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Regional Industrial Expansion



Investing in Canada's Medical Device Industry



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Investing in Canada's Medical Device Industry

Biotechnology and Health Care Products Directorate Department of Regional Industrial Expansion Government of Canada Ottawa, June 1987

Investing in Canada's Medical Device Industry

This document provides information on business and investment opportunities in Canada's medical device industry. It also indicates where to get further information and advice from Canadian government departments and agencies, including:

information on benefits of investing in Canada, and the procedures involved

business and investment opportunities in specific provinces and regions, and in other industry sectors

more detailed data on the medical device industry

Now is an excellent time to invest and do business in Canada's medical device industry:

Canada boasts a highly-diversified and burgeoning medical device industry which enjoys a strong domestic demand combined with ready access to lucrative U.S. and worldwide markets. With a healthy mixture of large multinational firms and smaller, typically more specialized domestic firms, the Canadian industry has ample room for expansion of production capacity for domestic consumption and export. With a long history of product innovations in the field, Canada is an excellent location for development, manufacture and marketing of innovative products.

With highly favourable provisions for tax treatment of research and development expenditures, a welcome attitude toward new investment, and a solid community of dedicated scientists, engineers and technologists, Canada is a superb place to invest in a wide range of medical device manufacturing opportunities.

Canada's Medical Device Industry

Ever since Frederic Banting and Charles Best developed insulin in 1922, Canadian medical researchers have kept Canada at the forefront of new frontiers of medicine. Other life-saving developments by Canadians which have reinforced this tradition include the cardiac pacemaker, the cobalt cancer treatment unit, the electron microscope, and the blood vessel stapler. Canadians have also developed a non-oxidizing tendon pin for the replacement of human joints, carbohydrate-based reagents for blood typing, and a technique to isolate and purify enzymes used in medical diagnostic test kits.

Canada's highly sophisticated and diverse medical device manufacturing sector boasts more than 1 200 distinct product lines, including materials, equipment and related components used to diagnose, monitor, treat or assist the ill or disabled. Canada's medical devices industry covers all key areas:

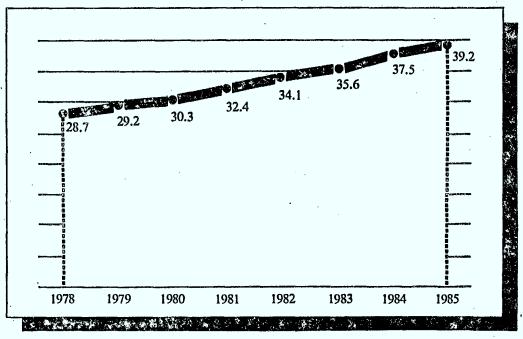
- · medical and dental instruments, equipment, parts and supplies
- ophthalmic goods
- surgical and medical supplies
- · hearing aids and orthopaedic appliances, and related parts
- specialized medical and dental furniture and accessories
- diagnostic equipment, materials and kits

Products range from tongue depressors and bandages to X-ray machines and radiation therapy equipment. Innovative products using new materials (e.g. bioceramics) and advanced technologies (e.g. robotics) are being developed or introduced almost daily.

Markets

With a population of more than 25 million, and annual public and private expenditures on health alone of \$39 200 million in 1985, Canada constitutes an impressive market for medical devices. In the period 1978 to 1985, Canadian expenditures on health increased 37% in real terms — that's an average of more than 5% per year, after adjustment for inflation:

Total National Health Expenditures (public and private) \$ 000 millions, constant 1985



In 1986, the total Canadian domestic market for medical devices was estimated to be about \$1.750 million, with projected real growth averaging 5% annually over the next few years.

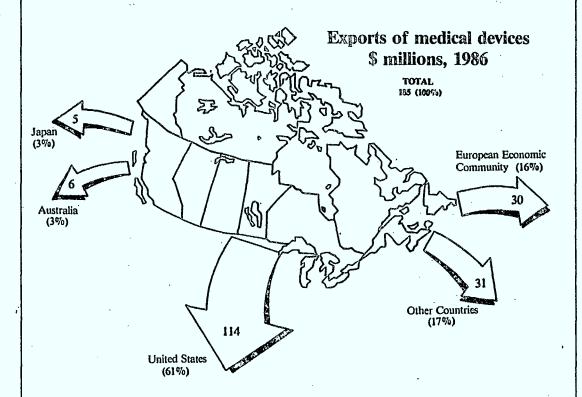
Since over three-quarters of Canada's domestic demand for medical devices is satisfied through imports, there is considerable scope for expansion or diversification of existing Canadian-based manufacturers or establishment of new enterprises to meet growing demand.

