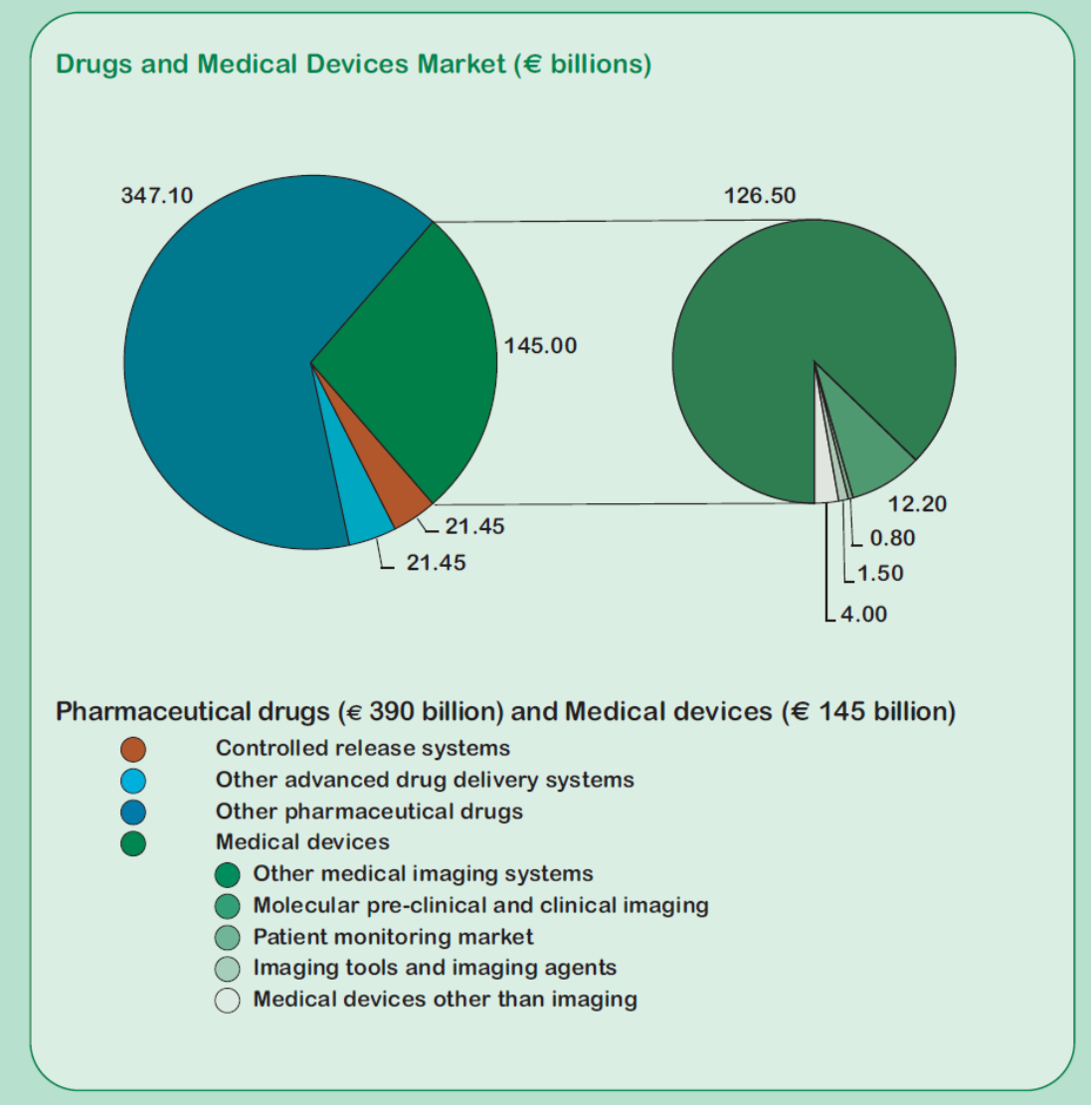


Figure 3.3 Drugs and Medical Devices Market

Source: European Technology Platform on NanoMedicine Nanotechnology for Health Vision Paper and Basis for a Strategic Research Agenda for NanoMedicine

3.2.2 Conclusion on Knowledge Base in Medical Technologies

Nanotechnology has enormous impact on many areas in medical technology. It is providing tremendous opportunities not only to improve materials and medical technology products but also to create novel "smart" and/or "personalized" devices and technologies. Combined with biotechnology the potential for medical technology is only limited to our imaginations. However, the risk benefit analysis and the behaviour of nanoparticulate materials in human body and their differences from "bulk materials" has to be analysed deeply both with a healthcare and with a regulatory aspect as well. Such a systematic approach to safety is a normal practice in the medical technology industry and is required by regulation.

The challenges for these convergent medical technologies, approval times, intellectual property rights, ethical considerations, regulative harmonization issues are foreseen.

The interdisciplinary character of the convergent medical technologies also face a regulatory challenge where the progress is more rapid than the regulations and the human resources in the regulatory bodies are far beyond the requirements of the interdisciplinary technologies. The safety concerns, increased health expenditures together restrict acceptance of new devices. This issue will be mentioned later in the reimbursement policies.

3.2.2.1 Knowledge Base in Medical Technologies in Turkey

Nanotechnology, which means the change of the structure of a material at nanoscale with providing the material new features while removing the unwanted, is foreseen to foster innovative development in MDs especially in implantable devices. Currently there is no specific regulation on nanotechnology use in MDs or medicines neither in EU nor in TR. The European Medicines Agency published a review in 2006 on nanotechnology based medicinal products. Within the existing regulatory framework medical devices are acted according to their risk classes where nanotechnology is not an ingredient and it is declared that risk classifications cover the risks associated with nanotechnology. Implantable devices, where nanotechnology has a wider use, are currently in highest possible risk groups. Nonetheless, a common nanoparticles terminology in particular, and

a common physicochemical characterisation in general, are being developed in Europe.

Considering the medical devices in Turkey, the high tech proponents of biotechnology and nanotechnology are evident in Turkey as well. Nanotechnology use has a lower initial investment cost in tools compared to biotechnology which requires a considerable investment in manufacturing goods as well as human capital. Nanotechnology use in materials has been active in Samsun especially in surgical equipment production. However as mentioned above the technology is rapidly increasing in nanotechnology use in imaging or therapeutics. On the other hand use of nanotechnology in a variety of subsectors are observed such as surgical room decoration equipment such as switches or wall paints with anti-bacterial etc. Biotechnology is harder to penetrate in production of traditional sectors. Still, there are a few firms in Turkey active in producing biotechnology products such as orthopaedic implants or wound patches that are regenerative. However, they are stressing the testing procedures which ensure their bio-safety are not possible in Turkey by accredited laboratories. In order to get the CE certificate they have to cooperate with notified bodies established in EU since the recently accredited (first in 2008) notified bodies in Turkey are active in lower levels of risk classification. For further insight on risk classifications please refer to entry to market conditions in section on institutions.

The Biomedical Technologies Centre in Hacettepe University which is a university-industry joint venture, applied triple helix model where university, industry and government are proposed to promote innovation. The Biomedical Technologies Centre is found to be an important asset where firms developed their production capacities well forward.

When more generic products are taken into account Turkey has the production capability of nearly all dental machinery and equipment. Some examples of devices that are produced in Turkey are: "the hospital equipment and textile such as hospital beds, armchairs, sedan chair, bones, masks, apron dresses; Operation Room devices such as operation tables, lamps, anesthesic equipment, all surgical equipment such as blades, surgical containers, surgical engines and electro-cautery devices, all orthopaedic equipment including implants or operation tables, medical gas systems, biotechnology products, laboratory

devices such as centrifuges, dry air sterilisation devices, some imaging devices such as a variety of X-Ray devices, Angiography devices, lithotripters, defibrillator, phototherapy devices, ambulances, many kinds of sterilization devices, and many single use devices and medical consumable materials. The

Figure 3.4 Map of the medical device production in Turkey, 2010

Source: TOBB Industry Database

The production in Turkey is dispersed around 33 cities shown in Figure 3.4 for 2010 and İstanbul, Ankara, İzmir, Samsun and Mersin have the biggest share. The map is not including detail enough to show the production sub-groups which is important in having a deeper understanding.

The GMDN categories which can be listed as follows have all different knowledge base needs and neither of them are homogenous in terms of complexity and technology required. 1. Active implantable devices: 2. Anaesthetic and respiratory devices: 3. Dental devices: 4. Electro-mechanical medical devices: 5. Hospital hardware: 6. In vitro diagnostic devices: 7. Non-active implantable devices: 8. Ophthalmic and optical devices:9. Reusable devices: 10. Single-use devices: 11. Assistive products for persons with disability 12. Diagnostic and therapeutic radiation devices: 13. Complementary therapy devices: 14. Biologically-derived devices: 15. Healthcare facility products and adaptations: 16. Laboratory equipment.

Not all categories are fully produced in a country, and product group specialization is observed in EU countries and USA. (Pammolli, Riccaboni, Oglialoro, Magazzini, Baio, & Salerno, 2005) Turkey has producers active in all of these categories even in the most high-tech ones. Non-active implantable devices, dental devices and hospital hardware subcategories are produced in Turkey nearly including all devices these subcategories include. To see the import and export values of these devices grouped from GTIP (HTS) codes into GMDN codes see Appendix M.

The Medical Devices has subsectors within, which can be mentioned as "high R&D-intensive" (such as convergent medical technologies, nano-biotechnology, active implantable devices etc) and "low R&D-intensive" (such as syringes, medical disposables etc). The "creative accumulation" in medical technologies are evident in some subsectors such as imaging technologies, active implantable devices or some segments of laboratory devices. There is little number of firms that produce these devices world-wide and a specialization among countries on different subsets can be pointed. (Pammolli, Riccaboni, Oglialoro, Magazzini, Baio, & Salerno, 2005).

Even though the firms in medical devices sector mention in the personal interviews, an ease in entering the market, due to its specific regulations, distribution networks it require and the rapid change existing in the sector, it is not easy to enter the market even if the technology is available to a firm. Even existing producers are experiencing marketing problems mostly because of a prejudice on local production.

Moreover, even though there are generic products such as hospital hardware or medical textiles, as put by Malerba (2004) traditional sectors are not necessarily low-tech or do not necessarily have low knowledge intensity; often they are innovative and they increasingly require the use and integration of advanced and differentiated knowledge which is the case valid for medical devices as well. Medical textile (including a range of different products from aprons to band aids) and even the disposables are affected by the progress in nanotechnology and biotechnology.

3.2.2.2 Medical Devices and Technology Penetration

Table 3.1 shows us the technology penetration of some high technology segments of medical devices.

Considering The MRI units per million population Turkey has doubled the numbers of Czech Republic and Slovak Republic from 2004 to 2008 while all countries preserve their number approximately stable. Even though an increase can be observed the numbers in these countries are not that high. The only countries with lower numbers of MRI units are UK and Hungary. On the other hand, Japan, USA, Italy and Greece hold the first ranks. Considering The CT numbers per million population Japan is holding 9 times CT's of Turkey. And USA Italy and Greece with 3 times more CT's than Turkey, again hold the upper ranks. Although the data is not comparable in Radiation Therapy devices the number of devices Turkey hold seems high compared to other countries. Since these devices are more expensive than an average medical device, their increase in number means increase of the medical device share in expenditures.

Considering Mammography devices per million population, no radical increases in numbers are observed in four years, and Turkey has a larger number of devices compared to UK but lesser than all other countries. Mammography devices are devices on diagnosis and their efficient and wide use may be considered as a factor that restricts the more expensive therapeutic applications. All these devices has high technology ingredient and are not produced in Turkey.

Generally medical devices are considered to involve two categories, high tech and conventional. The conventional group includes pieces like syringes, gauze, intravenous products, some conventional diagnostic and therapeutic devices, which are marked with high volumes, and low margins. On the other hand there are various new products that include high tech ingredients, as well as new improved products with the help of new technologies of nano and bio-sciences. These products face costly & risky R&D activities. As medical devices need to pass clinal trials, the process might be long as in pharmaceuticals if the device is in high risk categories. Moreover, pre-marketing activities include tedious administrative and regulatory procedures. Even though new products have promising markets and a high growth potential they also face the risk of being obsolete. "For companies specializing in the high tech sector, new products,

introduced within the preceding 2 years, typically account for more than 30 percent of sales. (Standart & Poor's, 2004a). Some companies mentioned to have new products introduced within the preceding year to have a 60 percent share of sales.

Table 3.2 Medical Devices and Technology Penetration Source: OECD 2010

Medical Devices and Technology Penetration

	Magnetic resonance imaging units (MRI)/ mill. pop.		Computed tomography (CT)/mill. Pop.		Radiation therapy equipment / mill. Pop.		Mammographs / mill. Pop.		Kidney transplant procedures / 100.000 pop	
	2004	**2008**	**2004**	**2008**	**2004**	**2008**	**2004**	**2008**	**1985**	**2007**
Austria	15,9	18,0	29,2	29,9	4,5	5,0	n.a.	n.a.	5,4	45,6
Belgium	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	14	44,2
Czech Republic	2,8	5,1	12,6	13,5	9,3	8,6	13,7	13,5	n.a.	n.a.
Denmark	10,2	15,4	14,4	21,5	5,9	11,7	10,0	14,4	10,7	34
Finland	14,0	16,2	14,2	16,5	8,8	8,7	37,7	34,8	13,9	44,7
France	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	8,7	43,8
Germany	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	5	30,6
Greece	13,2	19,6	25,2	30,7	5,3	5,5	36,5	45,0	5	20
Hungary	2,6	2,8	6,8	7,1	2,7	3,4	12,6	14,2	n.a.	n.a.
Ireland	8,0	9,4	10,6	15,1	7,0	8,9	12,6	14,8	n.a.	n.a.
Italy	14,0	20,0	26,0	31,0	4,6	5,9	26,9	30,3	n.a.	n.a.
Luxembourg	10,9	12,7	28,4	27,6	4,4	4,2	21,8	23,4	n.a.	n.a.
Netherlands	6,2	10,4	7,1	10,3	n.a.	n.a.	3,9	n.a.	12,6	41,9
Portugal	5,8	8,9	26,3	26,0	6,0	10,0	34,7	35,4	1,9	47,3
Slovak Republic	3,7	6,1	10,2	13,7	9,3	13,2	13,0	14,1	3,6	15
Spain	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	5,5	43,6
Sweden	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
United Kingdom	5,0	5,6	7,0	7,4	3,9	4,9	8,2	9,0	10,2	34,7
Turkey	**3,0**	**6,9**	**7,8**	**10,2**	**n.a.**	**1,5**	**n.a.**	**10,2**	**n.a.**	**n.a.**
USA	26,6	25,9	32,2	34,3	n.a.	n.a.	n.a.	40,1	11,2	50,7
Japan	40,1	43,1	n.a.	97,3	6,8	n.a.	n.a.	29,7	1,0	4,1

The market of medical devices grows due to the decline in the endemic diseases and correspondingly increasing chronic diseases which in turn also affect the demographic factors of aging population. Another factor that sustains the growth

of the sector is the income growth and the increasing demand for high tech health services as well as the health insurance systems (public or private) developed concurrently. On the other hand, these macro trends that enabled constant growth of the sector yet Medical Devices also face the cost containment policies accompanying global health reforms. Price revisions of the reimbursement prices for MDs often reflect a reduction. The medical devices as a part of manufacturing sector is grouped under NACE DL 33.1 (Medical and Surgical Equipment and Orthopaedic Appliances) yet this classification doesn't include not only high tech chemical and biochemical based devices such as IVD (that are grouped under "chemicals") and medical impregnated products such as gauzes and bandages (that are grouped under pharmaceutical preparations") but also some other MDs. The NACE 33.10 data under-represent the Medical Devices sector in magnitude and in its high-tech components.

3.3 Agents in Medical Devices

Sectoral System of Innovation perspective stresses the agents, their interaction and networking as an important ingredient to understand the innovation in a given sector. Accordingly firms are suggested as key actors around which the innovation, production, sales are occur and firms are the agents realizing the generation, adaptation and use of the new technologies. Firms are in relation to other firms and they can hold a position of user, supplier, and service provider and so on. For sure Agents in a sectoral system of innovation is not limited to firms but include NGO's, Universities, Clusters, Scientists. When we consider medical devices we can include hospitals - healthcare service providers and professionals as well as an important agent.

Medical Devices Sector has a variety of agents in Turkey, firms with diverse functions are evident: manufacturers, distributors and importers, technical service providers, calibration firms. Most of the time, a firm is active more than one area of activity. This multi-tasking may be interpreted as a source of increased interaction among firms. The networks and linkages are left out of the scope of this thesis.

According to the evolutionary theories technological knowledge is not shared equally among firms, nor is it easily imitated by or transferred across firms with lower costs. Due to the tacit part of the technology, technology transfer is not

costless but requires investment of the receiving firm. Since firms operating within a technology doesn't know much about dissimilar technologies of the same sector, they operate not on a production function but rather "localized" around a point which is determined by their technological efforts and skills. Lall quotes Dosi affirming evolutionary theories' success in explaining the "permanent existence of asymmetries among firms, in terms of their process technologies and quality of output". Considering Firm Level Technological Capabilities (FTC) Lall distinguishes between functions as investment capabilities, production capabilities and linkage capabilities and provides a matrix where complexity or difficulty is measured by the activity from which the capability arises (Lall, 1992) In his words,

> Investment capabilities are "the skills needed to identify, prepare, obtain technology for, design, construct, equip, staff, and commission a new facility (or expansion)". Production capabilities are "range from basic skills such as quality control, operation, and maintenance, to more advanced ones such as adaptation, improvement or equipment "stretching," to the most demanding ones of research, design, and innovation." Linkage capabilities are "the skills needed to transmit information, skills and technology to, and receive them from, component or raw material suppliers, subcontractors, consultants, service firms, and technology institutions." (p.170)

In addition to these factors that are firm specific, there are also some factors common to a country determined by their policies, skill endowments and institutional characteristics which Lall calls National Technological Capabilities(NTC). NTC are not just the sums of FTC in a country even though there is externalities resulted from spill-over and interlinkages between firms. At the country level, Lall's classification of the NTC includes "physical investment", "human capital" and "technological effort". (Lall, 1992, p.170)

Physical investment can be interpreted as "basic" capability, in that it is a necessity for an industry to exist, but it is the efficiency with which capital is utilized, is of greater interest. On human capital, "it is not just the skills generated by formal education and training, but also those created by on-the-job training and experience of technological activity, and the legacy of inherited skills, attitudes and abilities that aid industrial development." According to Lall,

the quality of formal education, especially of technical training, and the relevance of the curriculum to changing technical needs are clearly very important. To the extent that public or private training facilities do not meet the need for such skills, firms have to invest in training themselves, but this also is possible only if the workforce mobility is low and their investments yield appropriate benefits.

On the other hand it is not only the skilled labour and existence of physical capital but these two have to be combined with technological efforts on improving themselves. Within the firm the technological effort is on production, design and research but this effort has to be supported by an infrastructure of information, scientific knowledge, standards, and other facilities that go beyond firm capacity. The previous section on knowledge base of medical devices has provided the scientific knowledge needed; the institutional requirements will be mentioned in section with the title "institutions in relation to medical devices' innovation".

3.3.1 Trade Structure

Distribution of medical devices is mostly performed by intermediary importers or distributors. For example in the EU, direct distribution to hospitals and buying cooperatives as end-users is seldom practiced by large companies or by subsidiaries of transnational operating enterprises like B. Braun, Johnson and Johnson, Becton & Nicholson (CBI, 200 p.31). Likewise in Turkey, imported goods are often delivered by distributors while they mostly use other intermediaries in local sales to end-users. However producers in Turkey mostly act as distributors themselves and they may also involve in importing some related goods and distribute them.

The scheme on distribution structure for Medical Devices in EU markets and in Turkey is as follows:

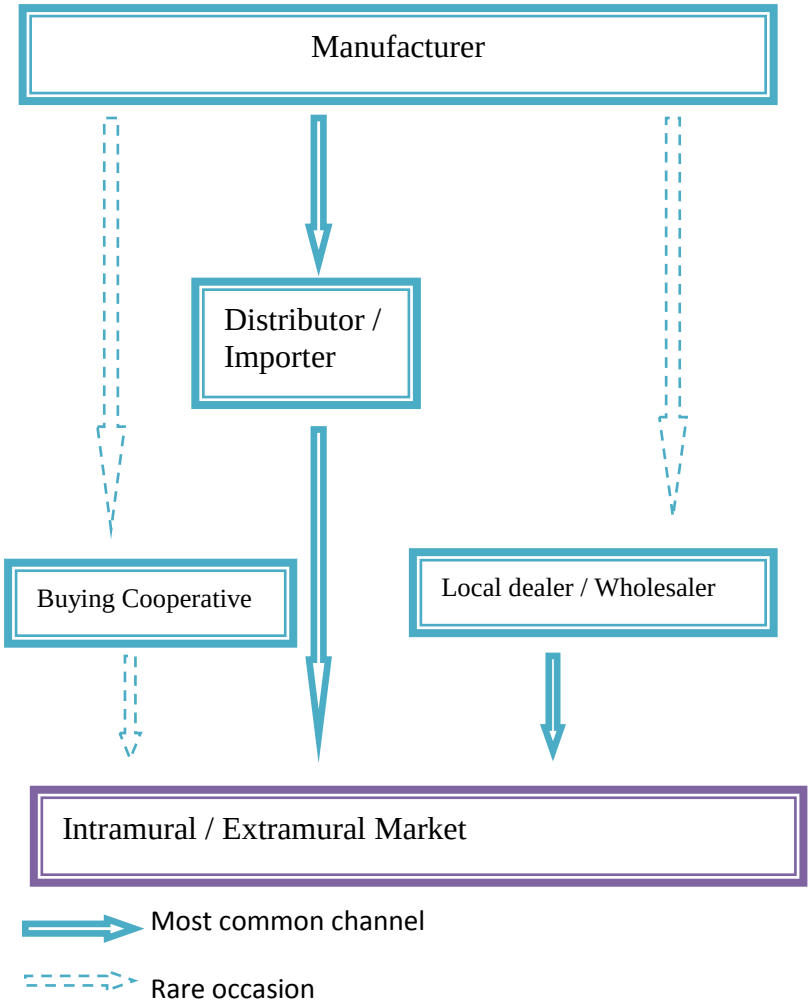


Figure 3.5 Trade channels
Source: Own compilation

As seen in figure 3.5 the main trading intermediary for medical devices is the importers and the distributors both in the EU and in Turkey. The distributor is the key figure in delivering the product to the end user along a nationwide / EU network. Local dealers or wholesalers are used to distribute and sometimes pursue marketing of the product in each location.

There are several buying co-operatives established in the EU, which act on behalf of several hospitals and hold a strong bargaining power due to mass purchases. Buying co-operators are suggested to overrule the position of the distributor and

to negotiate with the manufacturer directly, if they evolve strong enough to perform effective bargaining.

Some insurance companies in the Netherlands, the UK and Belgium are closing contracts with the suppliers. It is important to communicate for the manufacturers with the distributors working with the insurance companies in these countries to ensure market penetration, since insurance companies are closing the contracts with a group of hospitals for the use of the selected products.

In the EU it is also evident that there are some central warehouse establishments (i.e. Rotterdam port) where manufacturers may hire a company to distribute the product to the entire EU area.

Before Turkey uses e-trade actively, Europe established an online B2B platform available for the use of hospitals, distributors and producers. Global Healthcare Exchange is a site founded in 2000, and used by many market leaders. In Turkey on the other hand the TITUBB data and infrastructure is established to enable the public procurement procedures online.

3.3.2 Non-Firm Actors in Medical Devices Sector in Turkey

This section provides the reader with certain knowledge about civil society in the Medical Devices sector and the activities take place within the leadership and orientation of the civil society initiatives. Through the section, first, a project competition organized by an employers' association and its applications is mentioned. Second, a convention on medical devices production realized in Samsun, under the organization of Samsun Chamber of Mechanical Engineers is presented with an emphasis on its impact to the local production. Third, an organized industrial zone in Ankara, OSTİM, is presented. This zone is, currently, in the course of establishing a Medical Devices Clustering aiming to encourage the producers in the zone by providing them the necessary tools in order to work in cooperation and enhance their capacity further to generate exports. Forth, an innovation movement triggered by a Turkish scientist living in US is shown. This initiative has since been embraced by local actors and further turned to be a national innovation movement in the sector. The last case worth mentioning is on a specific company, namely "Improving Medical Technologies" (Medikal Teknolojileri Geliştirme, MTG) which is founded by a civil society initiative.

To start with the country wide organization of civil initiatives, one should mention the vendor-network and the linked local NGOs. In the Medical Devices Sector, the first NGO (namely SADER, Sağlık Gereçleri Üreticileri ve Temsilcileri Derneği) is established in 1993 and located in Ankara while it is defined to be national. However, most of the industry-specific NGOs have been local or regional, thus mostly represent the vendors and, to a lesser extent local producers. The sales network is important for distributors and these local NGOs provide a basic channel enabling an access to vendors for distributors and producers. The number of vendors active in the sector is pronounced to be 16.000 by the Ministry of Health records. These local NGOs are gathered under an umbrella organization (Tümdef) and represented through this confederation. Moreover, there are some other organizations of specification, like orthopaedics, hearing devices or spectacles where the regulations are slightly different and areas of interests are somewhat diversified. In addition to these organizations, an employers' association named Health Industry Employers' Association (SEİS) is established in 2003. The association mentions its support for innovative medical devices in its statute, as well as competence and skill development in the medical devices sector. SEİS, together with Tümdef, works on vocational education standards and try to enhance the human resources required by the sector. More, since 2006 SEİS have organized a project competition in medical devices, to suggest new and producible ideas into medical market and provide matchmaking between university-originated projects and the manufacturer who is having the capability to produce such products.

The competition is named Daha Çok Üretmeliyiz (meaning: More We Have to Produce) and faculty, students, or any other individual having relevant projects can submit their projects to the competition. The main goal is to encourage academic efforts meet and jointly work with industrial partners. Students with projects are offered to gain production experience and equally important a perspective to consider the commercialization of plausible ideas.

Pursuant to below mentioned evaluation criteria, the competition rewards the producible projects symbolically in cash and more importantly, provides a match-making with a manufacturer while disqualifying other projects.

To provide an overall assessment to the results of the contest, it can be concluded that the applicants are mostly in relation with academia. There is only

a nurse which is the winner of the 3rd year who is improving a device related to his daily working conditions. All the other winners are either university staff, or new graduates working with their professors, or spin-offs from university. The design projects owned by Hakan Gürsu are all producer-initiated orders and have obtained their industrial design protections. The main reason to the contest is declared to find a little more financial support to continue the R&D related projects. Usually, the producers aimed at finding additional financial support or creating awareness for their innovative products in applying the contest. Or the producers seem to focus on design improvements to create a competitive advantage. Other than these projects, there are engineering appliances that include high technology and research which are given prizes for the know-how and high technology they comprise, even though they are far from being produced. Some projects are given prizes even though they haven't finished their R&D process. The project owners consider the prize as a financial source for further improvement of the R&D.

The projects started to be produced are 8 in number. Even if the market position of these products are not clearly observed, it can be concluded as a general frame that, the further need in R&D is not easily offered by the producers although how much the idea is innovative, or easily applicable or has cost advantages. When the final products are new entrants to the market (like re-usable mesh or stomakit), the increased marketing finance need becomes an obstacle. Please refer to Appendix N for further detail in interviews and project contest data.

Second, a convention on medical devices production realized in Samsun, under the organization of Samsun Chamber of Mechanical Engineers is presented with an emphasis on its impact to the local production. The chamber takes action after the transformation of the arms producers into surgical instruments. The cluster contains 42 producers mostly specialized in surgical instruments. The region is hosting a national convention which creates awareness on the cluster and the sector as well. The convention is realized biannually with approximately 500 participants each year. All relevant parties are included in the program and the local producers have the chance to interact with many relevant government bodies as well as healthcare providers and professionals.

Third, the organized industrial zone in Ankara, namely OSTİM, is on the course of establishing a Medical Industry Cluster. Ostim defines the cluster as: "the organized concentration of the vertically and horizontally connected enterprises and supportive institutional structures (such as universities, chambers, sectoral organizations, and related public institutions), which operate in the same sector, in a specific geographical region. The purpose of the cluster studies, which all related institutions manage on the basis of a structure formed in line with common strategies, with equal representation and a common mind is, to increase the market share of the sector by joint competition." The cluster activity has been initiated according to the results of a survey conducted in 2007. "Study on the International Competition Level of in OSTIM Operating Sectors", illustrated the medical equipment market having a strategically importance for our country constitutes a competition opportunity for the medical sector which has been developing since OSTIM was founded. The Medical Industry Cluster Coordinator explains the sector as: "It has a constantly growing market in Turkey and abroad, it is open to the high value added, innovative production, although it is still 85% dependent upon foreign products, it is needed to be nationalized strategically." Furthermore he also mentions the support of national policies that support the sector which has a good potential in size and attraction of the market. His points in developing the idea of medical device cluster was :

- "Ankara, and specifically OSTIM, has a significant number of firms in medical sector and a significant production capacity,
- In OSTIM there exist production diversity and business lines to support the sector,
- Ankara is the centre of the health sector procurement, universities which produces knowledge for medical technologies, medicine schools which accommodates final consumers and researchers, NGO's which are operating in the field, and, most significantly, the only centre that harbours all elements of the value chain in respect of civil and military decision mechanism,
- Ankara, is a centre which lavishes health expenditure, especially important for its connections to the Middle East, Arab and African countries."

