

FOCUS MEDTECH AGENDA

HOW TO CREATE A SUCCESSFUL MEDTECH INDUSTRY IN SWEDEN

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1. STATEMENT OF THE FOCUS MEDTECH STEERING GROUP

Sweden has a unique history of excellence in the field of medical technology. Few, if any, countries can boast as many revolutionizing inventions per capita in this life-saving field as Sweden. Ingenuity, combined with business opportunities, has made medical technology one of the most expansive and vigorous industries in Sweden.

However, maintaining this leading position is dependent on two crucial factors: a supportive environment and a commitment to continuous improvement. The business environment in Sweden needs to keep pace with changing conditions internationally to ensure that the industry can continue its outstanding performance. The responsibility for creating a dynamic platform that can support companies in this industry lies with the government, which needs to accept this challenge and bring Sweden to the same level as other international leaders.

The Focus Medtech Steering Group is pleased to present this report on the industry's view of the competitive situation of Sweden and the opportunities available in the medical technology arena. It is our hope that the Focus Medtech Report will serve as a guide and an eye-opener to everyone involved in the Swedish medical technology industry.

The report will provide guidance as to what must be done to keep Sweden at the forefront of this fast-moving industry. We strongly urge the Swedish government to consider what a prosperous medical technology industry means to Sweden in the form of improved patient care, job opportunities and economic growth.

We would like to thank all individuals and companies that have been involved in and contributed to the results presented in the Focus Medtech Report.

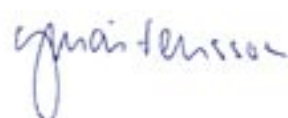
Stockholm, September 1st, 2005.



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2. EXECUTIVE SUMMARY

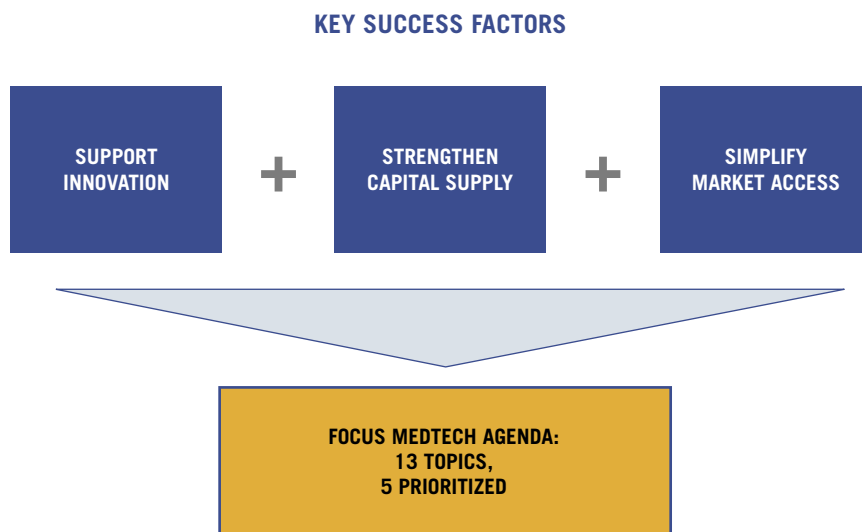
Sweden has a long and successful track record in medical technology. This has led to the development of a healthy industry sector characterized by strong growth and world-leading innovations such as the ventilator, hemodialysis and the pacemaker. Swedish innovations in the field have laid the foundations for world-renowned international companies such as Elekta, Gambro and Nobel Biocare.

In 2003, the Swedish medtech industry¹ involved with diagnostic and therapeutic products, reported a turnover of SEK 20 billion and employed over 8000 people in the country. This represents an increase of more than 60 percent over the previous decade. 50 percent of the Swedish medtech companies operating in 2003 were formed in the preceding 10 years.

However, over the past decade, national and international market conditions in the medtech industry have changed drastically. This has led to a recent decline in Swedish medtech exports and patent applications. The rate of commercialization of Swedish innovations has also been suboptimal.

The Focus Medtech analysis has been conducted as a collaborative effort of SwedenBIO, the Swedish Association of Medical Technology (SLF), the Swedish Trade Council and the Invest in Sweden Agency to identify the most urgently needed actions to enhance the competitiveness of the Swedish medtech industry. The objective is to produce tangible recommendations by which to improve the operating conditions of medtech companies. Workshops and interviews held with leading executives have led to the identification and prioritization of such recommendations.

This has resulted in the formulation of three key factors that are crucial to the strengthening of the Swedish medtech industry. Each factor involves a number of challenges and issues. If the issues and recommendations are addressed correctly and promptly, the medtech industry can truly become a cornerstone of the Swedish economy. A successful medtech industry will be able to maximize its benefits to both the Swedish corporate sector and to patients in need of improved medical care.



¹ As defined in the Vinnova report “National and regional cluster profiles. Swedish companies within biotech, pharmaceuticals and medical technology”, T. Dolk and A. Sandström, 2005.

THE MOST IMPORTANT MEASURES TO IMPROVE INDUSTRY CONDITIONS ARE:

IMPROVE USE OF SWEDISH HEALTHCARE AS SHOWCASE FOR SWEDISH MEDICAL TECHNOLOGY SOLUTIONS

Swedish companies must have a strong domestic market in order to prove the efficacy of their products to customers abroad. The Swedish healthcare system has an excellent international reputation and in using new products it sets standards that others may follow.

STRENGTHEN COMPETENCE IN INTERNATIONAL REIMBURSEMENT PROCESSES

Reimbursement processes are time-consuming and need to be started early in the product development phase in order to ensure that approval is obtained in time for the scheduled market entry. Since, experience in this matter is scarce in Sweden, a competence center should be established to facilitate the process.

CREATE PLATFORMS FOR COLLABORATION BETWEEN HEALTHCARE, RESEARCH AND INDUSTRY TO SUPPORT INNOVATION AND COMMERCIALIZATION.

Many inventions are the result of cooperation between industry and healthcare. Recent cost-reduction drives by hospitals have made the climate for such collaboration less favorable. A platform should be established whereby industry collaboration can be increased and industry and healthcare brought together.

STRENGTHEN MANAGEMENT COMPETENCE AND EXPERIENCE IN INTERNATIONAL MARKETING AND SALES

Swedish companies need top-level management and sales competence to effectively compete on the international stage. Sweden's medtech companies must focus on recruiting staff and board members with international experience to enable the company to adapt quickly to international competition and a variety of local conditions and practices.

SECURE THE AVAILABILITY OF SEED FINANCING

Young innovative companies need financial support in the initial phases to develop their product. Dedicated seed financing for early-stage medtech companies should be provided through government funding. Tax incentives and conditions encouraging business angels to invest in early-stage companies must be at international levels.

3. INTRODUCTION AND OBJECTIVES

The Swedish medical technology industry has held an internationally strong position over decades and has the potential to be a major driver of growth in the Swedish economy. However, in a changing environment, Sweden needs to adapt in order to maintain its leading position worldwide and maximize value creation to the industry and society.

This report was initiated by SwedenBIO and supported by the Swedish Association of Medical Technology (SLF), the Swedish Trade Council and the Invest in Sweden Agency (ISA), in order to identify the factors that need to be strengthened. The study, called “Focus Medtech” has identified three key success factors.



Focusing on diagnostic and therapeutic companies, the Focus Medtech analysis collected information about the industry and the opinions of 67 senior medical technology industry executives to obtain a comprehensive view of the conditions and challenges facing the industry. The following analyses were conducted in the second quarter of 2005:

- **INDUSTRIAL ANALYSIS:** A study of the development of therapeutic and diagnostic companies in Sweden over a ten-year period.
- **INTERVIEWS:** In-depth interviews with senior executives to identify issues and discuss actions to strengthen the industry.
- **INTERNATIONAL ANALYSIS:** An analysis was made to assess the position of the Swedish medical technology industry in an international perspective.
- **SURVEY:** A survey among companies in the medical technology sector was conducted to collect opinions and verify ideas gathered from the initial interviews.

Based on these analyses, the Focus Medtech project has assessed Sweden’s current competitiveness in medical technology and identified major areas where improvements are required to capture its full industrial potential. The authors of the Focus Medtech report strongly believe that the action – if implemented fully – will promote the success of the industry and result in substantial value to shareholders and to Swedish society.