Canadian Imports of Medical Devices \$ 000s 1986

MEDICAL AND RELATED INSTRUMENTS & EQUIPMENT	686	609
 physiological monitoring & recording equipment, systems, 		ľ
accessories & parts		784
 electro-medical and electro-surgical equipment apparatus & parts 		607
 surgical instruments of steel, accessories & parts 	60	964
 medical diagnostic instruments 	81	584
 dental instruments, equipment, accessories & parts 	45	979
• ophthalmic equipment, apparatus, accessories & parts	7	572
 physiotherapy and veterinary instruments, equipment & parts 	8	000
• sterilizers, autoclaves & parts (except industrial)	16	016
anaesthetic, and oxygen administering equipment, accessories		
& parts	47	517
• medical and hospital equipment & parts		067
• X-ray and related equipment & parts	160	
• X-ray film		495
	160	
OPHTHALMIC GOODS		741
• spectacle and eye glass frames		
• sunglasses, complete with lenses		465
 spectacles and eye glasses complete with lenses 		751
 parts for spectacle and eye glass frames 		812
o ophthalmic goods	59	023
SURGICAL AND MEDICAL SUPPLIES	412	174
bandages, surgical gauze, absorbent cotton & dressings		164
• sutures, suturing needles and sutures with needles		785
 blood handling, analyzing, collecting & processing supplies 		151
• urinary and ostomy appliances, supplies and parts		954
• catheters, bougies, drains and sondes		345
hospital supplies of chemical origin		003
		588
• surgical implements		641
 disposable syringes, syringe needles & parts disposable medical & surgical instruments and kits 		573
		970
 medical, surgical and hospital supplies 	0.5	270
HEARING AIDS AND PARTS	17	323
ORTHOPAEDIC APPLIANCES	34	770
• artificial limbs (prosthetic) & parts		016
<u> </u>		654
• elastic hosiery		252
• wheelchairs, invalid chairs & parts		848
orthopaedic appliances & parts		UTU
DENTAL SUPPLIES	47	070
• artificial teeth, dentures & parts		932
• dental supplies		138
- delitar supplies		
TOTAL IMPORTS	1 358	738

Location in Canada provides ready access to lucrative markets in the United States. The U.S. market for medical and dental equipment and supplies (including X-ray and electromedical equipment, surgical and medical instruments, surgical appliances and supplies, and dental equipment and supplies) was US \$17 900 million (C \$24 870 million). With more than one-tenth of U.S. domestic demand coming from foreign suppliers, U.S. imports amounted to approximately C \$2 920 million in 1986.

More than one-half of Canada's exports of medical devices are shipped to U.S. markets, while other overseas markets account for an appreciable proportion of Canada's total exports of medical devices:

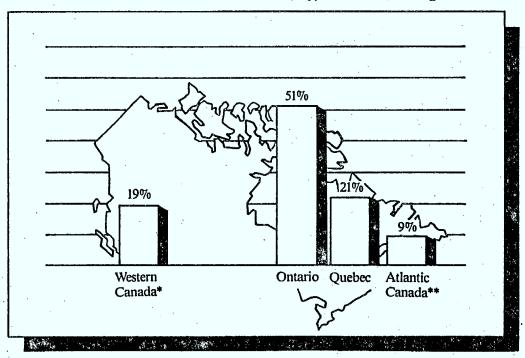


Industry Profile

With more than 400 active manufacturers, Canada's medical device industry employs about 10 000 persons, and accounts for shipments of approximately \$600 million annually.

Although Ontario accounts for slightly more than one-half of industry shipments, other regions account for shipments of approximately \$295 million annually.