At the course of this thesis, the zone hosted 44 firms established in OSTİM and produced a variety of medical devices, such as hospital hardware, montage of radiology devices, orthopaedic devices, baby incubators, sterilizers.

For Ostim, the road map for the cluster is as follows

· For Ostim, the road map for the cluster is as follows:

- Raise awareness by systematically explaining the force and feasibility of domestic production to all the parties of the topic,
- Putting the projects into production that already exist in the universities, and that is going to be turn into a product rapidly, or that is going to improve the standards of the products,
- Developing research and development projects with the doctors of GATA (Gülhane Military Medical Academy), who are the end users, and sustain the lacking dialog between the producer and the end users,
- Preparing a common web portal, organizing project market activities,
- To sustain the risk capital groups who would provide support to the medical area meet with the entrepreneurs,
- To build supportive mechanisms for the need assessments, during the product development process, can be prepared rapidly and accurately,
- To increase efficiency by conducting studies, co-operated by different Innovation in Health Centres in different regions of the country,
- Bringing the academicians and producers together,
- Defining the to-do's in the short, medium and long term,
- Organizing competitions about the medical devices and introducing the outcomes to the market,
- Developing projects to, in long term, reach to the technology and to produce products with high surplus value,
- Benefiting from the past attempts and experiences,
- To turn it to advantage that the state is the main purchaser,
- To lobby for the experiments, tests, certification, and calibration services that are procured from abroad can be provided inland,
- Coming together with all the parties of the health sector, and developing substructure projects as the Perfection Centre, by the mediation of DPT (State Planning Organization) and other supportive mechanisms.

(OSTİM, Medical Industry Cluster)

Statistics on the cluster:

Enterprise number accepted to the cluster	44
Number of Employees	1114
Number of Employees with University degree	383
Number of Engineers	139
Number of Employees with a 2nd language	104

Ostim, attaching importance to university-industry cooperation to provide international competition power to enterprises, carries out joint - projects together with the universities established in Ankara. Technocity Ostim Incubition Center has been established as a result of cooperative studies with Middle East Technical University that has great knowledge on technoparks. Ostim Technocity, has become active in 2006 by the cooperation of Ostim Organized Industrial Region and Middle East Technical University. It aims to provide companies producing and demanding to produce due to R&D, with modern facilities, new technologies and benefit from the supports.

Ostim has **7 firms active in Surgery Room Equipments (%15),** 1 firm in Biotechnology Products (%2.27) , 2 firms in devices for breaking nephrolithes (%4,54), a firm active in defibrillator production (%2.27), 1 firm in Dental systems (%2.27), 3 firm in X-Ray firms, **7 firms in hospital hardware (%15)**, 5 firms in Laboratory equipment, **7 firms in Medical Solution and partnership & R&D (%15) ,** 2 firms in Medical Gas Systems (%4,54), 2 firms in Oxygen systems (%4,54), 2 firms in Medical Consumables(%4,54), 6 firms in sterilization and disinfection devices (%13,6), 2 firms in clean room and biosafety systems (%4,54), , and a firm active in medical textiles (%2.27).

On the other hand, the firms in OSTİM doesn't produce a single category products but the number of categories they are active in, range from 1 to 4. Which is not an interesting finding considering medical devices but please note that not all diversification is within the same product group. Medical textiles and medical hardware producers tend to produce the variants of the same product group however, a firm producing X-Ray equipment can also produce gynaecological devices as well.

Forth, an innovation movement triggered by a Turkish scientist living in US is shown. This initiative has since been embraced by local actors and further turned to be a national innovation movement in the sector. Regional actors and producers meet with relevant institutions and regulators in 4 cities, İstanbul, İzmir, Ankara and Eskişehir. The wide participation of relevant bodies actively is obtained. The scientist is searching for opportunities for her students to return home and reverse the brain drain. She is currently in an administrative position in a reputable university in US, and having contacts with all actors in medical devices sector. She has named her initation for local cities as INOVA for Ankara, INOVIST for Istanbul, INOVIZ for Izmir and INOVES for Eskişehir. She currently mentions the frontier technologies that are produced in USA are produced by the researchers she and a group of her colleagues are guiding and further adds that she guides them back to Turkey. With the active positions she wants them in industry she suggests a growth in high tech-biotechnology production in Turkey might be realized. The local approach she has in her focus on cities is supported by her policy making contacts. She is active in creating localized platforms and asks the regulatory bodies in her platform as supporting organizations.

Having a successful example like the Unites States venture capital especially important for start-up and developing high-tech companies; financial channels and their regulatory and administrative infrastructure are started to be discussed not only among corporate circles and related government institutions and multilateral organizations but also among scholars of innovation. However Turkey lacks this efficient organization of Venture Capital. And, it is highly suspectible that this initiave would be successful without the support of venture capital funds.

The last case worth mentioning is on a specific company, namely "Improving Medical Technologies" (Medikal Teknolojileri Geliştirme, MTG) which is founded by a civil society initiative which also forsees the need for a fund in order to finance the university based technological advances. The firm has been established in 2006 with 16 broad members among which there are producers, distributors or vendors, and calibration firms exist. The starting point of the firm was to develop a funding organization with a strong distribution and sales network for the novel ideas and commercialization of them. The firm is established by the initiative of the Health Industry Employers' Association of

Turkey with a letter to its members stating the aims and entry conditions. Each firm was entering MTG with a entry fee to be the starting capital but additional capital was increasing the share of the firm in MTG. The new firm was administered by the board members who had a share in MTG. The firm lived until 2009 and evaluated more than 20 projects. The initial expectations of the board members were diversified from each other and conflict among them arising dfrom various different sources including their own firms' market positions were experienced. The only project supported was a substitution of the techno logy frontier in sterilization devices which worked with another technological knowledge base. However, the intellectual property rights disputes, the producing technicians opening up new firms as rivals ended the project up. The first attempt was not as profitable as board members expected and new costs rising from the sustainiblity of MTG was not welcomed. And the attempt to create a venture capital and distribution and sales network for new medical technologies in Turkey with totally private initiatives has also ended. The actors initiating MTG are still active in such projects but need more guidance and resources in managing the process of venture capital as well.

3.4 Institutions in Relation to Medical Devices Innovation

Lall (1992) mentions the importance of incentives in order the firms to utilize the physical and human capital that exists. Incentives of market or policies will surely affect the outcome of the technological efforts of the firms. Lall classifies 3 broad sets of incentives that affect the development of the NTC: Macroeconomic incentives, Incentives from competition and Incentives from factor markets. Accordingly the first is a stable macroeconomic environment which is investment-friendly. The second is competition domestic or international where domestic competition is suggested to be "influenced by the size of the industrial sector, its level of development and diversification, and government policies on firm entry, exit, expansion, prices, ownership, small-scale industry etc." On the other hand, international competition due to imports, foreign investors or export activity is suggested to be a more important ingredient in technological development. Incentives from factor markets are suggested to positively affect efficient production and resource allocation. Accordingly, capital markets should enable long term financing and ease the risky projects to be financed as well and labour markets should be competent and flexible.

Moreover the institutional structure also affects the firm activities. The legal framework supporting industrial activity and property rights which shape the firm behaviour, industrial institutions that provide support, consultancy, inter-firm linkages, training, or many other facilities and the training institutions that provide skilled labour are important aspects of the institutional structure. In this respect the institutions related with the medical devices sector and their sectoral spesifities if exists will be mentioned under this headline.

The related institutions can be listed as: Ministry of Health, Ministry of Trade and Industry, Public Procurement Institiution, Social Security Institiution, e-trade infrastructure, Science & Technology Policies, and Human Resources.

3.4.1 Ministry of Health & First Approval of Devices By Authorities

Ministry of Health in Turkey has harmonized the medical devices regulations with that of EU and accordingly, a risk assessment based classification is used to permit a product into the local market.

From a risk assessment perspective medical devices are classified into four classes: class I (low risk), II a (medium risk), II b (elevated risk) and III (high risk) varying with the degree of risk linked to the device. The higher the classification, the more complicated the level of assessment required by the notified bodies will be. Medical devices have to be distinguished from pharmaceuticals. Sometimes, however, the distinction is not that clear as in the case of a device is used to insert a drug.

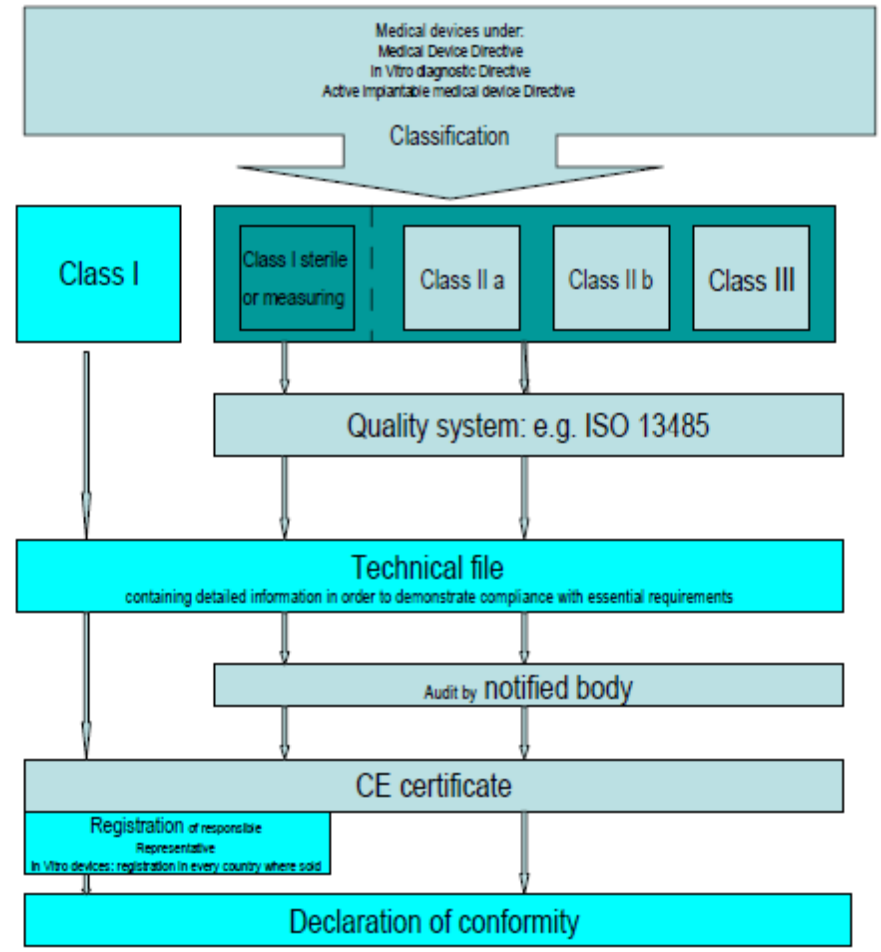


Figure 3.6 Risk Assessment of Medical Devices.
Source: KCE Reports vol. 44A, 2006

A Notified Body is an organization that has been nominated by a European Union member state and they are notified by the European Commission. A Notified Body will be nominated based on designated requirements, such as knowledge, experience, independence and resources to conduct the conformity assessments. Notified bodies are selected to assess the conformity with the essential requirements, and to ensure consistent technical application of these requirements according to the relevant procedures in the directives concerned. It is the replacement of FDA regulations of USA in EU with an outsourcing approach. That is, a notified body is the responsible body that investigates, prepares, monitors and controls the medical devices. New therapeutic advances and the growing complexity and sophistication of devices require scientific and technical expertise that cannot always be provided at national level. In Turkey

there are a few notified bodies who deal with medical devices of specific classes usually with low levels of risks. However they are not adequate for all device groups especially in high risk groups. For most of the devices that will enter to the Turkish market, to some degree there may be a need for a foreign (EU) notified body. The notified body has to inform the other notified bodies and the competent authority about all certificates suspended, withdrawn, issued or refused.

The increase in risk means increased investigation and increased testing and monitoring by the notified bodies, which also means increased costs on the manufacturer. Thus operating in a higher risk group device production is costly compared to lower levels of risk. In addition, if the notified bodies are abroad, the monitoring of production becomes more expensive.

3.4.2 Social Security Institution (SGK) and Reimbursement Strategies

In recent decades, most healthcare systems, public and private, are affected by increasing public expenditures. They have undergone major reforms and change of policies to increase efficient use of sources and limit the use of medical technologies by rational drug use. Reforms aimed at improving the efficiency of the health systems at the micro level have been introduced by most countries (besides measures such as caps on spending, administered prices and volumes, and shift of costs onto the private sector through increased cost-sharing as in storage management policies).

The first reform aiming efficiency is the separation of budgets of previously integrated systems, public insurers from healthcare providers (mainly hospitals). The reforms also aimed the increased financial autonomy and responsibility of the healthcare service suppliers. During the 1980s, OECD countries generally made hospital contracts better attuned to achieving the goals of cost control, efficiency and quality of care, with greater attention paid to the incentives inherent in specific payment methods (Docteur & Oxley, 2003). Turkey is still in a process of healthcare reform. These reforms that continued for decades, sought to deal with which medical providers can pass on costs when consumers pay for medical care through a third party. Under this trend, most systems have seen the move from "retrospective systems" – whereby healthcare providers are paid

on the basis of costs incurred – to "prospective systems" – in which the sum paid are exogenous and independent from the costs incurred. In these systems a treatment is paid in sum and all the medical technology needed for that treatment is spent under this sum. If a hospital spends more than or less than the assigned expenditure, the healthcare provider is in loss or profit. The healthcare provider and proffessionals is thus enforced to act as a private company.

Insurance systems operating the retrospective payments are suggested to encourage overuse of medical resources; on the contrary, under prospective payments, where revenues for patients admitted are largely exogenous and fixed and depend on the diagnosis, the organisation's financial health depends on its ability to control cost of treatment. This induces healthcare providers to consider the cost consequences of their decisions. (Feldstein & Friedman, 1977). The tendency, initiated in both the US public and private health insurance systems in the early 1980s, in subsequent years spread to most healthcare systems. Means of this current of reforms are schemes such as the Diagnosis-Related Groups (DRG) that have had several national applications and variations, but that in all systems consist of fixed reimbursements to hospitals/providers per diagnosis/treatment (e.g. appendicitis) based on the average cost of the treatment.

The economic incentives – that drive circularly the interaction between insurance, R&D and innovation – are not invariant to these. Retrospective pricing suggests to the innovation system to develop new technologies that enhance the quality of care, regardless of the effects on costs. While with the prospective pricing the innovation system is engouraged to develop new technologies that reduce costs, provided that quality does not suffer too much. High technology medicine is generally regarded as a source of significant professional prestige, and in general, social values favour its application, especially for life-threatening conditions.

Before the cost containment policies were adopted and in the presence of generous insurance, if the new technologies were seen as offering health benefits compared with existing practices, these were adopted. The feedback were often in efficacy and safety and operational problems, but not cost reduction.

With the growing budget pressures and application of perspective payment systems, the incentives in the system has changed in favouring cost reduction in innovation. As a consequence, technology improvements started to be directed not just at enhancing performance but also at reducing costs, of equipment and of treatment. (Gelijins & Rosenberg, 1994).

Considering Turkish insurance system, there is no clear entry procedure into the reimbursement scope. The firms active in medical devices have no obstruction if they enter the market for the replacement of an existing import material that is already being paid. However, when a new product is introduced, even if it is registered by Ministry of Health, qualifies certain standards, it is not possible to be included in the reimbursement lists even without referencing the cost benefits it brings up if so. This ambiguity restricts the innovative activities of the firms to generic products.

The SGK policy is a disincentive for investing in R&D and encourages the innovative activities that aim at gaining a price advantage by reducing the costs.

The involvement in reimbursement lists is not a transparent and clear procedure even if it may change many times a year. Further many devices are tried to be included in prospective systems according to relevant Diagnosis-Related Groups which suggests the healthcare professional to focus on cost-containment rather than quality. As a result, the quality improving innovation is not paid in the market, or sometimes the cheapest product having at least a CE certificate is preferred to the better quality ones.

Concerning pay-back system, the insurance system pays the reimbursement to the hospitals which are responsible for paying their purchases and health care providers have control over their budgets more responsibly. However, ill managed hospitals tend to pay the invoices later than expected and extend this delay up-to 2 years. Since they provide a public service they cannot be hypothecated by the payee firms. The firms pay their income taxes before they receive the payment.

3.4.3 Human resources

The vast range of Medical Devices and the variety of relevant disciplines especially under medicine and engineering made the sector highly dynamic and specialized. The human resources working for the technical services were taking on the job trainings and product trainings mostly provided by the producer firm. The product renewals, upgrades and vendors' responsibility to provide a technical service to a medical device all needs much training. The product trainings are either in the vendor's country or in the producer's country but mostly in foreign languages. Many technical service technicians reported to have learned some key terminology in English after a few trainings. The staff needs to have basic English skills in order to benefit from the product trainings. On the other hand, considering workers in production, the vast range of devices means a huge diversification in the devices' production processes. Still, the increased technology ingredient results in higher capacity workforce – as in magnetic resonance imaging even the technical service staff have masters or PhD's in physics.

The human resources needed had been required from relevant departments of universities such as biology, physics, electronical engineering, and veterinary or other health proffessions and supported by intra-firm or abroad product trainings. Yet, the working conditions of the technical personnel especially the technical services are hard to pursue. Since the producers and distributors are responsible for providing a solution to the crash in 24 hours. The staff is working with doctors or nurses mostly at the healthcare service providers where the situation is critically important and cannot be postponed. Like medical staff, these technical staff also can work at night whenever needed. The technical service staff sometimes assists the doctor in controlling a device's pace, voltage etc, and actively participate in the operations in cardiology, orthopaedics and brain operations. There is a repeatedly mentioned need for qualified technical staff which can be only possible through specific product trainings, and the worker turnover rate is observed to be high. A worker after expensive trainings may leave job due to harsh working conditions and sometimes leave the sector as well, since they mostly have other university degrees. This situation is also a factor that increases the costs.

At the same time, renown universities in Turkey like METU and Boğaziçi, established a post-graduate department on Biomedical Engineering. A private university with a medicine faulty as well started to obtain students for Vocational Higher Education Schools (2 years after high school) and a 4 years undergraduate program of Biomedical Engineering in addition to a year English preparatory classes.

Following these schools, 5 more universities, 4 private and 1 public started to give Biomedical engineering and technician education. Each year 220 students graduate from these schools. (Koçak O. , 2009). These new schools being positive in providing a formal training to a group of students, still, the special needs of the Biomedical Education is the other side of the story. These schools need to teach students variety of devices' and their functioning yet to provide students with practical knowledge about the devices is harder than assumed. First, it is hardly ever possible if not impossible for any school to provide a fully equipped laboratory for their students when we consider the cost of medical devices and their special needs like radiation protection, magnetic waves etc. The devices found in hospitals are not allowed to be used by students not of course to repair or to montage. Second, the devices are bound in hospitals even if they are hacked, since the doctor replacing a very expensive device is still responsible for this choice. It is possible to acquire a hacked device only if the receiving institution is aware of the device and demands a donation from the hospital. This is a highly bureaucratic operation even the university or institution is a part of the donor hospital as in the case of university hospitals. Private sector universities with private hospitals in their body are luckier in this sense. Since the students may find an opportunity to have vacancy positions in the hospitals maintenance units.

Other than higher education institutions and undergraduate programs there are also high school vocational education in Biomedical Devices Technologies. Apart from higher education institutions, these high schools are organized in 4 different branches: Physiological Signal Monitoring Devices, Laboratory Devices, Imaging Devices and Diagnosis Devices. The first school established is in Ankara with a huge laboratory. The laboratory is established with the help of some financial donors as well as the device donors of military hospitals in addition to some international donors. After the establishment of the department in a pilot school, the numbers of the vocational high schools opening has raised to twenty-two.

The trainers training programmes had been organized via an EU project and realized web-based. It is most probable for these new schools to suffer from lack of devices and fully prepared trainers. Still, the number of graduates of these vocational high schools will be approximately 500 per year if 20 students enrol each. In the curriculum of these vocational high schools, the students are subject to medicine terminology, electrical, electronics, machinery and software repairs and technical English.

The human resources in Turkey concerning Biomedical is stated to be low in many groups, yet the training institutions started to focus on the sector and promise a decent number of labour force in the near future.

The intermediary positions in industry in Turkey have been a problem announced for a time. The vocational high schools and vocational higher education institutions lack to provide the qualified technical staff the employers need. Even though there is a systemic problem in vocational education sociologically in the low status perception of vocational education; recently the industry – education relationship has been tried to strengthen. One of the political actions in this respect is the establishment of Vocational Qualifications Institution in 2006. One of the main objectives of the institution is to provide the public and private institutions with the documents prepared by industry which describe the standards and define the performance criteria of an occupation. These documents called Vocational Standards and Vocational Qualifications can be used in preparation of training programs, certificate programs, and performance evaluation in a firm, or even when to hire the appropriate candidate. If adapted well by national education system and higher education council, the possibility of establishing a bridge between industry and education may be built and the possibility of mobility of labour in Europe will be enhanced.

In this context, the industry representatives – an employers' association and an NGO, have signed a contract with the Vocational Qualifications Institution in order to prepare the vocational map and standards of each vocation in a way most appropriate to the industry needs. These actions, also promise a better human resources in near future.

CHAPTER 4

AN ANALYSIS OF MEDICAL DEVICES FIRMS IN TURKEY

4.1 Methodology & Problems in classification and statistical data

Data sources for the thesis is OECD, WHO, TURKSTAT and EUCOMED. In addition to these the only available source on the Medical Device sector, Medical Devices Competitiveness Report prepared for EU Commission (2005) is also used. The report mentions valid and reasonable difficulties in compatible data. The thesis considered the NACE Section D 33.1, which reports data on "Manufacture of medical and surgical equipment and orthopaedic appliances" as the main statistical category.

The data on Europe cover the period 1995-2005(2002) and Turkey until 2009 and include

- manufacture of instruments and appliances used for medical, surgical, dental or veterinary purposes (electro-diagnostic apparatus such as electrocardiographs, ultrasonic diagnostic equipment, scintillation scanners, nuclear magnetic resonance apparatus, dental drill engines, sterilisers, ophthalmic instruments);
- manufacture of syringes, needles used in medicine, mirrors, reflectors, endoscopes, etc.;
- manufacture of apparatus based on the use of X-rays or alpha, beta or gamma radiation, whether or not for use in human or animal medicine (X-ray tubes, high-tension generators, control panels, desks, screens, etc);
- manufacture of medical, surgical, dental or veterinary furniture (operating tables, hospital beds with mechanical fittings, dentists' chairs);
- manufacture of mechano-therapy appliances, massage apparatus, psychological testing apparatus, ozone therapy, oxygen therapy, artificial respiration apparatus, gas masks, etc.;
- manufacture of orthopaedic appliances (crutches, surgical belts and trusses, splints, artificial teeth, artificial limbs and other artificial parts of the body, hearing aids, pacemakers, etc.).

A major limitation of the NACE classification is the exclusion from the medical device aggregate of the high-tech chemical and biochemical-based devices such as in vitro diagnostics (that are classified under "chemicals") and medical-impregnated products such as gauzes and bandages (that are grouped under "pharmaceutical preparations"). As a result, estimates of the R&D intensity of the sector are biased downwards. Turkey started using NACE (Rev 2) in 2009 where "Manufacture of medical and surgical equipment and orthopaedic appliances" NACE 1- 33.10 is divided into 2 categories of 26.60 & 32.50. Still,

the medical devices, both in 33.1 or in the divided revision 2, doesn't include all medical devices. Moreover, there are more classifications in Medical Devices than available in NACE codes permit. Considering Turkey more detailed data may be collected in future through the use of TITUBB, after the data is processed by the MoH.

On the inefficiency of the statistical data available currently, the EU Competitiveness Report suggests: "The lack of systematic effort at an international level to collect, integrate, update and diffuse primary data and information on the state and the evolution of the medical device industry represents a severe limitation to this study and to previous analytical efforts. This also dramatically reduces the possibility of formulating any reliable policy action to enhance the competitiveness and productivity of the EU medical device industry, limit the effect of market failures in healthcare systems and design and support the constitution of a European system of innovation."

The production R&D, data for NACE 33.1 (rev.1.1) and trade data compiled into GMDN codes are gathered in Appandix M and O.

4.1.1 Survey on Medical Devices Manufacturers

The survey has been conducted online via use of an online survey tool and sent to approximately 300 firms. The total surveys answered is 44 and a response rate of %14,66 has been achieved. The questionnaire was long enough and thus a question of city has not been asked. However they had provided the name of the company which was asked to have a contact if the answers were not accurate. When the company names are searched their locations are also obvious.

The locations answering the questionnaire are as follows:

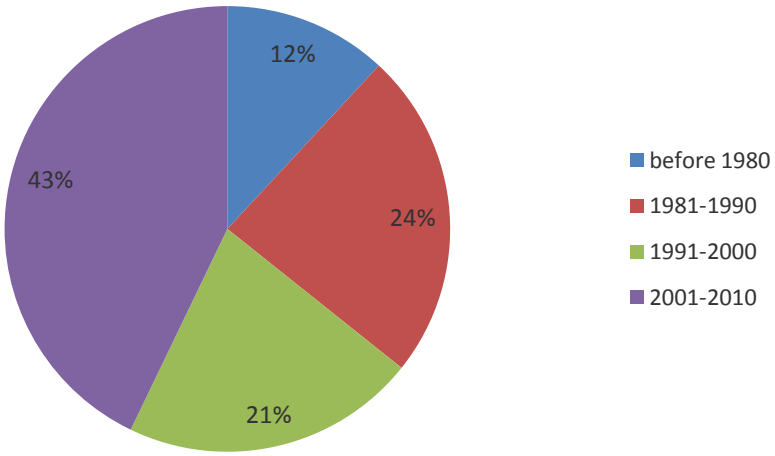
Tabel 4.1 Participating Firms by Their Cities

No. of Participant Firms by city	No.of Participant Firms
Ankara	26
İstanbul	4
İzmir	5
Samsun	5
Eskişehir	1
Sakarya	1
Malatya	1
Bursa	1

The answers provided by the firms and the conclusions drawn are provided in the following section.

4.1.1.1 Survey Results and Conclusions

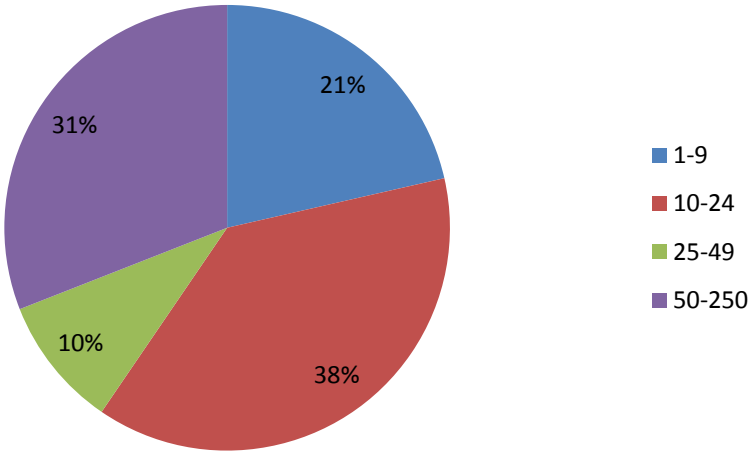
1. Please indicate the establishment year of your company.



Once we look at the establishment years of the companies which attend the survey, we see that the 11% of all the companies are the ones that have been

established before the year 1980. The percentage of the ones that have been established between 1981and 2000 is 48, while the ones that have been established after 2001 are 41% of the companies which are joined the survey. As we can see from the percentages, the number of companies that have been establish during the 20 years between 1981-2000 have been established in the last decade. Accordingly we can conclude that the knowledge base required to enter the sector is not marked by "creative accumulation". Creative destruction is relevant for the sectors where one can observe the technological ease of entry, important role for entrepreneurs and new firms in innovative activities. We can conclude the limited existence of firms that need "creative accumulation".

