# Meeting the Challenge

## Implementing the Medical Devices Sector Initiative Phase III

Health Care Products Directorate
Chemicals and Bio-Industries Branch
Industry, Science & Technology Canada

October 1991

Mailing address:
235 Queen Street
Ottawa, Ontario
K1A 0H5

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# Mission Statement
# Developed by Stakeholders at the Kananaskis Strategic Planning Workshop

"The mission of the sector campaign is to maximize the potential of the medical devices sector in Canada by enhancing international competitiveness and the quality of health care. This will be done in partnership with industry, government, the research community and health care providers.

This will be accomplished by providing an environment that will:

- attract capital
- ensure adequate human resources availability, and
- encourage and focus the development and commercialization of strategic technologies."

February 1991

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## EXECUTIVE SUMMARY

The medical devices industry in Canada is facing a period of tremendous challenge and opportunity. The world market for medical devices is growing very rapidly with some sub-sector and niche markets growing considerably faster than the rate of inflation. Unquestionably, the sector faces certain impediments to growth. Canada nonetheless has important infrastructural strengths that, with concerted collaborative efforts on the part of the various stakeholders can help the industry meet the opportunities which are unfolding and develop into a strong global competitor specializing in innovative, leading-edge products and technologies for niche markets worldwide.

The key driving forces in the industry over the next decade both globally and in Canada will be the aging population, the home/alternate site health care movement, the AIDS crisis, environmental sensitivities, the opening of new markets (e.g. Eastern Europe, Third World), trade liberalization and globalization of operations, breakthroughs in science and technology, and the need to control costs of health care delivery. While these factors create tremendous opportunities for the Canadian industry, they are also accompanied by threats.

The Study Phase of the Medical Devices Sector Initiative gave close examination of the issues affecting the sector through studies and extensive consultation with industry, researchers, health care deliverers and other areas of government. Among Canada's strengths, the Study Phase revealed a rich body of health-related institutional research which has significant potential for commercialization. As well, the sector has a core of innovative firms which are developing leading-edge technologies with excellent market potential; some of these are highly competitive internationally. In addition, Canada is seen as having a regulatory environment which makes it an excellent site from which to launch new products. Constraints to the growth of the sector include hospital buying practices, lack of financing, impediments to technology transfer, taxation issues, interprovincial trade barriers, lack of world product mandates for Canadian subsidiaries of multinationals (MNEs), foreign regulatory approval systems, lack of qualified human resources at various levels and underdeveloped trade associations and industry networks.

Because the constraints experienced by small and medium-sized Canadian-based manufacturers (SMEs) tend to be different from those facing Canadian subsidiaries of multinationals, certain elements of the proposed sector campaign Action Plan are geared specifically to address the challenges faced by these respective sector groups.

Key thrusts and priorities seen in the Action Plan for the sector include attracting investment and product mandates, improving access to financing, facilitating commercialization, improving access to both domestic and international markets, developing requisite human resources and building regional networks to facilitate sector development across the country.

The mechanisms set in place to carry out this Action Plan include a **National Campaign** to consolidate initiatives of the stakeholders into a strong coherent force, to raise the profile of the sector, to provide a forum to bring sectoral issues to the attention of Government and to provide ongoing advice on implementation of the campaign; a **Sector Team Toolbox program** which will address regional needs of the sector through assessments, networking and alliances, and training and

development; a **Medical Device Technology Assistance Program**, to be administered with assistance from the National Research Council; and **advocacy** relating to issues affecting the sector.

The Action Plan for this sector entails an expenditure of ISTC funds of $15.39 million over five years, composed of $9.95 million in G&C funds and $5.39 million in O&M. Incremental matching funds by industry and other sources will amount to at least $16.65 million, of which $10 million is direct industry matching of ISTC G&C funds and $5 million is industry matching of NRC's IRAP funding as well as an additional $1.65 million from other partners. Total expenditure by all stakeholders for this sector is estimated at $205.65 million over five years, including existing funds which will be much better focused through the Sector Campaign. Human resource requirements of ISTC-Ottawa over the five-year period of the campaign will total 11.3 PYs all of which will be sourced from a reallocation of existing PYs within the Chemicals and Bio-Industries Branch.

We know that Canada will continue to spend significant sums on health care. Currently 80% of the Canadian medical device market is served by imports. Canada's trade deficit in this area stands at $1.3 billion annually and could grow to $4 billion by the year 2000 if current trends continue. The medical device sector can be nurtured and developed to help reverse this trend. It can become an important force in the international marketplace and thus flow riches into the Canadian economy. A concerted effort among many players is required. The Study Phase revealed a strong will on the part of the many stakeholders to be partners and play their part with ISTC in the proposed Sector Campaign for Medical Devices. Consolidating and building upon this developing sector consensus will be the key to success for the sector campaign.

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Chemicals and Bio-Industries Branch
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# 1 MEDICAL DEVICES INDUSTRY —— STRATEGIC CONTEXT

## 1.1 Scope

Medical devices can be defined as health care products used for diagnostic or therapeutic purposes which are not drugs or medicines. For the purposes of this document, these include products specifically designed for hospital, doctor's office, laboratory, nursing home and home health care applications.

The medical devices industry in Canada is made up of a large number of firms which are dispersed among a number of manufacturing sectors including informatics, electronics, chemicals, biologicals, machinery, textiles, plastics, glass and wood products.

There are over 6500 classes of medical devices. Products range from low technology mass-produced items such as surgical dressings to high technology products such as radiation therapy devices and brain imaging equipment. The technology-intensive segments of the medical devices sector derive considerable inputs from advances in the three strategic technologies: biotechnology, advanced industrial materials and informatics.

Canada has many world renowned medical scientists and health care researchers who have made substantial contributions to the development of new medical devices, drugs and associated procedures. This wealth of medical expertise is spread across Canada and is based in hospitals, research institutions, universities and government laboratories.

Institutional research and development is significant in niche areas such as diagnostics and imaging. In 1989 gross institutional R&D expenditure in the health field in Canada was estimated to be $940 million. Institutional R&D expenditure devoted specifically to development in 1990 was estimated at $80 million.

Where technology has been developed and exploited in Canada, the industry has been competitive internationally. Examples include cobalt therapy equipment and dental burs.

## 1.2 Key Industry Characteristics

There are about 650 manufacturers of medical devices in Canada employing over 10,000. The majority of firms are very small (52% have less than 20 employees; 74% have less than 50 employees).

The industry consists of two distinct groups of firms: the small and medium sized Canadian-owned firms and the mostly large subsidiaries of foreign-based MNEs.

Canadian-owned firms, which are mostly small to medium-sized, account for 89% of the total number of firms. Of these firms, 43% have annual sales of less than $1 million, and 77% have sales below $5 million. Companies in this category tend to be entrepreneurial, export-oriented, and innovative with many investing heavily (up to 100% of sales) in R&D. These indigenous companies include a

number that have developed leading-edge technologies and unique innovative medical devices, such as ISG Technologies in three-dimensional imaging and Quantified Signal Imaging in brain-mapping. A few have created products that are technologically superior to the global competition and currently have no equal.