Per Svedenhag
Project leader

Hans Nyctelius
CEO SwedenBIO

Kjell Alenius
CEO SLF

4. SWEDEN HAS A UNIQUE POSITION IN THE MEDTECH INDUSTRY

The strong scientific focus in Sweden has been the basis of today's diversified and internationally competitive Swedish medtech industry which has given the world inventions like the pacemaker and the ventilator. Swedish innovations in this field have laid the foundations upon which some of the most well-known companies of today are based.

4.1 STRONG TRACK-RECORD IN MEDTECH

The story of the success of Swedish medtech has no single starting point. Inge Edler's and Hellmut Hertz' invention of ultrasound devices, along with Rune Elmqvist and Åke Sennings' invention of the implantable pacemaker, are early examples.



The pacemaker: In 1958, physician Rune Elmqvist developed a small, battery-operated pacemaker to stimulate a weak heart muscle. During the same year, the first device was implanted into a human. The invention was commercialized through the company Elema-Schönander, which was later bought by Siemens to form Siemens-Elema. Today, the pacemaker is marketed by the international company St. Jude Medical.

The Brånemark System: Per-Ingvar Brånemark's studies of how the body reacts to different materials resulted in "The Brånemark System." The essence of the discovery is that the metal titanium has the ability to integrate with living bone tissue. This method has many applications in prosthetics, dental implants (represented by Nobel Biocare) and the development of a hearing implant marketed by Entific Medical Systems.

4.2. WORLD-LEADING COMPANIES

Several internationally known medtech companies are founded on world-leading Swedish innovations. A unique characteristic of the Swedish medtech sector is the large number of companies and wide range of application areas represented. Astra Tech, based on implants and disposables, and Mölnlycke Healthcare, based on wound care, are well-known examples illustrating the strength and diversification. There are several innovative Swedish companies that deserve recognition. The following list describes a few of them:

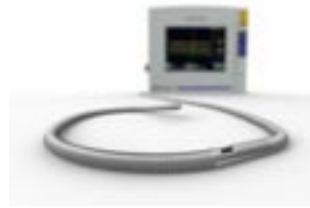
Gambro: The company was founded in 1964, based on the ideas of the nephrologist, Nils Alwall. In 1973, the dialysis market grew explosively due to a new US law requiring Medicare to cover dialysis treatment. The all-plastic dialyzer that had been launched the year before also contributed to the massive growth of Gambro. Today, Gambro employs over 23 000 people globally, and has a turnover of SEK 6,500 million.



Elekta: The Leksell Gamma Knife, a revolutionary method for treating brain tumors and neurological disorders, was invented in 1949 and commercialized by Elekta in 1972. In 1997, Elekta acquired the Philips radiotherapy division and has since then become the third-largest company in the world in the field of oncology. Elekta is presently valued at almost SEK 11,000 million and employs some 1,100 people worldwide.

Sectra: The company was founded during the late 1970s as a maker of security systems for banks. Sectra changed direction in the mid-eighties, beginning its focus on digital image processing for radiology departments in 1988. Since then, the company has grown rapidly and currently employs about 370 people globally. In 2004, it had a turnover of SEK 456 million.

Radi Medical: Founded in 1988, this company’s main business area is interventional cardiology, focusing on its unique guide-wire multisensor technology. Radi Medical has had steady growth, is represented around the world and employs a total of 200 people globally. The company’s turnover in 2003 was SEK 240 million.



4.3. SUBSTANTIAL GROWTH OF THE SWEDISH MEDTECH INDUSTRY

In 2003, the Swedish medical technology industry³ reported a turnover of SEK 20,000 million, as shown in figure 3.1. For the companies with a therapeutic and diagnostic product profile identified in 2004, an increase of 60 percent over the past decade can be seen. This is a remarkable growth rate, even though the numbers for 2003 show a decline in the total turnover for the industry. This is largely due to Siemens-Elema discontinuing large parts of their Swedish operations in 2003.

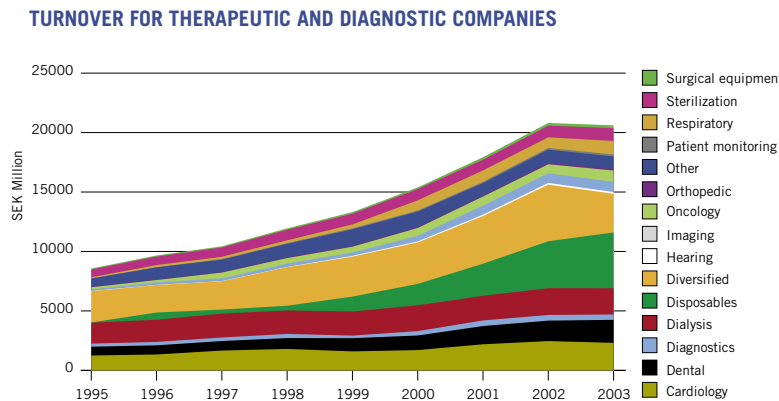


Fig 4.1. The therapeutic and diagnostic medical technology industry has seen steady growth over the past ten years, with the exception of 2002–2003. Source: MMPartner database, compiled by SwedenBIO.

The period has seen a strong growth in the number of companies formed. During 1995–2003, the number of companies⁴ increased by 20 percent. There has also been growth in the number of clinical applications of medtech, such as imaging, surgical equipment, etc. The Swedish medtech industry is one of the most highly diversified. Many other countries focus on fewer applications, whereas Sweden has companies operating in a wide range of clinical applications of medical technology.

4.4. SWEDEN AMONG THE TOP FIVE COUNTRIES IN INNOVATION

Sweden has a unique strength in its well-educated and scientifically driven population. A high percentage of Swedish clinicians have a doctoral degree as a complement to their medical degree and are active researchers. The highly developed Swedish Healthcare system has provided a strong base to further high-level research into patient care. Clinicians have been encouraged to collaborate with the industry, something that is explicitly forbidden in some countries, thereby providing the industry with marketable product ideas sprung from genuine medical need.

³ As defined in the Vinnova report “National and regional cluster profiles. Swedish companies within biotech, pharmaceuticals and medical technology”, T. Dolk and A. Sandström, 2005.

⁴ Here, the data refers to trade group 33101 since the data in the Vinnova report “Nationella och regionala klusterprofiler” in footnote 2 refer only to companies that existed in 2004. Group 33101 contains additional companies that are not classified as medical technology in the Vinnova report.

FOREIGN MEDTECH PATENTS GRANTED IN THE US, 2000-2004, ABSOLUTE NUMBERS

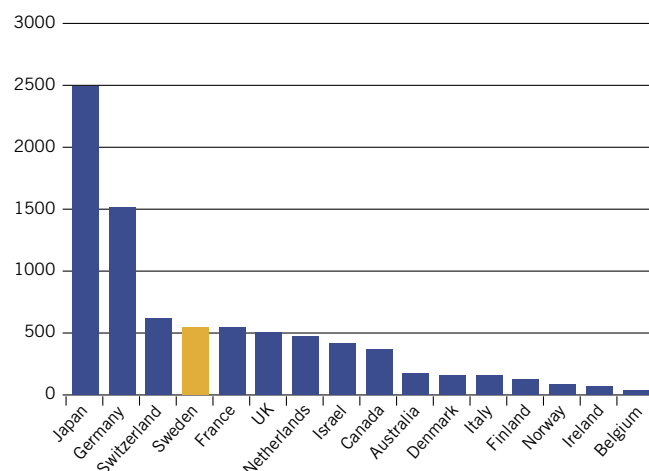


Fig 4.2 Absolute numbers of granted patents in the US.
Source: USPTO database 050609; IPC A61B, F, M, N, compiled by SwedenBIO.

The number of granted patents indicates a country's innovativeness. Sweden scores extremely high in Life Sciences and ranks fourth among foreign countries in granted US patents in medical technology, in absolute numbers. From a per capita perspective, Sweden ranks third, surpassed only by Switzerland and Israel. It is noteworthy that Sweden is ahead of larger countries like the UK, France and the Netherlands in absolute numbers.

4.5. SWEDEN EXCEPTIONALLY SUITABLE FOR THE MEDTECH INDUSTRY

Apart from its strong scientific and industrial track record as well as excellence in innovation, Sweden has a number of inherent strengths that makes the medtech industry a perfect growth industry to support the Swedish economy.