2. Please indicate the average number of the employees of your company in 2009.



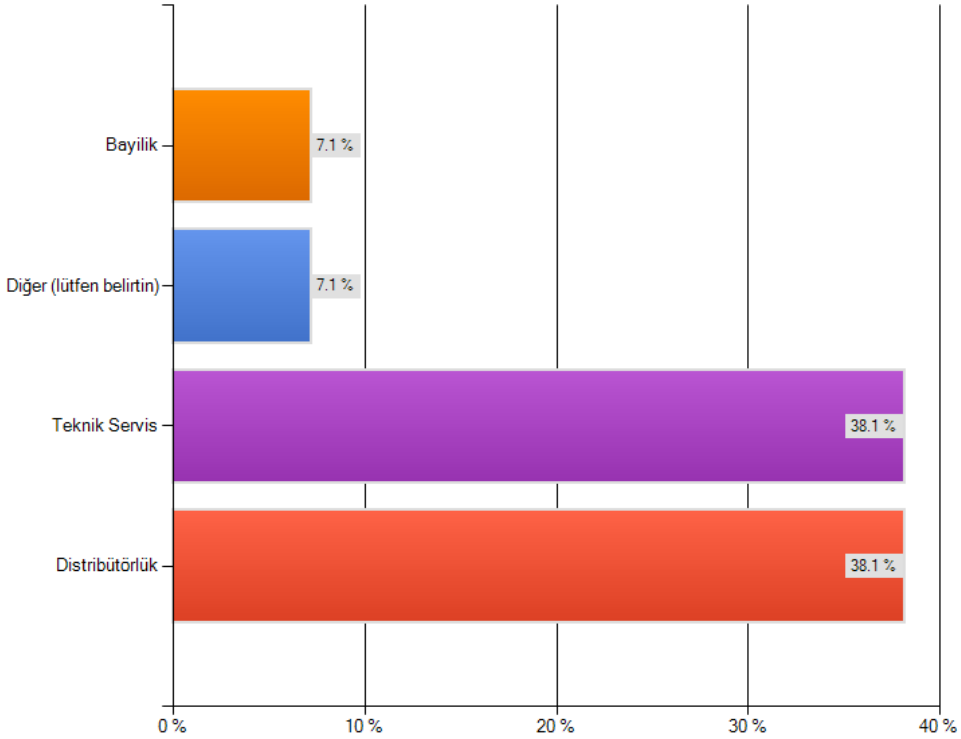
Looking at the companies which are joined to the survey, we see that 21% of them are microscaled ones that employ 1-9 people. Similarly, the percentage of the ones that employ over 50 people is 31%, and the ones that employ between 10- 49 people is 41% of all the companies. The company that covers at the most employee between all who joined the survey, declared the number of their employees as 200 people in 2009. The average number of the employees of the companies which are joined the survey is 41,5. As a result, we can conclude that the companies in the medical devices are mostly SME's.

3. In Turkey, which of the following activities are your company active in?

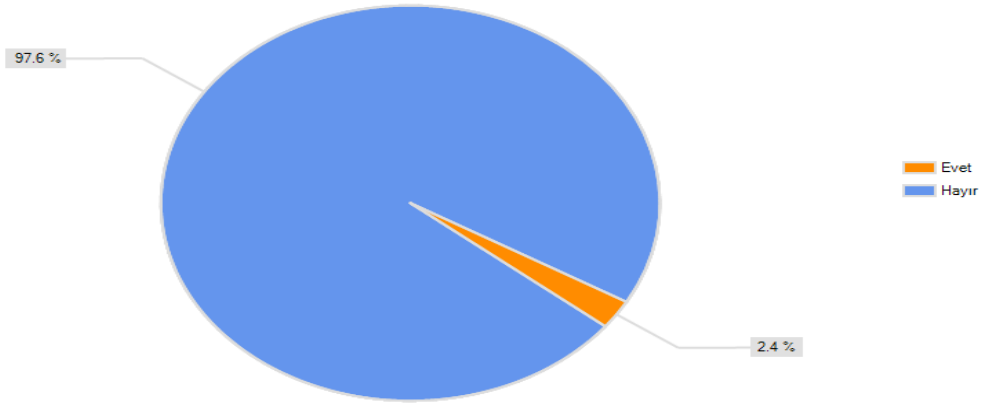
The survey is applied only to manufacturing companies. 38,1% of the producers, also serve as distributor in Turkey. 18,75% of these distributors are holders of vendorship as well.

Likewise, 38,1% of the companies offer technical services. 56,3% of the technical service provider companies also serve as distributors, and 1% of them are holders of a vendors.

The producers, add the "other" option; exportation, engineering services, consultancy, project management and R&D.



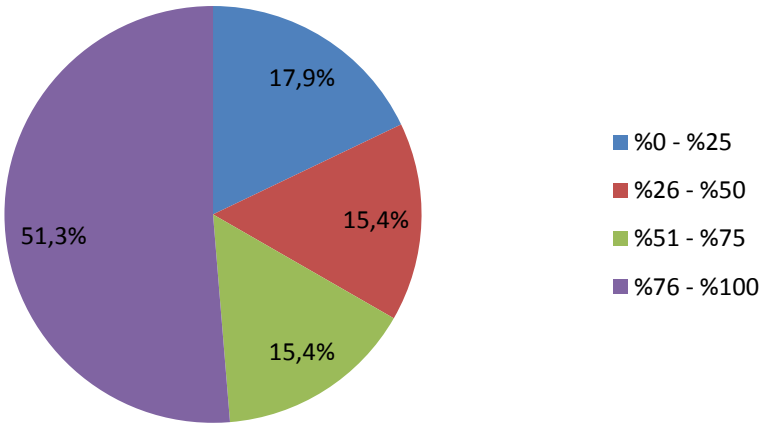
4. Do your company hold foreign capital investments?



The percentage of foreign capital investments is very low between the companies which attended the survey. Only one company (2%) has declared that they hold an investor from Turkish Republic of Northern Cyprus.

However it is known that there are companies which hold foreign capital investments in Turkey, these companies haven't joined the survey, or perhaps they haven't issued a statement about their capital structures.

5. How much of your endorsement is covered by medical devices in 2009?



51,3% of the companies which joined the survey have declared that 75% of their endorsement is covered by medical devices. The rate of the companies who report that their endorsement of medical devices is less than 25% is 18%.

6. Could you please state the GMDN Code and PRODUCT NAME of three products that had the highest rate of your endorsement of medical device production in 2009?

Unfortunately, not all the companies who took the survey had a similar attitude towards giving product details. For that reason it was not possible to collect data according to the GMDN codes, however the products that were standing out (were repeated more than once) were sterilizers, orthopedic products, surgical instruments, laboratory kits and chemicals.

7. Please state the most important markets your company is active in. (1 Much Important, 5 Least Important)

	Average	Total	Frequency
Domestic Market	1,45	55	38
European Countries	3,05	64	21
USA	3,38	27	8
Russia and Turkic Republics	3,42	65	19
Middle East	2,74	74	27
Asia	3,74	86	23
Africa	3,41	58	17

Looking at the answers it is clear that for all producers the most important market is the domestic market. Without regarding the importance attributed by the companies, the most important markets are; the domestic market (38 answers), Middle East (27 answers), Asia (23 answers), Europe (21 answers), Russia and Turkic Republics (19 answers), and Africa (17 answers). Nonetheless the difficulty of entering the US market can clearly be seen. Only 8 of the companies have stated the US as a market.

Regarding the importance of the companies the state of the market is as following: 1,45 points of average for the domestic market, 2,74 points for the Middle East and 3,05 points for European countries. Indeed it would not be

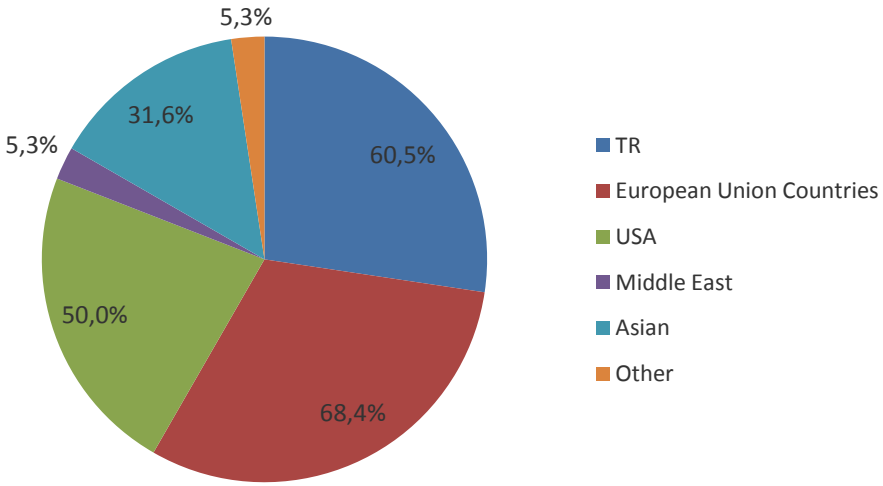
wrong to say that with the CE mark, the European countries are the most important market for us, followed by the Middle East.

For companies who attain more than 75% of their endorsement from medical devices the important markets are; with 1,45 points the domestic market, and with 2,57 points the Middle Eastern market. The importance of the other markets seems to be dispersed equally.

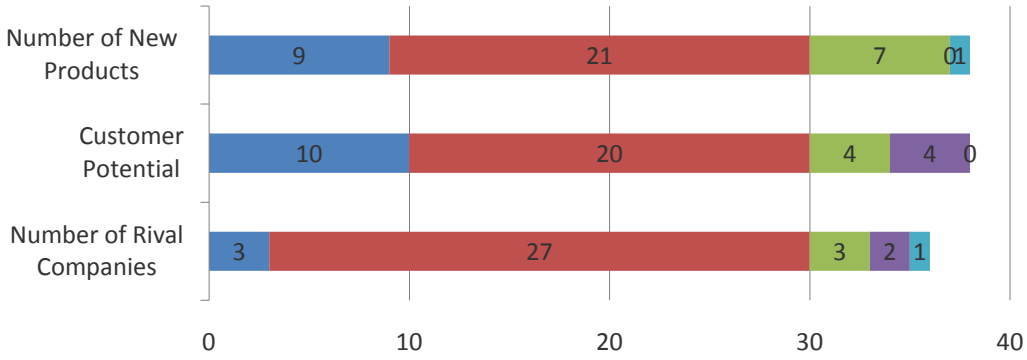
8. Please state where your primary competitors are located. (More than one option available)

The producers have stated that their most important competitors are producing in Europe. The domestic market also seems to be very important as a competitive market. More than a half of the companies who have participated in this survey have state European and Turkish originated countries as their competitors, while only the half was competing with the US origin products, %31,6 of them stated that they are in competition with the Asian market.

The US producers are marked with bigger companies that survive on "knowledge accumulation" while, EU and Asia are mostly produce with SME's. EU has more knowledge assets while Asia produces single use devices and disposables. The question shows us the rivals as well as gives us a crude understanding of the subsectors of production for the firms involved.



9. Which of the following is valid for Turkey in the field where your company is active in?



	Number of Rival Companies	Customer Potential	Number of New Products
Rapidly Increasing	3	10	9
Increasing	27	20	21
Remains Same	3	4	7
Decreasing	2	4	0

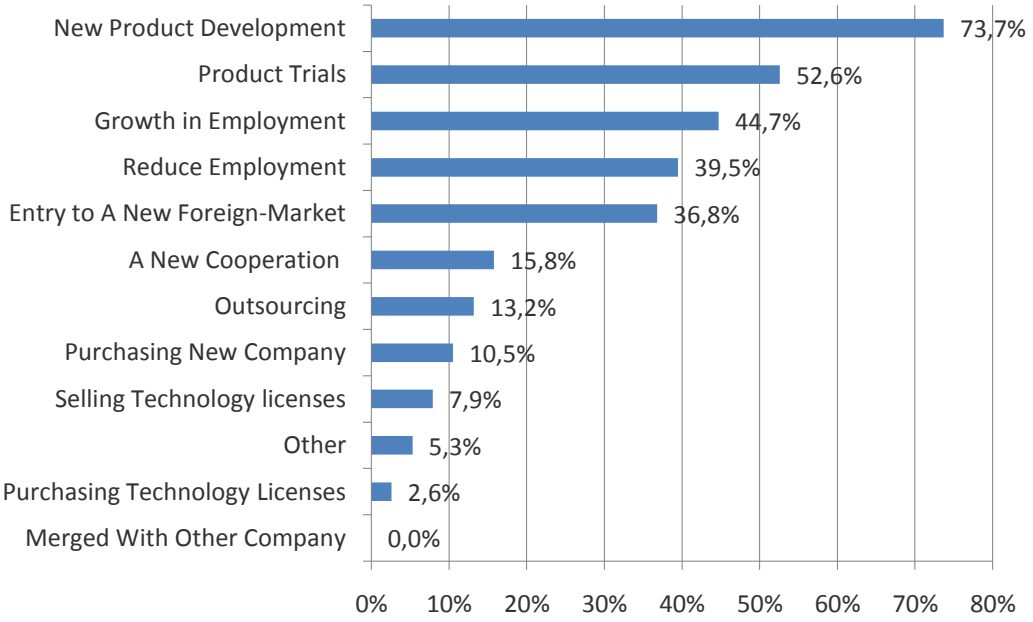
The sector seems to grow in terms of number of firms active, customer potential and the product diversity. Nearly all firms declared the increase and rapid increase in all three categories.

10. Please state the factors you find important in increasing your company's competitiveness. (1 Most Important, 5 Least Important)

	Average	Total	Frequency
Increasing the diversity of the current products in accordance with different necessities	2,50	85	34
Developing new products	2,16	80	37
Improving technical service, maintenance and repair and products guarantee service	3,81	61	16
Exploring new markets with current product range	3,09	99	32
Increasing productivity	3,72	67	18
Gaining a price advantage by reducing the costs	3,16	101	32
Becoming a renown brand	3,71	78	21

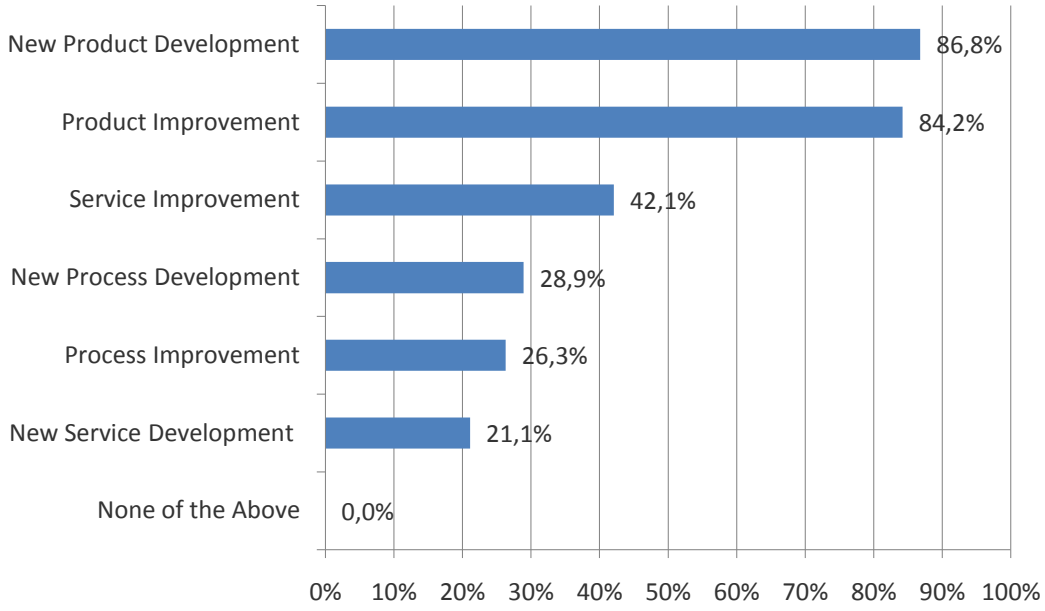
When they were asked to put the factors that affect their competitiveness to an order the producers stated the factors that were most important were; developing new products 2,16 points, increasing the diversity of the current products in accordance with different necessities 2,50 points. This was followed by exploring new markets with current product range (point average 3,09), gaining a price advantage by reducing the costs (point average 3,16), becoming a renown brand, increase of productivity and technical service guarantee etc. were less important.

11. Which strategies were used by your company in the last 2 years? (More than one option available)



The leading strategies the companies used were developing new products and product trials. 36,8% of the companies participating in the survey also opened themselves to a new market, 15,8% of them started a new cooperation and 13,2% of them signed with sub-contractors. The percentage of those selling technology licenses is higher than those purchasing technology licenses. Other answers were selling indicators to the US market and to be accredited by TÜRKAK.

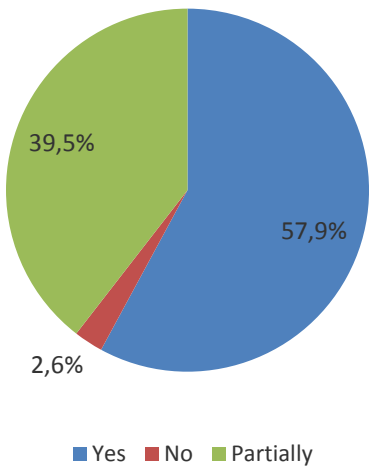
12. Which of those following activities did your company partake in? (More than one option available)



When we look at the product, process, service improvement and development activities, we see that developing new products and improving the products is very important. Improving service and developing a new process comes after them. There is no company that has not engaged in any improving activity.

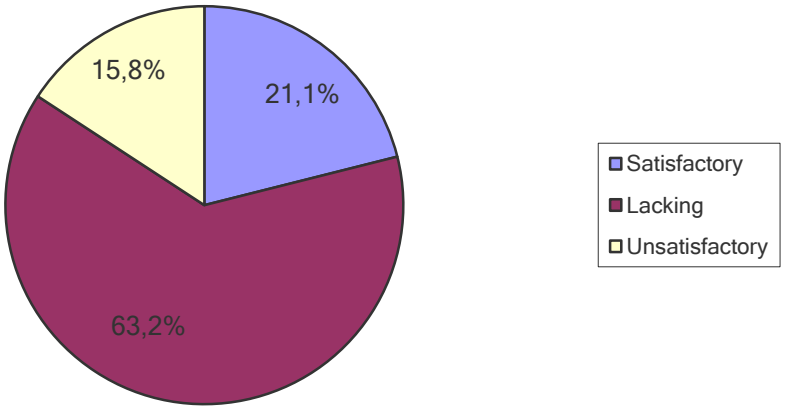
This table shows us that improving and developing products technologically is more important than improving or developing services and processes.

13. Do you have a strategic road map and product developing plan?



58% of the participants have stated that they have a strategic road map and a development plan, 40% of the participants stated that they have only partially a strategic road map. The answer no was very low with a percentage of 2,6%.

14. How do you find your current technological innovation capacity?

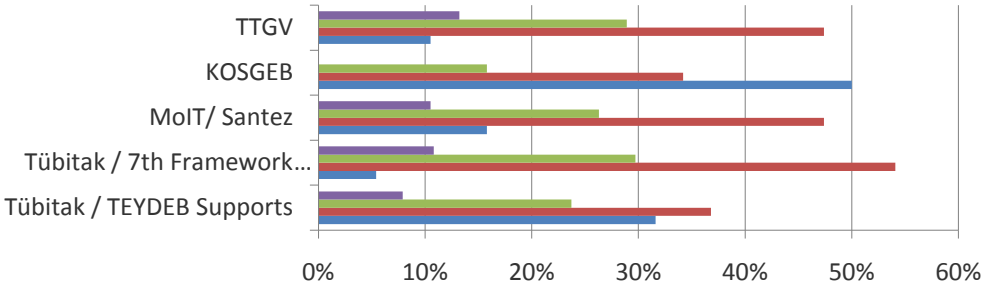


21,1% of the participants find their current technological innovation satisfactory, only 15,8% of the companies find their technological innovation lacking. The majority thinks their innovative capacity as improvable.

15. About the financial supports in regard to operations of technological innovation.

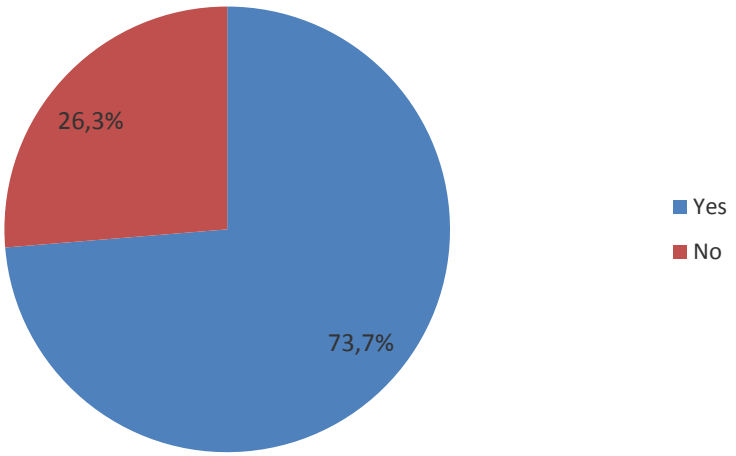
The most beneficial supports between all the companies who attended the survey is mentioned as KOSGEB. None the less, the ones who don't know about KOSGEB supports but want to learn about it are defined as 16%. KSOGEB is distinguished as the most known and the most commonly used support mechanism. TTGV is another corporation whose support is least interested. 13% of the companies have reported that the y were not interested in TTGV, 11% of them were not interested in the 7th Framework Programme, and 11% of them were not interested in SANTEZ programme. On the other hand, the percentage of the ones who don't know about the supports, substantially indicate that they are eager to learn about those. 24% of them want to learn about supports of TEYDEB, 30,1% 7th Framework Programme, 26% supports of SANTEZ, and 29% TTGV. When we look at the percentage of the beneficiaries of supports, we see KOSGEB with a 50% is the highest benefit offerer, and and the followers are;

with 32% TEYDEB, with 16% SANTEZ, with 11% TTGV, and with 5% 7th Framework Programme.



	Tübitak / TEYDEB Supports	Tübitak / 7th Framework Programme	MoIT/ Santez	KOSGEB	TTGV
Not Interested	8%	11%	11%	0%	13%
I Don't Know , Eager to Learn	24%	30%	26%	16%	29%
I Know, We Are Not Beneficiary	37%	54%	47%	34%	47%
I Know, We Are Beneficiary	32%	5%	16%	50%	11%

16. Did you have a project in 2009 aiming technological innovations?

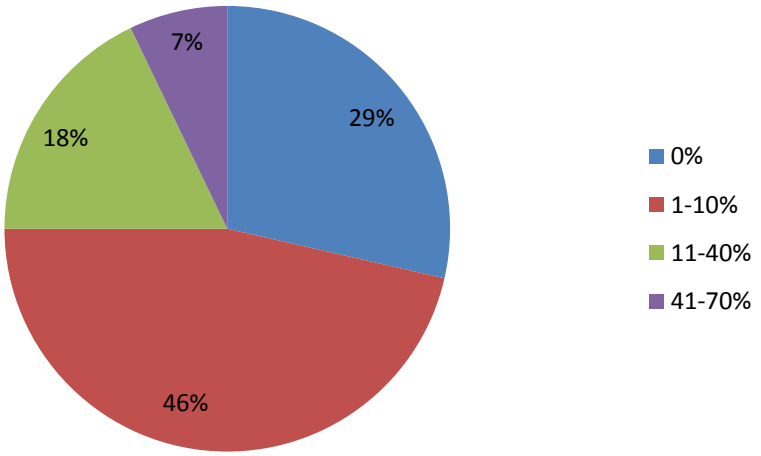


Over 70% of the companies that attended the survey have reported that they had a project that includes technological innovations in 2009. Further parts of the survey (other than intellectual property rights) have moved on with the companies that support innovational projects.

17. What is the number of your projects that include technological innovations in 2009, please rate it in terms of the results?

The answers to this question show that the question is not understood by participents. The answers to this question are rated as lower compared to other questions. One of the companies has reported their total project number as 115, and another one has reported theirs as 20. The total avarage number of project rate resulted as 2.25 for the oother companies apart from these two. The percentage of the companies which have answered this question is 62%, and and the total number of projects is 189. When asked about the projects given up due the payback of the Social Security Institution (SGK) at 2009 the answer was reduced to 28%, and similarly, it is reported that only 5 projects are given up because they were not included the payback of the Social Security Institution. However it should be kept in consideration that the question was not fully understood, and that it was nominally answered.

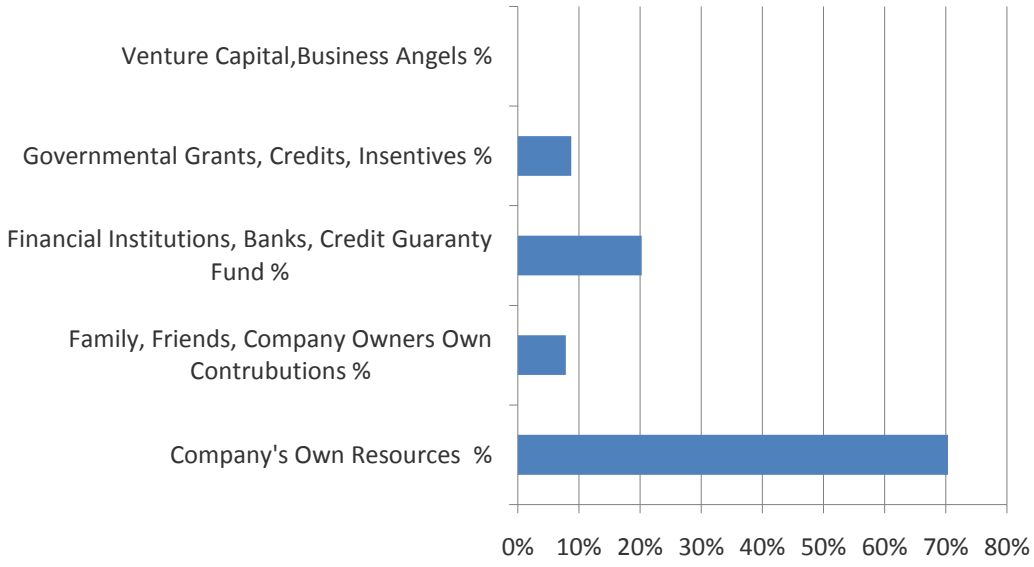
18. What is the percentage of your novel products or your services rate in your endorsement in 2009? (You may code it as 0 if you don't provide novel products or services.)



29% of companies have reported that their endorsement rate in their novel products and services as 0/ or that they don't porvide novel products or services. Likewise, 46% of them have declared their rate about the matter was between 1-10%, 18% of the companies have declared their rate about the same, between 11-40%. According to this correlation, 75% of companies have reported

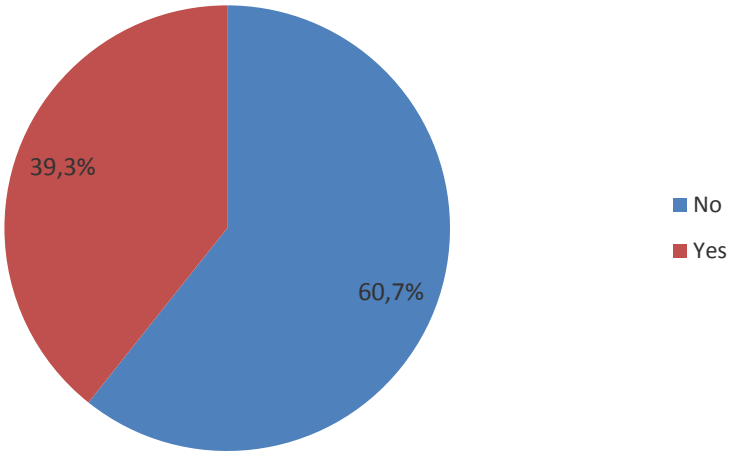
their endoresment rate as 10% in providing novet products or services. Yet, 7% of them have reported their endoresment rate as over 40% in providing novel products.

19. Can you rate your operations which include the technological innovation in terms of resources? (You may code it as 0 to nonbenefical resources.)



Looking at the resources of the operations which include the technological innovation, we see that none of the companies, who attended to the survey, are in relation with the venture capital or business angels. Governmental grants and credits are 8,75%, the contribution of the company owner is 7,84%, financial institutions are 20,25% of the providers. Nevertheless, 70,39% of the companies fund their technological innovations by their equity.

20. Do you face difficulties in finding labs (to test your products) for your technological innovation operations in Turkey?



39,3% of the companies, according to our survey, report that they face difficulties in finding labs in Turkey. The answers show that, especially services for experimental animal (mouse, pig, and sheep) studies, biocompatibility studies, a number of tests for CE certification are lacking.

21. Can you please mark how important are the sources below for your company's technological innovation operations? (Even though if they aren't in use at the moment) (1 Much Important, 5 Least Important).

	Points
National R&D financial supports (Tübitak TEYDEB, The Ministry of Industry and Trade, SANTEZ, KOSGEB, TTGV)	124
International R&D supports (7th Framework Programme, Bilateral cooperation etc.)	98
Regulations of joint tenancy of labs.	106
Promotions and supports for patent and utility model (Tübitak, KOSGEB)	111
To hold the rights of intellectual and industrial property rights (patent, utility model, designment registration etc.)	120
Technical consultation	92
Juricidial/Administrative consultation (regulations)	102

The rates that were given by the companies to these sources mainly prioritised, in terms of companies' technological innovations operations are listed below

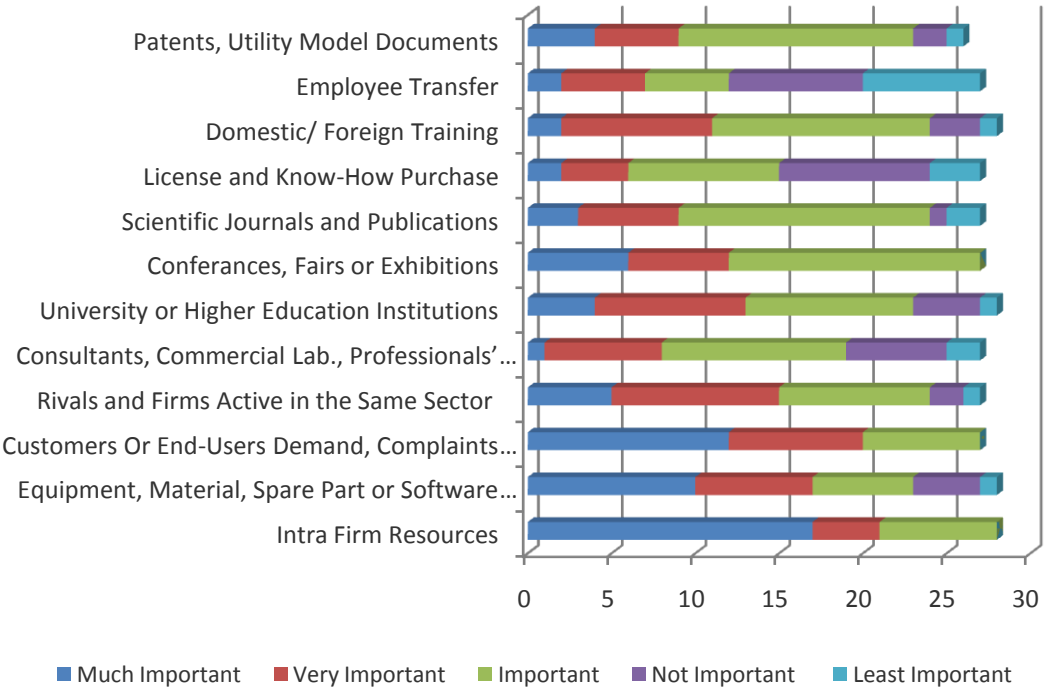
1. National R&D financial supports
2. To hold the rights of intellectual and industrial property rights (patent, utility model, designment registration etc.)
3. Promotions and supports for patent and utility model (Tübitak, KOSGEB)
4. Regulations of joint tenancy of labs.
5. Juricidial/Administrative consultation (regulations)
6. International R&D supports (7th Framework Programme, Bilateral cooperation)
7. Technical consultation

22. Do you cooperate with the following institutions for Technological Innovative activities? If you do, can you state the geographical position of that institution?