Companies in the second group are subsidiaries of foreign-based MNEs, and they tend to be larger. Over 63% of MNE's operating in Canada have annual sales in excess of $10 million, and 22% have annual sales of over $50 million. Most MNEs manufacture some product lines in Canada. By and large, these subsidiaries serve only the domestic market; only a few have a world product mandate (WPM) or a geographic export mandate for one or two products. These subsidiaries typically do not invest significantly in corporate R&D in Canada and tend to produce large volume "commodity-type" medical devices (e.g. bandages, gloves), product areas which are highly sensitive to costs and are vulnerable to rationalization in a global market.

In the current context of global restructuring, an effort has been demonstrated on the part of a number of Canadian subsidiary executives to influence their corporate headquarters to make their Canadian operations part of the companies' global strategies through the granting of R&D or export manufacturing mandates. Early efforts indicate that ISTC can have a role to play in helping to make MNE parent operations aware of strengths in Canada's infrastructure which make it an appropriate place to establish such mandates. Factors which can influence these decisions include institutional research strength in a relevant area, and Canada's system of R&D tax credits.

Eighty percent of the domestic market is served by imports, many of them through the distribution channels of these Canadian subsidiaries. In some instances, the subsidiary operations have served as effective distribution channels for devices manufactured by SMEs, where these devices are seen as complementary to the MNEs' product lines.

### 1.3 Present Situation

The world market (excluding East European Countries) for medical devices in 1990 was estimated to be $US 65.2 billion (Health Industries Manufacturing Association, U.S.A.) and is forecast to grow by 7% annually to the year 2000, with certain products growing by 20% or better annually. The U.S. market accounts for 59% of the world market; Japan 12%, West Germany 7%, and Canada 4%. The Canadian market totalled $2 billion, having grown at an average annual rate of 9% over the previous 13 years.

Imports exceeded $1.5 billion in 1988, capturing about 75% of Canadian consumption. The U.S. is by far the dominant source of imports. Other significant supplying countries are West Germany, the U.K. and Japan. Imports continue to grow faster than Canadian production. Canada is a net importer of medical devices with a trade deficit of some $1.3 billion annually. This deficit is growing and, based on current trends, could reach $3 billion annually by the year 2000.

Canadian production, which was estimated to be $650 million in 1988, accounts for about 1.5% of world production. Over one-third of total production is exported, with 60% of exports going to the U.S.A.

The Canadian market is not only a relatively small market by international standards, but is also highly fragmented. Buyers include dealers and distributors, hospitals, physicians, hospital and pharmacy buying groups, the Red Cross, the military, provincial governments, trading houses and end-users. Canada's 1200 hospitals account for 90% of the market for medical devices, excluding ophthalmic and dental equipment. Private clinical laboratories represent 2% of the market, and physicians' purchases for private practice account for the remaining 8%.

### 1.4 Driving Forces

Profound changes are taking place in the business environment affecting the medical devices industry. These changes present tremendous challenges and opportunities and are the driving forces for this industry worldwide over the next decade. Cost containment pressures in health care, the aging population, the alternate site/home health care movement, environmental sensitivities, the AIDS crisis, the trend towards preventative medicine and health maintenance, and the advances in strategic technologies are driving market demand and creating niches with enormous growth potential. Furthermore, liberalization of trade and globalization of operations are creating opportunities for the Canadian medical devices industry. The following is a brief discussion of these factors:

- **Cost Containment** A close look at the economics of the domestic health care system reveals an opportunity for a substantial increase in the growth rate of the Canadian medical devices industry. During the period 1977 to 1988, Canadian health care expenditures increased from $15.1 billion or 6.8% of GNP to $51.4 billion or 8.8% of GNP. The need to contain overall health care costs and improve treatment is expected to bring about a transition from the present labour-intensive health care delivery system (almost 70% of costs are labour-related) to methods that are more technology intensive. These include increased emphasis on outpatient versus in-hospital treatment, increased adaptation of devices for home-use, and the development of a variety of new diagnostic and therapeutic labour-saving devices which are less-invasive or non-invasive in nature, thereby minimizing surgical intervention. Thus a high market growth rate for medical devices can be expected through better utilization of science and technology. These cost containment pressures apply to health care systems world wide. In the U.S., for example, health care costs have risen from $215 billion in 1979 to $496 billion or 11.6% of total GNP in 1987. Costs are expected to rise further to $1.5 trillion or 15% of total GNP by the year 2000.

- **Aging Population** Over the past century, the average life expectancy has increased from 45 to 75 years of age, with over 30% of the population living beyond 65. More than 10% of the population is currently in the 65 plus age group. By the year 2030, 20% of the North American population will be over 65 years of age and will make up 60% of all hospital expenditures. This demographic shift has fuelled health care costs and resulted in a dramatic increase in demand for products which improve quality of life such as electronic cardiovascular devices and mobility aids. It has also provided momentum for the development of alternate site health care delivery modalities.

- **Home Health Care Movement** As a result of tightened government purse strings, hospitals are operating under more financially constrained conditions and have been discharging patients

occupying acute care beds more quickly and in a less fully-recovered state than in past years. In addition, hospitals are implementing alternate site health care programs to reduce the high institutionalization rate of elderly patients. The population has become more health conscious and home health monitoring is now routine. These trends have created a boon for the home health care market which was estimated at $8 billion in 1987 in the U.S. alone and is expanding at a 20-25% annual growth rate. Medical devices now being used at home include diagnostic kits, health monitors (blood pressure, blood glucose levels, cholesterol, salt), ventilators and dialysis units.

- **Environmental Sensitivities** Concern over the issue of waste management, focusing on packaging and methods of disposal of single-use products such as syringes and gloves which may be biologically contaminated, is leading to new opportunities for environmentally-sensitive products.

- **AIDS Crisis** The number of cases of AIDS in the U.S. is expected to increase from 53,400 in 1987 to over 344,000 by the end of 1991. An additional 3 million Americans may be infected with the virus but have not exhibited symptoms. The AIDS crisis has created many product opportunities for diagnostic kits, blood-handling products, and blood-screening tests to name a few. The market for AIDS products is expected to increase from $136 million in 1987 to over $1 billion by 1991, representing an annual growth rate of 65% (Biomedical Business International 1988).

- **New Third World Markets** An international climate of social consciousness and corresponding increases in aid to less developed countries, remote regions and victims of natural disasters through organizations such as the World Health Organization, the Red Cross, the World Bank, and CIDA has led to a sharp rise in demand for simple and easily transportable medical devices. Products such as mobile hospital units, blood analyzers, and portable x-ray units have witnessed unusually high market growth rates in the past five years.