Distribution of Shipments in Domestic Medical Device Industry, 1981-83 (Average)



* British Columbia Alberta Saskatchewan Manitoba

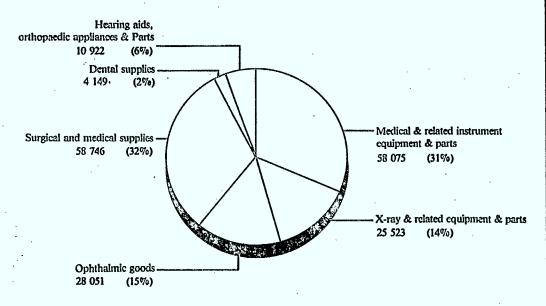
** New Brunswick
Nova Scotia
Prince Edward Island
Newfoundland

Many of the world's leading manufacturers of medical devices have established major plants in Canada including, for example, Johnson & Johnson Inc., Travenol Canada Inc., Kendall Canada, Division-CKR Inc., Picker International Canada Inc., Ethicon Sutures Ltd., Surgikos Canada Inc., and Everest & Jennings Canadian Ltd.

While the major international firms are well-represented in Canada, most manufacturers are small to medium-sized Canadian-owned firms. Many are highly-specialized, yet flexible. Approximately 80% of all companies employer fewer than 50 persons, while only 10% have more than 100 employees.

Canada's domestic manufacturers are heavily export-oriented, with almost one-third of total Canadian production destined for foreign markets:

Exports of Medical Devices, 1986 \$ 000s



TOTAL 185 466 (100%)

Industry Achievements & Developments

Smith and Nephew Inc. operates four large manufacturing plants and an R&D laboratory in Canada. Recent initiatives include a multi-million dollar project to establish a new facility, incorporating the latest state-of-the-art technology to manufacture a complete line of latex medical gloves for export as well as domestic markets.

The Johnson & Johnson family of companies, which includes Critikon Canada Ltd., Ethicon Sutures Ltd., Ortho Diagnostic Systems Inc., Surgikos Canada Inc. and Odonto Corporation Ltd., is the largest manufacturer of health care products in the world. This group operates eight medical device manufacturing facilities as well as a major research and development centre in Canada. The Canadian R&D operations have received international acclaim for the recent development of their "Nu-Gauze" sponge.

Picker International Canada Inc. is a major international designer and manufacturer of diagnostic imaging tools, including CAT-scanners and standard X-ray machines and components.

Beavers Dental Products Ltd. ranks among the world's largest manufacturers of dental burrs. Its research and development capabilities in Canada keep it at the leading edge of dental instrument technology.

Becton Dickinson Canada Inc., which manufactures a variety of medical devices in Canada, is currently undergoing a major plant expansion to increase the production of medical examination gloves, for international markets.

Everest & Jennings Canadian Ltd. is a leading manufacturer of wheelchairs and other related rehabilitation products. The company, which operates two manufacturing plants in Canada, recently developed an innovative therapeutic bathing system for geriatric patients.

Andronic Devices Limited of Vancouver, B.C. has developed a robotic device which holds limbs in position during arthroscopic examinations or surgery. The limbs can be moved into position by voice commands. It is likely that the robotic technology being developed will also have application in laboratory functions which are currently repetitive and manually done.

Another Canadian product currently being widely exported, is a needleless insulin injector which is manufactured and marketed by **Advanced Medical Technologies Limited** of Charlottetown, P.E.I. This painless device, delivering pre-measured insulin injections, has been a welcome relief to diabetic patients.

Atomic Energy of Canada Ltd. (A.E.C.L.) produces the majority of the world's supply of cobalt 60, (the conventional source of radiation therapy), and the related equipment. In addition, A.E.C.L. is the world's largest supplier of industrial irradiation plants, many of which are used in the sterilization of disposable medical products.

Regal Medi-Spa Co. Inc. of Scarborough, Ontario has developed and is marketing an innovative bathing system for ambulatory, geriatric and chronic care patients. This product features anti-scald safeguards, automatic mixing and blending of soap/shampoo and of disinfectant as needed, and is designed to eliminate the possibility of cross-contamination leading to infections.

Medionics International Inc. has developed an automatic, volumetric cycler for use by continuous ambulatory peritoneal dialysis and intermittent peritoneal dialysis patients which has been widely accepted in China and the United States. Several units are now in use in China.