	No Cooperation	TR	USA	EU Countries	Middle East	Asia	Others
University or Higher Education Institutions	42.9%	**57.1%**	0.0%	0.0%	0.0%	0.0%	0.0%
Consultants, Commercial Lab., Professionals' Association	**42.9%**	**42.9%**	3.6%	10.7%	0.0%	0.0%	0.0%
Equipment, Material, Spare Part or Software Suppliers	7.1%	**60.7%**	7.1%	14.3%	0.0%	3.6%	7.1%
Customers/ End-Users	28.6%	**57.1%**	0.0%	10.7%	3.6%	0.0%	0.0%
The Head-Office of the Company in Another Country / R&D Department	**82.1%**	7.1%	0.0%	10.7%	0.0%	0.0%	0.0%
R&D Centers	**64.3%**	21.4%	0.0%	14.3%	0.0%	0.0%	0.0%
Rivals and Firms Active in the Same Sector	**60.7%**	25.0%	0.0%	10.7%	0.0%	0.0%	3.6%

Turkish companies cooperate mostly with equipment, material, spare part or software suppliers (60,7%). This is followed by the customers / end-users (57,1%) and universities or other institutions of higher educatsion (57,1%). While consultants, commercial laboratories, professional organization (42,9%) cover a high percentage, rivals and other companies active in the same sector (25%), R&D centers (21,4%) stand out as not so popular cooperative sources. Because the foreign capitals are not proclaimed it is not surprising that the Companies Foreign / R&D center in another country has a low percentage.

23. Evaluate the information sources that contribute to the creation or development of your projects involving Technological Innovations according to their importance.

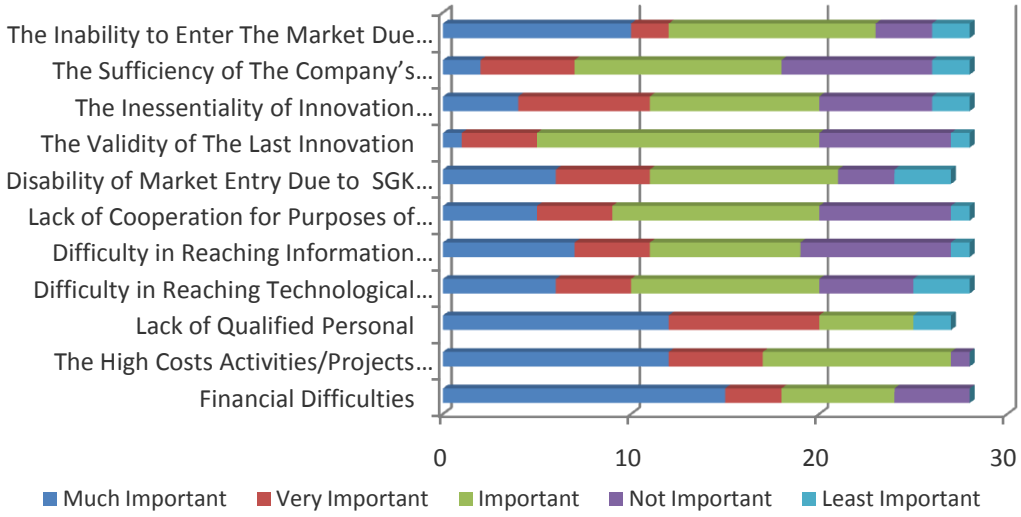


	points
Intrafirm Resources	122
Equipment, Material, Spare Part or Software Suppliers	105
Customers Or End-Users Demand, Complaints etc.	113
Rivals and Firms Active in the Same Sector	97
Consultants, Commercial Lab., Professionals' Association	80
University or Higher Education Institutions	95
Conferances, Fairs or Exhibitions	99
Scientific Journals and Publications	88
License and Know-How Purchase	74
Domestic/ Foreign Training	92
Employee Transfer	68
Patents, Utility Model Documents	87

When we look at the given answers we see the most important information sources are intercompany sources, customer/end-user demands/complaints etc. and equipment, material, spare parts or software suppliers. Employee transfer,

license and know-how purchase; and consultants, commercial laboratories, professional organizations are the least important information sources.

24. Evaluate the elements that RETAINED you from actualizing your projects involving Technological Innovations in the last two years.



	Points
Financial Difficulties	113
The High Costs Activities/Projects Involving Technological Innovations	112
Lack of Qualified Personal	109
Difficulty in Reaching Technological Knowledge and Know How	89
Difficulty in Reaching Information Related to The Market	92
Lack of Cooperation for Purposes of Technological Innovation	89
Disability of Market Entry Due to SGK (Social Security Institution) Reimbursement Policy	89
The Validity of The Last Innovation	81
The Inessentiality of Innovation (Standardization of The Product)	89
The Sufficiency of The Company's Current Innovation Activities	81
The Inability to Enter The Market Due to Harsh Competition	99

When we look at the main reasons why technological innovation projects fail we see financial difficulties in the first place. The high cost of innovative activities is the second reason, and the lack of qualified staff is the third reason.

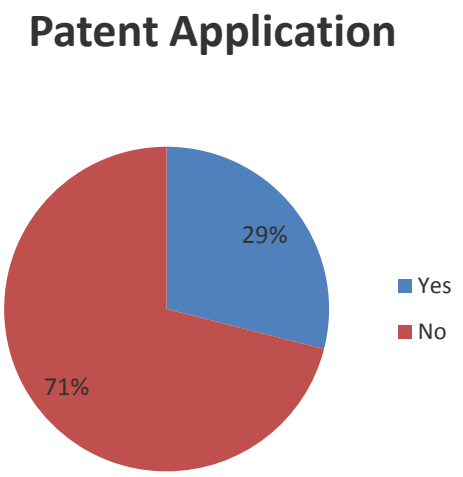
25. Did your company one of the following in the last 2 years;

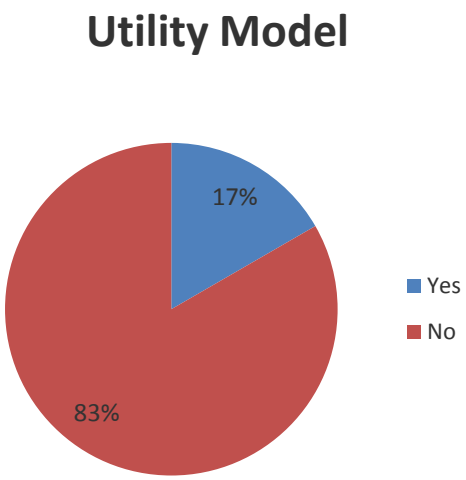
a. Patent application,

b. "Utility Model" application,

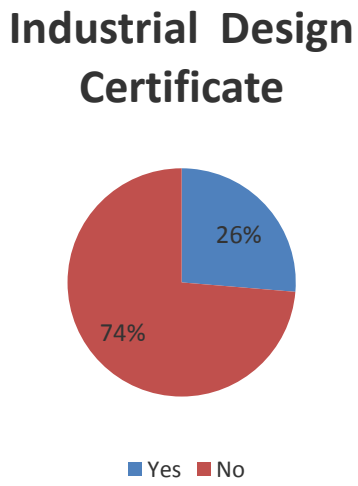
c. "Industrial Design Certified" application,

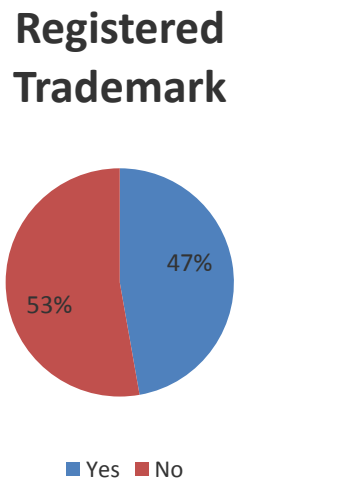
d. "Registered Trademark" application?



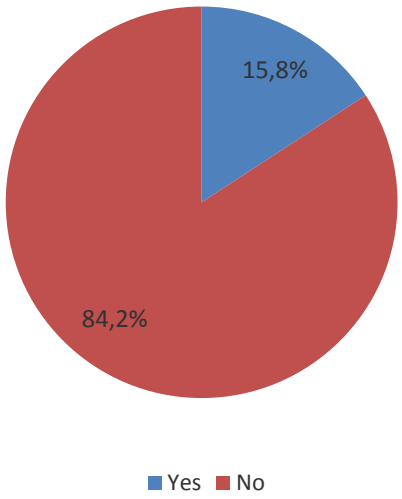


It can be seen that the percentage of applications of the "Utility Model" is little higher than the patent applications.



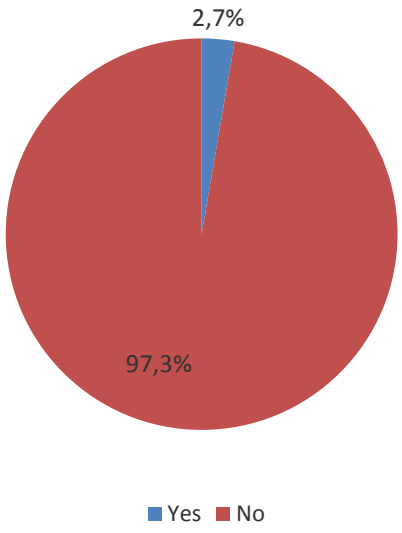


26. Did your company have any conflict regarding to the violation of intellectual property laws in the last 2 years?



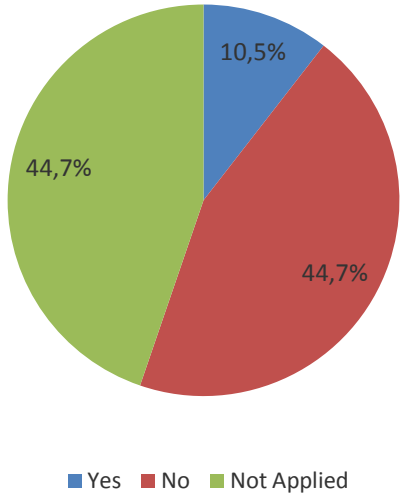
Only 15,8% of the companies had such a dispute.

27. Did your company earn any royalty out of intellectual property law in the last 2 years?



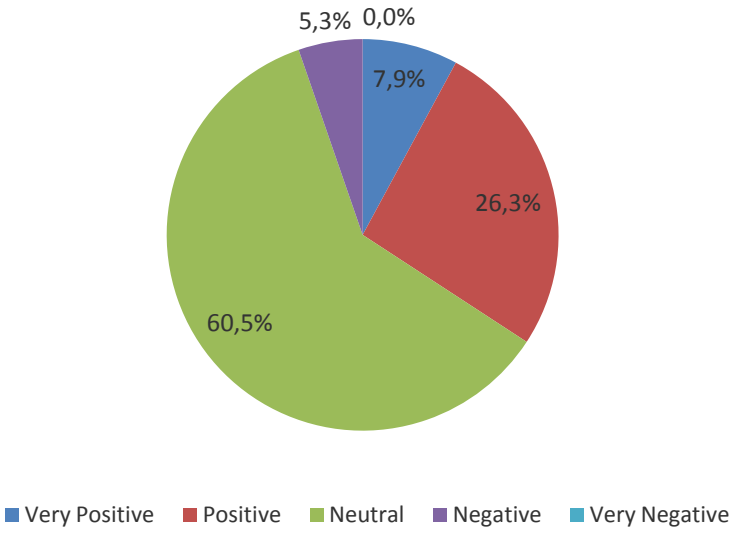
Only 2,7% of the companies stated to have earned royalties out of these laws.

28. Have you benefit from the supports involving your requests related to intellectual property in the last two years?



Only 10,5% of the companies stated to have profited of the supports involving their requests related to intellectual property. If we do not count the percentage that did not have any requests, we can say that 19,04% of the requests were supported.

29. What is your opinion about the effects the intellectual property protection over your projects regarding technological innovations?



None of the companies have described the intellectual property rights as too negative. Only 5,3% have stated them negative, and a great percentage has

stated their opinion as neutral. The positive and very positive answers cover a percentage of 34,2%.
The participants have answered the open ended question by saying they prefer commercial secrets that the costs were too high, that the law does not function well, that it does not serve its purpose very well and that it creates difficulties for imitations which is inevitable for innovative products.

4.2. Conclusions on the Survey Results and Interviews

The opinions gathered from various actors in the medical devices sector such as healthcare professionals, project contest nominees, firm owners are reflected in this section.

As repeatedly mentioned the medical devices has various subsectors under its umbrella which share similarities in their regulations, knowledge base and marketing strategies while at the same time diversified in their production processes and product groups. The medical devices combine multiple disciplines namely medicine, pharmacy, electronics, ICT, chemistry, mechanics and even textiles all of which are characterised by progressive scientific and technological components such as nano-bio technologies or micro-electromechanical systems (MEMS). The production in Turkey is supported by many programs by different organizations, however, firms are mostly benefit from the KOSGEB supports which are more available to all levels of firms in technological capacity. On the contrary the more technologically advanced programs such as 7th Framework has little concern as far as the survey reflect. Accordingly, one can conclude that the manufacturers in Turkey are still producing the generic products instead of radically new products. This conclusion is in concordance with the non- existence of an established and open reimbursement procedure to new products produced in Turkey by SGK. The SGK policy is a disincentive for investing in R&D and encourages the innovative activities that aim at gaining a price advantage by reducing the costs.

The involvement in reimbursement lists is not a transparent and clear procedure even if it may change many times a year. Further many devices are tried to be included in prospective systems according to relevant Diagnosis-Related Groups which suggests the healthcare professional to focus on cost-containment rather

than quality. As a result, the quality improving innovation is not paid in the market, or sometimes the cheapest product having at least a CE certificate is preferred to the better quality ones.
The most mentioned problem is the financial sources. The majority of the firms reported using the company resources for their innovation purposes where it is obvious that other financial actors remained insignificant.

Considering the sources of innovation medical devices is a sector where innovation need arises from the healthcare professionals, and accordingly the innovation is urged by these people. Correspondingly, the success of a novel product also comes from its widely acceptance and use by healthcare professionals. From an innovation perspective, the first claim suggests better interaction between the healthcare professionals and medical devices producers in product development and improvement, and the latter suggests the increased marketing expenditures since the pharmacy and medical devices are marketed via special marketing processes including direct marketing techniques such as product demonstration and customer (in this case healthcare professionals) visits enriched by promotions and sponsorships of medical exhibitions, conventions and congress. The marketing abilities of the firms are seemed insufficient compared to their European or US rivals and still the firms participated to the survey have declared the insignificance of becoming a trade mark in their areas of speciality.

CHAPTER 5

CONCLUSION

This thesis tried to analyze the medical devices sectoral systems of innovation and put forward the building blocks that affect the sector. The medical devices together with pharmaceuticals are main constituents of healthcare and are under the pressure of cost-containment policies. On the other hand they are undergoing a revolutionary change in knowledge base they operate on. The studies focusing on medical devices are either market surveys or industry analysis by commercial firms, or government reports and strategies. The large scope of medical devices with a variety of subgroups and the numerous agents and institutions specific to the sector involved makes it harder to provide an overall generalization.

The thesis has organized to cover the medical devices and its classifications to provide reader with the understanding of the scope of medical devices and its subsectors. Further the thesis stresses the importance of convergent medical technologies, which have ICT Nanotechnology and Biotechnology as components. Medical Devices is a sector where we can observe increased use of these three revolutionary technologies. The rapid change medical devices are subject to and ever increasing health costs linked with the innovations of medical technology on the one hand and the growth potential with the value added they create, medical devices is a challenging sector to analyze.

To answer the sectoral specifities of the medical devices innovation Malerba's Sectoral Systems of Innovation approach is adopted. The building blocks of a sectoral system is described and applied to the medical devices sector. Accordingly, the medical devices sector with the high technology knowledge base has been scrutinized. The potential peak of the technology in convergent medical technologies has been investigated. The economic aspects of the convergent medical technologies and the current situation in Turkey are examined. Considering agents, the trade structure and the non firm actors in the sector are mentioned with sight on Turkish case. The institutions those are important for the medical devices sectors which are Ministry of Health and Social Security Institution in Turkey are stated with a last inspection on Human Capital. The

methods and shortcomings on quantitative data has been stated and qualitative data used has been examined. The findings concerning the survey conducted with 44 manufacturers in Medical Devices Industry in Turkey are discussed. Following the survey results, the interviews and survey data are interpreted concurrently with a broader perspective relying on the sectoral systems approach.

The thesis concluded with that, the scarce financial and human resources as possible in many other sectors as well, medical devices sector also suffer from regulations that put extra-cost on innovative activities, reimbursement policies that aim at cost containment, lower degrees of consumer support (in terms of user-producer relationship), high marketing costs due to the specific market they act in. Nonetheless, the ambiguity in entrance and allowance to reimbursement lists is also found to be a blocking factor on innovation.

To provide policy recommendation on fostering innovation in medical devices, one should focus on the reimbursement strategy first. The local producer should be able to enter the reimbursement lists without the need of a previous "foreign" technology affirmed. Incentives on "on time payments" and support mechanisms that encourage local product use might be offered to healthcare service providers. A better competitive environment should be guaranteed. More facilities that enable and support user (healthcare professional/ applicant) and producer interaction should be created. Also more facilities to support user-producer collaboration in terms of finance, IPR support, new product introduction into market, and marketing is necessary. Moreover, since the firms are mostly SME's in this sector having difficulty in capital accumulation, the R&D incentives, the investment incentives should offer more chances to this "modest" SME dominated sector.

To conclude, this thesis indicated the sectoral specifities of medical devices sector in terms of innovation system composed of knowledge base, agents and institutions, yet this might only be an introductory study where a richness of issues are left untouched. Further research might focus on subsectors and benchmark the unique problematic they face both in production and innovation activities and might explain the reasons in specific constructs that affected one subsector differently than other.

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Appendix A: New Nanomaterials

Carbon-based Nanomaterials such as Carbon Nanotubes

Carbon nanotubes are essentially molecules that are formed entirely from carbon atoms and extended. They possess many very interesting and useful physical characteristics e.g. electronic, mechanical, thermal and optical, that exceed those of conventional materials. One such property currently under research is their ability to elongate or contract in suitable electrolytes under very low voltages which may render them very useful as actuators or sensors in a variety of medical devices. Other potentially valuable characteristics are their possible use as sensors, e.g. for CO2 monitoring in anaesthesiology, and their remarkable flexibility and resistance to breaking.

Nanowires

Nanotubes without inner cavity are Nanowires. The semiconducting silicon-based nanowires have the potentiality to detect the viruses in solution and their capabilities seem to exceed other methods.

Nanoporous Materials

Nanoporous materials, e.g. of carbon-, silicon-, ceramic- or polymer-based materials, with holes in the region of 100nm have greatly increased surface area and can have extremely useful catalytic, adsorbent and absorbent properties. These may have valuable applications in implant technology or in drug delivery.

Dendrimers

Dendrimers are macromolecules with a regular and highly branched three-dimensional structure comprising three major components, i.e. core with a central cavity, branches and end groups at the periphery of the molecule. The end groups may be chemically tailored in a variety of ways to provide differing properties. Dendrimers are currently being developed for use in in-vitro diagnostics, as carriers for contrast agents and drugs (given that the end groups may be modified to facilitate targeting within the body), and as light-sensitive carriers where the load may be activated by carefully-tuned frequencies of light which can be less physically damaging to tissues than other forms of energy.

Quantum Dots

Quantum dots are spherical nano-sized crystals and can be made from many semiconducting materials, e.g., CdS, CdSe, CdTe, ZnS, PbS, as well as metals, e.g. Au, and various alloys. They generally range from 2nm to 10nm with a semiconducting core and outer shell and surface layer, and take advantage of the quantum confinement effect to provide some unique optical and electronic properties. There are many potential applications in imaging and with biophotonic devices enabling diagnosis at very local and specific sites in the body.

(Source: Eucomed, Innovations in Medical Technology: Nanotechnology)

Appendix B: Nanotechnology in Surgery

Below there are the explanations for some nanotechnology products in use in surgery at present.

Nanocoated Surgical Blades: Nanoparticulate coating onto specially prepared hard metal substrate like plasma polished diamond nanolayers, makes it possible to produce surgical blades which have extreme sharpness and low friction. This feature of a blade makes it of greater used in optical surgery and neurosurgery**.**

Needles: Nanocoated needles provide fine suturing in demanding applications. Nanocoats provide the needles with extra ductility, increased strength and corrosion resistance.

Catheters for Minimally Invasive Surgery: Nanomaterials, like carbon nanotubes, have been added to catheters used in minimally invasive surgery. Nanotechnology helps to increase the strength and flexibility of the catheters and reduce their thrombogenic effect.

Optical Nanosurgery: Nano-Optical tweezers and nanoscissors are foreseen to be used for cell manipulation and immobilisation. With the help of laser use, medical or surgical procedures at the cellular level becomes possible with an enormous field of exploration.

Nanocoated or Nanocontoured Implant Surfaces: The surgical implants are likely to gain new characteristics on fixation and biocompatibility. In regenerative medicine, the nanocontoured implant or surfaces are expected to influence the cell proliferation.

Wound Management : Nanoformulated materials, e.g. silver nanoparticles, are already forming "smart" textiles used for improved wound dressings with antibacterial properties.

Biosensors and Biodetection

Cantilever Arrays

Nanomechanical cantilever arrays has potentiality in detecting diabetes mellitus and cancer and some viruses, bacteria and fungi. Biomarkers sticking to the cantilevers cause them to bend which is observable with lasers and electronically. Nanocantilevers are being improved to detect a vast number of

proteins at the same time in real time and this improvement has great potential in diagnostics.

Nanosensors

Addition to their use in blood glucose & CO2 monitoring and virus detection , nanowires can also be used for detecting peptides which can be associated with cystic fibrosis or dopamine and ascorbic acid for the diagnosis of Parkinson's Disease.

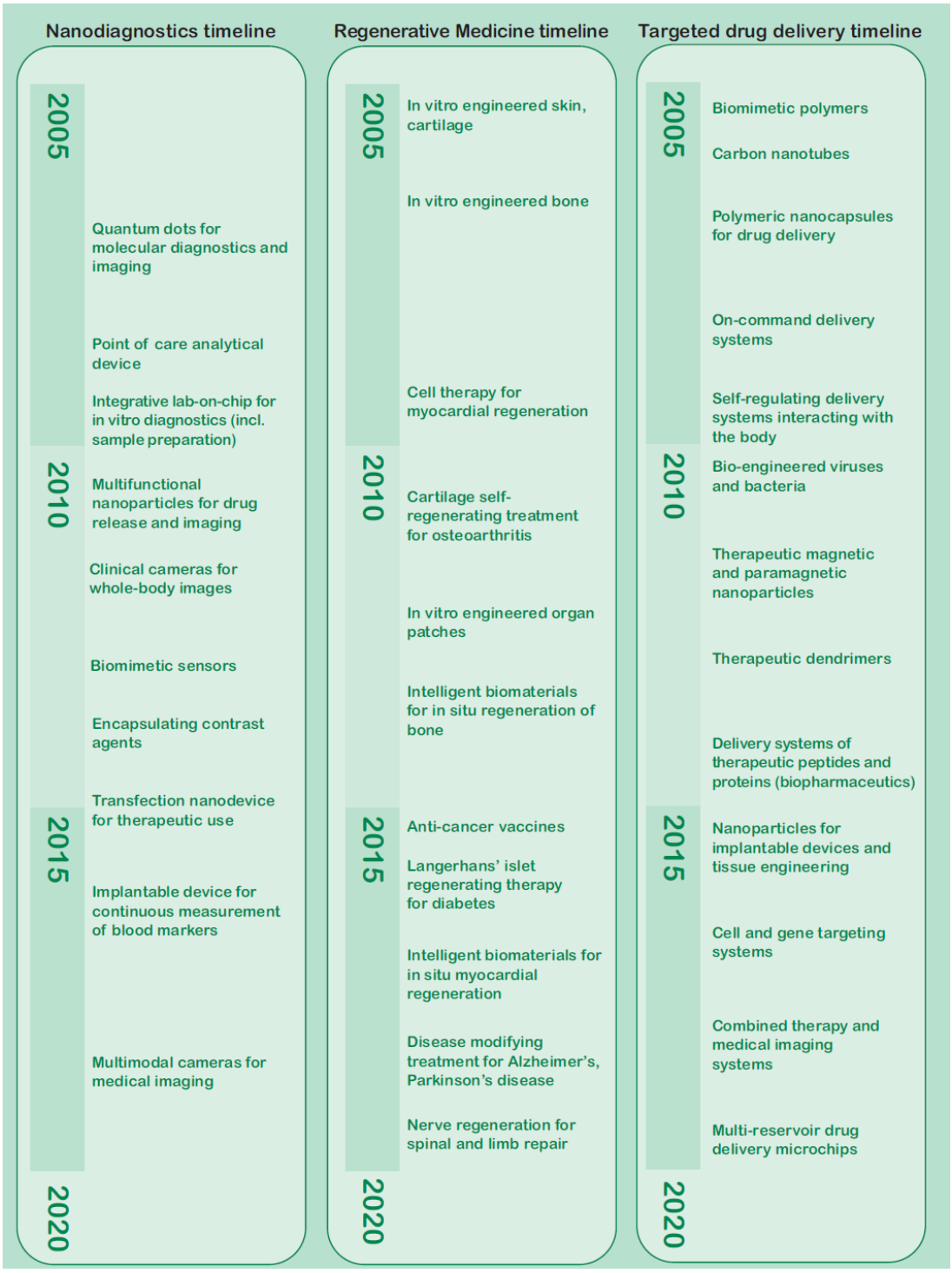
Optical Sensors

Raman spectrometry substrates are suggested to be in the future miniaturized to nanoscale devices that are implanted under skin enabling highly effective non-invasive glucose monitoring in eyes of the diabetic patients.

Nanoparticle Sensors and Detectors

Single nanoparticles, e.g. of gold, iron oxide or silica functionalised with poly- or monoclonal antibodies, are promising to be used for the detection of pathogenic biochemical markers or of individual bacteria.