- **Industry Trends** Three major industry trends are creating an immediate window of opportunity for the medical devices industry to grow in Canada: consolidation and rationalization, liberalization of trade, and increased availability of U.S. venture capital . However, these opportunities must be pursued aggressively and in a coherent fashion to ensure that Canada derives some of the benefit since they are global opportunities.

  The international movement towards consolidation and rationalization of multinational companies, which dominate the medical devices industry, can be influenced through government support and encouragement. The implementation of the Free Trade Agreement with the U.S. is beneficial to the medical devices industry in Canada since tariffs have generally been more favourable for U.S. manufacturers with over one-third of imports entering Canada duty-free (Economic Council of Canada, 1988), and foreign companies seeking to invest and engage in industrial cooperation activities will be attracted to Canada as an entry point to the largest health care market in the world provided that the strengths of Canada are effectively marketed. Several European companies have already begun investing in and collaborating with Canadian medical devices

companies. At Venture Forum '88, a major annual U.S. conference on venture capital, the Medical Health Care area was considered one of the top areas of growth opportunity based on emerging technology. It was suggested that venture capital firms invest in cost-containing technologies, products which improve hospital management, products which prevent disease and home-health care products.

The combined effect of all of the above-mentioned driving forces occurring simultaneously is creating unprecedented opportunities for the industry worldwide. Canada has infrastructural strengths which can serve our medical devices sector in seizing these opportunities for the development of technologically-advanced niche products for sale to world markets. In recognition of the significant growth potential of this sector, ISTC has for several years had extensive collaboration with representatives of the medical device industry, and has targeted this sector for a Sector Campaign.

## 1.5 Major Sector Players

The medical device sector encompasses a broad range of players which have various roles to play in supporting the development of the sector, as indicated in Table 1.

### Table 1
### Sector Stakeholders

| Industry Associations | Government | Other Organizations |
|---|---|---|
| **Medical Devices Canada (MEDEC)**, Toronto, 125 members in most of the provinces. Represents MNEs and SMEs. | **Industry, Science and Technology Canada** plays a catalytic role with regard to this sector. | **Technology Institute for Medical Devices for Canada (TIMEC)**, currently undergoing restructuring, was established as a link between researchers, industry and government to facilitate device commercialization. |
| **L'Association québécoise des fabricants de l'industrie médicale (AQFIM)**, Montreal, 35 Québec-based members, mainly SMEs. | **Health & Welfare Canada** is the lead agency for regulatory legislation on medical devices. | **MedTech** is a medical device technology transfer exhibition in London, Ontario, bringing together researchers, innovators, manufacturers and venture capitalists. |
| **Health Care Products Association of Manitoba (HCPAM)**, 65 local firms. | **External Affairs and International Trade Canada** supports the industry through its Program for Export Market Development (PEMD). | **Canadian Coordinating Office for Health Technology Assessment (CCOHTA)**, funded by federal and provincial health ministries, is a lead agency in studying cost and effectiveness of technology. |
| Industry associations are being formed in Alberta and BC. | **Investment Canada** is mandated to attract investment in Canadian manufacturing and works closely with ISTC. | **Canadian College of Health Service Executives (CCHSE)** provides a service for firms to present new products to hospital CEOs. |
| **Canadian Hospital Association (CHA)** represents the hospital community, a key user market. | **Medical Research Council (MRC)** and **Natural Sciences and Engineering Research Council (NSERC)** fund medical device-related institutional research, and university-industry linkages. | **Association of Provincial Research Organizations (APRO)**, a national association, Ottawa, and the various Provincial Research Organizations in each province, most of whom have interests in health care. |
| **Canadian Manufacturers' Association (CMA)** is leading a group AMTAP for health care firms focusing on quality standards. | **National Research Council (NRC)** assists innovative product development by SMEs through the Industrial Research Assistance Program (IRAP). | |
| | **Regional Agencies (ACOA, WED, and ISTC-Quebec)** fund industry development projects, including medical devices. | |
| | **Provincial Governments:** Strong health care industry focus in Ontario, Quebec, B.C., Alberta and Manitoba. | |

## 1.6 Sector Collaboration to Date

The medical devices industry sector and other stakeholders have collaborated with ISTC in the development of a sector strategy. Highlights of consultations and collaborations to date have included:

- **Memorandum of Understanding (MOU)** with the national medical device industry association, Medical Devices Canada (MEDEC), setting out specific objectives for increasing research and development and exports to world markets from Canadian-based manufacturing firms.

  MEDEC has taken leadership through the MOU to: (1) encourage its multinational members to adopt world product mandates for Canadian-based operations, increase the Canadian content of their products, and adopt R&D mandates for Canadian operations; (2) facilitate the implementation of advanced technology in processes and new products as a means to achieve and maintain international competitiveness; (3) assist small Canadian firms and entrepreneurs to improve their productivity through management seminars, close interactions with multinational enterprises who can act as mentors, promotion of strategic alliances, and dissemination of information on technological, marketing and investment opportunities, regulatory requirements, etc.

- **Technology Institute for Medical Devices for Canada (TIMEC)** was established under MEDEC and funded jointly with ISTC to provide a source of intelligence about technology, products, markets, sources of technology, recipient firms and potential partners to serve the scientific and industrial communities. The contract between ISTC and MEDEC has been terminated and TIMEC operations have been closed. Nonetheless, TIMEC was separately incorporated and has recently expanded the stakeholder base on the Board of Directors. The latter is now in the process of examining options for restructuring a technology centre with a mission similar to the original concept.

- **Sector Campaign Studies.** During 1990 four major studies and 13 mini-studies (listed in Appendix A) of the medical devices sector were conducted by outside consultants. The six mini-studies dealing with strategic analysis of industry subsectors were industry-led and the other seven dealt with specific issues relevant to the sector. The four major studies were as follows:

  **Science and Technology**: Identification of Canadian strengths in medical device-related institutional research and factors which facilitate or inhibit transfer of technology.

  **Strategic Industry Analysis and Options**: Identification of world market opportunities, assessment of the international competitiveness of the industry, based on analysis of twelve segments, and evaluating strategic options.

  **Business Climate:** Analysis of capital/investment availability, domestic market access, human resource availability and regulatory requirements.

  **Performance Indicators**: Inventory of existing statistics; options for improving the usefulness of available statistical data for industrial development and performance monitoring purposes.

Working groups for each study area were formed with representation from the key stakeholders: industry, the research community, health care delivery groups, ISTC, and other interested federal and provincial agencies. Industry representatives were selected to chair the meetings and lead discussions and planning for the consulting contracts.

- **Medical Devices Sector Strategic Planning Workshop**, sponsored by ISTC, was held in Kananaskis, Alberta, in February 1991. The workshop provided stakeholders with the opportunity to review the results of the studies, to discuss options for Phase III implementation, to establish priorities and to contribute to the development of a coherent national sector strategy. Over 130 stakeholders from across Canada participated in this workshop which saw consensus and unity of vision develop among the participants on the strategy for Canada, as reflected in the Mission Statement developed at Kananaskis (see the preface of this document).