EIGHT REASONS WHY SWEDEN IS RIGHT FOR MEDTECH

- Excellent base of knowledge and experience
- World-leading innovation platform
- Strong industry platform including leading international companies
- Dedication to IT and technologies essential to medical technology
- World-class health care system including technically advanced hospitals
- Skill in manufacturing of critical devices.
- Culture of cooperation between companies, physicians and hospitals
- World-leading brands such as Nobel, Karolinska Institutet

Manufacturing of medical technology products demand world-class quality and is typically located in Sweden. The products are often high-tech and low-volume products that don't benefit from production in low-cost countries. Sweden is also very competitive on research and development in other high-tech industries, such as biotechnology, pharma and telecom, which are industries with strong connections to medical technology.

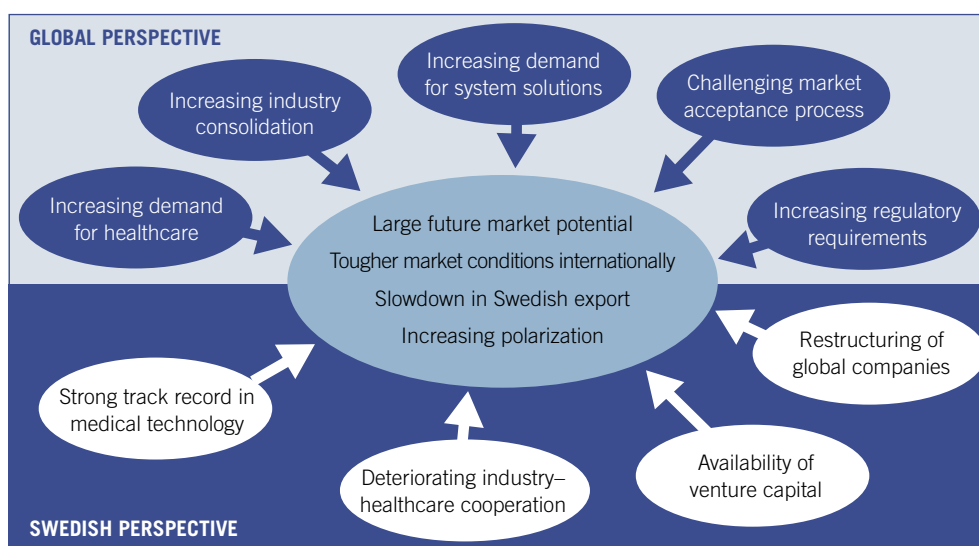
These factors support the conclusion that medical technology is well suited to becoming a growth industry in Sweden. The opportunities available in international markets, combined with the industry's fit with Swedish competence profiles and with Swedish society, render the industry capable of bringing substantial value to Sweden in the future.

All industries, however, require a supporting environment that is suited to their needs in order to be successful. As the next section will show, Sweden has a number of issues that must be addressed before it can realize the full potential of its medical technology industry.



5. CHANGING MARKET CONDITIONS CREATE CONSEQUENCES FOR SWEDISH MEDTECH

Market conditions in the medtech industry have changed drastically over the past decade. To retain its leading position in medical technology, Sweden must manage these forces. Some of the drivers of change described below are global, while others are more local.



GLOBAL PERSPECTIVE

INCREASING DEMAND FOR HEALTHCARE

The populations of western countries are aging and life expectancy increases globally. The increasing number of baby-boomers entering retirement age will lead to a growing demand for sophisticated healthcare.

INCREASING INDUSTRY CONSOLIDATION

Over the past decade, the industry has undergone significant consolidation, in which large multinationals have acquired smaller companies in order to enter new markets or new market segments. Examples of this are e.g. Philips' acquisition of Marconi and Agilent, General Electric's acquisitions of Marquette, Instrumentarium and Amersham, Elekta's acquisitions of Philips radiotherapy business and Impac Medical Systems as well as Ortivus' acquisitions of Sweet Computer, AVeL-TECH and Medoc.

Due to the wide spectrum of applications in medical technology, synergistic effects between Swedish medtech companies are rare – hence consolidation within companies in Sweden is uncommon.

INCREASING DEMAND FOR SYSTEM SOLUTIONS

As IT technology and system solutions become available to hospitals and healthcare providers, there is increasing demand for new products and solutions to be integrated into these systems. The more comprehensive integration solutions are supplied primarily by multinational companies, making it increasingly difficult for the smaller ones to compete.

CHALLENGING MARKET ACCEPTANCE PROCESS

It is increasingly difficult to gain market acceptance for new products and solutions, mainly due to three factors:

- **CLINICAL ACCEPTANCE:** To gain acceptance for a product in the medical environment, its clinical efficacy needs to be proven and demonstrated. This often need to be done in each individual market before acceptance by local physicians and caregivers can be obtained. This problem is accentuated for younger companies that haven't yet achieved brand recognition and a reputation among the customers.
- **REIMBURSEMENT:** Hospitals and clinics are today unwilling to invest in medical technology products that are not reimbursed. This means that companies developing new products need to implement reimbursement strategies early in the product development phase in order to meet the clinical evidence requirements from reimbursement payer organisations.
- **COST EFFICIENCY:** The pressure is increasing on healthcare providers to supply more advanced and more efficient care to an aging population. This leads to an increasing pressure on suppliers to deliver not only solutions with improved clinical effect but also with increasing cost efficiency for the caregiver.

INCREASING REGULATORY REQUIREMENTS

The requirements for obtaining regulatory approvals have been rising steadily over time, due to increasing requirements on product safety and efficacy. Although attempts are being made to harmonize the regulatory systems of some markets, regulatory requirements will most likely continue to increase.

SWEDISH PERSPECTIVE

STRONG TRACK RECORD IN MEDICAL TECHNOLOGY

Sweden has a long history of innovative products and successful companies in medical technology, which provides a strong foundation for continued industry growth. It should also be noted that the medtech industry has generated indirect supply and employment effects in that it requires the engagement of a substantial number of local sub-suppliers, often with high-quality expertise.

DETERIORATING INDUSTRY-HEALTHCARE COOPERATION

One of the cornerstones of Sweden's strong position in medical technology has been the culture of cooperation between industry and healthcare. Recent years have seen a decline in this area with implications for the industry.

- **INNOVATION:** Historically, time and resources have been available for collaboration on new product ideas and concepts between leading clinicians and industry representatives. Many of Sweden's innovative products and companies were initially nurtured by such cooperation. There has been a decline in this type of fruitful cooperation, now that the climate in healthcare and the corporate sector has become tougher.
- **CUSTOMER IMPLEMENTATION:** Formerly, the initial development phases of many companies were facilitated by early-stage contracts with Swedish healthcare, enabled by e.g. LFTP (Landstingens fond för teknikupphandling och produktutveckling). LFTP supported implementation of new, yet unproven products and technologies, providing risk sharing but also making Swedish healthcare a demanding and competent initial customer for innovative products and companies. These supporting funds are no longer available. Leading industry representatives in successful companies state that it would not have been possible to get their companies off the ground in the restrictive purchasing environment currently prevailing in Swedish healthcare.

AVAILABILITY OF VENTURE CAPITAL

The venture-capital market has developed significantly over the past decade, making venture capital a viable resource for the development of early-stage medical technology companies. However, as seed financing is limited, start-up companies have difficulty getting through the start-up phases and venture capital investors are forced to invest in projects earlier than would usually be desired. Limitation of expansion capital needed for the expansion phase, is also a major bottleneck for medtech companies due to the difficult market acceptance process.

RESTRUCTURING OF GLOBAL COMPANIES

Siemens-Elema and Instrumentarium recently carried out major reductions of their activities in Sweden. As large companies have a profound impact on their industry sector, this could have long term effects:

- **DRAINAGE OF EXPERTISE:** Large medical technology companies have been nurseries for fostering professionals with extensive international experience. A large portion of the Swedish medical industry is benefiting from these experienced professionals. However, as these larger operations are phased out in Sweden, the industry may well face a future shortage of certain forms of expertise.
- **DECLINING CLUSTER EFFECT:** Large companies create cluster effects, from which innovations and new companies can develop. Several companies have been founded on the know-how and ideas of former employees of, for instance, Gambro, Siemens-Elema and Instrumentarium. This effect may decline given this development.