Appendix C: Expected Development in Nano-biotechnology



Appendix D: Total Health Expenditure as A Percentage of GDP

Total health expenditure as a percentage of GDP						
	2000	2001	2002	2003	2004	2005
Austria	10,0	10,0	10,1	10,2	10,3	10,2
Belgium	9,1	9,3	9,5	9,5	9,7	9,6
Denmark	8,3	8,6	8,8	9,3	9,4	9,4
Finland	6,6	6,7	7,0	7,3	7,4	7,5
France	9,6	9,7	10,0	10,9	11,0	11,2
Germany	10,3	10,4	10,6	10,8	10,6	10,7
Greece	9,3	9,8	9,7	10,0	9,6	10,1
Ireland	6,3	6,9	7,1	7,3	7,5	8,2
Italy	8,1	8,2	8,3	8,3	8,7	8,9
Luxembourg	5,8	6,4	6,8	7,5	8,1	7,7
Netherlands	8,0	8,3	8,9	8,9	9,0	9,2
Portugal	8,8	8,8	9,0	9,7	10,0	10,2
Spain	7,2	7,2	7,3	7,8	8,1	8,2
Sweden	8,2	8,6	9,0	9,1	9,2	9,2
United Kingdom	7,2	7,5	7,6	7,7	8,0	8,2
Cyprus	5,7	5,7	6,1	6,5	6,3	6,1
Czech Rebuplic	6,5	6,7	7,1	7,4	7,2	7,1
Estonia	5,3	4,9	4,9	5,0	5,2	5,0
Hungary	6,9	7,2	7,6	8,3	8,1	7,8
Latvia	6,0	6,1	6,2	6,1	6,8	6,4
Lithuania	6,5	6,3	6,4	6,5	5,7	5,9
Malta	6,8	7,2	7,8	8,1	8,2	8,4
Poland	5,5	5,9	6,3	6,2	6,2	6,2
Slovak Republic	5,5	5,5	5,6	5,9	7,2	7,1
Slovenia	8,4	8,7	8,8	8,8	8,5	8,5
Norway	8,4	8,8	9,8	10,0	9,7	9,1
Switzerland	10,3	10,7	11,0	11,4	11,4	11,4
EU15	8,2	8,4	8,6	9,0	9,1	9,2
EU 25	7,4	7,6	7,9	8,1	8,2	8,3
Europe 27	7,6	7,8	8,0	8,3	8,4	8,4
USA	1,2	13,9	14,7	15,1	15,2	15,2
Japan	7,6	7,9	8,0	8,1	8,0	8,2
Turkey	4,9	5,6	5,9	6,0	5,9	5,7
SOURCE: The World Health Organization						

Appendix E: Indicators of Health and Medical Devices Expenditures in 2005

	MD expenditure as a % of total health expenditure	Total health expenditure as a % of GDP	MD expenditure per capita (€)	THE expenditure per capita (€)
Austria	3,7	9,1	101,5	2764,5
Belgium	3,3	9,2	86,4	2648,5
Denmark	5,7	8,5	187,0	3491,4
Finland	4,5	7,1	95,6	2142,3
France	5,8	10,5	165,4	2867,1
Germany	8,6	10,3	242,5	2814,9
Greece	4,8	10	72,3	1500,6
Ireland	3,7	7,1	94,0	2596,4
Italy	5,6	8,8	121,8	2189,3
Luxembourg	2,6	8	132,7	4867,3
Netherlands	5,6	8,9	153,5	2745,4
Portugal	4,8	10,1	61,9	1284,6
Spain	8,2	7,4	128,8	1576,4
Sweden	5,2	8,9	147,9	2835,2
United Kingdom	4,5	8,4	112,0	2478,5
Cyprus	4,7	5,7	47,9	958,1
Czech Rebuplic	8	6,4	49,0	616,9
Estonia	14,1	5,5	66,9	446,1
Hungary	7,8	7,4	50,5	643,1
Latvia	11,7	5,1	34,8	304,3
Lithuania	9	6	32,2	351,6
Malta	6,1	8,9	49,5	990,1
Poland	6,9	6,5	23,0	330,0
Slovak Republic	12,3	5,1	39,0	315,9
Slovenia	6	8,4	95,0	1599,2
Norway	4,6	9,2	217,8	4769,2
Switzerland	4,7	11,6	215,2	4533,2
EU-15 average	5,1	8,8	126,9	2586,8
New Member States average	8,7	6,5	48,8	655,5
EU-25 average	6,5	7,9	95,6	1814,3
Europe average	6,3	8,7	127,5	2073,5
United States	5,5	15,3	270,5	4905,4
Japan	n.a.	n.a.	n.a.	n.a.

Source: Eucomed, Competitiveness and Innovativeness of the European Medical Technology Industry- Evaluation of the Survey Results, 2007

Appendix F: Medical Device Real Production Value

Medical device real production value (constant 1995 € million)

Country	1997	1998	1999	2000	2001	2002
	€	€	€	€	€	€
US	48112	50220	52886	54698	55002	52100
Japan	12368	12444	12363	12597	13057	13118
EU-25	n.a.	n.a.	n.a.	29155	32139	33803
EU-15	n.a.	n.a.	29228	28212	31059	n.a.
New Member States	n.a.	n.a.	510	561	614	705

Source: AdvaMed (2004); MHLW (2004); Eurostat (2004); OECD (2004).

Appendix G: Medical Device Value Added at Factor Cost

Medical device value added at factor cost (constant 1995 € million)

Country	1997	1998	1999	2000	2001	2002
	€	€	€	€	€	€
US	31778	33790	35257	36776	37625	38911
US (excl. IVD)	27163	29201	30188	31590	32197	35246
Japan	14729	14838	14467	14706	14779	n.a.
EU-25	n.a.	n.a.	n.a.	13937	14709	n.a.
EU-15	n.a.	n.a.	14606	13527	14255	12739
New Member States	n.a.	n.a.	n.a.	228	271	305

Source: AdvaMed (2004); MHLW (2004); Eurostat (2004); OECD (2004).

Appendix H: Number of Employees (thousands) in Medical Devices

Number of employees (thousands) in medical devices

Country	1997	1998	1999	2000	2001	2002
	n.	n.	n.	n.	n.	n.
US	341	354	352	351	353	373
US (excl. IVD)	302	314	311	311	312	346
Japan	239	234	223	213	213	n.a.
EU-25	n.a.	n.a.	326	333	352	n.a.
EU-15	n.a.	n.a.	299	304	319	n.a.
New Member States	n.a.	27	27	28	32	35

Source: AdvaMed (2004); MHLW (2004); Eurostat (2004); OECD (2004).

Appendix I: Medical Device Real Gross Value Added Per Person Employed

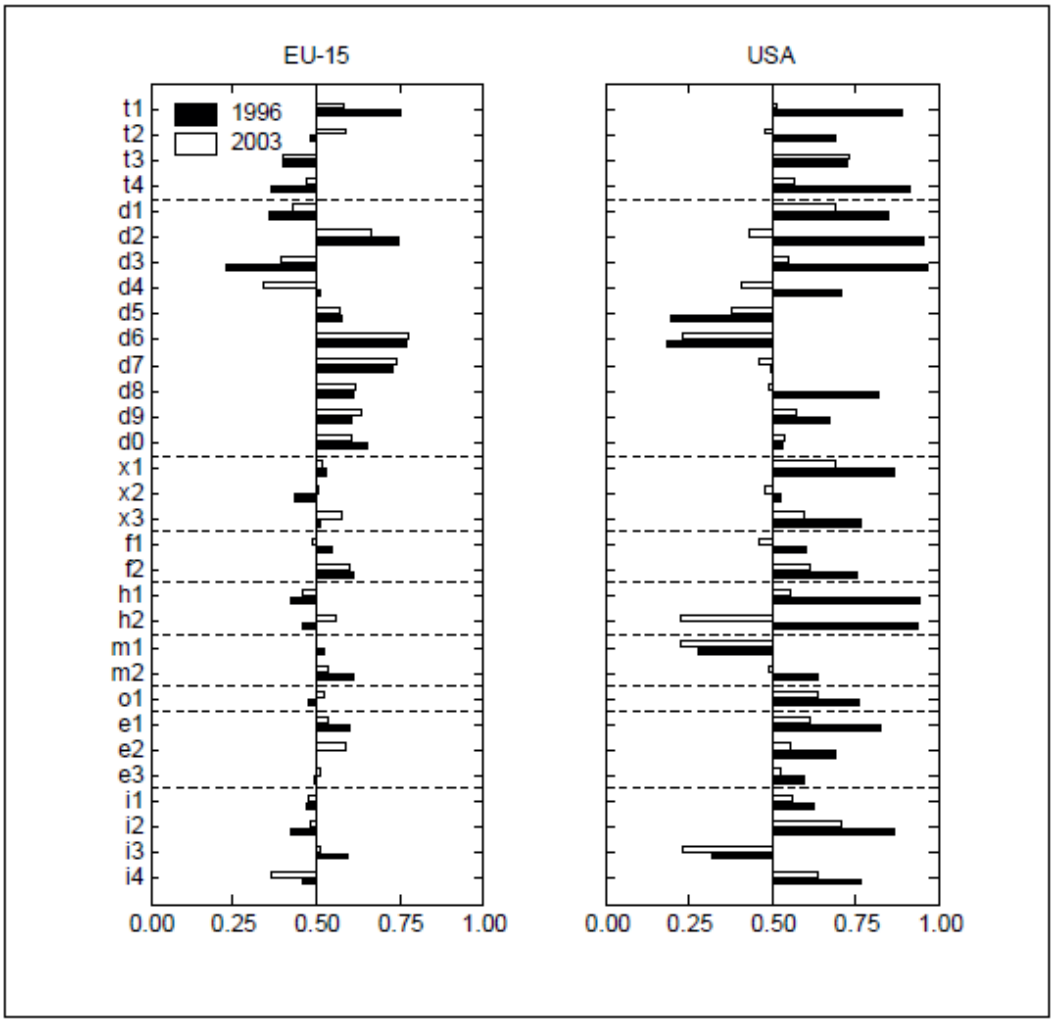
Medical device real gross value added per person employed (apparent labour productivity) (1995 € thousands)

Country	1997	1998	1999	2000	2001	2002
US	93,2	95,5	100,2	104,8	106,6	104,3
Japan	61,6	63,4	64,9	69	69,4	n.a.
EU-25	n.a.	n.a.	n.a.	36,8	36,6	n.a.
EU-15	36,4	35,8	39,1	41,7	40,5	n.a.
New Member States	n.a.	n.a.	n.a.	9,1	5,5	n.a.

Source: AdvaMed (2004); MHLW (2004); Eurostat (2004); OECD (2004).

Appendix J: Trade Balance

Trade Balance (ratio of export over total trade) at the sub-market level, EU-15, US, 1996, 2003



Source: Eurostat (2004b), US International Trade Commission (2004).
Note: see Box 2 for the correspondence of the abbreviations.

The abbreviations are submarkets not provided here. The table has put to provde an insight on product diversification and country specialization. For more detail please refer to the EU Competitiveness Report. (Pammolli, Riccaboni, Oglialoro, Magazzini, Baio, & Salerno, 2005)

Appendix K: Value added Medical Devices Sector (NACE DL 33.1)

Medical devices (NACE DL 33.1)in the EU-25 manufacturing sector, 2001 as a % of total EU-25 manufacturing		
Value added	€17.2 billion	1,1
Employment	352,00	1,2

Source: EU competitiveness report 2005

Value Added Created as a percentage of Production Value	
Medical devices	45,8
Pharmaceuticals and medicinal chem.	37,4
Paper, publishing and printing	36,3
Basic metals and metal products	33,1
Electrical machinery	32,4
Textiles and textile products	31
Manufacturing total	28,7
Basic chemicals	26,7
Food and beverages	24,5
Radio,tv and communication equipment	23,8
Motor vehicles	17,9
Office machinery and computers	17,5

Source: EU competitiveness report 2005

Share of R&D in value added (%)	
Radio,tv and communication equipment	24
Motor vehicles	19
Pharma and medicinal chemicals	18
Basic chemicals	8,8
Electrical machinery	8,4
Office machinery and computers	7,7
Medical devices (NACE DL 33.1)	5
Manufacturing total	3,8
Metals and metal products	1,5
Textiles	1,1
Food and beverages	0,4
Paper, publishing and printing	0,1

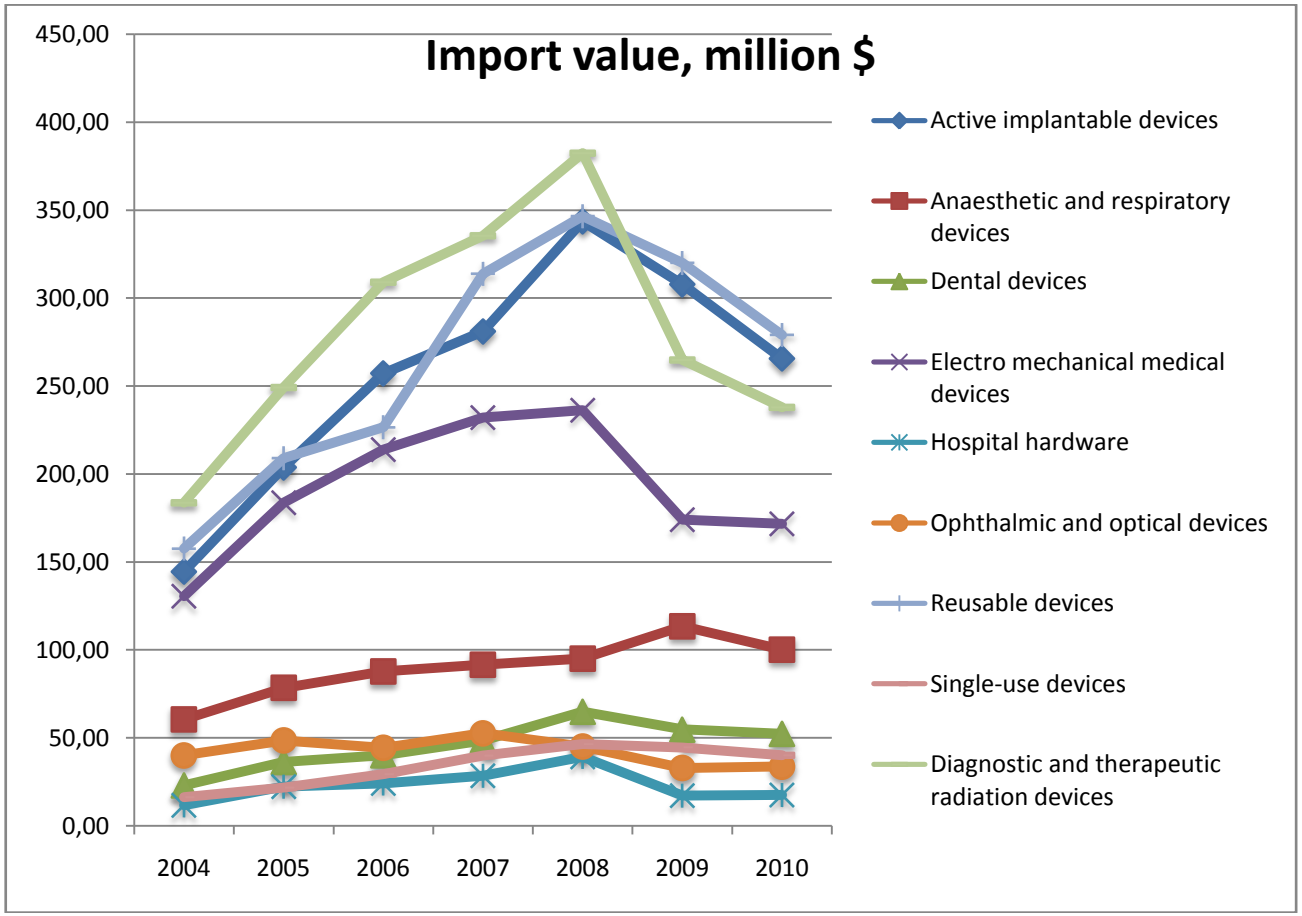
Source: EU competitiveness report 2005

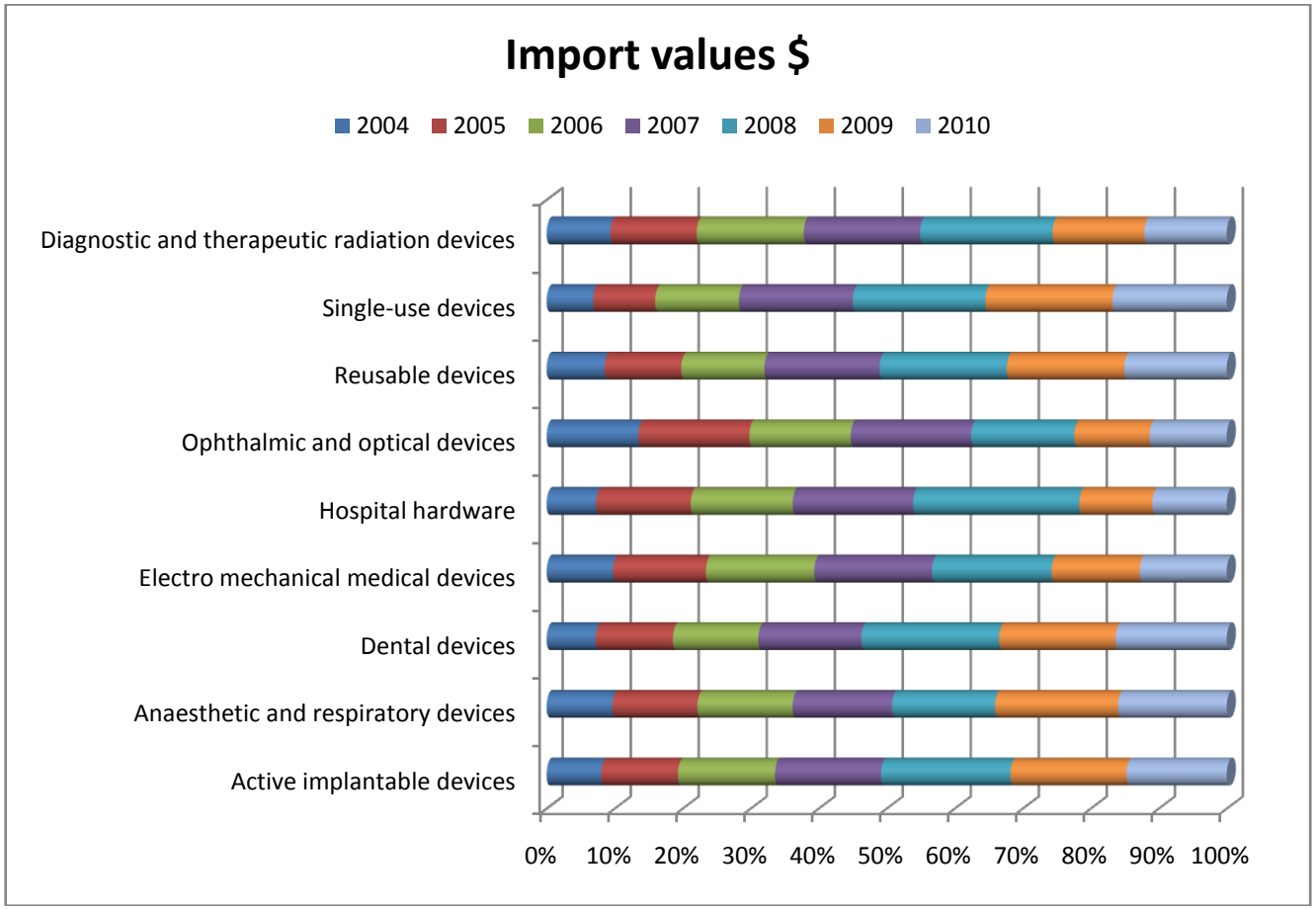
Appendix L: Share of corporate ownership, by establishment country

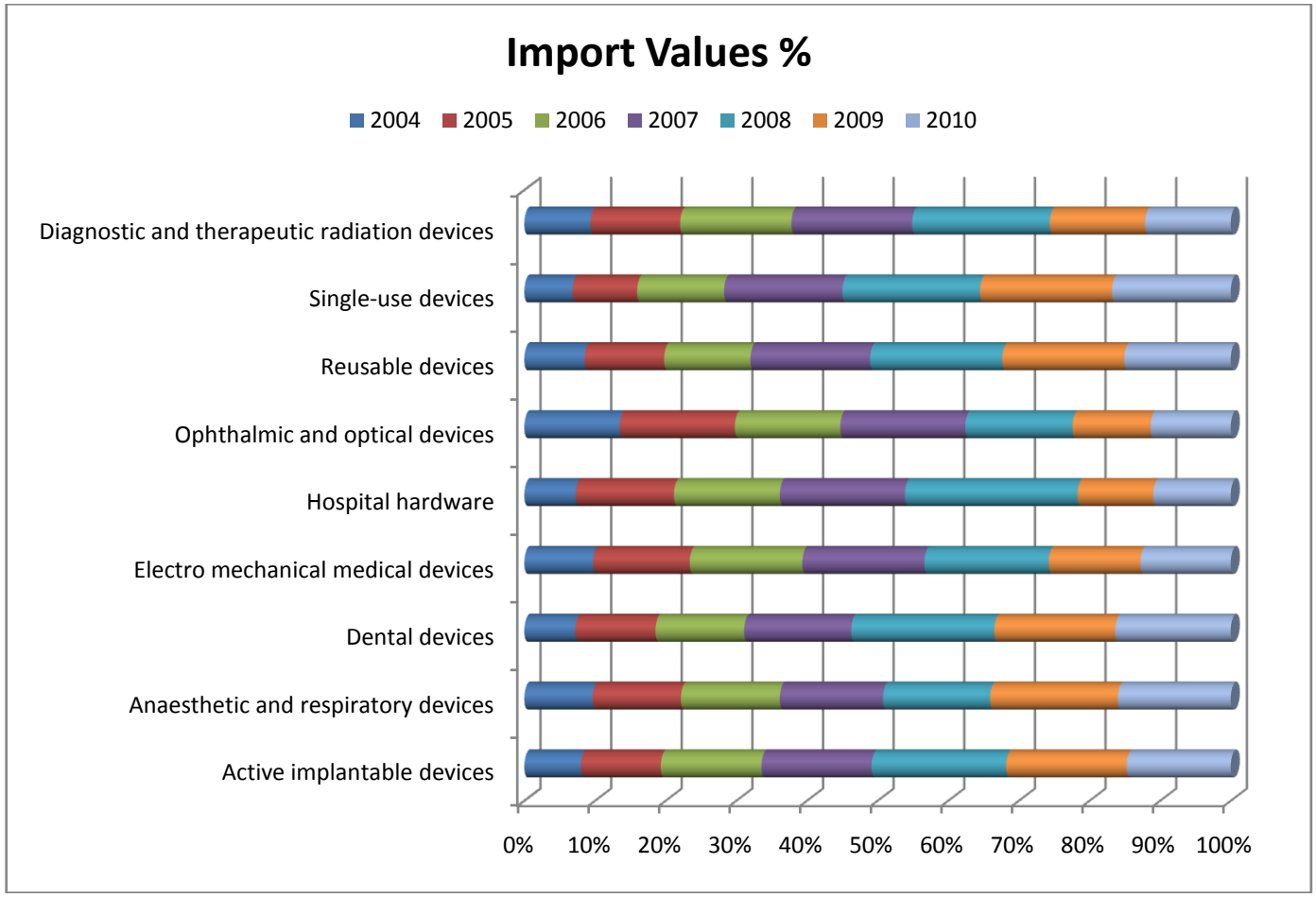
Establishment Country	Owner/Operator Group Country (%)					
	Europe	Home	Japan	Other	US	N
US	1,29	98,24	0,15	0,32	0	11,406
Germany	92,94	91,07	0,21	0,21	6,65	963
Canada	0,37	91,7	0,18	0	7,75	542
UK	86,76	83,88	0,38	0,38	12,48	521
Japan	0,6	97,82	0	0	1,59	504
Italy	96,67	93,79	0	0,67	2,66	451
France	88,54	84,72	0,35	1,04	10,07	288
Switzerland	98,02	83,82	0	0,58	10,4	173
Sweden	91,52	86,67	0	0,61	7,88	165
Netherlands	88,51	81,61	0	0	11,49	87
Denmark	91,77	90,59	0	1,18	7,06	85
Ireland	38,56	31,33	0	1,2	60,24	83
Spain	90	80	0	0	10	60
Belgium	91,49	87,23	4,26	0	4,26	47
Finland	82,61	78,26	0	0	17,39	46
Austria	95,55	84,44	0	2,22	2,22	45
Hungary	20	65	0	0	15	20
Norway	90	85	0	0	10	20
Poland	6,25	93,75	0	0	0	16
Czech Republic	7,69	84,62	0	0	7,69	13
Estonia	25	50	0	0	25	4
Luxembourg	100	100	0	0	0	4
Portugal	75	50	0	25	0	4
Slovakia	33,33	0	0	0	66,67	3
Ukraine	33,33	66,67	0	0	0	3
Lithuania	0	100	0	0	0	2
Malta	50	0	0	0	50	2
Greece	100	100	0	0	0	1
Slovenia	0	100	0	0	0	1