### 1.7 Key Findings of the Sector Studies

The sector studies highlighted several areas of remarkable opportunity for Canadian manufacturers of medical devices, as well as cataloguing the constraints and problems facing the industry. These findings provide a basis for a sector strategy to assist the industry to exploit the identified opportunities and to provide an agenda for government advocacy, targeted support and stakeholder action to reduce the impediments to industry growth.

- **SMEs and MNEs Face Different Constraints** A major theme in the sector studies was that the SMEs and the MNEs, as categories of firms, had substantially different problems. The SMEs were mostly small entrepreneurial firms facing difficulties in the areas of financing, marketing expertise, acceptance in the marketplace and human resource constraints. The MNEs main problem is securing world product mandates from parent organizations, and fighting the pressures of global rationalization. The Sector Action Plan recognizes that both groups have important contributions to make to the growth of the sector but that activities to assist these respective groups must, for the most part, be organized along two separate tracks. Most elements of the Action Plan address needs which are of common concern to the SMEs, although a number of these elements may respond as well to problems experienced by MNE subsidiaries. Nonetheless, the major area where MNEs require help is securing R&D and product mandates from parent organizations.

- **Domestic Market is Important** Although the domestic market is small, it is important that Canadian producers achieve some level of acceptance at home, before tackling international markets. The point was made repeatedly in consultation with firms, that buyers, distributors and potential foreign partners need to see that prospective Canadian exporters have established sales and credibility in Canada before they would want to do business with them. This finding underlines the importance of the domestic market access issue. If Canadian firms aspire to global markets, it is important that they achieve some market share in Canada.

- **International Market is Key** While the domestic market provides a base of support and is important in building the credibility of firms, access to international markets is critical to fuel the growth and expansion of these firms and to provide the economies of scale to achieve

competitiveness. This industry is a global industry with global markets. To be successful particularly as a niche player requires access to the global market.

The Strategic Industry Analysis and Options study identified world market opportunities over the next 10 years through an analysis of seven major foreign markets for medical devices. The market for these seven countries amounted to $50 billion in 1989. Projections to the year 2000 set annual growth rates for the medical device market at around 7%, with much higher rates in some product segments.

Medical device imports in these promising target markets in 1989 were as follows:

- U.S. $3.5 billion
- Germany 2.2 billion
- France 1.9 billion
- U.K. 1.4 billion
- Japan 1.3 billion
- Sweden 590 million
- Australia 448 million

- **Growth Opportunities for Canadian Industry** In terms of specific product areas, the same study identified the following as representing some of the best opportunities for Canada to pursue globally:

  - Imaging (software, therapy and diagnostic - e.g. - ultrasound)
  - In-vitro diagnostics
  - Assistive devices
  - Dental devices

  Extensive opportunities exist for commercialization of the institutional research being carried out across Canada. The Science and Technology study included an inventory of medical device related research in 30 of Canada's top institutions, revealing a rich body of research and innovation which could be more fully exploited by the manufacturing sector.

  The regulatory environment in Canada is less adversarial and more co-operative than in the U.S. This is a positive factor which may favourably influence decisions by foreign firms to locate in Canada to gain early access to market.

- **Lack of World Product Mandates** With a few notable exceptions, Canadian subsidiaries of foreign MNEs are not given global mandates to conduct R&D or export manufacturing from Canada. Comparative costs are cited as the primary factor. Specific components of the cost identified as important by companies interviewed during Phase II include: wages (vs. Mexico, Puerto Rico), taxes, exchanges rates, interest rates, transportation costs. It should be noted, however, that most manufacturing done by Canadian subsidiaries has been in low-technology commodity-type products for which less developed areas of the world arguably offer cost advantage. It is, therefore, generally seen to be more appropriate for Canada to pursue world product mandates in technology-intensive products or technology-based manufacturing.

- **Constraints facing Canadian firms.** A number of specific constraints to the development and growth of a competitive medical devices sector were identified. These include: 1) gaps in the product development cycle; 2) business climate issues such as investment capital, human resources, market access and regulatory compliance; 3) the lack of a coherent strategy for the Canadian medical devices sector; and 4) inadequate communication within and between industry, the research community and government departments.

  - **Gaps in the Product Development Cycle** Two major studies in Phase II (Strategic Industry Analysis, Business Climate Analysis) identified as a serious gap the lack of sufficient funding for young companies to help them in the development and commercialization of new products.

    Government and universities offer support for university-based health-related research at a more substantial level than do most OECD countries. However, beyond the university or hospital laboratory, a funding gap exists which is not met by either government or the investment community to a degree that is adequate to facilitate commercial exploitation of a large proportion of relevant research. Companies which are already well-established in manufacturing and sales can often secure funds through the traditional investment channels. However, small companies taking a new technology from the research stage through to development and launch of a new product often find investment capital unavailable in Canada. The findings indicate that even venture capital companies in Canada avoid long-term, high risk investments.

    The Science and Technology study found that mechanisms, skills and resources to transfer research results to industry are generally still in early stages of development. Problems identified include (1) lack of business orientation on the part of institutional researchers; (2) lack of financial incentives for institutional researchers to commercialize their innovations; (3) lack of appropriate match-making mechanisms between institutional research facilities and commercially-motivated companies; (4) the expense of prototype development; (5) the high cost of clinical trials; (6) determination of market demand.

  - **Business Climate Issues** The major concern identified repeatedly by Canadian companies interviewed as part of Phase II studies was the lack of available and accessible investment capital for start-up and early stage companies in Canada. The findings indicate that Canadian venture capital companies act more as merchant bankers than risk takers. Venture capitalists in the United States and Europe were found to be more open to making the longer-term, high risk investments required by start-up companies in the medical devices sector. Conversely, venture capital and pension fund managers indicated that many Canadian companies lack good management skills, knowledge of how to put together a viable business plan, and international marketing expertise.

    The majority of small to medium sized Canadian manufacturers interviewed had difficulties in penetrating the Canadian market. Interprovincial trade barriers, new device evaluation and procurement practices by hospitals were identified as difficulties.

    Constraints relating to human resources were also identified. The lack of skilled manufacturing and process development personnel, and individuals with expertise in

international marketing of technology-intensive products create difficulties for Canadian companies in turning technologies into marketable medical devices.

Difficulty in accessing information on and satisfying foreign regulatory requirements (licensing, environmental, health and safety) was cited as a major problem in being able to market products abroad.

- **Inadequate Communication** Study findings underlined the fact that information about existing programs and initiatives is not being adequately communicated to the industry. In addition, information respecting investment and technology transfer opportunities requires broader dissemination.