5.1. DECLINE IN SWEDISH EXPORT

Swedish export of medical technology has been increasing steadily since the 1980s. However, this changed in 2002 when export of diagnostic and therapeutic medical technology took a sharp downturn. This can be largely attributed to the withdrawal of Siemens-Elema and Instrumentarium, as there was a 50-percent drop in the export of respiratory equipment and x-ray/radiation equipment between 2002 and 2004, whereas other product segments remained constant.

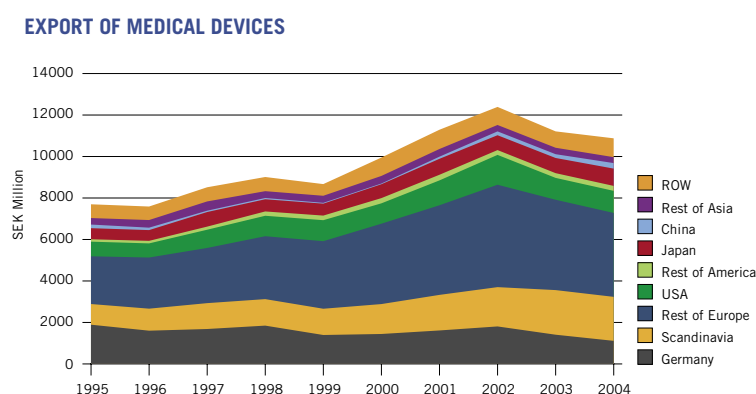


Fig 5.1 Swedish export of medical technology.
Source: Data from SCB, compiled by Lena-Kajsa Sidén, May 2005.

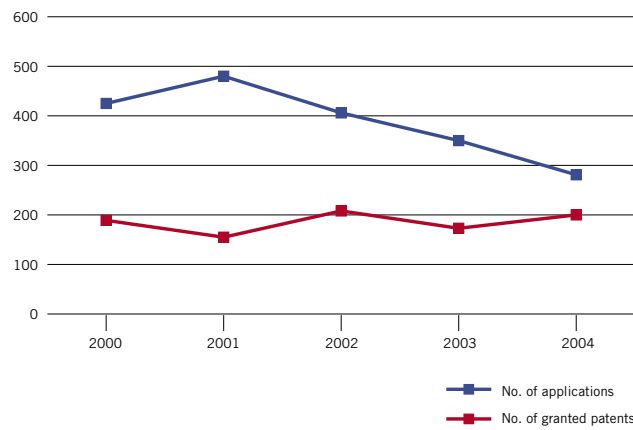
The export markets with the largest decreases in medical technology are Germany, which reported a drop of 38 percent between 2002 and 2004, the US, which reported a drop of 24 percent, and the rest of Europe (excluding Germany and Scandinavia), which reported a drop of 18 percent. The decline in export to the US, however, is attributable to currency changes over the period.

5.2. DECLINE IN SWEDISH INNOVATION

The number of patent applications for medical technology in Sweden has decreased sharply since 2001, by as much as 33 percent. There is an average lag of three years between application and approval⁵, which is why no decline in granted patents can be seen yet. During the same time period, the number of patent applications in medical science in Europe has increased substantially.

The general decline in patent applications could be attributed to companies' adoption of new patent strategies. However, even excluding the largest companies, there has been a significant decline in the patent applications. Therefore, it must be concluded that the decline is general and not the result of changes in the IP strategies of the larger companies.

APPLICATIONS AND GRANTED PATENTS FOR MEDICAL DEVICE TECHNOLOGY IN SWEDEN, GROUP A61



PATENT APPLICATIONS FOR MEDICAL SCIENCE IN EUROPE, GROUP A61

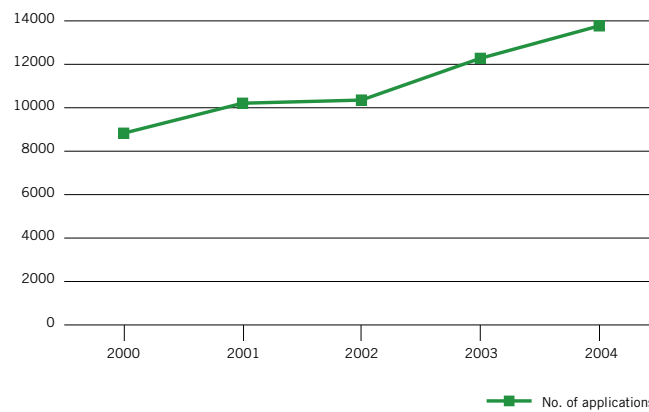


Fig 5.2 Patent statistics for group A61, medical technology.
Source: PRV and the European Patent Office.

⁵ The time between application and approval varies greatly but is on average three years. Common reasons for delays are incomplete applications or other formalities. In Europe, the applicant can also choose the date of publication to some extent, thereby skewing the statistics somewhat.

5.3. INADEQUATE COMMERCIALIZATION OF SWEDISH INNOVATIONS

Sweden has not received the full benefit of its historical strength in innovation. As shown in fig 5.3, Sweden has a leading position in innovation, but only a mediocre position in trade.

Sweden belongs to a cluster of highly innovative countries consisting of Sweden, Israel, the US and Switzerland. However, in terms of trade and commercialization, Sweden must be considered to be the least successful country, as:

- Switzerland is a top-performing country, both in trade and innovation, with great similarities to Sweden with respect to size, population and educational level.
- The US has low trade values due to an enormous home market (equal to approximately 45 percent of world market). In addition, countries with large population tend to have low values in per capita comparisons.
- Israeli companies typically commercialize their inventions in the US, and thus obtain low trade values.

It should be noted that Ireland, which over time has developed a manufacturing profile in its industry⁶, has secured a unique position in trade.

TRADE VS INNOVATION

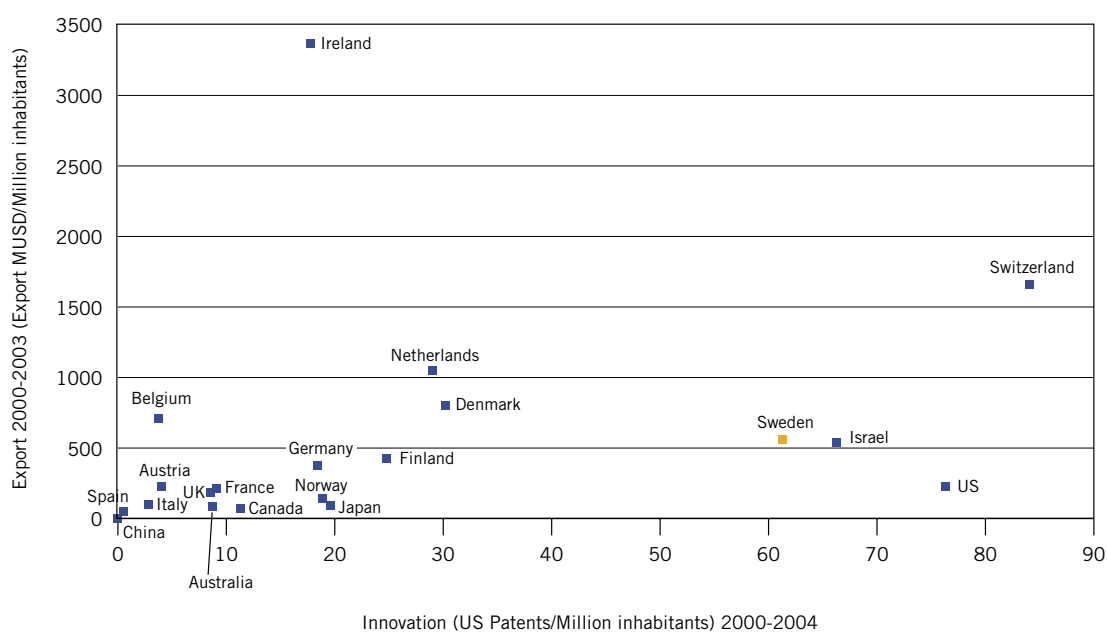


Fig 5.3 Patent statistics for group A61, medical technology. Source: PRV and the European Patent Office.

⁶ See page 24, "Medtech in Ireland", for more information.

AEROCRINE – MANAGING THE CHALLENGES

Aerocrine was founded in 1997 by scientists from Karolinska Institutet. The new company was based on scientific findings that proved that nitric oxide (NO) could be used as a marker of inflammation. The lead product improves asthma control by using exhaled NO as a biomarker of inflammation to optimize treatment in a manner similar to that of glucose monitoring in diabetes.