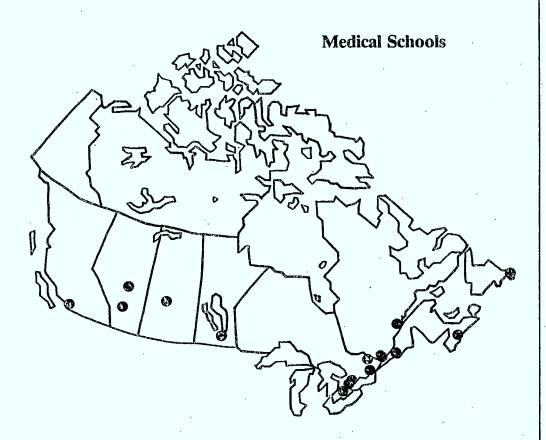
Canapharm Inc. of Saskatchewan, which is jointly owned by Canadian and West German interests, recently established a \$4.5 million state-of-the-art facility to produce a range of hospital solutions including intravenous and dialysis solutions used to maintain the bodily functions. The firm has also announced plans to invest a further \$12.5 million to establish a facility at Swift Current, Saskatchewan to produce medical textiles such as bandages, dressings and tapes.

Phoenix Biomedical Products Inc. of Mississauga, Ontario, is a recognized world leader in the manufacture of petri dishes (over 200 million units annually) and other related products. More than 90% of its annual sales of \$7 million are destined for export markets throughout the world.

Kendall Canada, Division-CKR Inc. has recently invested some \$2 million to establish production facilities in Toronto to produce adult incontinent diapers and other related products.

Infrastructure

There are 16 world-class medical schools located in major centres across Canada:



In addition there are more than 100 active and associate members of the Association of Canadian Teaching Hospitals, representing institutions in more than 30 centres across Canada. Canada's teaching hospitals play an important role in the development, testing and promotion of innovations in the medical device industry.

Canada's universities provide a focus for innovation in the design and application of medical devices. For example:

The Institute of Biomedical Engineering at the University of Toronto has world-class technological capabilities and is particularly renowned for its research expertise in the areas of biomedical acoustics and hearing, ultrasound, biomaterials, prosthetics, imaging, biomedical signal processing and visual field tracking.

Technical University of Nova Scotia in association with Dalhousie University has particular expertise in research and development of medical devices relating to the cardiovascular system.

The Bioengineering Institute of the University of New Brunswick is prominent in the area of myoelectric control systems used in children's prostheses.

In addition, McGill University, University of Western Ontario, University of British Columbia, Simon Fraser University and other prominent universities carry out research essential to the medical device industry.

Each major university has at least one officer dedicated to assisting the transfer of technology from research laboratories into industry.

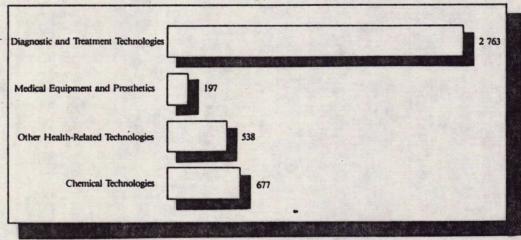
Thirteen institutions provide specialized training in biomedical engineering disciplines.

With one of the most comprehensive and sophisticated education systems in the world, Canada provides a steady supply of university and community college graduates with advanced training in all key disciplines essential to the medical device industry:

University Graduates, 1984

Discipline	Bachelor and First Professional Degree	Masters and Doctoral Degrees
Medicine	2 129	459
Pharmacy	654	33
Dentistry	487	21
Nursing	1 746	78
Rehabilitation	857	111
Other Health Professions	135	131
Chemical Engineering	746	188
Electrical Engineering	1 768	371
Mechanical Engineering	1 827	207
Biomedical & Other Engineering	1 529	454
Biochemistry	420	64

Community College Graduates, 1984



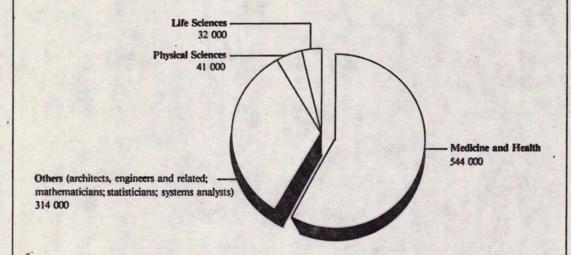
Research and Development

Some \$300 million is spent annually in Canada in the area of health care-related research and development, thus generating an abundance of intelligence which can contribute to the development of medical devices in Canada.

In the period 1977 to 1985, total annual in-house industry expenditures for research and development in the scientific and professional equipment sector alone increased from \$14 million (\$s constant 1985) to \$37 million. That represents a real increase of 164% over the eight-year period, after adjustment for inflation — an average growth in R&D of more than 20% per year.

