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**MANUFACTURING IN CANADA FOR
NORTH AMERICA'S HEALTH CARE MARKET**

A Brief to Finnish Managers



**INVESTMENT
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**Investment Canada
February 1989**

CANADA WANTS FINNISH BIOMEDICAL FIRMS

Canada is a prime point of entry into North America's health care market. This report presents key facts for senior managers of Finnish biomedical and biotechnology companies who are poised to establish new facilities in Canada.

Canada seeks your attention and business. We give priority to building an even stronger health care industry and are ready and able to help young and growing Finnish biomedical companies get started in North America through Canadian subsidiaries or joint ventures.

Governments at every level, together with banks, investment firms, universities and joint venture partners, are eager to work with you to build your business in North America.

CANADA'S OFFER TO FINNISH BIOMEDICAL FIRMS

The Canadian Embassy in Helsinki will prepare a specific fact-finding trip for you to Canada so you can assess:

- * suitable manufacturing sites
- * government financial support for capital investment and operating phases
- * private financial support for off-balance sheet financing of your North American venture
- * the regulatory approval process
- * university connections for product development
- * interim or prospective managers and consultants to get your project going
- * distributors
- * joint venture partners
- * tax specialists
- * other contacts you require.

WHY THIS IS A GOOD TIME TO ENTER THE NORTH AMERICAN MARKET

The 1990s is an attractive period to establish a North American base in Canada for your products.

Consolidated North American markets: The Canada-U.S. free trade agreement, effective January 1, 1989, will consolidate these two markets in the 1990s as tariff and many non-tariff barriers to trade are removed, enhancing access to the entire Canada-U.S. market of over 266 million people. By contrast, policy measures to correct the U.S. trade deficit, should they be enacted, may also be a factor in planning for entry into the U.S. market.

Exchange rate: Trade and government budgetary imbalances in the United States are likely to persist and cause European currencies to remain at high levels against the U.S. dollar. Canada's dollar historically has remained at a favourable level in relation to the U.S. dollar, providing Canadian firms with operating and production cost advantages.

Restructuring of the North American health care system: Cost containment pressures, an aging society and rationalization of the health delivery systems are resulting in new markets for new products in North America. There are many opportunities for entrepreneurial biomedical firms in this market. In 1987, the combined Canada-U.S. market for health care products was estimated at Can\$705.3 billion, which was considerably greater than that for Europe.

**THIRTEEN REASONS WHY CANADA IS A GOOD
POINT OF ENTRY INTO NORTH AMERICA**

1. Favourable exchange rates and relatively low manufacturing costs.
2. Competitive tax structures.
3. Virtually free access to the entire U.S.-Canada market for most health care products.
4. Government cost sharing on capital investment in most regions, cost sharing on basic R&D, and incentives for product development.
5. Relatively rapid regulatory approval for most health care products.
6. International calibre universities and research institutions eager to do business with you.
7. Good clinical trial sites and a homogeneous market for product launch.
8. Universal access to a national health care system.
9. Strong interest by investment firms and venture capitalists in biomedical companies with a proven product.
10. Strong support for industrial research and development.
11. Efficient transportation to major markets.
12. A fast growing biomedical industry interested in doing business with you.
13. Availability of a highly qualified workforce.

**FOR MORE FACTS AND FIGURES
SEE CHARTS 1-13**

**HOW DO YOU PURSUE OUR OFFER TO INVESTIGATE
CANADA?**

Please contact:

Mr. C.C. Charland
Commercial Counsellor and Consul
Canadian Embassy
Pohjois Esplanadi 25B
P.O. Box 779
00100 Helsinki 10
Finland
Tel: (0) 17-11-41
Telex: (Destination code 57) 121363

who will assist you in arranging your visit to Canada so that you can meet all the necessary contacts for planning a North American facility.

CHART 1

COMPARISON OF CANADIAN AND U.S. HOURLY EARNINGS
IN MANUFACTURING

In the table below, the average U.S. manufacturing wage in 1987, expressed in Canadian dollars, is shown as 97¢ an hour higher than the average Canadian manufacturing wage. In 1986, the U.S. wage was \$1.57 an hour higher.

	1983	1984	1985 (Can\$ per hour)	1986	1987
Canada	10.61	10.87	11.29	11.62	12.25
U.S.	11.88	11.90	13.02	13.52	13.14
Wage Gap	0.27	1.03	1.73	1.90	0.89

Sources: Statistics Canada 72-002, *Employment, earnings and hours*, 1987; U.S. Department of Labor, Bureau of Labor Statistics, *Employment and Earnings*, 1987. Exchange rates are annual averages provided by the Bank of Canada.