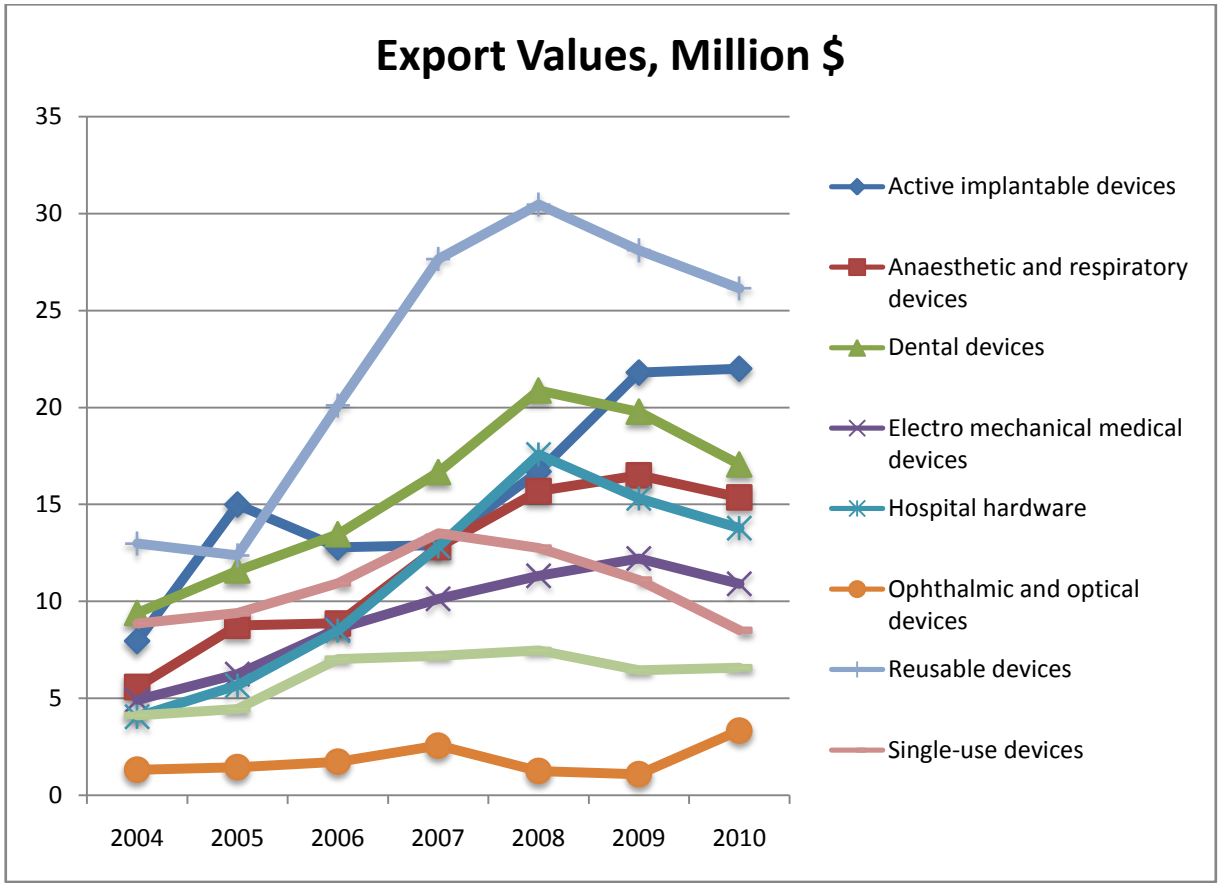
Source: MPRI

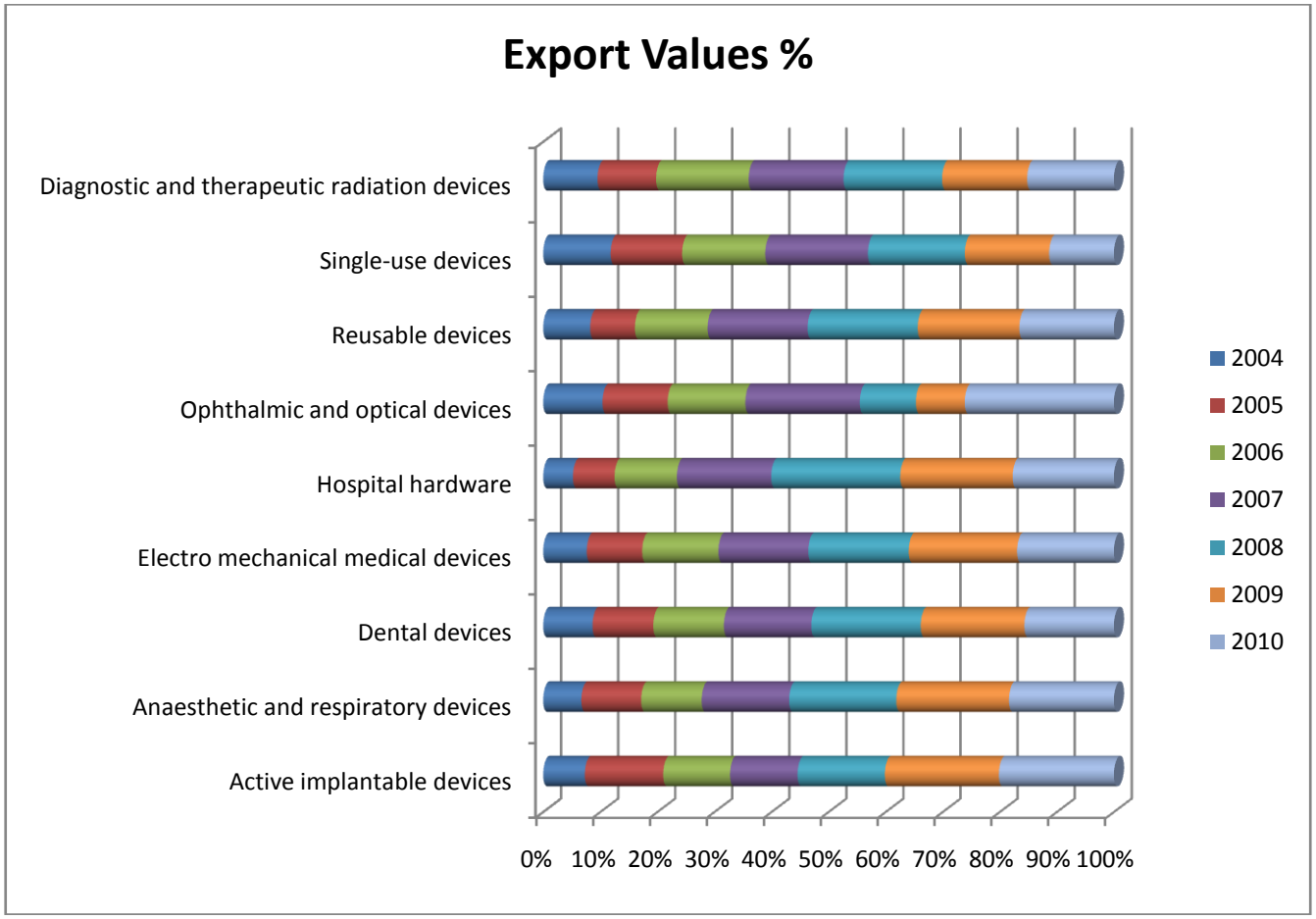
Appendix M: Trade Statistics on TURKEY

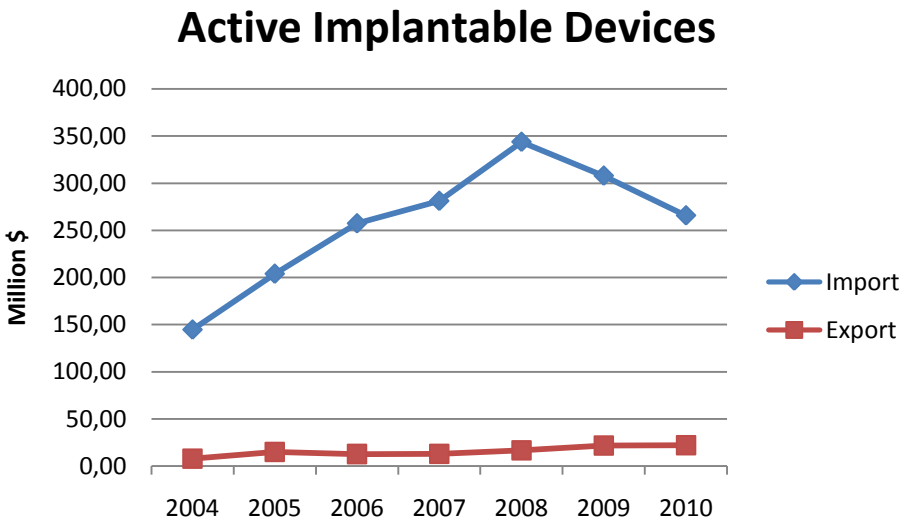


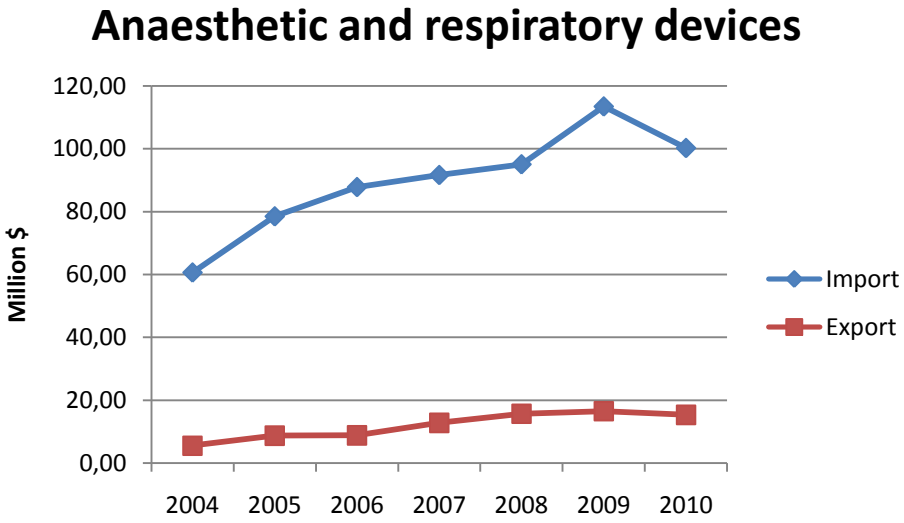

Import values $
2004
2005
2006
2007
2008
2009
2010
Diagnostic and therapeutic radiation devices
Single-use devices
Reusable devices
Ophthalmic and optical devices
Hospital hardware
Electro mechanical medical devices
Dental devices
Anaesthetic and respiratory devices
Active implantable devices
0%
10%
20%
30%
40%
50%
60%
70%
80%
90%
100%


Import Values %
2004
2005
2006
2007
2008
2009
2010
Diagnostic and therapeutic radiation devices
Single-use devices
Reusable devices
Ophthalmic and optical devices
Hospital hardware
Electro mechanical medical devices
Dental devices
Anaesthetic and respiratory devices
Active implantable devices
0%
10%
20%
30%
40%
50%
60%
70%
80%
90%
100%

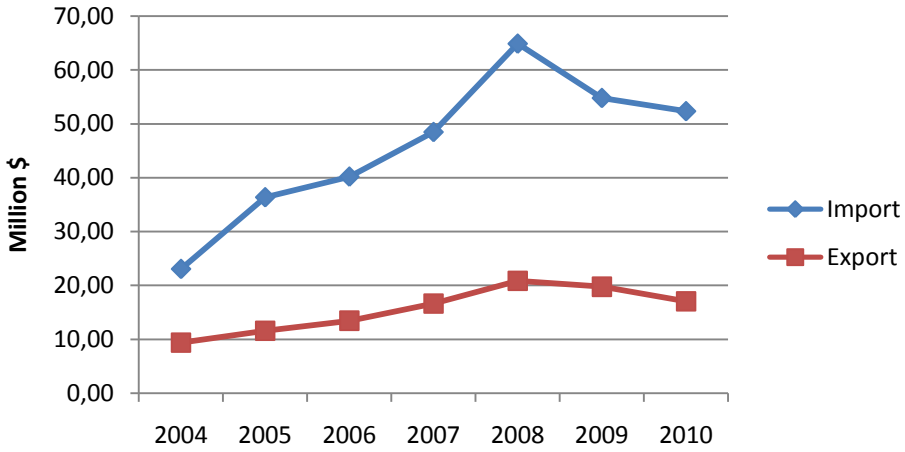

Export Values, Million $
35
30
25
20
15
10
5
0
2004
2005
2006
2007
2008
2009
2010
Active implantable devices
Anaesthetic and respiratory devices
Dental devices
Electro mechanical medical devices
Hospital hardware
Ophthalmic and optical devices
Reusable devices
Single-use devices


Export Values %
Diagnostic and therapeutic radiation devices
Single-use devices
Reusable devices
Ophthalmic and optical devices
Hospital hardware
Electro mechanical medical devices
Dental devices
Anaesthetic and respiratory devices
Active implantable devices
0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%
2004
2005
2006
2007
2008
2009
2010

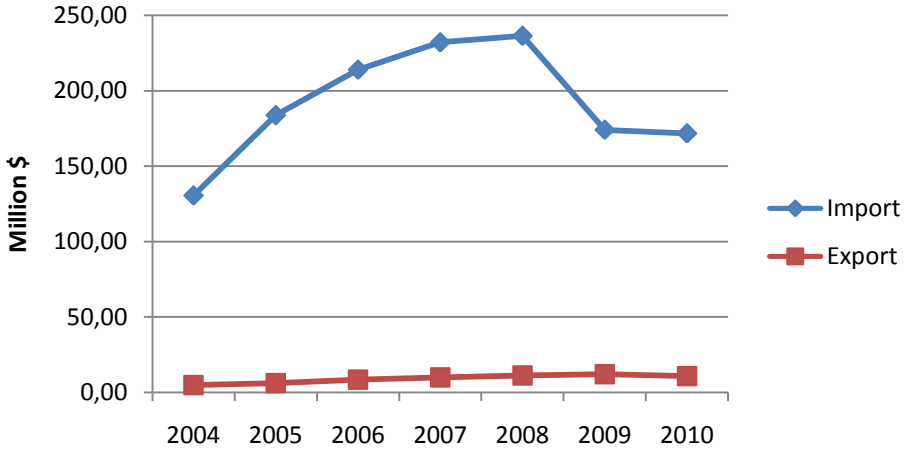

Active Implantable Devices
400,00
350,00
300,00
250,00
200,00
150,00
100,00
50,00
0,00
Million $
2004
2005
2006
2007
2008
2009
2010
Import
Export


Anaesthetic and respiratory devices
120,00
100,00
80,00
60,00
40,00
20,00
0,00
Million $
2004
2005
2006
2007
2008
2009
2010
Import
Export

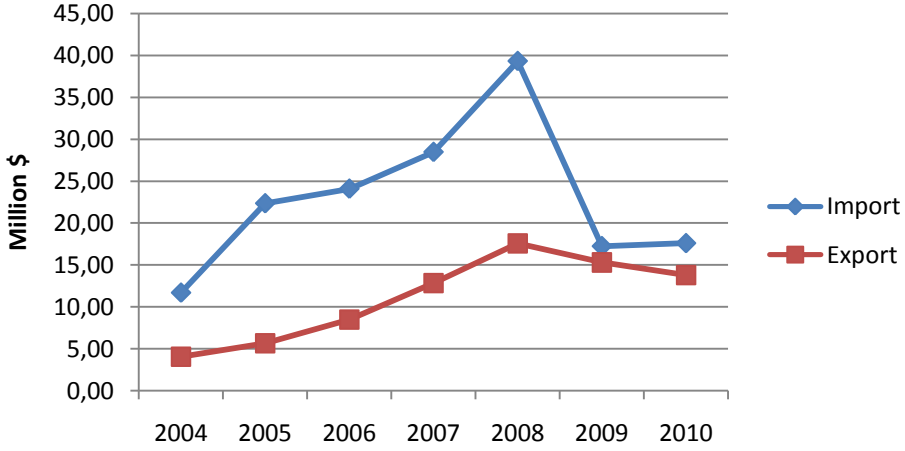
Dental devices



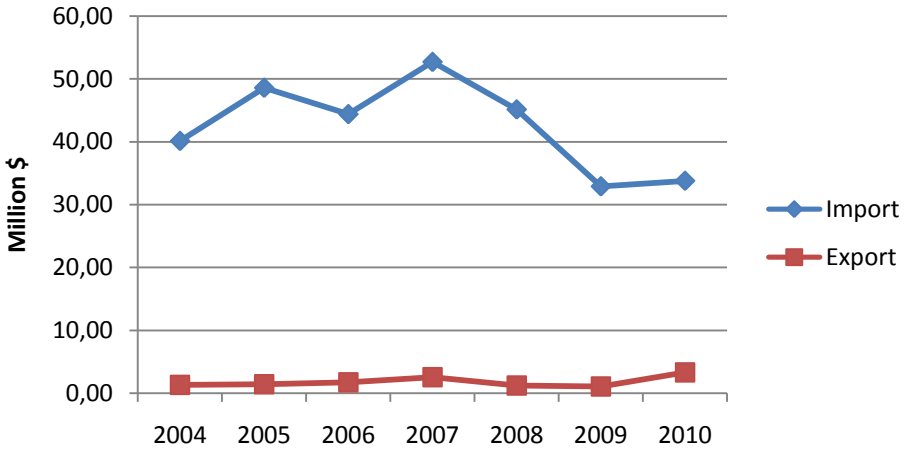
Electro mechanical medical devices



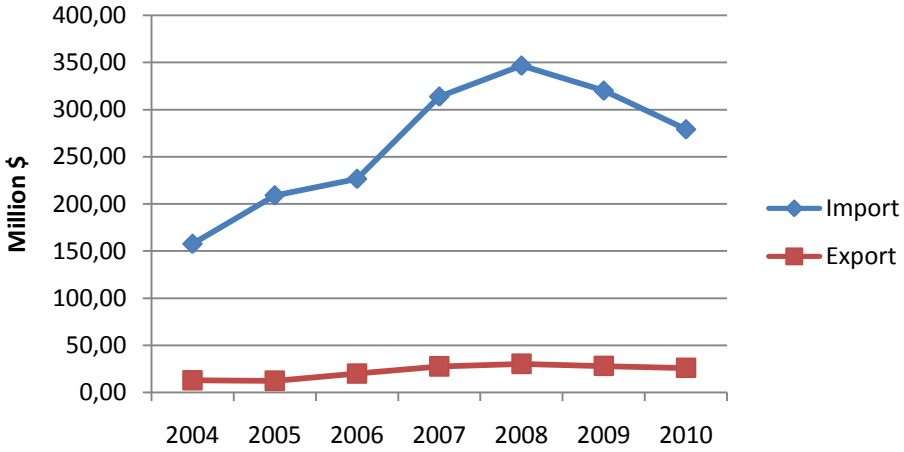
Hospital Hardware



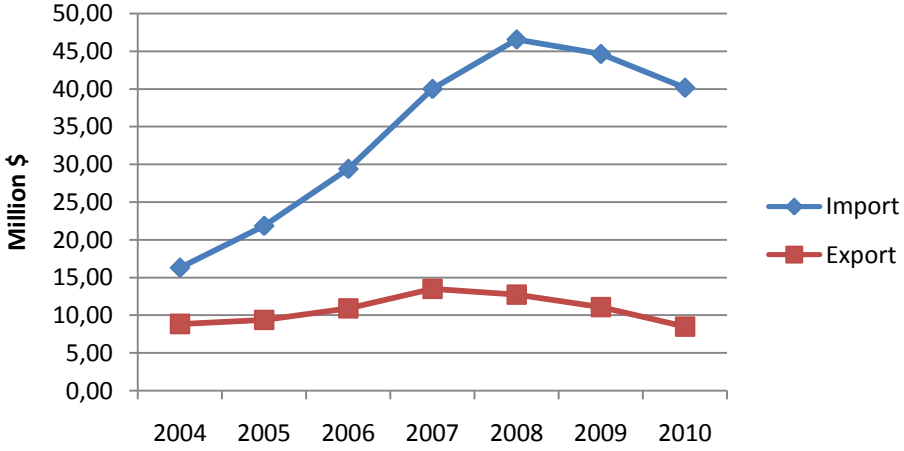
Ophthalmic and optical devices



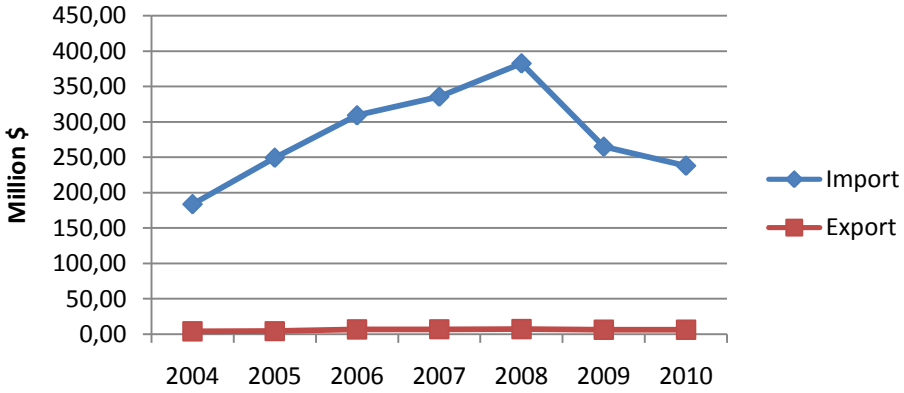
Reusable devices



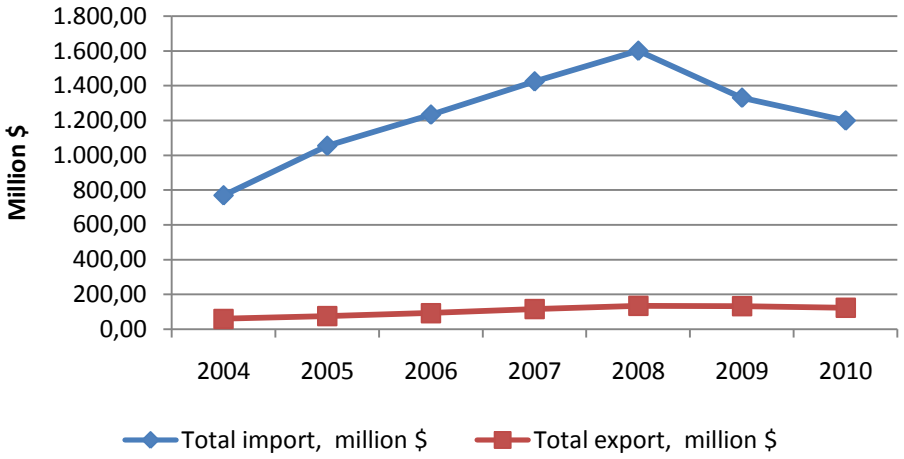
Single-use devices



Diagnostic and therapeutic radiation devices



Total Import vs Export



Appendix N: Interviews on Project Contest

Project Contest Evaluation Questions

1. Does the Project hold an original value (scientific, intellectual, technological or professional competence)?
2. Is the evaluation of current situation accurate?
3. Is the diffusion/penetration effect of project sufficient?
4. Is the purpose of the project realistic?
5. Is the purpose of the project significantly scientific?
6. Is the purpose of the project consistent with the estimate of the situation for the project?
7. Is the purpose of the project consistent with the scope of the project?
8. Is the suggested research method valid?
9. Is the research method consistent with the purpose of the project?
10. Is the project applicable?
11. Is the personal evaluation of the jury favourable?

According to these criteria, the following projects were awarded each year since 2006.
The first year's winner projects and their industrial status are:

Prof. Dr. Özcan EREL- New Generation Ceruloplasmin Measurement Test Project

Prof. Erel from Harran University, Faculty of Medicine, in the application form defines his project as the generic Ceruloplasmin Measurement which is based on immunoturbidimetrics and holds some negativity, and widely used in diagnosis and treatment of many illnesses However its local production does not exist. The developed test is based on a novel method and measures the ceruloplasmin kinetically. It is more reliable, cheaper and adaptable to any laboratory measurement system. He mentions his project as "it has been invented with national resources only and it has the potential to subsidize imports through exporting the technology". He adds, "Until now, the test item has been imported material, however with the development of the new generation ceruloplasmin measurement, Turkey may hold a position to export this technology". He describes his test as low in cost, higher in quality and technical standards, and a

new generation test kit. Ceruloplasmin is a protein, the level of which increases in blood in some medical conditions and when removed causes Wilson's Disease. According to the project owner, the widely used methods to measure the level of protein in blood include some disadvantages. The new suggested test is using the ferroxidase activity in blood. In the new test, separators and blood serum is mixed and the results are obtained in two minutes. It shows a high correlation with the conventional test and it is reliable, sensitive, practical, and very cheap compared to its alternatives.

The project is considered to be produced by the firm MTG which will be further investigated. Regarding the tests, the test was considering only one parameter when met the producer, and to be fully commercialized, it is stated that the project needed to be developed further to include two other parameters. The remaining R&D process was not supported by the matching firm. However the project is later revised and started production.

Barış ÜNLÜ - Improved Wheelchair Project

Barış Ünlü, the project owner was a fourth year student in Biomedical Engineering in Başkent University when he applied to the competition with his dissertation project. The project is based on an improvement of the wheelchair with extra abilities and special functions. The main purpose of the project, as mentioned in the application form is: "to provide people dependent on wheelchairs with more healthy, comfortable, technological and multi-purpose devices." Most wheelchairs available in Turkey, it is stated, are not satisfying enough for the disabled, and the expensive and more technological wheelchairs generally used in developed countries are hard to obtain for economic reasons. Project owner states that he detected the needs of the disabled and configured main functions of his improved wheelchair. He described its main functions as follows:

- Disabled people's need to transfer between bed and wheelchair without the help of a second person is realized by the attaching feature.
- The need for periodical stand up position for the disabled people without the help of a second person is met by the features of stand-up and raising up.
- The feature of joystick controlled electric-motor is to provide the disabled with more comfort during travel.

- To ensure the safety of the disabled, the wheelchair is supplied with photocells to stop before crashing a wall and before voids and avoid falling.
- The wheelchair is ergonomically designed.

The wheelchairs available in the Turkish market are suggested to be far from satisfying and the high quality wheel-chairs are not affordable for the majority. The project is designed to create an alternative with high quality hardware to the wheelchairs available for Turkish market.

According to Ünlü, the new wheelchair is produced by integrated circuits and a programmable microcontroller. It is able to head directions further than standard wheelchairs can, while it is ergonomic, comfortable, and user-friendly. To increase the number of directions a special wheel system and four special DC motors are used. With the help of the microcontroller, all four motors can be controlled separately. The project portfolio contains data on wheelchairs, relevant standards, Turkish wheelchair use and production statistics, directions included, seat ergonomics, and electronic basis.

He later founded his own firm and started production of wheelchairs. However, he couldn't been get in touch with again to update the current situation.

Mustafa BAŞARAN - Re-usable Devices for Retropubic and Transobturator Intravaginal Tape Methods in Surgical Therapy of Female **Urinary Incontinence (RP-IVT, TO-IVT) Project**

Frequently observed urinary incontinence for women is mostly treated with retropubic and transobturator tension-free intravaginal sling methods. In these methods the aim is to locate meshes retropubically or transorburatory. All devices used for this purpose in Turkey are single use disposables and due to their high costs, they are not covered by insurance systems. Rather patients with this problem are treated with less efficient temporary procedures like Kelly-Kennedy sutures or operational procedures like Burch operation which needs laparotomy. In this project, it is aimed to develop a low cost re-usable operational device to enable mesh locating.

This project aims to replace imported products necessary for efficient surgery of urinary incontinence in women, each unit of which costs between $500 and $1500. The project owner, Mustafa Başaran provides the data of the USA

expenditure on treatment of urinary incontinence in women as 12.4 billion dollars annually (in 1994 foresights). He states that his method, which is more patient-friendly and not temporary, cannot be widely used for masses and can only be applied to a limited number of patients. The project is suggested to provide a re-usable device for replacement of single-use disposable and expensive import item, and thus enables the technology to penetrate increased number of women. Moreover, the social benefits of the project are mentioned to include elderly population in nursing homes. The project owner also states that the primary reason for women who are left to nursing homes has been urinary incontinence in USA.

The project portfolio includes computerized anatomic models, human cadaver measures, computer drawings, prototyping of the operational devices, testing of the devices on computer models and human cadavers, and the testing of the way the device operate as explained in literature. The meshes located as literature explains, are realized in the project, in prolene material which is commonly used in other sling operations and the results are expected to be the same with the literature. Even though, there is no systematic production of prolene mesh, the cost of the item will be expected to be under $20 in May 2007.

The project has been produced by a producer located in Samsun. However, concerned doctors continue to use the disposable meshes. The main problem has been seen as the marketing of the new device.

Mustafa Kemal ALTINEL - The Design of A Sedimentation Device Project

Mustafa Kemal Altınel is a biomedical graduate and he enrolled the contest while he and a group of classmates were pursuing their master's program in METU.
Mustafa Kemal Altınel suggests that the project provides an alternative to import laboratory devices. The device has an average of 400 test capacity, low production costs, user-friendly interface, and compatibility with the laboratory information systems, and accordingly an alternative to existing devices. The sedimentation device presents in almost all biochemistry laboratories and the project aims to disseminate the utilization of the device owing to its price advantage and to replace the imported material. This project presents a sample

to measure the settling velocity of erythrocytes in 30 minutes for 20 samples. The sedimentation velocity measuring method is compatible with the standard hand-measurement method of Westergren. This technique suggested providing an ease in laboratory use. The validation tests have been continuing when the project team claimed the prize.
The second year's noteworthy projects are listed below.

Ali Doğan BOZDAĞ - Videoanoscope Project

Prof. Dr. Ali Doğan Bozdağ, suggests that the videoanoscope he has improved, can be used in a modular form through which the operation is easier for the surgeon. The videoanoscope can be attached to a telescope (camera with light) and can view and record the operation which can later be used for educational purposes. When the sliding cover of the videoanoscope is replaced, the haemorrhoid operation can be performed in classical operative methods. Alternatively the videoanoscope, with the help of the length adjustable sliding cover, helps to avoid haemorrhoid pakes to fill the anoscope and eases the sewing of the region as the stapler way is easily controllable. The telescope and the removal of the sliding cover to return back conventional methods when required are stated as not available in any anoscope around the world.
SEIS matched the project with a qualified producer in İzmir. Together with the project owner, the producer wanted to apply for a Tubitak support. However, the consultant they work with suggested undesired ways to ensure Tubitak support and the producer didn't want to get the support under such circumstances. The project owner still looks for a producer at the date of the preparation of this study.

Beytullah AKGÜN - Sterilization Project

Dr. Beytullah Akgün is a chemist who left academy and currently works on production of chemical indicators. He declares the aim of his project as the production of a chemical indicator used for sterilization verification with local inputs and technology. The project aims to subsidize imports, and a saving of 80% on costs while enhancing the value added through domestic production and sustain his R&D oriented firm.

As he suggests, the domestic indicator has a 280% price difference with the imported product. The domestic production of the indicator is assumed that Turkey will subsidize a $15 million annually. The project aims whole inputs – goods and services, including the indicator chemistry, R&D and post-production phase to be met via local sources. He declares that the indicators of sterilization were 100% dependent on imports until this project was realized. His firm developed a non-toxic UV cationic polymer in the indicator technology process and in two years before the application to the contest, chemicals, paper, cartoons, films and press process application R&D has been finalized. After the second half of 2007, pilot production and hospital trials had started. In concordance with the feedback provided by the trials, both the product and production process are standardized. In 2008, the product has got its conformity documents like CE, TSE EN ISO 867-1 and ISO 11140-1 and mass production has been launched.

Mr. Akgün, continues his studies on R&D based chemical production, mostly indicators, yet wants to share his experience with credible young chemists or local firms. He suggests that, foreign firms want to purchase his firm however, he wants his firm and the "R&D culture" he created to live after him. He wants a capital owner to share his R&D expenditures and effectively distribute his goods or he wants to encounter with a new graduate, visionary chemist for sharing the "know how", in his words; "in his head".

Uğur BAYSAL - Training Set for Magnetic Resonance Imaging System Project

Dr. Uğur Baysal is an academician who earned his PhD in the USA and currently teaches at Hacettepe University. Medical electronics is one of his research interests and his project is a training set for Magnetic Resonance Imaging System which can be used in biomedical engineering education, and technician and lower levels of vocational training as well as for the purposes of lifelong learning. The set is designed as a smaller version of real MRI system with all necessary functions and it can be used for experiments and teaching purposes. It may also serve as a function to improve the training quality of various biomedical branches.

According to Uğur Baysal, if the project is commercialized, it will be the first product in the world in its category, and a one to one model helpful in understanding the working principles of MRI systems while it will only cost one fiftieth or a percentile (1/50, 1/100) of real systems. Moreover, the project owner also suggests an increased competitive power against developed economies in the field of medical diagnostics education.

Throughout the project, a complete but smaller scale MRI system with full functions is aimed to be developed. The device has electrical and electronic parts that ensure it to work in the DC and radiofrequency areas. In developing the training kit, an electromagnet is used and improved to provide a constant and steady-state magnetic field. Also the project includes the design of the holder that will stabilize the animal or the object to be imaged. Moreover, there will be an electromagnetic power supply, a main circuit, and integrated regulatory units.

The project was an unfinished project when it was announced as a winner, yet the project owner declared that he would use the prize money to continue his other R&D projects not only limited to this one. The project still needs further efforts to be commercialized. However, to produce a smaller version of an MRI is still an important know-how which can be capitalized later.

Hakan GÜRSU - Antimicrobial Sensitivity Test System Project

Hakan Gürsu an industrial product designer and a lecturer in METU as well, has produced this item as an order from domestic producers of Antimicrobial Sensitivity Test System and as how he mentions for producers who produces with totally domestic sources. The design of new disk dispenser system is believed to provide the producers a more effective position in world markets. Moreover an aim the project declares is to gain a renowned position globally in solving the system problem by designing a cartridge dispenser.

The antibiogram disk dispenser test unit has differences from the two valid patents (British and German) in method and it is an innovative product system which has the value for the 3rd patent. One of the aims of the project is stated as improving the product of monopoly and increase the market-share of our country in the sector. The project was already an order project for a producer and has been produced.

The third year of the project contest is marked with:

Özlem BEKTEŞ, Dr. Mustafa UYSAL and Prof. Dr. Bülent OKTAY - Stomakit Project

Özlem Bekteş, is a nurse working in Bursa Uludağ Hospital mostly with patients with colostomy –a surgical procedure to form a stoma on the abdominal part of the body. A stoma is an artificially created opening to the colon that allows the removal of feces out of the body. The project aims to minimize the applicator differences in stoma dressings and treatment, and to provide a standard for this. To provide a standard, the project owner imagined the best application possible which can insulate the stoma from the wound and allow to apply antiseptic treatment procedures. In order to insulate the stoma from the wound, the project suggests to leave scissors usage and hand-cut and to replace the application with a smooth edged adaptor. So, she developed a disposable product which she called Stomakit which can also be used as an easing apparatus for the nurses. As far as the project owner suggests, the stoma treatment and dressing is being provided with imported material and used more than necessary due to user errors.