With a broad base of more than one-half million scientists, engineers and technologists active in the medicine and health occupations alone, Canada has a rich supply of trained technical experts available for design, research, testing and application of medical devices and related products:

Scientist's, Engineers and Technologists in the Natural Sciences and Engineering Sector



In 1984, a total of 9 000 scientists, engineers and technologists in the medicine and health fields alone were directly involved in manufacturing industries. An additional 27 000 in the physical and life sciences were directly employed in the manufacturing sector.

In 1985, the European Management Forum ranked Canada fifth among 20 OECD nations (ahead of the U.S., Japan, France, Italy and the United Kingdom) in terms of the rate of growth in the number of R&D personnel in business enterprises.

In the period 1978 to 1983, Canada accounted for 5% of the world's potential product inventions for scientific and professional equipment. This was equal to that of West Germany, and only slightly less than that of Japan.

The National Research Council is a government agency responsible for developing, maintaining, applying and promoting science and technology to meet Canadian needs for economic, regional and social development. Among other things N.R.C. is dedicated to promoting and encouraging expertise in various healthcare fields in Canada and, in this regard, assists industry in undertaking commercially promising research or obtaining the required technology from external sources. The Division of Biological Sciences pioneers research in the life sciences, while the medical engineering unit within the Division of Electrical Engineering conducts exploratory and applied research on equipment related to the biological sciences.

The Medical Research Council is a government corporation dedicated to the promotion and assistance of basic, applied and clinical research in the health sciences, and the training and development of research manpower. In the 1985-86 fiscal year, the Council's total expenditures were \$157.7 million.

The Natural Sciences and Engineering Research Council promotes research in the natural sciences and engineering. It also encourages research and development links between universities and industry. Grants totalling \$8.8 million were awarded to university researchers in health fields. A further \$14.5 million in grants were committed to university research on industrial productivity and development. In addition, grants are available for research, capital expenditures and manpower in a broad range of fields including biotechnology, industrial materials and processes.

In addition, most provincial governments have placed a high priority on the development of a domestic medical device industry, and in this regard have institutions dedicated to research in the field.

Industry Climate

Canada's tax allowances for R&D expenditures are considerably more generous than those of the United States. In fact, among all the OECD members plus the five most important "Newly Industrialized Countries" (Brazil, India, Mexico, Singapore and South Korea), Canada ranks third in the tax treatment of R&D.

In Canada the R&D tax credit varies from 20% overall (20% refundable) to 35% for small firms (totally refundable). In addition, the R&D tax credit favours disadvantaged regions. In Atlantic Canada the credit is 30% for large companies (20% refundable).

Other factors which make Canada's tax treatment of R&D particularly attractive include:

- Canada's R&D tax credit applies to both the capital and non-capital portion of R&D, whereas in the United States the R&D credit applies only for the non-capital portion of R&D.
- In Canada the capital portion of R&D is completely written off in the first year.

For domestic marketing of most medical devices, a manufacturer must only submit notification information to appropriate government officials, provided that the manufacturer can demonstrate on request that a device is safe, effective and adequately labelled.

Devices which have been designated as new or for which there is a prescribed standard must undergo a pre-market review before they can be marketed.

Canada's Medical Devices Regulations do not require manufacturers to have products approved for sale in the domestic market before they may be exported.

Canada's procedures for making devices available for tests and clinical trials are reasonable and simple.

The Canadian Association of Manufacturers of Medical Devices, which is the industry spokesperson, is actively promoting and pursuing strategies to encourage the growth and development of the Canadian medical device manufacturing industry.

In addition, federal and provincial governments in Canada are particularly supportive of new investments in growth sectors such as the medical device industry. While the Ontario/Quebec industrial heartland remains an attractive location for new or expanding medical device manufacturers, increasing attention is being paid to supporting the growth and diversification of the industry in western and eastern regions of the country. For example, in western Canada, several provinces are implementing major initiatives to encourage new investments in health care industries.