- **Lack of a Coherent Sector Strategy** The absence of a coherent national sector strategy was identified as an impediment to the development of an internationally competitive industry. This contributes to the continued existence of a fragmented domestic market, inter-provincial barriers to trade, duplication of effort, inadequate flow of information, hospital procurement difficulties, credibility problems for Canadian industry and ineffective industrial development initiatives.

# 2 STRATEGY AND ACTION PLAN

## 2.1 The Vision for the Sector

The vision for this sector is to develop the medical device manufacturing industry in Canada into a well-capitalized technology-based sector which will have a significant competitive presence in the world medical devices market and which will contribute substantially to the health of the Canadian economy.

The growth of the sector will result in part from optimum use of the infrastructural strengths existing in this country. These include linking Canada's rich base of health-related institutional research, the positive image of our health care system, and the production of high quality health care products. This will enhance and reinforce the image of Canadian medical products in the world marketplace. Development of this sector will result, as well, from the partnership of industry, the research community, health care providers and government working to fulfil the mission of the Sector Campaign.

Given the size and growth prospects for the world medical devices market, and the infrastructure that Canada has in place to support the growth of the sector, Canada should strive to capture 2% ($1.3B exports) of world markets in medical devices by the year 2000 and 5% ($3.3B exports) by the year 2010.

## 2.2 Strategic Thrusts and Priorities

The proposed strategy focuses on initiatives that will have long-term effects in enhancing the competitiveness of the industry and enabling it to grow from its current embryonic state into a strong dynamic industry. The key thrusts and priorities, especially for SMEs, are:

- attract **financing** to the industry through various means, notable among which is a proposal improve communications and awareness of investment opportunities by working closely with venture capital associations, major pension funds and other large pools of investment capital;

- facilitate **technology application** through networking assistance, including the establishment of a Medical Devices Technology Centre to succeed TIMEC, to assist in mobilization of institutional research, and through the establishment of a technology assistance program;

- improve **market access**, both domestic and international through joint programs with the Canadian Hospital Association, through joint funding with H&WC of a proposed Office of Small Manufacturers Assistance, and through EAITC-sponsored export initiatives;

- assist industry to upgrade **human resources**, by working with industry associations to identify company needs at all levels and to develop and implement appropriate training initiatives; and

- build or expand **regional networks** which will establish priorities in the regions and work to stimulate and sustain industry development across the nation.

Some MNEs in Canada will share interests with smaller firms in the above, although the key thrusts and priorities identified for MNEs, are:

- target MNEs having subsidiaries in Canada for **new investment** and the development of **R&D/manufacturing/export mandates** from a Canadian base;

- encourage alliances with SMEs for finance and distribution, encourage linkages to R&D community, and encourage sourcing of components from a Canadian base.

**Government Role**

Industry and other major players look to government to act as a catalyst and provide direct assistance, as follows:

- **Advocacy**: Reasoned advocacy on behalf of the industry with other parts of ISTC (e.g. STP, DIPP), other government departments (e.g. Finance - taxation issues, H&WC - regulatory issues, DOE - environmental issues), provinces (interprovincial trade barriers), associations (e.g. Canadian Hospital Association - hospital buying practices), and foreign regulatory agencies (e.g. the U.S. FDA).

- **Shared Funding**: Industry repeatedly identified this need, particularly with respect to new product development. In addition, shared funding is needed for feasibility studies, R&D, and international marketing.

- **Facilitator**: There is a need in this sector for bringing the diverse stakeholders together to discuss major issues, to exchange views and information, to enhance goodwill and collaboration, to reap synergies from the many individual and disconnected initiatives across the country, and to collect and disseminate information.

### 2.3 Action Plan Elements and Rationale

The proposed Action Plan is intended to address the key priorities and issues which emerged from the consultation phase. As stated previously, these priorities include: attracting financing, facilitating technology application, improving market access, assisting industry to upgrade human resources, building or expanding regional networks, targeting MNEs for new investment in Canada and encouraging MNE/SME alliances.

The Action Plan is made up of four major components:

- The **National Campaign** component establishes profile and commitment for the initiative. It provides an infrastructure for monitoring and measuring the results of the campaign, and for supporting the industry by opening doors at home and abroad.

- The **Sector Team Toolbox Program** provides funding vehicles for supporting the kinds of company-specific projects that assist firms to search out and assess opportunities, and support

non-profit industry organizations to bring needed information, training and networking support to Canadian industry.

- The **Medical Devices Technology Assistance Program** is intended to address the serious lack of financial support for technology application to commercialize medical device product innovations. The program is focused on assisting the development of medical device products that have world market potential and justify exploitation in Canada.

- The **Advocacy** initiatives suggest an agenda for ISTC in dealing with the priority issues of the industry sector. These proposals indicate direction and intent, but it is understood that they will evolve and adapt to opportunities and problems.

# 3 NATIONAL CAMPAIGN

**Establish an Advisory Council:** Composed of high-level representation by all stakeholder groups, with periodic access to an appropriate senior official of ISTC. The Council will advise the Department on the impact of government policies and programs on the sector, identify gaps and propose solutions. It will also monitor and provide advice on the implementation of the Sector Initiative. The Council will meet twice annually and will have a secretariat and various Task Groups. The Council would have a role during the five-year campaign, but the need for any follow-on role and sources of financial support would need to be reviewed towards the end of the campaign period.

**Marketing the Sector:** A logo, a slogan, a video presentation and promotional brochures will be developed and distributed in key countries. The goal is to make Canada synonymous with quality innovative medical devices similar to the association of teak furniture with Denmark or watches with Switzerland. Sector studies found that Canada has many small manufacturers of high quality innovative medical devices. These companies are cash poor and budgets for marketing are often limited. A domestic and international "awareness campaign" to be guided by the Advisory Council and aimed at promoting Canada as a source of quality medical devices would open new doors for these small firms.

A two-phase approach is planned:

**Planning.** A review of existing programs and similar initiatives in other sectors will be undertaken and a detailed plan developed. Elements of this plan would include identifying the target group for this campaign; the most effective activities and vehicles for "creating a demand" for Canadian-made products; how to link with EAITC and their export development activities; and how to reconcile public concerns respecting environmental issues with appropriate use of technology. Some financial commitment from industry will be sought; however, initial industry contributions are expected to be low. Increased industry commitment would be expected in later years of this campaign as confidence in its value is demonstrated. The completed plan will be presented to the departmental management for approval prior to implementation.

**Implementation.** This phase will follow the approval of an acceptable plan.

**Industry Performance Monitoring and Campaign Evaluation:** While the principal strengths and weaknesses of the sector are well-known as a result of the study phase of the Sector Campaign, more comprehensive data on actual sector performance (e.g. employment, shipments, imports, exports) would assist government and industry in strategic planning and would provide a means of monitoring changes effected through the Sector Campaign.