THE CHALLENGES AND HOW THEY HAVE BEEN HANDLED

Aerocrine has faced several challenges in its efforts to capture the commercial potential of its IP portfolio and build shareholder value.

GAINING APPROVAL AND ACCEPTANCE OF A NEW, UNPROVEN METHOD

In order to create international awareness and acceptance for the clinical applications of the method, the company started early on to build a strong network of influential opinion-leaders at leading academic centers, primarily in the US and EU. Quality Assurance, Good Manufacturing Practice processes and a legal framework for relationships with external partners have been in place from the start. This has provided invaluable support during all stages of the company's development.

BUILDING AN ORGANIZATION WITH APPROPRIATE COMPETENCIES

Aerocrine is a project-focused organization with several external partners. To gain access to relevant competencies and technologies, the company has built and maintained a network of competent partners. To control costs, these competent partners have, for the most part, not been kept in-house but as consultants. The company has also succeeded in recruiting top competencies for key positions, aided partly by the dismantling of the pharmaceutical industry in the region.

BUILDING SALES AND MARKETING CHANNELS

Establishing local sales and marketing channels is a very costly exercise and, when it involves an unproven concept, also an enormous risk. The strategy has been to carefully select each market and work through already established channels, cooperating with distributors in the local markets. Each market has been looked at individually and the local distributor has had to qualify on its own merits. The company keeps in constant touch with major opinion-makers and maintains a presence at leading global conferences.

SECURING CAPITAL FOR DEVELOPMENT

Companies like Aerocrine that are financed by venture capital face ongoing financial challenges. Renowned, competent and enduring investors have been a key in bringing Aerocrine to its current position. The crucial factors in attracting and retaining long-term investors have been the ability to demonstrate progress and achieve predefined goals within a specified time-frame.

CURRENT SITUATION

NIOX[®], the company's first-of-a-kind asthma test, was cleared by the FDA in May 2003, and has opened up a new clinical market. The method is now being incorporated in the EU's National Clinical Guidelines for asthma. Today, NIOX is used by more than 300 leading academic institutions in the US, the EU and Asia. There is increasing acceptance of exhaled NO for routine clinical use as well as a growing interest from the pharmaceutical industry. Aerocrine is now moving from selling devices to selling tests, directly and via distributors.

6. CHANGING MARKET CONDITIONS CREATES CONSEQUENCES FOR SWEDISH MEDTECH

The Focus Medtech Group has performed interviews with leading industry representatives to identify issues of high importance to the medtech sector. A survey based on key topics from the interviews has also been completed by 50 medtech companies operating in Sweden. From this have emerged 5 topics central to the continued development of the Swedish medtech industry. They are:

- FINANCING
- REGULATORY ISSUES
- MARKETING AND SALES ISSUES
- ACCESS TO DISTRIBUTION CHANNELS IN INTERNATIONAL MARKETS
- INNOVATION

LIMITING FACTORS FOR GROWTH

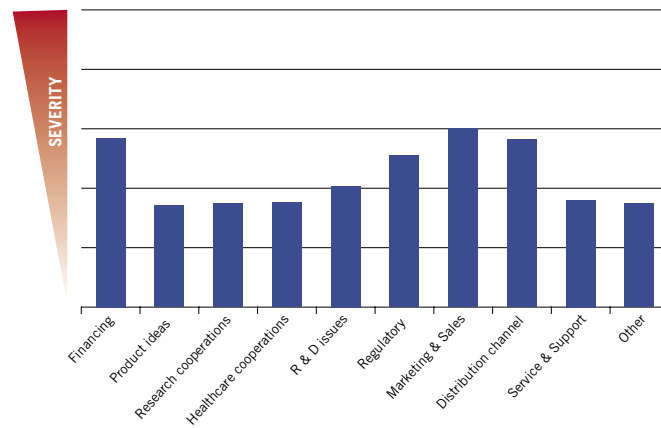


Fig 6.1 Rating of growth-limiting factors. *Source: SwedenBIO.*

These five issues can be clustered together to form three major groups, as visualized in figure 6.2. Each group is detailed in following sections



Fig 6.2 Primary issues facing the medtech industry in Sweden. *Source: SwedenBIO.*

6.1. LIMITED SUPPORT FOR THE INNOVATION SYSTEM

The companies have stated that the basis for innovation has begun to deteriorate during recent years. Areas in trouble are cooperation with healthcare and research and the possibility to perform translational research.

DECLINING COOPERATION BETWEEN INDUSTRY AND HEALTHCARE/RESEARCH

The trend seen today is that the climate for cooperation between industry and healthcare is declining. In this survey, 51 percent of the industry respondents stated that cooperation between them and healthcare was very good ten years ago. The proportion reporting good cooperation now is 38 percent.

In addition, the perception of the climate for cooperation with research institutions is that it has also declined. As many as 41 percent of the respondents stated that their cooperation with research institutions was very good ten years ago. Today, this proportion has dropped to 28 percent.

“Ten years ago, 41 percent of the respondents claimed to have very good relations with research institutions. Today, this has dropped to 28 percent.”

LACK OF TRANSLATIONAL RESEARCH

A number of Swedish companies, including larger corporations, have chosen to locate their cooperation with research institutions abroad. This is due to lack of appropriate interest and response from research institutions in Sweden regarding translational research.

6.2. INADEQUATE FINANCING FOR STARTUP COMPANIES

In this survey, 53 percent of the respondents stated that financing issues are limiting industry growth either significantly or to a large extent.

IS FINANCING AN ISSUE FOR THE MEDTECH INDUSTRY?

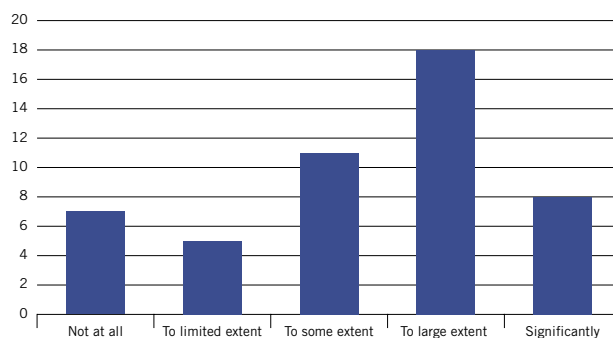


Fig 6.2 Primary issues facing the medtech industry in Sweden.

NEED FOR ADDITIONAL SEED FINANCING

There is a general observation in the industry that seed financing is more limited today than in the past, and that this is a key factor restricting growth. Industry opinions state both that current government seed financing is too limited and that the tax incentives for business angels to invest in start-up companies are too poor.

INADEQUATE FUNDING FOR COMMERCIALIZATION AND INTERNATIONAL EXPANSION

Several correlated effects can be seen, involving research funding, seed financing and later-stage financing through venture capital. In situations of limited research funding, research projects are transformed into corporate entities at extremely early stages. Adding on the lack of seed financing results either in these projects being discontinued or in venture capital being forced into the projects too early, limiting the supply of capital available in the commercialization phase.

WEAK MEDTECH COMPETENCE AMONG INVESTORS

There is an opinion in the industry that too few investors have sufficient background in and experience of the medical technology industry. It is perceived that this restricts companies' the ability to receive financing, as the investors do not have sufficient knowledge to properly assess the potential of a company. It is also perceived that investors' lack of experience of the medical technology industry is a limiting factor in the management of the portfolio companies.

"Investors must learn more about the complex and time-consuming process of bringing a medical technology invention from an idea to successful sales. It is an extensive process that takes 5-10 years."

*Hans Dablin, CEO,
ONCOlog Medical AB*

6.3. INADEQUATE FOCUS ON COMMERCIALIZATION

Since Sweden is too small a market to sustain a medtech company, internationalization is an early requirement for growth. International laws and regulations, as well as business culture, are therefore key factors in a successful expansion. The primary issues brought up by the industry are:

REGULATORY AND CLINICAL EVALUATION

REGULATORY ENVIRONMENT IN EUROPE INSUFFICIENT FOR MARKET ACCEPTANCE

A CE marking is a verification of the safety of a product but does not constitute any definite measure of its clinical efficacy. This means that a company needs to gain clinical acceptance in each country and each major institution separately, which leads to a tedious, time-consuming and expensive process.

"The absence of a strict regulatory framework in the EU is a factor that is negative for the industry. A qualified regulatory approval like the FDA in the US is preferred, as it involves both product safety and clinical efficacy, even though it makes life tougher with costs and time."