Investment Opportunities

There are significant investment opportunities for expansion of existing manufacturing capacities in Canada's medical device industry, or establishment of new facilities for the research, development, testing and/or manufacture of medical devices. The opportunities cover all major sectors of the industry:

MEDICAL INSTRUMENTS & EQUIPMENT: There are a number of opportunities for the creation or expansion of Canadian capacities to manufacture physiological monitoring & recording equipment, electro-medical and electrosurgical equipment and apparatus, diagnostic instrumentation devices, and X-ray and related equipment. In all these areas, there is growing interest in increasing Canadian production capacity, while taking advantage of existing Canadian technological capacities in the design and manufacture of sophisticated electronic equipment and related instruments. There is a particular demand for medical instruments and equipment which can enhance diagnostic methods and treatment procedures. Some examples of emerging products for which there are potential investment opportunities include:

- ultrasonic, radiologic and magnetic resonance imaging devices
- patient monitoring systems
- non-invasive surgical devices
- · laser equipment for cardiac and other sophisticated forms of surgery
- artificial organs & implants

OPHTHALMIC GOODS: There are investment opportunities for the establishment of domestic production capacity for certain ophthalmic goods, including intraocular lenses and plastic ophthalmic lenses for spectacles. In addition, there are investment opportunities for the feasibility testing, initial production and subsequent marketing of innovative Canadian ophthalmic goods such as new forms of contact lenses and therapeutic and prosthetic devices.

SURGICAL, MEDICAL & DENTAL SUPPLIES: With increasing emphasis being placed upon hygienic and efficient forms of disposable surgical & medical supplies, there are potential investment opportunities for product development and production. Examples include disposable kits and trays for certain medical and surgical procedures.

ORTHOPAEDIC APPLIANCES, HEARING AIDS AND SELF-CARE DEVICES: With an aging population and almost daily developments in ambulatory aids, prosthetic devices and similar products of use to the aged, infirm and/or handicapped sectors of the population, there are new and expanding opportunities for Canadian manufacturers of such devices. Investments are sought in the development and production of various forms of prostheses, orthopaedic devices, incontinence products, as well as products for nursing homes and in-home care.

DIAGNOSTIC EQUIPMENT, MATERIALS AND KITS: This sector constitutes perhaps one of the fastest growing segments of the health care products market, with growth anticipated to be in the order of approximately 10-20% per annum over the next five years. There are a number of established Canadian companies in this field which are highly receptive to joint venture and technology-transfer opportunities, especially in the biotechnology fields. Opportunities include both home or self-diagnostic test kits and supplies used by hospitals and major health care institutions and clinics.

COMPUTER HARDWARE AND SOFTWARE: There are significant opportunities for investment and development of hardware and software for computer-aided medical applications, including:

- computer facilities and processes for enhancing the speed, image, clarity and/or analytical capabilities of medical imaging equipment and other medical devices
- computer-aided design and manufacture of prosthetics and surgical implants
- computer-based medical information systems dealing with financial and administrative records, patient medical histories, pharmacy inventories, and medical service schedules.

Government Assistance

The Department of Regional Industrial Expansion is a department of the Government of Canada devoted to serving needs of Canadian businesses, as well as foreign businesses operating or wishing to invest in Canada. These range from single-person enterprises to large multinationals. The department has more than 30 offices to serve businesses in every province and territory in Canada. In addition, the department works in close cooperation with international offices of External Affairs Canada and Investment Canada, as well as domestic agencies such as the National Research Council.

The objectives of Regional Industrial Expansion are to promote and support the productivity, profitability and competitiveness of Canadian businesses in a manner which respects the different business opportunities and conditions in each region of the country.

Regional Industrial Expansion helps businesses to gain access to information, advice and money needed to meet their business and investment objectives. Assistance and support is available for businesses at any stage in the business cycle, from setting up operations to expanding or modernizing facilities. In many cases, special support is available for targeted industry sectors and regions of the country in support of Canadian and provincial industrial development strategies.

For Further Information, Contact The Nearest Canadian Embassy Or Consulate.

Or:

DEPARTMENT OF REGIONAL INDUSTRIAL EXPANSION Director Biotechnology and Health Care Products Directorate 235 Queen St., 9th Floor East (IRPI) Ottawa, Ontario K1A 0H5 Canada

Tel.: (613) 954-3077 Telex: 053-4123 (IRPI)

INVESTMENT CANADA 235 Queen Street, 5th Floor West P.O. Box 2800, Station 'D' Ottawa, Ontario K1P 6A5 Canada

Tel.: 1-800-267-0490 (Toll Free in Canada and United States, excluding Alaska and Hawaii)

Telex: 053-4450

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