The only method to obtain reliable performance data on this diverse and widely dispersed industry is through a comprehensive survey of firms. The last comprehensive survey was conducted in 1978 (13 years ago). In the meantime, the industry has undergone dramatic changes. A survey is proposed for year 1 of the campaign. A second survey is planned towards the end of the campaign to update sector data and to evaluate the effect of the campaign. These data together with specific program

evaluation data for each of the Campaign initiatives, which will be specified during the detailed implementation planning process, will provide a basis for evaluating the Sector Campaign.

**Information Dissemination:** Three types of information and means to disseminate them are planned. First, the studies conducted in Phase II contain much useful information and should be made available upon request. Secondly, a newsletter reporting on important developments in the sector will be produced and distributed on a contract basis. It is envisaged that other appropriate organizations (e.g. Canadian Hospital Association) will contribute "in-kind", non-monetary resources to this activity. In addition, the Canadian Medical Device Directory, an ISTC publication, which has been updated every two to three years, will be privatized.

# 4 SECTOR TEAM TOOLBOX PROGRAM

The Toolbox Program is a grouping of activities which will be used during the Sector Initiative to improve the international competitiveness of Canadian manufacturers within the Sector, increase market penetration of Canadian medical devices, increase the attractiveness of this sector to potential investors and develop the human resources needed. Toolbox Program activities fall within three categories: assessments (G&C funds); networking and alliances (G&C funds); and training and development (G&C funds). O&M resources will be required for program delivery materials and services (e.g. contract support personnel, brochures, training, travel).

These Toolbox Program initiatives address the key problems the industry faces, as identified in Phase II: (1) human resource deficiencies; (2) difficulties in accessing capital and attracting investors; and (3) difficulties in penetrating both domestic and international markets.

The Health Care Products Directorate of Chemicals and Bio-Industries Branch will, in collaboration with the regional offices, plan and control the Toolbox Program budget, coordinate implementation and monitor the operation of the overall program. On an annual basis, regional and headquarters health care specialists will propose an activity plan and, in accordance with annual allotments under the Toolbox, funds will be transferred to the regions for delivery of Toolbox activities. A portion of the Toolbox funds will be retained by Health Care Products Directorate for activities having a national scope. A quarterly report will be submitted by the regions updating projects and expenditures. A joint financial review will be undertaken quarterly at a sector team meeting to revise budgets as necessary.

Individual regional offices will be encouraged to set up review committees drawn from the local network of sector stakeholders to evaluate and recommend projects.

The Toolbox provides a means of addressing the varied needs of each region, and of ensuring ongoing building of consensus on a regional level among stakeholders.

## 4.1 Program Delivery Considerations

A general requirement for eligibility under the Toolbox element is that the proposed activities benefit or promote medical device manufacturing in Canada.

All assistance under this element will utilize G&C funds. Toolbox delivery will use the generic terms and conditions of Sector Campaign for all items except the technology centre, which will conform to the Technology Outreach Program terms and conditions. For some items it will be necessary to modify the generic terms and conditions to permit support for alliances and non-profit organizations, such as the Canadian Hospital Association.

Toolbox activities have been developed to address the priority needs within this sector. Not all activities will be appropriate in all regions. As previously noted, the regional health care specialists will on a yearly basis provide a plan to Headquarters identifying which activities are planned in their region during the next year.

## 4.2 Toolbox Program Activities

## 4.3 Assessments

This category provides funds to cover consulting costs, on a cost-shared basis, to identify corporate or sector needs and opportunities relative to market access, including a special program for first-use assistance, as well as technology and human resources.

- **Market Access** - Assessments of market opportunity, where not provided for under EAITC programs, could target specific product and/or geographic areas, including information on regulatory requirements respecting sale of medical devices in a given jurisdiction. It is noted that EAITC's Program for Export Market Development (PEMD) Special Activities projects can apply to the cost of consultants' work in this area for industry associations, but not for individual companies. Other areas which would be considered priorities include export strategy development, assessments of corporate marketing and promotional practices and strategies, and development of strategies for Canadian subsidiaries to obtain world product mandates.

- **First-Use Evaluation** - This is a unique program, cost-shared with industry, to facilitate early evaluation of products in the market place for first time users (e.g. hospitals, physicians). At present many hospital biomedical groups conduct evaluations on a device before making a purchase decision. This generally involves a request to the manufacturer for "loaners" or free samples and thus entails a considerable burden to small manufacturers.

  The goal of this program element is to assist SMEs with the cost of having evaluations carried out by user groups. ISTC would share with the manufacturer the cost of having this evaluation carried out by a hospital or other user group. This assessment would cover non-safety aspects of the device, such as ease of use, maintenance and its compatibility with prevailing systems within the hospital. It is to be noted that ISTC would have no involvement with safety and health issues relating to the device, this being within the legislative purview of the Health Protection Branch of Health and Welfare Canada.

  Evaluations generated through this program would be distributed by the Canadian Hospital Association to the hospital community (see elaboration of the Network for Hospital Evaluation under "Advocacy" section). The First-Use Evaluation component is a response to the difficulty that small companies have in gaining a toehold in the Canadian market and thereby establishing the credibility needed to consolidate a place in the domestic market and begin to sell internationally.

- **Technology** - Assistance could be applied to the cost of assessment of the commercialization potential of an innovation, including its technical merits. It is noted that this program element would cover the feasibility aspect of projects which might eventually make use of the Medical Device Technology Assistance Program.

- **Human Resources** - This would cover assessments in the general area of corporate training needs. It is the intention of ISTC to work with industry to optimize use of the excellent programs already provided by Employment and Immigration Canada, Labour Canada and various provincial bodies, and to provide complementarity to them.

### 4.4 Networking and Alliances

Funds would be provided on a cost-shared basis to cover the costs of holding and attending meetings for the purpose of promoting networking among the financial, research, industry and health care provider communities. It is intended that this activity promote interaction leading to partnering/alliances for purposes of commercializing products from a Canadian base through technology transfer and through improved access to financing and to domestic and international markets. Treasury Board approval will be required for the market access and technology search proposals and the training component.

The following project-focus areas are considered priority ones:

- **Financing** - Financial assistance could be made available to cover travel costs for bringing together venture capitalists and medical device innovators - e.g. - for an innovator to exhibit products at a venture capital conference or other venues where venture capital may be available.

- **Market Access** - Funding could be provided to cover the cost of travel for the formation of alliances which will result in improved access to domestic and international markets, including regulatory-oriented trips (pre-market). It is intended that this element be complementary to funding provided through EAITC's Program for Export Market Development (PEMD). Internationally, it is recognized that PEMD has the lead in assisting in this area; however, in the medical device area, where compliance with foreign regulatory requirements may necessitate more than one trip to a target country for a given product, ISTC funding assistance could be used toward travel costs when a second trip is justified.