*Akbar Seddigh,
Chairman, Elekta
and Ortivus*

INADEQUATE COMPETENCE FOR ADVANCED REGULATORY PROCESSES

Companies with advanced innovative products lack competent guidance in Sweden on managing advanced regulatory processes such as PMA (Pre-Market Approval) in the US. Foreign expertise is often necessary, but many steps in these processes become unnecessarily complicated due to a lack of top competence in this area in Sweden

UNDERESTIMATION OF CLINICAL EVALUATION, CLINICAL ACCEPTANCE AND REGULATORY PROCESSES.

A common opinion in the industry is that the time, effort and resources needed to go through the clinical evaluation, clinical acceptance and regulatory approval processes are frequently underestimated by younger companies.

MARKETING AND SALES

INCREASED NEED FOR INTERNATIONAL MARKETING AND SALES EXPERIENCE IN MANAGEMENT

The increasingly competitive international environment demands more experience in international marketing and sales. It is a challenge to find internationally experienced managers to work in Sweden.

“In Sweden it is difficult to find individuals with the right competence profile for international sales and marketing i.e. with a combination of clinical, technical and sales/marketing background.”

*Simon Grant
CEO, Neoventa*

WOULD ACCESS TO TOP SALES COMPETENCIES MAKE A CHANGE FOR YOUR COMPANY

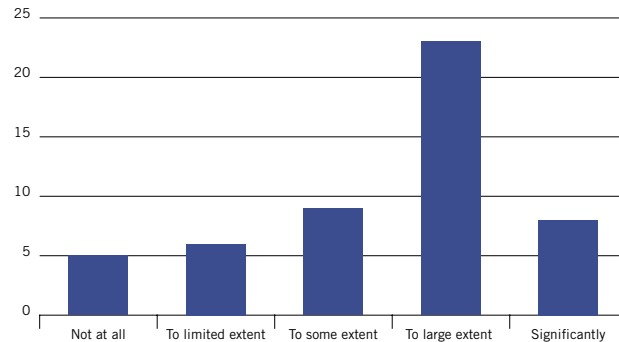


Fig 6.3 Rating of whether access to top competencies would make a difference for medtech companies. *Source: Focus Medtech Survey, June 2005.*

INSUFFICIENT UNDERSTANDING OF THE COMPLEX REIMBURSEMENT PROCESS

In order to achieve market acceptance and sales, the product must be embraced by the local reimbursement system. This involves a long and complex process, especially in cases where new reimbursement classifications need to be developed. In addition, since reimbursement classifications and rates vary over time, companies need to continuously update their reimbursement strategies.

DIFFICULTIES IN FINDING OPTIMAL MARKET STRATEGY

Swedish medical technology companies find it difficult to identify which markets to address and how to address remote markets in an efficient manner, as regards the management of the clinical and market acceptance process, the selection of distribution channels, etc.. In our survey, 35 percent of the respondents stated that difficulties in establishing a local distribution channel severely or to a very large extent limited their company’s ability to undertake international expansion.

“35 percent of the respondents stated that difficulties in establishing a local distribution channel severely or to a very large extent limited their company’s possibilities for international expansion.”

INCREASED NEED FOR COMPANIES WITH CRITICAL MASS TO SUSTAIN INTERNATIONAL EXPANSION

Substantial resources are vital to successfully commercialize products on international markets. In this survey, 43 percent of the respondents stated that limited financial resources severely or to a very large extent were restraining issues for an international expansion. In addition, it is also perceived that a limited product portfolio and the size of the company are limiting factors.

NEED FOR INCREASED CONSIDERATION OF INTERNATIONAL MARKET REQUIREMENTS.

For an innovative product to be successful, it often needs to be adapted to clinical practice. As clinical practice varies significantly from country to country, the product concept has to be modified for the product to be marketable in different countries.

MEDTECH IN IRELAND – CREATING AN EXCEPTIONAL GROWTH INDUSTRY

Ireland is a small country with a population of less than four million. Over the past decade, the Irish economy has had tremendous growth – three times the EU average – and the second-highest in Europe.

The medical technology sector in Ireland has developed at a comparable pace, its current growth rate approaching 10 percent. The sector is generating exports in excess of EUR 4 billion and employs over 22,000 people, which amounts to 10 percent of all people working in manufacturing industry in Ireland. This has been achieved through a favorable corporate environment for remote operations of foreign companies, including a 12.5 percent corporate tax rate and a well-educated workforce. The development can in some part also be attributed to the EU's structured funds for small- and medium-sized enterprises.

SOME REASONS WHY THREE OUT OF EVERY FOUR NEW GREENFIELD MEDICAL TECHNOLOGY PROJECTS THAT ESTABLISH THEMSELVES IN EUROPE CHOOSE IRELAND:

TECHNICAL AND MANAGERIAL TALENT

Ireland has the technical and managerial talent, including mechanical, electronic, materials engineering and science specialists, all readily available to medical technology companies

COMPETITIVE CORPORATE TAX RATE

Ireland has a corporate tax of 12.5 percent on all trading activities, and this is combined with a range of other tax advantages such as R&D tax credits and patent royalty tax exemptions.

SUPPORTIVE ENVIRONMENT FOR R&D

Science Foundation Ireland, with EUR 646 million in Irish Governmental funding, and dedicated research centers, such as the one at the National Centre for Biomedical Engineering Science at NUI Galway, have been established to raise the research base in Ireland to new heights of internationally recognized excellence.

Source: IDA Ireland

The Irish Medical Device Association (IMDA) has defined a vision for the industry in Ireland:

“Ireland as a globally recognized center of excellence in medical devices and diagnostic technologies. To make Ireland the location of choice for research and development, manufacture and marketing of bigbly innovative products.”

TWO MAIN DRIVERS OF THE CONTINUED DEVELOPMENT OF THE MEDICAL TECHNOLOGY INDUSTRY HAVE BEEN IDENTIFIED:

- Healthcare consumers are demanding ever higher levels of care
- Healthcare providers require ever more cost-effective ways of meeting this demand

In order to meet the challenge of this future competitive environment, the Irish medical technology industry is now moving towards products offering more added value and towards integrating additional activities, such as R&D, customer support and distribution.

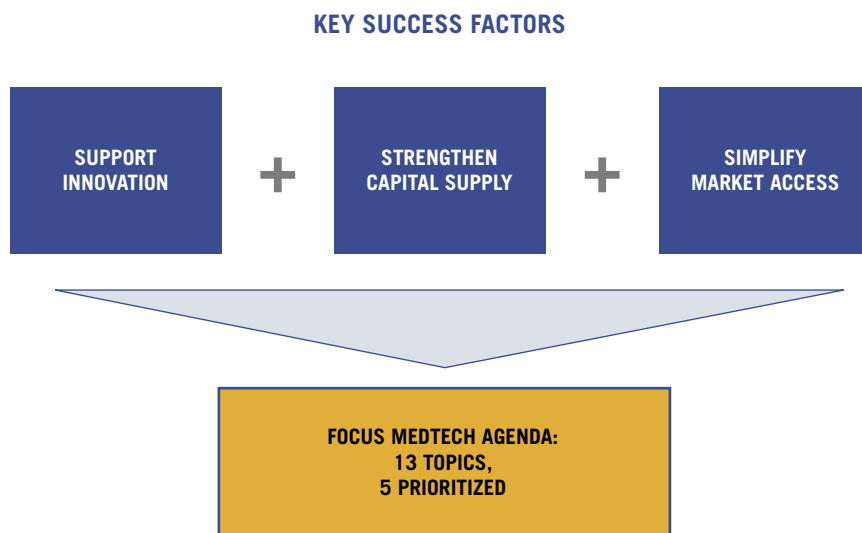
A STRATEGY HAS BEEN DEFINED BASED ON SIX RECOMMENDATIONS OF WAYS TO ENSURE THE SUSTAINED SUCCESS OF THE MEDICAL DEVICE AND DIAGNOSTICS INDUSTRY IN IRELAND:

- Establish an environment that actively supports innovation and R&D
- Secure the availability of skilled and adaptable employees
- Significantly improve Ireland's cost-competitiveness
- Build world-class infrastructure
- Cultivate a favorable regulatory environment
- Establish a balanced framework of social and human resources legislation

7. THE SWEDISH MEDTECH INDUSTRY – A CORNERSTONE OF THE SWEDISH ECONOMY

Sweden offers a unique setting for the medtech industry. As this report has shown, changing conditions are threatening our internationally leading position and action is needed to prevent a decline. It is imperative that Sweden’s advantage be managed with great care and leveraged to further develop the industry, thereby generating value for the industry and for the Swedish economy through job opportunities and growth.