EXCHANGE RATE

Can\$* per unit of:

Year	U.S. Dollar	Finnish Markka
1980	1.1690	.3144
1981	1.1990	.2756
1982	1.2341	.2578
1983	1.2324	.2216
1984	1.2948	.2162
1985	1.3652	.2215
1986	1.3894	.2743
1987	1.3260	.2995
1988	1.2309	.2948
February 1, 1989	1.1896	.2760
Percent Change		
1980-88	5.3	-6.2
1987-88	-7.2	-1.6

*Average of noon spot rates.

Source: Bank of Canada

CHART 2
COMPARISON OF CANADIAN AND U.S.
CORPORATE INCOME TAX

	Canada	U.S.
Federal Tax Rates*		
General Business	28%	34%
Manufacturing	26%	34%
Provincial/State Tax Rates	5.5% to 17%	0% to 12%
Depreciation	Tax reforms in both Canada and the U.S. reduce the rate at which assets can be depreciated for tax purposes. Canadian depreciation rates are somewhat lower than U.S. rates, but are still higher than those based on the economic life of the asset.	
Capital Gains	Inclusion rates: 1988 - 66-2/3% 1990 - 75%	Taxed as ordinary business income
Treatment of Operating Losses	Carry-over: back 3 years forward 10 years	Carry-over: back 3 years forward 15 years
Consolidation	Not permitted	Permitted for subsidiary (at least 80% owned)
Minimum tax	No minimum corporate tax	Alternative minimum tax of 20% of AMT taxable income
Intercorporate Dividends	100% deductible	80% deductible

*The Canadian federal tax rates are effective July 1, 1988. At present there is also a 3% federal surtax on corporate income tax.

Source: Investment Canada, 1988

CHART 3

BIOMEDICAL PRODUCTS UNDER THE FREE TRADE AGREEMENT

Goods manufactured in Canada and exported to the United States shall be subjected to a revised system of tariffs commencing January 1, 1989, and in most cases be free of duty by January 1, 1998.

Code	Description	Base Rate	Free of Duty
2937.10.00	Pituitary Hormones	1.8%	January 1, 1993
2937.21.00	Adrenal Cortical Hormones	6.0%	January 1, 1993
2937.91.00	Insulin	1.8%	January 1, 1998
2937.92.00	Estrogens and Progestins	3.2%	January 1, 1993
3002.10.00	Antisera	FREE	
3002.20.00	Human Vaccines	FREE	
	Veterinary Vaccines	FREE	
3006.20.00	Blood-grouping Reagents	FREE	
3006.30.00	Diagnostic Reagents	FREE	
9018.11.00	Ultraviolet Apparatus	4.2%	January 1, 1998
9018.50.00	Ophthalmic Instruments	10.0%	January 1, 1998
9018.90.60	Electro-Surgical Instruments	7.9%	January 1, 1998
9021.11.00	Artificial Joints	7.2%	January 1, 1998
9022.21.00	Alpha, Beta or Gamma Radiation Equipment	4.0%	January 1, 1998
3003.10.00	Medicaments with Penicillin	6.9%	January 1, 1998
3004.50.-	Medicaments with Vitamins	3.1% to 16.8%	January 1, 1998

See Annex 401.2 of *The Canada-U.S. Free Trade Agreement*, Department of External Affairs, 1987, for specifics.

CHART 4

WHAT'S POSSIBLE IN CANADA

Typically, the Canadian government supports new ventures in a partnership with private-sector financing, technology and know-how. Canadian investment policy is flexible and accommodates the needs of the particular investment situation. The government can help at the front end of a new North American venture with capital subsidies, and can help on feasibility studies and analysis. The government also helps in the crucial early operating stages with assistance in product development, solving technical problems, finding export outlets and training.

Canadian federal and provincial governments particularly favour fast growing, profitable firms with proprietary technology, capable of taking on a new North American presence and seeking to utilize Canadian capabilities in the biomedical sciences.

Examples of Government Incentives

	Ontario	Quebec	Alberta	Saskat- chewan	Mani- toba	British Columbia	New Brun- swick	Nova Scotia	Federal
Funds Committed to Venture Capital Program	X	X	X	X	X	X	X	X	X
Entrepreneurial Assistance Available to High-tech Firms	X	X	X	X	X	X	X	X	
R&D Grants Available	X	X	X	X	X	X	X		X
Technology Transfer Programs	X	X	X	X	X	X	X	X	X
Provincial Funds Committed for Setting Up Incubators			X	X	X	X	X	X	
Tax Exemption for R&D			X						X
University R&D Facilities Available to Industry	X	X	X	X	X	X	X	X	
Provincial Funds Committed to Setting Up Research Parks	X	X	X		X	X		X	

Note: The table provides a general indication of support programs available. Funding for any specific project is often negotiated between the firm and the governments involved, and may involve support mechanisms not shown in the table.