She further mentions the first gain of project is the entry of the Stomakit to global and national markets as a Turkish-patented stoma dressing. For public health, the stoma dressings are assumed to get better disposal and they are applied easily with the use of the Stomakit apparatus. And for the economic gains, the project owner mentions the prevention of over-use of imported dressing aids.

She summarizes her project as follows: "We've started our work on Stomakit two years ago. First we had the diagrams drawn on paper and then we produced the prototype mould. We tried these prototypes in our hospital and asked experienced people to use them. Pursuant to the results and other suggested improvements we have developed the final product. However, we still think on the project to further develop it.

The project is matched with a producer, while the idea and the product were found very smart and reasonable. There has been more than one producer eager

to work with the Stomakit project. On the other hand, since the nurses are still performing treatment and applying dressing in conventional ways, the produced material couldn't be commercialized yet. The product marketing needed much capital than a priori benefits.

Mustafa ÇAVUŞOĞLU and Assist. Prof. Dr. Mustafa KAMAŞAK - Acoustic System Design for Sleeping Disorders Research Project

This project has been part of a bigger project which is designed to distinguish the snoring vocals through an acoustic system and to analyze the sleeping agent's movements and their relations with and effects on the sound. The project applied to the competition as the only acoustic system that analyses the sounds and categorizes the vocals and it was found very successful in doing so. One of the group members is from METU while the other is a graduate and employee of Max Planck Institute in Germany. Project owners claimed that subsequently an innovative bed can be designed that recognizes the snoring sound, analyzes it to find the most appropriate position for the sleeping agent and adjusts the person without waking him/her up until the snoring ends. Such an approach to sleeping disorders is interesting and may be considered as non-medical since it focuses on a symptomatic therapy rather than a persistent treatment like surgical operations.

When the project was awarded, the system was only able to distinguish and categorize sounds. While the declared aim in the application form is to do so, even though the project may not be materialized, the project was found competent enough with the innovative idea behind and the engineering experiments provided.

Serdar ÖZTÜRK and Rıfat UĞURLUTAN - Mecatronic Mandibular Distraction Project

Distraction osteogenesis is one of the modern methods to cure mandibular (lower jaw bone) tissue lost due to birth deformities, firearm injuries, injuries related to cutting and drilling failures and trauma. The treatment as a fully mechanical process necessitates a long and severe period of patient-physician-hospital interaction with high medical costs. Besides, manual distractors carry

severe risks due to their mode of utilization which requires superior dexterity during treatment. Such a situation causes an increase in the length of hospital stay and raises the risk of hospital infections. Taking into account these circumstances, the Mecatronic Mandibular Distraction project of two plastic surgeons is a robotic system removing patient's dependency on physicians. It proposes autonomic functioning and prevention of human-related errors. It will reduce the length of hospital stay and decrease the risks of hospital infections which also help to reduce treatment expenses. Moreover, it will increase the comfort of the patient and prevent potential psychological complications.

The design of the system presupposes a relatively easy and low-cost manufacturing which allows domestic production. Project owners also consider a versatile application of the system other than a mandibular distraction only. An implementation of the system on a sheep subject has been planned. Implementation on human subjects will follow later.

The fourth and the last one resulted as:

Nevzat G. Gençer , H.Balkar Erdoğan, Berna Akıncı, Erman Acar and Ali Bülent Uşaklı -
Design of An Efficient and Low-Cost Brain-Computer Interface System and Practice of A Prototype

The project aims to develop a prototype for a brain-computer interface system which will help individuals with apoplectic disorders and muscular dystrophy to sustain themselves without any outside assistance.
The intention behind brain-computer interface applications is to raise life standards of patients with severe motor neurone diseases, to accelerate their rehabilitation period and to help them regain their social identities. These applications are based on electroencephalography (EEG) system which works as a mediator for patients to control electronic devices like wheel chair through their brains' electrical activities. By measuring brain's activity, EEG devices also transfer brain actions into spelling applications and other basic commands. Such interfaces are the only tools to communicate with outside world for patients with amyotrophic lateral sclerosis and EEG may also be used as a diagnostic device in medical care centres.

The R&D content of the project and the development of prototypes increase the potential of domestic production of the system. It can also be possible to upgrade it with new features pursuant to future needs. Consequently, it will help lessening the dependency of domestic medical devices sector on foreign markets and economic gains will stay in the country. Moreover, the system proposed will lead to further R&D efforts in this field which will eventually help to increase the quality of health services and the competences of the national health industry.
Moreover, as a part of the application being developed, a 10-channel electrocefalografic data collection method is expected to decrease medical expenditures on this field of therapy. While the technological level of the project is substantially high, during its development process, the researchers have faced with financial difficulties and the launch of its production has not yet come because of its rising production costs with the necessities of its employability.

Hakan Gürsu, Sözüm Dogan, Gülsüm Baran and Sedef Ala Gümüşlü - Self-Smear Testing Kit Project

The gynaecological diagnosis is a avoided procedure. Pap Smear testing is a preventative diagnosis which should be repeated annually. On the other hand the testing needs vaginal diagnosis by the doctor which some women try to avoid for psychological reasons.

The self-smear test project aims to provide a self-done Smear test for women in order to facilitate and disseminate Pap Smear testing without any risk to harm tissues. Testing kit is the first innovative product in Turkey in its range. The kit is designed as a composition of three constituent parts including a handle, a mechanism which is activated by the handle and a caption holding the body and the brush. Along with a forward motion of the handle, the caption unfolds and releases the soft brush which is designed to collect sample from the uterus. The sample which is taken with the help of the brush, is then put into the compact sample box to store for Pap Smear test. The test might be done by one’s self of with the help of a nurse in primary health care facilitators which also reduces the time in the gynaecology polyclinic. The project is designed anticipates an increase of Turkey's share in the medical devices sector with such innovative products. The project was already an order project for a producer and has been produced.

Rıfat Uğurlutan and Serdar Öztürk - Robotic Electro-Pneumatic Compression Suit Project

Production of compression clothing will enable appliance of a standard and scientific treatment and will be an alternative to existing suits which became inadequate in preventing the formation of hypertrophic scar tissue which occurs as a complication soon after burn injuries. Compression clothing is used for the prevention of hypertrophic scar or cheloid formation since 1970s. However, as a result of changing body size and structure, many times it cannot serve as expected. Moreover low quality products produced by the tailors rapidly become deformed. Thus the success of the treatment is largely affected. The reasons behind the handling of this project are engineering faults of existing products, in-accordance between clothing and body size as result of unscientific methods applied in production, and decrease in pressure after deformation which is inevitable after long treatment process.

"Adjustable-Pressure, Pic-Controlled Electro-Pnomatic Compression Suit" as a new treatment method, will end up the disadvantages of standard clothing. Moreover, due to its robotic design, treatment will be applied scientifically. Its main logic is based on providing consistent surface pressure by means of a balloon located in the clothing. It will also ensure the wearing of the same clothing during the treatment preventing any mismatch of the silicone based clothing. It will decrease the work burden of the physician and improve the results. Project owners think that the suit, besides increasing treatment quality and meeting rate of the patient need by the best treatment method, is important regarding prevention of deformation, eradication of faults caused by wrong sizing, ready production by forming standard patterns. The cost of production will eventually decrease as a result of standardized production and easy access to the product will be ensured.

Appendix O: Statistics on Turkey in Rev.1.1 NACE 33.1

Number of Enterprises						
NACE Rev.1.1	2003	2004	2005	2006	2007	2008
Turkey	**1 740 353**	**2 002 834**	**2 393 578**	**2 473 841**	**2 567 704**	**2 583 099**
Section D	**236 275**	**281 029**	**302 459**	**309 841**	**316 596**	**321 652**
33	1 360	1 423	1 090	1 539	1 921	2 462
331	1 208	1 256	942	1 173	1 523	1 954
3310	1 208	1 256	942	1 173	1 523	1 954

Turnover (YTL-TRY)						
	2003	2004	2005	2006	2007	2008
Turkey	**748 289 918 232**	**1 047 056 650 467**	**1 192 635 869 805**	**1 383 759 222 784**	**1 558 920 172 502**	**1 766 486 418 815**
Section D	**230 690 521 729**	**298 230 286 730**	**328 781 491 700**	**397 916 986 422**	**435 892 945 051**	**499 430 702 785**
33	809 895 526	909 559 729	1 082 093 231	1 546 297 218	1 735 713 404	2 139 316 343
331	349 039 220	434 439 690	556 364 160	709 519 810	834 996 655	1 121 961 395
3310	349 039 220	434 439 690	556 364 160	709 519 810	834 996 655	1 121 961 395

Production Value						
	(YTL-TRY)					
	2003	2004	2005	2006	2007	2008
Turkey	**436 555 647 063**	**557 320 217 178**	**658 081 304 144**	**791 339 863 468**	**882 089 413 338**	**1 019 306 315 984**
Section D	**224 284 680 228**	**285 330 450 561**	**311 885 425 845**	**379 215 461 557**	**414 732 875 431**	**477 136 614 405**
33	801 740 082	883 668 737	1 052 200 626	1 512 543 350	1 626 049 959	2 040 878 546
331	335 853 500	409 474 364	537 840 659	675 448 701	759 736 190	1 043 088 481
3310	335 853 500	409 474 364	537 840 659	675 448 701	759 736 190	1 043 088 481

Value-added at factor cost						
	(YTL-TRY)					
	2003	2004	2005	2006	2007	2008
Turkey	**143 318 607 847**	**174 004 663 245**	**185 797 967 886**	**210 976 441 499**	**231 880 826 661**	**270 493 624 299**
Section D	**56 356 919 519**	**66 924 669 484**	**60 244 921 983**	**74 797 613 225**	**79 000 058 982**	**93 803 616 114**
33	282 385 365	293 645 469	297 097 889	393 255 661	472 119 106	652 225 247
331	111 389 937	122 202 772	151 703 748	186 188 813	238 322 275	380 627 061
3310	111 389 937	122 202 772	151 703 748	186 188 813	238 322 275	380 627 061

Gross investment in tangible goods (YTL-TRY)						
	2003	2004	2005	2006	2007	2008
Turkey	**40 111 978 110**	**42 583 781 796**	**56 059 170 067**	**136 624 049 402**	**104 407 695 869**	**101 645 818 162**
Section D	**16 917 600 060**	**18 855 584 257**	**20 374 006 925**	**53 002 041 771**	**38 773 401 307**	**36 347 711 245**
33	30 210 444	71 407 211	74 413 915	166 679 372	155 316 844	148 272 154
331	15 557 288	36 123 454	41 258 896	96 031 962	73 727 094	74 720 776
3310	15 557 288	36 123 454	41 258 896	96 031 962	73 727 094	74 720 776

Number of Employees						
	2003	2004	2005	2006	2007	2008
Turkey	**4 626 213**	**5 251 561**	**6 369 926**	**6 747 521**	**7 007 493**	**7 380 490**
Section D	**1 897 521**	**2 084 944**	**2 266 496**	**2 368 861**	**2 459 904**	**2 538 318**
33	10 602	12 462	13 245	14 524	17 673	22 749
331	5 707	6 732	7 470	8 186	10 072	15 673
3310	5 707	6 732	7 470	8 186	10 072	15 673

Number of Female Employees						
	2003	2004	2005	2006	2007	2008
Turkey	**1 006 197**	**1 168 125**	**1 376 990**	**1 761 950**	**1 526 320**	**1 645 863**
Section D	**446 485**	**472 024**	**493 765**	**547 956**	**533 204**	**538 506**
33	2 860	3 404	3 697	4 158	4 552	5 328
331	1 523	1 829	2 085	2 563	2 360	3 464
3310	1 523	1 829	2 085	2 563	2 360	3 464

Number of male Employees						
	2003	2004	2005	2006	2007	2008
Turkey	**3 620 016**	**4 083 436**	**4 992 936**	**4 985 571**	**5 481 173**	**5 734 627**
Section D	**1 451 036**	**1 612 920**	**1 772 731**	**1 820 905**	**1 926 700**	**1 999 812**
33	7 742	9 058	9 548	10 366	13 121	17 421
331	4 184	4 903	5 385	5 623	7 712	12 209
3310	4 184	4 903	5 385	5 623	7 712	12 209

Personnel Cost (YTL-TRY)						
	2003	2004	2005	2006	2007	2008
Turkey	**47 719 172 700**	**62 449 089 229**	**76 207 292 805**	**87 836 550 093**	**103 468 454 970**	**117 823 139 049**
Section D	**20 005 385 463**	**25 840 480 328**	**30 146 731 265**	**34 267 726 286**	**38 716 105 207**	**43 682 175 379**
33	88 375 390	135 541 332	170 051 662	192 550 531	265 187 596	337 755 290
331	42 999 421	63 455 927	81 038 834	94 029 757	120 939 809	198 423 270
3310	42 999 421	63 455 927	81 038 834	94 029 757	120 939 809	198 423 270

Wages and Salaries (YTL-TRY)						
	2003	2004	2005	2006	2007	2008
Turkey	**40 765 120 372**	**52 875 372 572**	**64 323 071 546**	**74 326 120 897**	**87 606 354 502**	**100 282 441 020**
Section D	**17 062 156 859**	**21 858 828 531**	**25 384 889 279**	**28 976 198 312**	**32 720 034 222**	**37 160 929 095**
33	74 532 107	113 913 617	143 022 727	161 788 161	222 385 430	284 752 254
331	35 722 142	53 209 415	67 570 667	78 589 392	100 925 505	165 900 612
3310	35 722 142	53 209 415	67 570 667	78 589 392	100 925 505	165 900 612

Contributions to Social Security						
(YTL-TRY)						
	2003	2004	2005	2006	2007	2008
Turkey	**6 954 046 763**	**9 573 719 802**	**11 884 221 224**	**13 510 429 280**	**15 862 100 468**	**17 540 698 029**
Section D	**2 943 228 023**	**3 981 649 622**	**4 761 842 009**	**5 291 528 119**	**5 996 070 985**	**6 521 246 284**
33	13 843 273	21 627 708	27 028 936	30 762 377	42 802 166	53 003 036
331	7 277 268	10 246 506	13 468 165	15 440 372	20 014 304	32 522 658
3310	7 277 268	10 246 506	13 468 165	15 440 372	20 014 304	32 522 658

Gross investment in tangible goods						
(YTL-TRY)						
	2003	2004	2005	2006	2007	2008
Turkey	**40 111 978 110**	**42 583 781 796**	**56 059 170 067**	**136 624 049 402**	**104 407 695 869**	**101 645 818 162**
Section D	**16 917 600 060**	**18 855 584 257**	**20 374 006 925**	**53 002 041 771**	**38 773 401 307**	**36 347 711 245**
33	30 210 444	71 407 211	74 413 915	166 679 372	155 316 844	148 272 154
331	15 557 288	36 123 454	41 258 896	96 031 962	73 727 094	74 720 776
3310	15 557 288	36 123 454	41 258 896	96 031 962	73 727 094	74 720 776

Gross investment in land						
(YTL-TRY)						
	2003	2004	2005	2006	2007	2008
Turkey	**1 391 564 686**	**1 680 625 649**	**3 000 343 130**	**8 872 673 096**	**8 292 915 230**	**8 710 266 714**
Section D	**402 631 972**	**780 705 206**	**857 873 708**	**2 274 121 888**	**2 037 533 608**	**2 278 807 818**
33	187 457	10 141 021	7 679 135	16 482 743	7 958 599	8 543 706
331	158 671	(***)	(***)	(***)	(***)	(***)
3310	158 671	(***)	(***)	(***)	(***)	(***)

Gross investment inexisting buildings and structures						
(YTL-TRY)						
	2003	2004	2005	2006	2007	2008
Turkey	**6 897 935 877**	**7 961 165 646**	**12 699 527 412**	**28 848 035 500**	**22 250 996 568**	**26 212 810 215**
Section D	**2 727 361 991**	**3 099 454 111**	**3 545 769 756**	**10 132 659 154**	**7 239 125 706**	**7 560 502 413**
33	1 170 529	10 651 776	11 408 955	29 746 836	24 111 823	34 670 485
331	725 038	4 594 038	(***)	21 804 351	11 618 271	23 209 554
3310	725 038	4 594 038	(***)	21 804 351	11 618 271	23 209 554

Gross investment in construction and alteration of buildings						
	(YTL-TRY)					
	2003	2004	2005	2006	2007	2008
Turkey	**1 277 201 518**	**1 329 680 348**	**2 082 082 676**	**4 332 265 508**	**3 547 386 384**	**4 128 737 020**
Section D	**495 351 067**	**567 391 015**	**647 502 675**	**1 962 392 096**	**1 796 911 383**	**1 136 076 361**
33	2 634 656	1 000 665	1 870 910	3 236 926	2 362 406	4 205 214
331	849 428	779 573	1 202 214	1 978 707	(***)	(***)
3310	849 428	779 573	1 202 214	1 978 707	(***)	(***)

Gross investment in machinery and equipment						
	(YTL-TRY)					
	2003	2004	2005	2006	2007	2008
Turkey	**28 364 103 366**	**28 402 814 763**	**35 102 417 568**	**90 608 268 163**	**67 005 579 981**	**58 490 484 809**
Section D	**12 375 424 584**	**13 455 362 553**	**14 144 845 238**	**37 026 622 224**	**26 145 138 999**	**23 606 859 747**
33	25 818 913	45 038 152	52 255 048	115 590 094	106 164 267	98 377 082
331	13 760 112	26 282 522	31 226 490	65 002 279	44 478 065	45 250 604
3310	13 760 112	26 282 522	31 226 490	65 002 279	44 478 065	45 250 604

Gross investment in other tangible goods						
(YTL-TRY)						
	2003	2004	2005	2006	2007	2008
Turkey	**2 181 172 663**	**3 209 495 390**	**3 174 799 281**	**3 962 807 135**	**3 310 817 706**	**4 103 519 404**
Section D	**916 830 446**	**952 671 372**	**1 178 015 548**	**1 606 246 409**	**1 554 691 611**	**1 765 464 906**
33	398 889	4 575 597	1 199 867	1 622 773	14 719 749	2 475 667
331	(***)	(***)	(***)	1 331 403	14 345 615	2 004 359
3310	(***)	(***)	(***)	1 331 403	14 345 615	2 004 359

Fixed capital sales						
(YTL-TRY)						
	2003	2004	2005	2006	2007	2008
Turkey	**2 880 568 117**	**3 721 395 844**	**7 129 097 728**	**12 530 103 559**	**9 331 890 600**	**9 739 261 024**
Section D	**1 643 595 378**	**2 130 009 587**	**2 579 262 646**	**3 470 430 222**	**3 077 134 014**	**3 028 430 525**
33	3 063 253	9 527 544	5 971 761	3 571 889	5 250 106	8 320 451
331	(***)	5 547 133	737 983	2 070 448	2 372 606	(***)
3310	(***)	5 547 133	737 983	2 070 448	2 372 606	(***)

(***) Confidential data

Appendix P: UNSPC Code System

United Nations Services and Products Standard Codes (UNSPC) provides an open sectoral classification standard. In development and improvement of Turkey Medicine and Medical Devices Data Bank (TITUBB) this classification has been used by the project team in order to classify pharmaceuticals and medical devicesd.

This system of classification is used in, consumption analysis, optimization of cost efficient procurement, e-trade support and support for management of the database. İlaçlar 51 ile başlayan ana dal altında, tıbbi cihazlar ise 41 ve 42 ile başlayan ana dallar altında tanımlanmıştır. In the database of TITUBB, pharmaceuticals are classified with WHO oriented Anatomic, Therapeutic and Chemical Classification (ATC) however, for medical devices the code of "41000000 - Laboratuvar, ölçüm, gözlem ve test donanımı" (Laboratory, measurement, observation and test hardware) and "42000000 Tıbbi Donanım ve Aksesuvarları ve Malzemeleri" Medical Hardware and Accesories and their subgroups are used.

UNSPC Codes are as follows:

UNSPC Code	UNSPC Name Tr
41000000	**Laboratuvar, ölçüm, gözlem ve test donanımı**
41100000	**Laboratuvar ve bilimsel donanım**
41103000	Laboratuvar soğutma donanımı
41103200	Yıkama ve temizlik amaçlı laboratuvar donanımı
41103300	Akışkan mekaniği donanımı
41105100	Laboratuvar pompaları ve boru hattı
41105200	Laboratuvar lam boyama aleti donanımı ve aksesuvarları
41105300	Laboratuvar elektroforez, kurutma sistemi ve malzemeleri
41101500	Karıştırıcı, dağıtıcı ve homojenleştirici donanım ve malzemeler
41101700	Laboratuvar delme, öğütme, kesme, ezme ve sıkıştırma donanımı
41101800	Elektron ve katı hal fiziği ile ilgili laboratuvar donanımı
41101900	Laboratuvar iyon donanımı
41102400	Isıtma ve kurutmaya yönelik laboratuvar donanımı
41102500	Entomolojiyle ilgili laboratuvar donanımı ve aksesuvarları
41102600	Hayvan laboratuvarı donanımı ve aksesuvarları
41102700	Kristalografi donanımı
41102900	Histoloji donanımı
41103400	Çevre ile ilgili laboratuvar havalandırma donanımı
41103500	Laboratuvar muhafaza alanları ve aksesuvarları
41103700	Laboratuvar banyoları
41103800	Laboratuvar amaçlı karıştırma, çalkalama ve sallama donanımı ve malzemeleri

UNSPC Code	UNSPC Name Tr
41103900	Laboratuvar santrifüjleri ve aksesuvarları
41104000	Örnekleme donanımı
41104100	Parça toplama ve aktarma konteynerleri ve malzemeleri
41104200	Laboratuvar su arıtma donanımı ve malzemeleri
41104300	Fermantasyon donanımı
41104400	Laboratuvar enkubasyon donanımı
41104500	Laboratuvar fırınları ve aksesuvarları
41104600	Laboratuvar ocakları ve aksesuvarları
41104700	Laboratuvar amaçlı soğuk kurutucular, liyofilizatörler ve aksesuvarları
41104800	Su aktarma ve damıtma ve buharlaştırma ve ayırma amaçlı laboratuvar donanımı ve malzemeleri
41104900	Filtreleme ile ilgili laboratuvar donanımı ve malzemeleri
41105000	Laboratuvar elekleri, eleme donanım ve malzemeleri
41105500	Nükleik asit ayırma ve saflaştırma ve ölçüm kitleri ve bileşenleri
41105600	Deoksiribonükleik asit DNA dizilim ürünleri
41105700	Gen dizilimleri
41105800	İn vitro transkripsiyon (protein yapım) ve translasyon (çeviri) ürünleri
41105900	Kitaplıklar ve ilgili malzemeler
41106000	Nükleik asit işaretleme ve saptama sistemleri
41106100	Deoksiribonükleik asit, DNA analiz kitleri
41106200	Mikroorganizma üreme ve dönüşüm besiyerleri ve kitleri ve donanımları
41106300	Polimeraz zincir reaksiyonu PCR ve ters transkriptaz polimeraz zincir reaksiyon RT PCR ürünleri
41106400	Primerler, bağlaçlar ve adaptörler
41106500	Protein ekspresyon ürünleri
41106600	Vektörler
41110000	**Ölçüm, gözlem ve test araçları**
41111500	Ağırlık ölçüm aletleri
41111600	Uzunluk, kalınlık ve mesafe ölçüm aletleri
41111700	Gösterme ve gözlem araçları ve aksesuvarları
41111800	Hasar vermeyen inceleme donanımı
41111900	Gösterge ve kayıt araçları
41112100	Çevireçler/transdüserler
41112200	Sıcaklık ve ısı ölçüm araçları
41112300	Nem ve nem derecesi ölçüm aletleri
41112400	Basınç ölçüm ve kontrol araçları
41112500	Sıvı ve gaz akım ölçüm ve gözlem araçları
41112600	Hijyen takip ve test donanımı
41112700	Ek ve besle donanımı
41112800	Taşımayla ilgili donanım ve aletler
41112900	Navigasyon donanımı ve araçları
41113000	Kimyasal değerlendirme aletleri ve malzemeleri
41113100	Gaz analizörleri ve monitörleri
41113300	Sıvı, katı ve eleman analiz aletleri
41113400	Nükleer değerlendirme araçları
41113600	Elektronik ölçüm ve testdonanımı
41113700	Elektronik ve iletişim ölçme ve test araçları
41113800	Jeofizik ve jeoteknik araçlar
41113900	Toprak ölçüm donanımı
41114000	Kaya ve katman ölçüm donanımı
41114100	Sismoloji araçları
41114200	Saha anket araçları
41114300	Hidroloji aletleri
41114400	Meteoroloji araçları

UNSPC Code	UNSPC Name Tr
41114500	Mekanik aletler
41114600	Metal, metalürji ve yapısal malzemeler için test araçları
41114700	Kağıt, tahta ve dokuma test araçları
41114800	Seramik ve cam test araçları
41115100	Kömür ve maden cevheri test araçları
41115200	Radar ve sonar sistemleri ve parçaları
41115300	Işık ve dalga oluşturma ve ölçüm donanımı
41115400	Spektroskopik donanım
41115500	Ses oluşturma ve ölçüm donanımı
41115600	Elektrokimyasal ölçüm aletleri ve aksesuvarları
41115700	Kromatografi ölçüm aletleri ve aksesuvarları
41115800	Klinik ve tanısal analiz aygıtı, aksesuvar ve malzemeleri
41116000	Klinik ve tanısal analiz aygıtı ayıraçları
41116100	Elle test kitleri, kalite kontrol ve ayarlama cihazları ve standartları
41116200	Hasta dikkat noktası testi malzemeleri ve donanımı
41116300	Laboratuvar parlama noktası test aletleri
41116400	İvme ve titreşim ölçüm araçları
41116500	Alet parşaları ve aksesuvarları
41120000	**Laboratuvar malzemeleri ve demirbaşları**
41121500	Pipet ve sıvı kullanma donanımı ve malzemeleri
41121600	Pipet uçları
41121700	Test tüpleri
41121800	Genel amaçlı cam ve plastik laboratuvar aletleri ve malzemeleri
41122000	Laboratuvar veya örnekleme enjektörler
41122100	Doku kültürü ve hızlı işleme tarama malzemeleri
41122200	Döküm potaları
41122300	Laboratuvar tezgah/masa koruyucusu ve kaplamaları
41122400	Laboratuvar aletleri
41122500	Laboratuvar tıpa, stoper ve aksesuvarları
41122600	Laboratuvar mikroskop lamları ve malzemeleri
41122700	Laboratuvar bant ve etiketleri
41122800	Laboratuvar sehpa, raf ve tepsileri
41123000	Sikatif laboratuvar kurutma alet ve maddeleri
41123100	Laboratuvar diyalizi malzemeleri
41123200	Korunmuş örnekler ve malzemeler
41123300	Genel amaçlı laboratuvar depo kutu ve dolapları
41123400	Dozaj aleti
42000000	**Tıbbi Donanım ve Aksesuvarları ve Malzemeleri**
42120000	**Veterinerlik donanımı ve malzemeleri**
42130000	**Tıbbi giysi ve dokumalar**
42131500	Hasta giysileri
42131600	Tıp personeli için giysi ve ilgili eşyalar
42131700	Cerrahi dokumalar
42132100	Hastane mefruşatı
42132200	Tıbbi eldivenler ve aksesuvarlar
42140000	**Hasta bakım ve tedavi ürünleri ve malzemeleri**
42141500	Uygulamaya yönelik pamuk (yumağı) ve süngerler
42141600	Pansuman kapları ve sürgüleri uygulama kitleri
42141700	Dekübit yaralarını önlemeye yönelik ürünler
42141800	Elektroterapi donanımı
42141900	Lavman uygulama malzemeleri
42142000	Yer tipi araçlar
42142100	Sıcak ve soğuk terapisi ürünleri
42142200	Hidroterapi ürünleri