- **Technology** - Networking for the purposes of transfer of technology and the formation of corporate alliances and joint ventures relating to the development in Canada of technological innovations would be appropriate project areas. Support would include the cost of travel, both domestic and international, to seek licensing arrangements relating to technology inflow for the purposes of device commercialization in Canada. The cost of patent searches and legal fees related to licensing would be eligible for support. As well, networking to create better linkages between the different sector groups would be eligible, e.g. meetings organized on the "reverse trade show" concept, where hospital users would present their product requirement ideas to industry, and/or industry presents their needs to researchers.

- **Medical Devices Technology Centre** - The Technology Institute for Medical Devices (TIMEC), which was sponsored by MEDEC for two years, was terminated March 31, 1991. Nevertheless, there remains a critical need for a national technology diffusion centre operating in the field between the research community, government and manufacturers, which was the mandate of TIMEC.

  This Sector Campaign proposal for a Medical Devices Technology Centre is the ISTC response to this need. Proposals for five-year funding support which meet all the terms and conditions of the TOP program, will be considered in the normal ISTC approvals process. If a proposal is approved, some funds from the Sector Campaign would be transferred to TOP.

### 4.5 Training and Development

It is intended to contribute funds on a project basis to non-profit organizations to address long-term and short-term human resource development needs in the Sector. Delivery is expected to be principally in the form of training seminars, workshops and round-tables. Eligible costs would include the hiring of specialists to prepare and/or present required subject matter, their travel expenses to make presentations and the rental of premises and equipment for such presentations. In addition to the use of private sector expertise, efforts will be made to develop human resources in this sector through the expertise available through other government departments - e.g. - EAITC for export market development, Health and Welfare Canada for quality assurance and other regulatory issues and Federal Business Development Bank for business plan preparation for companies.

Priorities include the establishment of a medical devices oriented co-op program with universities and management training with a focus on business strategies, how to approach the financial community, domestic and foreign market penetration strategies.

# 5 MEDICAL DEVICE TECHNOLOGY ASSISTANCE PROGRAM

The study phase of the Sector Initiative identified a serious lack of financial resources in the precommercial development of medical devices. The development of device innovations into marketable products frequently requires a variety of partners to share the costs of commercialization. It is proposed that a Medical Device Technology Assistance Program (MEDTAP) address the precommercial research and development phase of eligible projects.

## 5.1 Targeting

MEDTAP is aimed at Canadian SMEs who are developing technology-intensive innovations, and need assistance for reasons of financial burden, incrementality, or risk. As well, support may be appropriate as a tool to lever an MNE world product mandate to Canada. Projects will be worked up regionally by members of the ISTC Sector Team and NRC IRAP Industry Technology Advisors (ITAs), and reviewed by a ISTC-NRC committee. It is recognized that the combined strengths of a number of players can be important in maximizing chances of success in product development. Projects near the commercialization stage may in many cases require vertical alliances, e.g. innovators in partnership with well-capitalized manufacturers or with companies having appropriate distribution networks. Consequently, strategic alliances and consortia will be encouraged in projects given consideration under MEDTAP.

## 5.2 Program Delivery Considerations

The program will add a new component to IRAP, clearly identified as a joint initiative with ISTC. A total of $10 million over five years, composed of $5 million in ISTC G&C funds, to be matched by National Research Council (NRC) funds, for industry R&D projects to apply technology to the pre-commercial development of medical devices. ISTC funds will be transferred to NRC for the program, with program policy set by a senior ISTC-NRC oversight committee.

The program will focus on R&D projects which are aimed at global markets, and will encourage strategic partnerships.

To be eligible, projects must be industry-led and must be accompanied by a business strategy for developing a world-competitive medical device for sale domestically and in world markets.

# 6 ADVOCACY ACTIVITIES

Certain issues raised during the Sector Initiative Study Phase require concerted advocacy efforts on the part of ISTC's Headquarters. The following advocacy items relate to problems of access to capital, markets and subsidiary R&D/export mandates.

## 6.1 Improved Access to Financing and Funding

Lack of investment capital was a recurring theme heard throughout the Phase II consultations. At Kananaskis this was seen as the number one concern of industry representatives.

- **Investment Promotion**

  Funding is for consulting, the preparation of case studies, and information packages to promote the medical devices sector to the investment community.

  The information package would highlight the medical devices sector as a high-growth area and be targeted at the investment community. It would include Canadian success stories and draw as well on examples from the U.S., where venture capitalists have attained high returns through their targeting of this industry sector.

  Promotional material would be used in meetings with managers of venture capital and pension funds as well at venture capital conferences.

  ISTC officials will work with the venture capital groups and other sources of capital on ways and means of attracting greater investment in this sector, examining informational needs, and improving the channels of communication and opportunity awareness on both sides of the financing equation.

  In support of investment promotion, a Competitiveness Factor Analysis (CFA) will be conducted to examine options for improving access to capital and making Canada an attractive place to do business. The CFA activities will draw on the business climate information in the studies conducted by the National Advisory Board on Science and Technology (NABST).

- **Access to existing government funding programs**

  **Strategic Technologies Program (STP)** Efforts will be made both in Headquarters and the Regions to promote greater use of the Strategic Technologies Program (STP) for medical device projects, which are ideal high value-added products for these technologies. STP take-up by medical device applications has been very low, yet the potential for applying these strategic technologies in this sector seems very promising.

**Other government programs** ISTC will work closely with ACOA and WED to ensure complementarity in financial support and to ensure that these agencies are fully informed about the Sector Campaign and have every opportunity to enhance it.

Negotiations are underway with the Medical Research Council (MRC) and the Natural Sciences and Engineering Research Council (NSERC) for targeting of medical device-related research through their existing programs.

Measures will be taken to heighten awareness within the industry sector of other relevant programs, such as the University-Industry Cooperative R&D Activities of MRC and NSERC, as well as these Councils' relevant Strategic Grant areas.

Discussions will be held with officials of the Federal Business Development Bank to sensitize them to the needs of this industry sector.

### 6.2 Improve Market Access

The Business Climate Analysis found many factors inhibiting penetration of the domestic market by Canadian companies. Hospitals tend to stay with known, established products, 80% of which are imported. Lack of a toehold in the domestic market is further seen as detrimental in establishing credibility in the export market. One problem relating to domestic market access involves individual evaluation of equipment by each hospital's biomedical engineering department. For manufacturers to supply loaners or free samples to a large number of hospitals for evaluation is an onerous burden on the company.

Certain provinces have in the past established policies which favour hospital purchasing of goods manufactured within that province, thus reducing market access to other Canadian firms.

The Performance Indicators Analysis found that most firms perceive a need for better and more affordable domestic and foreign market data for strategic planning purposes.

Consultations with companies throughout Phase II revealed frustration in dealing with foreign regulatory bodies; this included both information gaps and a perception of prejudicial treatment by the U.S. F.D.A. in some instances.