There are three critical factors for success. If they are addressed, the medtech industry could truly become a cornerstone of the Swedish economy. The medtech arena has three key players: government, owners and the industry itself. Together they have the means to coach the companies in their endeavor. A successful medtech industry can maximize the benefits it provides for the Swedish corporate sector and for patients in need of improved medical care.



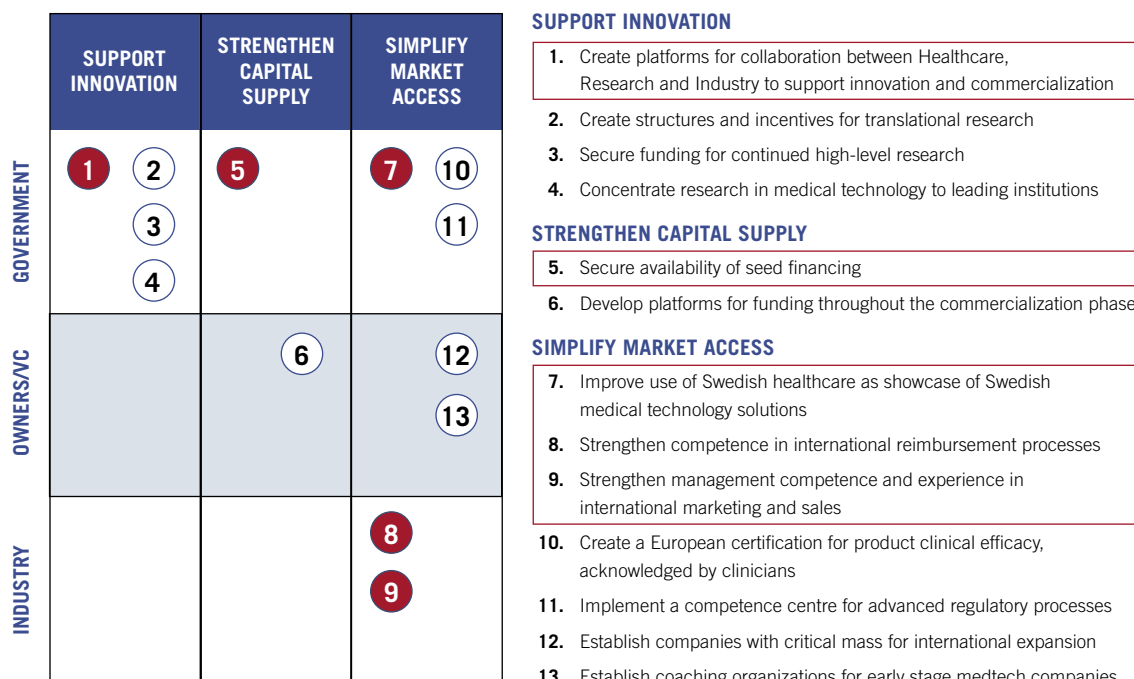


Fig 7.2 Interviews and results from the questionnaire have resulted in 13 issues that need to be addressed in order to secure Sweden's position in m

7.2 CREATING A WORLD-CLASS INNOVATION SYSTEM

Sweden's primary strength has always been the innovations upon which many of its global companies have been founded. To maintain this asset, and improve it, a number of requirements must be met. The Swedish government is the party most suited to address the areas in need of improvement.

1. CREATE PLATFORMS FOR COLLABORATION BETWEEN HEALTHCARE, RESEARCH AND INDUSTRY TO SUPPORT INNOVATION AND COMMERCIALIZATION
 Many inventions are the result of cooperation between industry and healthcare. Recent cost reduction drives by hospitals have made the climate for such collaboration less favorable. Another important explanation for the decline in industry–healthcare cooperation can be found in the exposure of unethical behavior in the pharmaceutical industry, which has led to the establishment of new public-health policies. A platform should be established whereby industry collaboration can be increased and industry and healthcare brought together.
 TIME FRAME: SHORT-TERM

2. CREATE STRUCTURES AND INCENTIVES FOR TRANSLATIONAL RESEARCH
 Although basic research is important, translational research also needs to improve in order to supply the industry with marketable technologies and products. It is therefore essential that structures and incentives to support translational research are created.
 TIME FRAME: LONG-TERM

“Given the current climate and conditions in Sweden for clinical medtech research, we have chosen to locate the majority of our translation research cooperation in other countries, such as the Netherlands, Canada, the UK and the US “

*Tomas Puusepp
 CEO, Elekta*

3. SECURE FUNDING FOR CONTINUED HIGH-LEVEL RESEARCH

Basic research at universities must be supported by additional funding to ensure its continued excellence and support for future innovations. Innovation has always been key to the leading position of Swedish medical technology and it is imperative that this position be maintained.

TIME FRAME: LONG-TERM

4. CONCENTRATE RESEARCH IN MEDICAL TECHNOLOGY TO LEADING INSTITUTIONS

To secure Sweden's position, Swedish research needs to be on par with, or even better than, that of the other countries in the top five countries for granted US patents. This means funding should be directed to a select few in order to create units that meet the standards of the tough international competition.

TIME FRAME: SHORT-TERM

7.3. STRENGTHENING THE CAPITAL SUPPLY

Since medtech is a research-intensive industry, the need for capital and funding to take companies through the initial development phase is huge. Sweden needs a system whereby appropriate funding may be channeled to start-up companies with high potential. The interviews have also revealed that funding for the expansion phase is lacking. The Swedish government can support the seed financing and is therefore best suited to addressing weaknesses in this area. Sufficient availability of state seed financing will enable venture capital to better support the costly expansion phase.

5. SECURE AVAILABILITY OF SEED FINANCING

Young, innovative companies need support throughout the initial phases to develop their product. Dedicated seed financing for early-stage medical technology companies should be provided through government funding. In addition, it is also important that incentives and conditions to encourage business angels to invest in early stage companies be brought up to with international levels, as business angels often bring both capital and extensive experience to the companies.

TIME FRAME: SHORT-TERM

“My perception is that in the absence of a true structure for seed financing, the EU and Swedish venture capital seems to be getting involved earlier in the seeding phase and hence exits earlier than VCs in the US. This means that there are less funds available for the later phases”

*Thomas Almesjö
CEO, Aerocrine*

6. DEVELOP PLATFORMS FOR FUNDING THROUGHOUT THE COMMERCIALIZATION PHASE

Securing long-term financing is central for all companies. This can be achieved through e.g. venture capital or through foreign direct investments. If sufficient seed financing is available to start-ups, VC investors can focus their efforts on companies in later stages of development. This enables these companies to make a better market entry and ensures that more resources will be available for the increasingly challenging and resource-intensive commercialization phase.

TIME FRAME: SHORT-TERM

7.4. SIMPLIFYING THE MARKET ACCESS

Commercialization is something that companies need to prioritize. The industry has been permeated by the feeling that “innovative products sell themselves”. The goal should be to achieve strength in trade that is equal to that in innovation, by bolstering the expertise of the marketing and sales department. Sweden should be at least on a par with Switzerland – the leader – whose export level is three times that of Sweden while its innovation level is only 1.2 times that of Sweden, in terms of per capita.

Reimbursement is a difficult issue that is sometimes overlooked. In many countries, however, it is one of the key success factors for companies that are trying to enter a market. If the product is not included in the reimbursement system, there is no incentive for hospitals to use the new treatment. These issues can be most easily addressed by the industry itself.

7. IMPROVE USE OF SWEDISH HEALTHCARE AS SHOWCASE FOR SWEDISH MEDICAL TECHNOLOGY SOLUTIONS

Swedish companies must have a strong domestic market in order to prove the efficacy of their products to customers abroad. The Swedish healthcare system has an excellent international reputation and in using new products it sets standards that others may follow. Access to the latest technology in Swedish hospitals also means better healthcare for Swedish citizens.