CHART 5A

REGULATORY APPROVAL IN CANADA - DRUGS

In Canada the Health Protection Branch of Health and Welfare Canada is responsible for the administration of the regulatory process. The regulatory process in Canada is internationally recognized as applying high standards in determining the safety and efficacy of new drugs.

The current process and time frame for a typical approval is indicated in the chart below. Changes to this approval process are currently being introduced, making it more efficient and less time consuming.

Stages in the Development and Approval of a New Drug in Canada and the United States

		<u>Average Clearance Time for Notice of Compliance 1981-84</u>	
		Canada	United States
Research	Regulation		
Animal toxicological studies prior to Preclinical New Drug Submission		18 months	12 months
Discovery of new drug; chemical synthesis or extraction, analysis, formulation	Preclinical New Drug Submission (PNDS) all available information on new drug. Review by Health Protection Branch (HPB) of Health and Welfare Canada. If approved, company may proceed to clinical testing. Protocols: detailed descriptions of proposed clinical tests on humans; each is reviewed and approved by HPB and is subject to ethical review of research institution and informed consent of subjects.	4.7 months	5.0 months
Phase I clinical research	Phase I protocol: toxicology, small sample of healthy subjects.	Phases	Phases
Phase 2 clinical research	Phase 2 protocol: therapeutic effect, toxicology, small sample of patients.	1 - 3	1 - 3
Phase 3 clinical research	Phase 3 protocol: therapeutic effect, toxicology, large sample.	33.1	69.0
	New Drug Submission (NDS) with complete information on new drug including full report on clinical tests. If approved, company receives Notice of Compliance (NDS/NOC) and Product Monograph.	24.6 months	12.3 months (19.5 for minor advance drugs)
Marketing			
Phase 4 clinical research:	No approval is required.		

Note: research reported for PNDS and NDS need not be done in Canada.

Source: *Report of the Commission of Inquiry on the Pharmaceutical Industry*, Supply and Services Canada, 1985.

CHART 5B

REGULATORY APPROVAL - MEDICAL DEVICES

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 are new "implantable"* products or which fall under specially designated device classes 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.

* "implantable" refers to devices implanted for 30 days or more.

CHART 6

EXAMPLES OF EXPERTISE IN CANADIAN UNIVERSITIES

Rehabilitation and Biomedical Engineering:

- * University of Toronto and associated Sunnybrook Medical Centre
- * University of Montreal and associated Institut Clinique
- * University of Alberta

Genetic Engineering:

- * Mount Sinai Hospital Research Institute (Toronto)
- * Hospital for Sick Children (Toronto)
- * University of British Columbia Medical School
- * McMaster University Medical Centre

Hybridomas:

- * all Canadian medical schools

Biomaterials:

- * Centre for Biomaterials, University of Toronto

Plant Biotechnology:

- * University of Guelph
- * McGill University

Animal Health:

- * McDonald College, McGill University
- * Ontario Veterinary College, University of Guelph
- * University of Saskatchewan

CHART 7
CLINICAL TRIAL FACILITIES IN CANADA

	Universities with Medical Faculties	Hospitals and Other Clinical Trial Facilities
Alberta	2	11
British Columbia	1	5
Manitoba	1	2
New Brunswick		1
Newfoundland	1	4
Nova Scotia	1	6
Ontario	5	27
Quebec	4	26
Saskatchewan	<u>1</u>	<u>5</u>
TOTAL	16	87

CHART 8A

**HEALTH CARE EXPENDITURES
IN CANADA AND THE UNITED STATES**

(Public and private, Can\$ million)

	Canada	United States
1983	34.7	579.3
1984	37.4	636.4
1985	39.8	658.5

Note: United States figures are converted using average noon spot rates of exchange for each year.

Sources: Health and Welfare Canada, 1988; and U.S. Department of Health, 1988.