- **Domestic**

**Establish a network for hospital evaluation** The objective is to establish, in collaboration with the Canadian Hospital Association (CHA) a hospital network wherein device evaluations by specified hospitals in their particular areas of specialization would be recognized throughout the network. For example, the Ottawa Heart Institute could be an appropriate institution to evaluate cardiovascular devices.

O&M funds will be required to cost-share with the CHA, the costs of designing and developing an appropriate network. In particular it will be necessary to assist the CHA to undertake the following work:

- system design and criteria framework
- promotion of the network evaluation concept to hospitals
- dissemination of evaluations to the hospitals.

Nominal O&M funds would also be targeted towards travel and meeting costs for procurement managers in federal hospitals. The information gathered from network evaluations would then be shared with the hospitals.

The Canadian College of Health Service Executives may have a role in concept and pre-market evaluation of new products.

**Encourage early use of Canadian device innovations by federal hospitals** This activity would target purchase decision-makers in federal hospitals such as those run by National Defence and Health and Welfare Canada's Medical Services Branch. Information resulting from network evaluations would be shared with these hospitals. The indicated O&M funds represent nominal travel and meeting costs.

**Support measures to reduce interprovincial trade barriers** The federal and provincial governments have been working towards the elimination of preferential purchasing practices within provincial health care systems. ISTC will lend support to this dialogue and monitor its progress.

**Develop useful market/industry statistics** Data on the Canadian hospital market are currently available from ResCan Consultants of Montreal. This database does not at this time have a sufficient customer base to be self-supporting. Sources of other market/industry data of actual or potential usefulness include Statistics Canada, ISTC's Market Intelligence Division and Health Protection Branch's medical device notification database. ISTC proposes to work with these and other sources of data to identify ways in which the available data could be made more useful and accessible to the sector and to disseminate data, as appropriate, to industry. As well, the harmonized nomenclature recently adopted by both Health and Welfare Canada and the U.S. F.D.A. will be examined for utility in working toward greater concordance of data from the various sources.

The indicated O&M funds are for data acquisition by ISTC for market intelligence and analysis and studies on ways in which data could be improved and made more accessible to industry.

- **Foreign**

**Promote informed and equitable market access under foreign regulatory regimes** It is proposed that ISTC contribute funding towards the establishment of an Office of Small Manufacturers' Assistance (OSMA), in cooperation with Health & Welfare Canada, to be located at H&W Canada, but operating at arms length. This office would provide Canadian SMEs with information on regulatory requirements in Canada and in foreign markets, which is a major market access factor. In particular, OSMA would have the following functions:

- provide information on regulatory requirements for sale of devices in foreign markets;
- provide a brokering or matching service between small firms and qualified clinical investigators;
- examine the issue of equitable accessibility of the U.S. and other foreign markets and propose solutions as appropriate.

This proposal is in the early stages, and it will be necessary to clarify a number of questions including the legal implications, organizational and mandate issues, and sunset provisions to ensure that ISTC support is not open-ended and that industry will provide sustaining support if the office fills a critical need. Discussions are underway relating to Health and Welfare Canada's contribution to this project of office space and secretarial support.

Collaboration between the two departments for the establishment of such an Office is seen as serving the mandates of both departments. The trend in medical device regulation is toward international harmonization with Canada using ISO 9000 as the framework for its impending medical device good manufacturing practice (GMP) legislation. As ISO 9000 is the framework for the upcoming requirements for the European Community, and is also being adopted by the U.S. Food and Drug Administration for its device GMPs, domestic and foreign compliance requirements will increasingly be in harmony. Furthermore, while the implementation of quality assurance standards which are implicit in ISO 9000 are predicted to improve the efficiency, cost effectiveness and competitiveness of firms adopting them, they are also designed to reduce the rate of defective production, which carries with it risks to health.

### 6.3 World Product Mandates

Restructuring and rationalization of operations are being carried out by multinationals throughout the world. Canadian medical device subsidiaries have already suffered plant closures and reduction in manufacturing operations. Canadian subsidiary CEOs consulted throughout Phase II are understandably concerned at the disappearance of Canadian manufacturing jobs.

MNEs in Canada control about 80% of the domestic market, and about 10 to 15 of the larger and more important firms are considered to be good prospects for acquiring world product mandates from their parent organizations. The Canadian subsidiaries need ISTC support in making a case for mandates: they need advice, information, moral support and a well-prepared case for getting a mandate.

The proposed initiatives do not involve financial incentives aimed specifically at tilting the balance in favour of Canada. Rather, the focus will be on Canada's strengths in medical research, R&D linkages, regulatory climate and other advantages.

**Project to Increase Investment in Canadian Subsidiary Operations** A pilot project is in progress with Investment Canada to develop generic and company-specific promotional packages targeting CEOs of U.S.-based multinationals to advocate the granting of R&D/export mandates to their Canadian subsidiaries. In Year 1 this package will be put into use in meetings with the targeted CEOs. In Year 2 a brochure will be developed based on this package and will include alliance opportunity profiles. Year 3 will focus on European-based multinationals operating in Canada, and in Years 4 and 5 opportunity profiles in other areas will be developed.

### 6.4 Human Resources

The Business Climate Analysis identified human resources as an issue of concern to this industry sector.

- **Maximize the human resource development benefit of existing government programs:**

**NSERC Chairs.** Discussions have been initiated with NSERC regarding the establishment of interdisciplinary chairs which could contribute knowledge important in the development of leading-edge medical devices.

**Canada Scholarships Program** Efforts will be made to increase industry sponsorship of scholarships in disciplines which can serve as a knowledge base for the medical devices sector, with the clear understanding that this not create an obligation for the federal government to increase its funding of the scholarships.

### 6.5 Regional Strategy Development

The members of ISTC's medical devices Sector Team will work with provincial governments and agencies to encourage cooperation in developing and implementing strategic frameworks for the medical devices sector. There is an opportunity for each province to contribute to the development of sector priorities, build on regional strengths and draw on national linkages.

# 7 RESOURCE REQUIREMENTS

The proposed approach calls for utilizing existing programs and organizations to the extent possible, channelling sector campaign funds through these, and where possible, securing co-funding from these programs, organizations and industry to lever limited resources to address the needs identified in Phase II. Thus, it is estimated that the implementation of this Action Plan would require a total expenditure of ISTC funds of $15.34 million ($9.95 million in G&C and $5.39 million in O&M) over a 5-year period.

# 8 SECTOR CAMPAIGN MANAGEMENT

The Director General, Chemicals and Bio-Industries, with the advise of the Sector Campaign Advisory Council, will have overall management responsibility for the Sector Campaign. The various programs and activities will be planned, budgeted, managed and evaluated in conjunction with the Branch's operational planning process, and reviewed quarterly for performance and revision. The Medical Devices Sector Team is an integral part of the delivery process, and members of this Team will have primary delivery responsibility at the field level, for case work-up and management systems input.