UNSPC Code	UNSPC Name Tr
42142300	Tıbbi dokümantasyon ürünleri
42142400	Tıbbi emme (suction) ve vakumlu ürünler
42142500	Enjeksiyon ve aspirasyon iğneleri ve aksesuvarları
42142600	Enjektörler ve aksesuvarları
42142700	Üroloji malzemeleri
42142800	Vasküler ve kompresyon tedavi donanımı ve malzemeleri
42142900	Görme düzeltme veya kozmetik göz örtüsü ve ilgili ürünler
42143100	Obstetrik ve jinekolojik donanım ve malzemeleri
42143200	Doğurganlık ve kısırlık tedavisi donanımı ve malzemeleri
42143300	Kemoterapi donanımı ve malzemeleri
42143400	Hiperhidroz kontrol donanımı ve malzemeleri
42143500	Kulak burun boğaz KBB tedavi ürünleri ve aksesuvarları
42143600	Sabitleyiciler/korseler ve aksesuvarları
42150000	**Diş donanımı ve malzemeleri**
42152200	Diş hekimliğiyle ilgili laboratuvar ve sterilizasyon donanımı ve malzemeleri
42151500	Kozmetik diş hekimliği donanım ve malzemeleri
42151600	Diş hekimliğine ve alt ihtisas dallarına ait alet ve cihazlar
42151700	Diş hekimliğiyle ilgili klinik mefruşat
42151800	Diş doldurma, parlatma ve cilalama malzemeleri
42151900	Diş hijyeni, önleyici bakım donanımı ve malzemeleri
42152000	Diş görüntüleme donanımı ve malzemeleri
42152100	Diş kalıp ve şekillendirme donanımı ve malzemeleri
42152300	Diş hekimliği lazer ve aydınlatma ve fiberoptik donanım ve malzemeleri
42152400	Diş hekimliği malzemeleri
42152500	Diş hekimliğiyle ilgili genel amaçlı malzemeler
42152600	Diş hekimliği ameliyatlarıyla ilgili özel malzemeler
42152700	Ortodontik ve prostodontik donanım ve malzemeler
42152800	Periodonti donanımı ve malzemeleri
42160000	**Diyaliz donanımı ve malzemeleri**
42161500	Peritan ve denge diyalizi donanımı ve malzemeleri
42161600	Ekstrakorporeal hemodiyaliz donanımı ve malzemeleri
42161700	Hemofiltrasyon donanımı ve malzemeleri
42161800	Sürekli böbrek replasmanı tedavisi CRRT donanımı ve malzemeleri
42170000	**Acil ve saha tıbbi hizmetleri için ürünler**
42171500	Afet ile ilgili acil tıbbi hizmet müdahale ürünleri
42171600	Acil tıbbi hizmetler için kurtarma, sabitleme ve taşıma ürünleri
42171700	Acil tıbbi hizmetler için battaniyeler
42171800	Acil tıbbi hizmetler için havayolu açma donanımı
42171900	Acil tıbbi hizmetler için depo çanta ve torbaları
42172000	Acil ve saha tıbbi hizmetleri için kitler
42172100	Acil tıbbi hizmetler için resüsitasyon ürünleri
42172200	Acil tıbbi hizmetler için malzemeler
42180000	**Hasta inceleme ve izlemeye yönelik ürünler**
42181500	Genel amaçlı tanısal değerlendirme ve muayene ürünleri
42181600	Kan basıncı üniteleri ve ilgili ürünler
42181700	Elektrokardiyografi EKG ünitesi ve ilgili ürünler
42181800	Darbeli oksimetreler
42181900	Yoğun bakım izleme üniteleri ve ilgili ürünler
42182000	Tanı amaçlı tıbbi muayene için skoplar, spekulumlar ve aksesuvları
42182100	Stetoskop ve ilgili ürünler
42182200	Tıbbi termometreler ve aksesuvarları
42182300	Nörolojik muayene ürünleri
42182400	İşitme testi ürünleri
42182500	Burunla ilgili fonksiyon ölçüm aletleri

UNSPC Code	UNSPC Name Tr
42182600	Tıbbi inceleme ışık veya lambaları
42182700	Tıbbi inceleme amaçlı boyut ölçüm aygıtları
42182800	Tıbbi teraziler
42182900	Özel muayene masaları ve ilgili ürünler
42183000	Gözle ilgili tanısal inceleme ürünleri
42183100	Tatma işlevi ölçerler
42183200	Alerji muayene donanımı ve malzemeleri
42183300	Kulak burun boğaz KBB muayene ünitesi aksesuvarları ve ilgili ürünler
42190000	**Tıbbi tesis ürünleri**
42191500	Tıbbi tesis malzemeleri için tutacak ve dağıtım donanımı
42191600	Tıbbi tesis inşaatı sistemleri
42191700	Tıbbi gaz ürünleri
42191800	Hasta yatakları ve aksesuvarları
42191900	Klinik amaçlı marangozluk hizmetleri
42192000	Klinik işlem ve muayene masaları
42192100	Klinik amaçlı oturak, tabure ve ilgili ürünler
42192200	Hasta taşıma ürünleri
42192300	Hasta kaldıraçları
42192400	Tıbbi donanım taşıma ve nakil ürünleri
42192500	Tıbbi donanım koruyucuları
42192600	İlaç dağıtım ve ölçüm cihazları ve malzemeleri
42200000	**Tıbbi tanısal görüntüleme ve nükleer tıp ürünleri**
42201500	Tıbbi bilgisayarlı tomografi CT - BT veya CAT sistemleri ve ilgili ürünler
42201600	Manyetik rezonans ile tıbbi görüntüleme MRI - MR ürünleri
42201700	Tıbbi ultrasonografi, doppler ve eko görüntüleme ürünleri
42201800	Tıbbi tanısal x-ışını ürünleri
42201900	Tıbbi röntgen filmi aydınlatıcısı/negatoskopu ve izleme donanımı
42202000	Tıbbi tanısal gamma kameralar ve ilgili ürünler
42202100	Brakiterapi ürünleri
42202200	Gamma ışın tedavisi ürünleri
42202300	Tıbbi lineer akseleratör yoğunluk ayarlı radyoterapi IMRT ürünleri
42202400	Tıbbi (medikal) pozitron emisyon tomografisi PET donanımı ve ilişkili ürünler.
42202500	Bilgisayarlı tıbbi tek fotonlu emisyon tomografisi SPECT donanımı ve ilgili ürünler
42202600	Radyoimmünterapi ve radyoizotop uygulama ürünleri
42202700	Radyoterapi teleterapi ürünleri
42202800	Litotripsi aletleri ve ilgili ürünler
42202900	Düşük enerjili tıbbi x-ışını donanımı
42203000	Tıbbi linear akseleratörler ve ilgili ürünler
42203100	Radyobiyoloji araçları
42203200	Radyoterapi simülatörleri
42203300	Tıbbi stereotaksi sistemleri
42203400	Vasküler görüntüleme, girişimsel kardiyoloji ve kalp kateterizasyonu amaçlı laboratuvar ürünleri
42203500	Kalp pacemaker aygıtları ve ilgili ürünler
42203600	Tıbbi radyolojik görüntüleme bilgi ve arşivleme ürünleri
42203700	Tıbbi görüntü işleme donanımı ve malzemeleri
42203800	Tıbbi radyoloji yerleştirme yardımcıları
42203900	Tıbbi radyasyon saptama veya izleme ürünleri
42204000	Tıbbi radyolojik koruyucu ve muhafaza ürünleri
42210000	**Fiziksel engelliler için bağımsız yaşam yardımcıları**
42211700	Fiziksel engelliler için iletişim yardımcıları
42211800	Fiziksel engelliler için giyinme ve traş yardımcıları
42211500	Fiziksel engelliler için kaldırma, nakil ve yerleştirme yardımcıları
42211600	Fiziksel engelliler için banyo odası ve banyo yapma yardımcıları

UNSPC Code	UNSPC Name Tr
42211900	Fiziksel engelliler için yeme, içme ve yemek hazırlama yardımcıları
42212000	Fiziksel engelliler için ev temizliği ve işleri yardımcıları
42212100	Fiziksel engelliler için boş zaman ve eğlence yardımcıları
42212200	Fiziksel engelliler için ilaç almaya yönelik yardımcılar
42212300	Fiziksel engelliler için uzanma ve tutmaya yönelik yardımcılar
42220000	**İntravenöz ve arteryel uygulama ürünleri**
42221500	İntravenöz ve arteryel kanül, kateter ve aksesuvarları
42221600	İntravenöz ve arteryel giriş ve uygulama setleri ve ilgili ürünler
42221700	İntravenöz ve arteryel infüzyon torbaları, hazneleri ve ilgili ürünler
42221800	İntravenöz ve arteryel kateter ve iğne konumlama yardımcısı ve aksesuvarları
42221900	İntravenöz veya arteryel akım ölçüm ve düzenleme ürünleri
42222000	İntravenöz infüzyon pompası, analizörleri, algılayıcıları/sensörleri ve aksesuvarları
42222100	İntravenöz ve arteryel donanım askı ve nakil sistemleri
42222200	İğnesiz intravenöz enjeksiyon ve geri çekme sistemleri
42222300	Kan alma ve nakil ürünleri
42230000	**Klinik beslenme**
42231500	Enteral beslenme donanımı ve malzemeleri
42231600	Gastrostomi ve jejunostomi giriş aygıtları veya aksesuvarları
42231700	Nazoenterik sondalar
42231800	Beslenme desteği için formüller ve ürünler
42231900	Memeyle besleme donanımı ve malzemeleri
42232000	Tablet/hap kırma aletleri ve ilgili ürünler
42240000	**Ortopedi, protez ve spor hekimliği ürünleri**
42241500	Alçı yapma ve tahta ile sabitleme malzemeleri
42241600	Alçı donanımı, parçaları ve aksesuvarları
42241700	Alt uzuv/ekstremite için yumuşak ortopedi malzemesi
42241800	Üst uzuv/ekstremite ve gövde için yumuşak ortopedi malzemeleri
42241900	Dinamik ve parmak fleksiyonlu bilek ortozu malzemeleri
42242000	Protez cihazları veya aksevuarları ve malzemeleri
42242100	Ortopedik traksiyon malzemeleri ve aksesuvarları
42242300	Ortopedi aletleri/donanımı ve malzemeleri
42250000	**Fiziksel, uğraş terapisi ve rehabilitasyon ürünleri**
42251500	Bilişsel, hünere dayalı, algısal ve duyusal gelişim ve terapi ürünleri
42251600	Rehabilitasyon egzersiz cihaz ve donanımı
42251700	Yürüme antrenmanı ürünleri
42251800	Rehabilitasyon veya terapi amaçlı iş zorlaştırma donanımı
42260000	**Ceset ve morg donanımı ve malzemeleri**
42261500	Patoloji diseksiyon araçları ve malzemeleri
42261600	Otopsi donanımı ve malzemeleri
42261700	Otopsi mefruşatı
42261800	Kadavra nakil ve saklama donanımı ve malzemeleri
42261900	Klinik adli tıp donanımı ve malzemeleri
42262000	Kadavra tahnitine yönelik donanım ve malzemeler
42262100	Morg donanımı ve malzemeleri
42270000	**Solunum, anestezi ve resüsitasyon ürünleri**
42271500	Solunum izleme ürünleri
42271600	Pulmoner fonksiyon test ve tedavi ürünleri
42271700	Oksijen tedavisine yönelik dağıtım sistemleri ve aygıtları
42271800	Respiratuvar nem ve aeorol terapi ürünleri
42271900	Havayolunu açık tutmaya yönelik ürünler
42272000	Entübasyon malzemeleri
42272100	Mekanik negatif basınç vantilatörleri
42272200	Pozitif mekanik basınç vantilatörleri ve aksesuvarları
42272300	Resüsitasyon malzemeleri

UNSPC Code	UNSPC Name Tr
42272400	Torasentez ürünleri
42272500	Anestezi aygıtı, aksesuvarları ve malzemeleri
42280000	**Tıbbi sterilizasyon ürünleri**
42281600	Soğuk sterilizasyon ve dezenfektan çözeltiler
42281700	Sterilizasyon öncesi temizleme donanımı ve çözeltileri
42281800	Sterilizasyon göstergeleri ve kontrolleri
42281900	Sterilizasyonla ilgili örtü ve paketleme malzemeleri
42281500	Otoklav ve sterilizatör/etüv donanımı ve aksesuvarları
42290000	**Cerrahi ürünler**
42294800	Endoskoplar, aksesuvarlar ve ilgili ürünler
42294900	Endoskopi aletleri ve malzemeleri ve aksesuvarları ve ilgili ürünler
42291500	Cerrahi kemik biyopsisi araçları ve ilgili ürünler
42291600	Cerrahi kesme araçları, boğma araçları ve ilgili ürünler
42291700	Cerrahi el matkapları, burgular, delme araçları, aksesuvarları ve ilgili ürünler
42291800	Cerrahi klempler, forsepsler, cerrahi bağlayıcılar ve ilgili araçlar
42291900	Cerrahi araç ve tüp/hortum tutacakları ve pozisyon verme aletleri
42292000	Cerrahi aynalar
42292100	Cerrahi yerleştirme/geçme, çıkartma aletleri ve ilgili ürünler
42292200	Cerrahi yaklaştırma, kompresyon, depresyon aletleri ve ilgili ürünler
42292300	Cerrahi eğme demirleri, kıvırma aletleri, kıskaçlar, gericiler, anahtarlar ve ilgili ürünler
42292400	Cerrahi musluklar/kılavuzlar, sürücü aletler ve ilgili ürünler
42292500	Cerrahi çekiçler, tokmaklar, balyozlar, presler ve ilgili ürünler
42292600	Cerrahi genişleticiler, sondalar, yiv açma aletleri ve ilgili ürünler
42292700	Cerrahi diseksiyon aletleri, kaldıraçlar, ?kazıyıcılar, ve ilgili ürünler
42292800	Cerrahi işaretleme araçları
42292900	Dikiş (sütür) ve cerrahi dolu kapama araçları ve ilgili ürünler
42293000	Cerrahi ölçüm araçları ve ilgili ürünler
42293100	Cerrahi ekartörleri ve ilgili ürünler
42293200	Cerrahi myom aletleri
42293300	Cerrahi çekme, ezme ve ayırma aletleri ve ilgili ürünler
42293400	Cerrahi uygulayıcılar, implant konumlandırma/pozisyon aletleri ve ilgili ürünler
42293500	Cerrahi emme (suction) ve irigasyon (yıkama) kanülleri, uçları, stileler ve ilgili ürünler
42293600	Cerrahi buji, sonda, obturator ve ilgili ürünler
42293700	Cerrahi ezme, boşaltma, parçalama aletleri ve ilgili ürünler
42293800	Cerrahi geçirme, arama, yol açma, ayırma aletleri ve ilgili ürünler
42293900	Cerrahi yara sarma aletleri ve ilgili ürünler
42294000	Cerrahi spatüller, kaşıklar, kepçeler ve ilgili ürünler
42294100	Cerrahi iskelet traksiyon aygıtları ve ilgili ürünler
42294200	Cerrahi alet setleri, sistemleri ve tepsileri
42294300	Minimal invaziv meme biyopsisi araçları ve malzemeleri ve donanımı
42294400	Vasküler ve kardiyak sistemler
42294500	Göz uzmanlık aletleri ve ilgili ürünler
42294600	Ototransfüzyon ürünleri
42294700	Açık kalp perfüzyon donanımı, monitörleri, aksesuvarları ve ilgili ürünler
42295000	Endoskopik donanım ve aksesuvar ve ilgili ürünler
42295100	Cerrahie donanım ve aksevuarları ve ilgili ürünler
42295200	Cerrahi güç kaynağı donanımı tesisi, aksesuvarları ve ilgili ürünler
42295300	Açık kalp cerrahisi malzemeleri, aksesuvarları ve ilgili ürünleri
42295400	Cerrahi destek malzemeleri
42295500	Cerrahi implantlar, genişleticiler, uzatmalar, cerrah, teller ve ilgili ürünler
42300000	**Tıbbi eğitim ve uygulama malzemeleri**
42301500	İyileştirici antrenman için yardımcılar

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42310000	**Yara bakım ürünleri**
42311500	Sargı, pansuman ve ilgili ürünler
42311600	Hemostatik egzojen topikal ajanlar
42311700	Uzmanlık gerektiren tıbbi cerrahi yapışkan bantlar ve ilgili ürünler
42311900	Tıbbi kesi dren, drenaj torbası, rezervuar ve ilgili ürünler
42312000	Tıbbi doku kapatma ürünleri ve ilgili ürünler
42312100	Ostomi malzemeleri ve cerrahi olmayan yara drenaj ürünleri
42312200	Dikiş ve ilgili ürünler
42312300	Yara temizleme ve debritman ürünleri
42312400	Yara sarma ürünleri
42312500	Yara destekleri, malzemeleri ve aksesuvarları

Appendix R: Various Medical Device Definitions

Medical Devices (MDs) branch is a part of life sciences industry where the scope of the term is ambiguous and diversified as it covers a wide array of items, like hospital textiles, disposables, laboratory kits or diagnostics and monitoring devices. According to Eucomed, an association representing EU medical devices sector, there are over 500.000 devices under 10.000 categories in this industry. US office of Technology Assessment defines medical technologies which include medical devices as one of its constituents, as "the drugs, devices and medical and surgical procedures used in medical care, and the organisational and supportive systems within which such care is provided" (OTA, 1984). Yet, throughout this thesis, even though they are in close interaction and sometimes converge, the procedures and drugs are excluded in accordance with the European Union Medical Devices Directive (93/42/ECC), article 1, which covers "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."

One major group of medical devices is in vitro diagnostics (IVD) tools and equipment. This study is in consent with the definition adopted in the "In Vitro Diagnostic Medical Devices Directive (98/79/EC)", where IVD is defined as "any medical device which is a reagent, reagent product, calibrator, control material,

kit instrument, apparatus, equipment, or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information: concerning a physiological or pathological state; or concerning a congenital abnormality; or to determine the safety and compatibility with potential recipients; or to monitor therapeutic measures". Here, the term in vitro refers to the utilization of patients' body fluids with devices under laboratory conditions, while in vivo devices are directly in contact with patients and sometimes remain in patients' body. In Vitro Diagnostic (IVD) tools are commonly known as Laboratory Devices. Throughout the study "Laboratory Devices" is used as a term to explain the devices that are subject to above mentioned IVD Directive.

Another directive, 90/385/EEC covers 'active implantable medical devices' (AIMDs). A medical device is categorized as an 'active implantable medical device' if it is both "active" and 'implantable'. As the Directive puts it:

- '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;

- 'custom-made device' means any active implantable medical device specifically made in accordance with a medical specialist's written prescription which gives, under his responsibility, specific design characteristics and is intended to be used only for an individual named patient;

- Where an active implantable medical device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product within the meaning of Article 1 of Directive 65/65/EEC, that device must be evaluated and authorized in accordance with the provisions of this Directive.

To specify, AIMD category covers implantable cardiac pacemakers, implantable defibrillators, adaptors for these devices, leads, electrodes, implantable nerve

stimulators, bladder stimulators, sphincter stimulators, diaphragm stimulators, cochlear implants, implantable active drug administration device and its sensors, catheters, implantable active monitoring devices, their programmers, software, and transmitters. (European Commission DG Health and Consumer, 2010)
Medical Devices is a major constituent of medical technologies industries together with pharmaceuticals. Even though medical devices and medical technologies are different conceptually, due to the convergence in pharmaceuticals with devices and to the same area of use pharmaceuticals and MD's share, "medical technologies" can be used to refer and provide a crude understanding of the "medical devices". Eucomed mostly uses this term to refer to medical devices.

This feature of being composed of all devices which are not pharmaceutical, masked medical devices as a particular sector until devices gain rapidly increasing importance in health care. The large scope of medical devices, the specific medical knowledge they require, and rapid improvements make it harder for other disciplines to focus on the sector, to classify statistically, to analyse, or to regulate. EU, Japan and USA use different classifications for some of the product groups, which in turn result in incompatible data. However, a study by Global Harmonization Task Force, is going on to ease harmonization of data for the use of reimbursement strategies or other levels of interests. (Global Harmonization Task Force, 2008) In GHTF Retrospective Assessment Key Findings and Recommendations, published in 2008, GHTF describes itself as "formed in 1992 to promote worldwide harmonization of medical device regulatory practices. Membership in the voluntary partnership was initially limited to regulatory officials and industry representatives from the five Founding Member jurisdictions—Australia, Canada, the European Union/European Free Trade Association (EU/EFTA), Japan, and the United States (US)".

The wide range of Medical Devices include more traditional products like medical disposables, wadding, gauze and bandages, latex medical disposables, syringes, needles and catheters, wound closure products, nappies and similar hygiene products and more electronic based devices like ophthalmic instruments, x-ray equipment, or laboratory diagnostics etc. The highly dynamic nature of medical devices causes traditional group of devices to change with nanotechnology and biotechnology applications and even traditional products become high-tech. Even

the basic products like nappies, syringes or gauzes are subject to technological change.

Medical devices (MDs) are not only an innovative industry but also a key contributor to healthcare supply. Albeit unseen in daily routines, the medical devices are crucial to accurate diagnosis, treatment and even for prevention of diseases. Being able to prolong human life, medical technologies are also an item of expenditure with rising costs. Even though publicly it is normal to wish for the best healthcare possible, yet how to fund for these ever-increasing costs is a question hard to answer. Moreover, increasing healthcare expenditures are often related to innovation and R&D expenditures in medical devices and pharmacy. Mostly reimbursed by governments, health industry becomes an issue of importance that needs to be appropriately regulated.

Throughout the thesis, Standard & Poor's has been a major data source, and the Standard & Poor's definition of medical devices ".. include commodity-type items such as kits, trays, gloves, gowns, syringes, and other disposable medical supplies, as well as higher technology products, among which are infusion and related intravenous supplies and equipment, diagnostic and laboratory products, wound-management supplies, orthopaedic reconstructive implants, spinal devices, surgical devices, cardiac products, and diagnostic equipment." (Gold, Industry Surveys Healthcare: Products & Supplies September18,2008, 2008)

Another source of data is Datamonitor, where medical devices are defined as health care equipment and supplies that "include active implants, aids for the disabled, anaesthetic & respiratory devices, dental devices, drug delivery systems, emergency medical equipment, electro-medical devices, hospital equipment, imaging & radiotherapy devices, ophthalmic & optical devices, passive implants, single use disposables, and surgical instruments". (Pammolli, Riccaboni, Oglialoro, Magazzini, Baio, & Salerno, 2005)

The difference between Standard & Poor's and Datamonitor definitions is that the latter excludes laboratory products and their kits and the former has a wider understanding.

The ever increasing wide range of medical devices make it even harder to group them under meaningful / functional taxonomies. There are various taxonomies addressing different needs. The data obtained from those taxonomies are not

easily transferred to each other. This is an obstacle on studying and also having an comprehensive understanding on Medical Devices. Hence the need for harmonization is accepted worldwide and a group of healthcare professionals, social scientists and industry members formed "Global Harmonization Task Force" (GHTF) and work on a Global Medical Devices Nomenclature (GMDN). Throughout the study, GMDN codes will be referred as main categorical reference as far as the data allow.

The wide range of the medical devices can be observed by the examples below:

> Anaesthetic machines and monitors, Apnoea monitors, Artificial eyes, Artificial limbs, Blood transfusion and filtration devices, Breast implants, Cardiac monitors, Cardiopulmonary bypass devices, Clinical thermometers, Condoms, Contact lenses and prescribable spectacles, CT scanners, Diagnostic kits and tests, Dialysers, Electrosurgery devices, Endoscopes, Equipment for disabled people, Examination gloves, Hearing aids and inserts, Heart valves , Hospital beds, Intra-uterine devices, Intravascular catheters and cannulae, Laboratory equipment, Medical lasers, Medical textiles, dressings, hosiery and surgical supports, Orthopaedic implants, Operating tables, Pacemakers, Physiotherapy equipment, Prescribable footwear, Pressure sore relief devices, Radiotherapy machines, Scalpels, Special support seating, Stents, Suction devices, Surgical instruments and gloves, Sutures, clips and staples, Syringes and needles, Vaginal speculae and drainage bags, Ventilators, Walking aids , Wheelchairs...

These diverse products are all classified as Medical Devices, and they are classified in various forms according to specific needs. A global study on categorization of MDs including manufacturers, healthcare authorities and regulators had been initiated for decades and still continues to be developed by Global Harmonization Task Force. Global Medical Devices Nomenclature (GMDN) was then mandated by European Commission to ease the regulations over the concerning Directives. Additionally, USA (FDA), Canada, European member states, Japan, Australia and many other countries refer to GMDN and work with GHTF to meet similar needs. Throughout this study the GMDN categories are used to classify medical devices into significant comparable classes. However, risk groups of the devices used to analyse technical risks involved in a device is

another useful classification which is totally independent from this classification and will be mentioned under the headline of regulations. For UNSPSC codes, where one can clearly distinguish between laboratory devices and other medical devices please refer to Appendix A.

The main categories pursued and expropriated by Global Harmonization Task Force are as follows:

GMDN Categories

1. Active implantable devices: Devices that operate with an integral power source (i.e., independent of energy from the human body or gravity), that are totally or partially introduced, surgically or medically, into the human body or body-orifice, where they are intended to remain temporarily or permanently. Examples of devices in this category include cochlear implants, implantable defibrillators, implantable infusion pumps, implantable stimulators, pacemakers, and their accessories.

2. Anaesthetic and respiratory devices: Devices used to supply, condition, monitor, dispense, or deliver respiratory or anaesthetic gases, vapours or other substances to provide and/or control respiration and/or anaesthesia. Examples of devices in this category include airways, anaesthesia systems, breathing circuits, humidifiers, tracheal tubes, ventilators, and their accessories.

3. Dental devices: Devices used to diagnose, prevent, monitor, treat, or alleviate oral, maxillo-facial, and dental disease/disorders. Examples of devices in this category include dental amalgam, dental cements, dental hand instruments, dental implants, dental materials, dental tools/laboratory devices, and their accessories.

4. Electro mechanical medical devices: Devices that operate on electrical energy (electromedical) and/or through some integrated physical mechanism or machinery (mechanical). Examples of devices in this category include specialized beds, defibrillators, dialysis systems, electrocardiographs (ECG), electroencephalographs (EEG), endoscopes, infusion pumps, lasers, operation/examination tables/lights, suction systems, and their accessories.

5. Hospital hardware: Treatment-related devices that typically are not directly or actively involved in the diagnosis or treatment of patients, but that support or facilitate such activities. Examples of devices in this category include air cleaners, baths, detergents, disinfectants, removable floor coverings/mats, portable incinerators, patient beds, patient transfer equipment, sterilizers, and their accessories.

6. In vitro diagnostic devices: Devices used to examine clinical samples taken from the human body to evaluate physiological or pathological conditions. Examples of devices in this category include analysers, blood glucose monitoring devices, in vitro diagnostic (IVD) test kits/calibrators/controls, dedicated laboratory equipment, microbial sensitivity systems, and their accessories.

7. Non-active implantable devices: Devices without an integral power source that are totally or partially introduced, surgically or medically, into the human body or body-orifice, where they are intended to remain for longer than 30 days. Examples of devices in this category include cardiovascular clips, embolization implants, orthopaedic fixation systems, intrauterine devices, heart valves, bone prostheses, and their accessories.

8. Ophthalmic and optical devices: Devices used to diagnose, prevent, monitor, treat, correct, or alleviate diseases or disorders related to the eye. Examples of devices in this category include contact lenses, keratomes, intraocular lenses, slit lamps, ophthalmic test instruments, phacoemulsification systems, tonometers, and their accessories.

9. Reusable devices: Devices that can be used for more than one application period, often involving cleaning and/or sterilization between the periods (excluding capital equipment). Examples of devices in this category include drills, elastic bandages, haemostats, medicine administration kits, saws, scar management garments, reusable surgical instruments (chisels, scissors, retractors, scalpels), and their accessories.

10. Single-use devices: Devices intended to be used only once, or for only one patient during one medical procedure or short term, and then discarded if not already rapidly absorbed. Examples of devices in this category include adhesive tapes, bandages, blood collection devices, catheters, condoms, dressings,

electrodes, kits/sets (biopsy, intravenous infusion), needles, single-use surgical instruments/products (cannulae, scalpels, absorbents), and disposable bedding.

11. Assistive products for persons with disability: Devices specially produced or adapted which compensate for, relieve, prevent, or neutralize an impairment, disability, or handicap. Examples of devices in this category include artificial limbs, audiometers, crutches, hearing aids, lifts, orientation aids, rehabilitation devices, wheelchairs, and their accessories.

12. Diagnostic and therapeutic radiation devices: Devices that use radiation energy including in vivo isotopes, excited particle energy, magnetic resonance imaging, nuclear energy, ultrasound, and x-ray for the purpose of providing diagnostic imaging and/or therapeutic radiation treatment. Examples of devices in this category include accelerator systems, bone absorptiometric systems, accelerator systems, computed tomography (CT) systems, magnetic resonance imaging (MRI) systems, positron emission tomography (PET) system, X-ray systems, and their accessories. Radiant warming devices are excluded.

13. Complementary therapy devices: Devices that use traditional or alternative methods to diagnose or treat illness. These devices may be used alone or to complement allopathic medicine. Commonly their use is related to the body's innate energy system. Examples of devices in this category include acupuncture needles/devices, bio-energy mapping systems/software, magnets, moxibustion devices, suction cups.

14. Biologically-derived devices: Devices incorporating human and/or animal tissues or cells, or tissue-derived products (excluding in vitro diagnostic products). Examples of devices in this category include tissue heart valves, biological products for tissue regeneration, and natural grafts.

15. Healthcare facility products and adaptations: Building-related products and furnishings for the function and utilization of healthcare facilities, or for home healthcare, which are not involved in patient diagnosis or disease-related treatment. Examples of products in this category include electrical outlets, safety systems (e.g., electrical fail-safe systems, personnel assistance warning systems), fixed generators, sanitation products (e.g., special toilets and baths for routine hygiene), permanent floor/wall coverings, goods transportation systems, adapted and standard furniture, and their accessories. Even though these group

of devices are used in hospital environment and share some similarities with the other, they are not considered as medical devices as the EU directives suggest.

16. Laboratory equipment: Devices used to contain, handle, process, measure, examine, and identify clinical specimens or other substances typically in the evaluation of physiological and pathological conditions. Examples of devices in this category include analysers, microscopes, microtomes, centrifuges, scales and balances, test tubes, pipettes, cabinets, containers, and the equipment necessary to manage a laboratory.

These categorizations are sold to governments and relevant bodies who want to integrate the classification into their system. The classification includes all devices exist into above mentioned categories. However the dynamic nature of the sector and the main purposes of the classification may result in use of a device in more than one category. Throughout the study, the duplicates are not welcomed.