TIME FRAME: LONG-TERM

“Create means and incentives for customers to purchase new technologies from local Swedish companies. A competent and demanding customer, willing to take risks, was a prerequisite for Sectra’s early development”

*Torbjörn Kronander
President, Sectra ImtecAB*

8. STRENGTHEN SWEDEN’S COMPETENCE IN INTERNATIONAL REIMBURSEMENT PROCESSES

Reimbursement processes are time-consuming and need to be started early in the product value chain in order to obtain approval in time for the scheduled market entry. Expertise in this matter is scarce in Sweden and a competence center should be established to facilitate the process.

TIME FRAME: SHORT-TERM

“Reimbursement issues must be given a higher priority in med tech companies since it is a must for a successful market launch”

*Jan Lundahl
Senior Partner, CapMan*

9. STRENGTHEN MANAGEMENT COMPETENCE AND EXPERIENCE IN INTERNATIONAL MARKETING AND SALES

Swedish companies need to have top-level expertise in management and sales in order to effectively compete in the tougher international environment. Swedish companies are typically very good at developing leading product solutions, but weaker as regards the sales and marketing process. Swedish companies must focus on recruiting staff and board members with international experience, to enable the company to quickly adapt to international competition and local conditions and practices.

TIME FRAME: LONG-TERM

“One of the key factors seen in all our successful investments is the presence of top management”

*Johan Christensen
Partner, HealthCap*

10. CREATE A EUROPEAN CERTIFICATION FOR CLINICAL EFFICACY ACKNOWLEDGED BY CLINICIANS

The largest market, the US, is strictly controlled by the FDA, and all of the products that are to be sold as medical devices must be approved by this agency. Once an approval is received, the product is typically readily accepted by clinicians. In Europe, the CE marking is established, but is not broadly accepted by clinicians as an evidence for the clinical efficacy of the products. This severe obstacle can to a large extent be removed by e.g. creating a certification for medical technology products in Europe, or some other means for clinical acceptance, to enlarge the home market for European companies.

TIME FRAME: LONG-TERM

11. IMPLEMENT A COMPETENCE CENTER FOR ADVANCED REGULATORY PROCESSES

Regulatory processes are generally complex and time-consuming. The more stringent regulatory approval processes, such as the PMA, are challenging and enormously complex. Since few companies go through these processes, Swedish consultancy firms have little or no experience with them. Sweden should establish competence centers at which companies can enlist experienced consultants to assist them in these processes.

TIME FRAME: LONG-TERM

12. ESTABLISH COACHING ORGANIZATIONS FOR EARLY-STAGE MEDTECH COMPANIES

Small or early-stage companies often lack experience and expertise in specialized areas as to how to best manage the company in a competitive international environment with regulatory requirements. Coaching organizations with experienced personnel would be a great help to these companies. These might take the form of startup-factories like STING in Stockholm (Stockholm innovation and growth) and IDEON in Lund, management companies with solid knowledge of international business that can support and manage several smaller companies, or specialized medtech incubators.

TIME FRAME: LONG-TERM

13. ESTABLISH COMPANIES WITH CRITICAL MASS FOR INTERNATIONAL EXPANSION

Market entry in several countries is expensive and places great stress on an organization. Single-product companies often lack the financial resources needed for a breakthrough. To lessen the financial risk, companies should strive to form larger units that can provide sufficient resources to undertake international expansion. This can be achieved through e.g. acquisitions or partnerships with Swedish or foreign companies.

TIME FRAME: LONG-TERM

8. APPENDIX

8.1. ADDITIONAL GRAPHS

The appendix contains some graphs that will provide background information and better understanding of facts in the report.

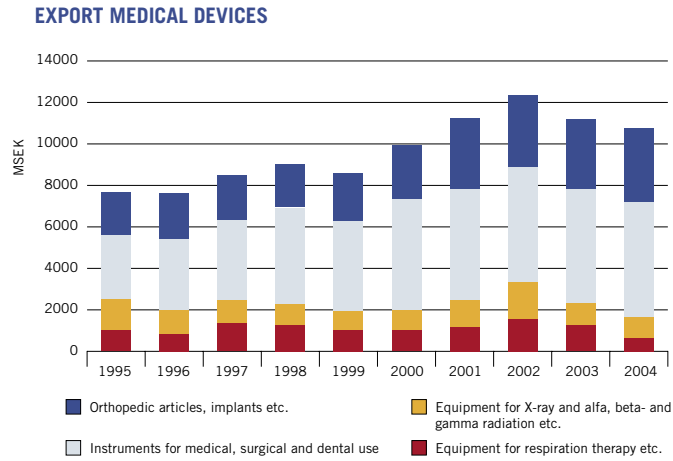


Fig 8.1. The trend for export of medical devices from Sweden to all countries has had a positive trend during 1995-2003. The drop seen from 2003 is mainly in the groups for x-ray equipment and respiration therapy equipment. *Source: L-K Sidén.*

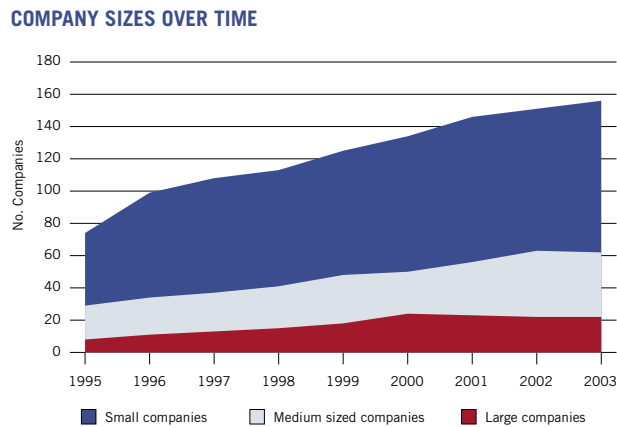
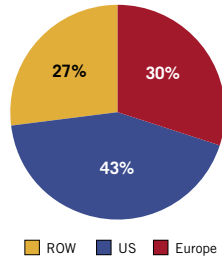


Fig 8.2. This graph shows the growth of the companies identified for the study in 2003. 50 percent of the companies were formed less than 10 years ago. *Source: MMP Database, compiled by SwedenBIO.*

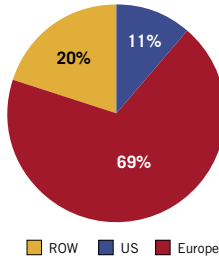
MARKET SIZES VS SWEDISH EXPORTS

WORLD MARKET 2002: EURO 184 BN



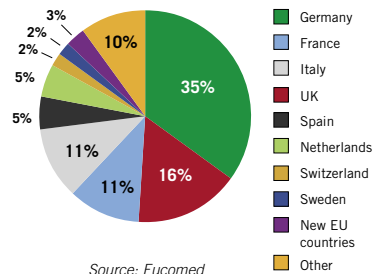
Source: Eucomed

SWEDISH EXPORTS WORLD 2004: SEK 12.4 BN



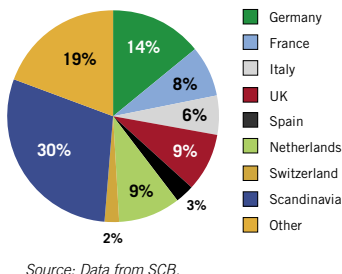
Source: Data from SCB, compiled by Lena-Kajsa Sidén

EUROPEAN MARKET 2002: EURO 55 BN



Source: Eucomed

SWEDISH EXPORTS EUROPE 2004: SEK 8.5 BN



Source: Data from SCB, compiled by Lena-Kajsa Sidén

Fig 8.3. These graphs shows the market for medical technology on European and world basis as well as how Sweden's exports are distributed. There is clearly a potential to increase the export, as Sweden only addresses the largest markets, such as the US, Germany and France, to a limited extent.

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8.3. REFERENCE LITERATURE AND SOURCES

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8.4. ACKNOWLEDGEMENTS

We would like to thank all of the individuals and companies that were involved and contributed to the results presented in the Focus Medtech Report.

We reserve special thanks for *Lena-Kajsa Sidén*, who with her insight into the development of the industry and expertise as an information specialist, providing us with everything from export data to industry reports, has been enormously helpful to the project.

We also want to thank *Anna Sandström*, Vinnova, who generously supplied us with information from her study “Nationella och regionala klusterprofiler – Företag inom bioteknik, läkemedel och medicinsk teknik.”

Finally we are grateful to *Mattias Kyblstedt*, CEO Synergus, who supported the project in its initial phase and helped us develop the web-based questionnaire.

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