CHART 8B

IMPORTS OF MEDICAL DEVICES INTO CANADA
(Can\$million, 1987)

Medical and Related Equipment	671.2
Physiology monitoring and recording equipment, systems, accessories and parts	78.2
Electro-medical and electro-surgical equipment, apparatus and parts	47.1
Surgical instruments of steel, accessories and parts	68.6
Medical diagnostic equipment	83.9
Dental instruments, equipment, accessories and parts	48.4
Ophthalmic equipment, apparatus, accessories and parts	7.3
Physiotherapy and veterinary instruments, equipment and parts	9.3
Sterilizers, autoclaves and parts (except industrial)	19.4
Anaesthetic- and oxygen-administering equipment, accessories and parts	48.4
Medical and hospital equipment and parts	90.2
X-ray and related equipment and parts	170.5
X-ray film	
 Ophthalmic Goods	 176.8
Spectacles and eye-glass frames	67.5
Sunglasses, complete with lenses	33.7
Spectacles and eye-glasses complete with lenses	2.3
Parts for spectacles and eye-glass frames	3.8
Ophthalmic goods	67.5
 Surgical and Medical Supplies	 454.9
Bandages, surgical gauze, absorbent cotton and dressings	13.6
Sutures, suturing needles and sutures with needles	20.0
Blood handling, analyzing, collecting and processing supplies	26.4
Urinary and ostomy appliances, supplies and parts	15.5
Catheters, bougies, drains and sondes	27.0
Hospital supplies of chemical origin	112.4
Surgical implements	72.2
Disposable syringes, syringe needles and parts	36.8
Disposable medical and surgical instruments and kits	35.8
Medical, surgical and hospital supplies	95.4
 Hearing Aids and Parts	 17.4
 Orthopedic Appliances	 41.6
Artificial limbs (prosthetic) and parts	3.6
Elastic hosiery	1.9
Wheelchairs, invalid chairs and parts	23.2
Orthopedic appliances and parts	12.9
 Dental Supplies	 51.7
Artificial teeth, dentures and parts	8.6
Dental supplies	43.2
 Total Supplies	 1,413.6

Source: 65-007, Statistics Canada, 1988; (figures may not add exactly due to rounding)

CHART 8C
IMPORTS OF PHARMACEUTICALS INTO CANADA

(Can\$million 1987)

Biological Products for Humans	66.9
Penicillin	49.2
Antibiotics	77.1
Hormones	33.1
Vitamins and Preparations	53.0
Other Medicinal & Pharmaceutical Products	316.7
Veterinary Antibiotic Preparations	5.9
Veterinary Biological Products	12.4
Veterinary Medicines	25.1
Antibiotic Vitamins for Feed Supplements	38.6
Other Veterinary Medicine for Feed Supplements	14.4
Total Supplies	692.0

Source: Statistics Canada, *Publication 65-203*, Imports by commodity

N.B. Figures may not add exactly due to rounding.

CHART 9

VENTURE CAPITAL IN CANADA

(Can\$ million, number of investments in brackets)

	1985	1986	1987
Capital under management	1,257	1,531	2,300
New funds	250 (190)	206 (177)	800

VENTURE CAPITAL IN THE
MEDICAL AND GENETIC ENGINEERING SECTORS

(Can\$ million, number of investments in brackets)

	1985	1986
Genetic Engineering	24.4 (9)	18.1 (8)
Medical-related	5.0 (8)	16.2 (12)

Source: *Venture Capital in Canada: An Overview*, M. MacDonald, Investment Canada, November 1987; and *Canadian Venture Capital*, Venture Economics, February 1988.

CHART 10
**COMPARISON OF CANADIAN AND U.S.
 TAX INCENTIVES FOR R&D**

Tax Measure	Canada	U.S.
Deduction for R&D Expenditures		
Buildings	Depreciated over life of asset	Depreciated over life of asset
Equipment	Immediate	Depreciated over life of asset
Operating	Immediate	Immediate
Tax Credit for R&D		
Buildings	none	none
Equipment	20%	none
Operating	20%	20% on incremental R&D expenditures

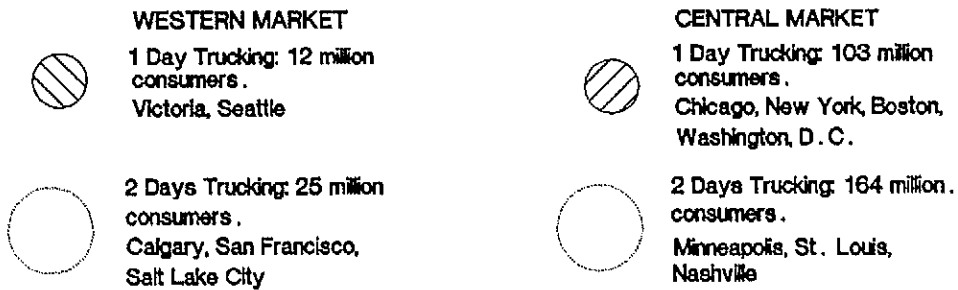
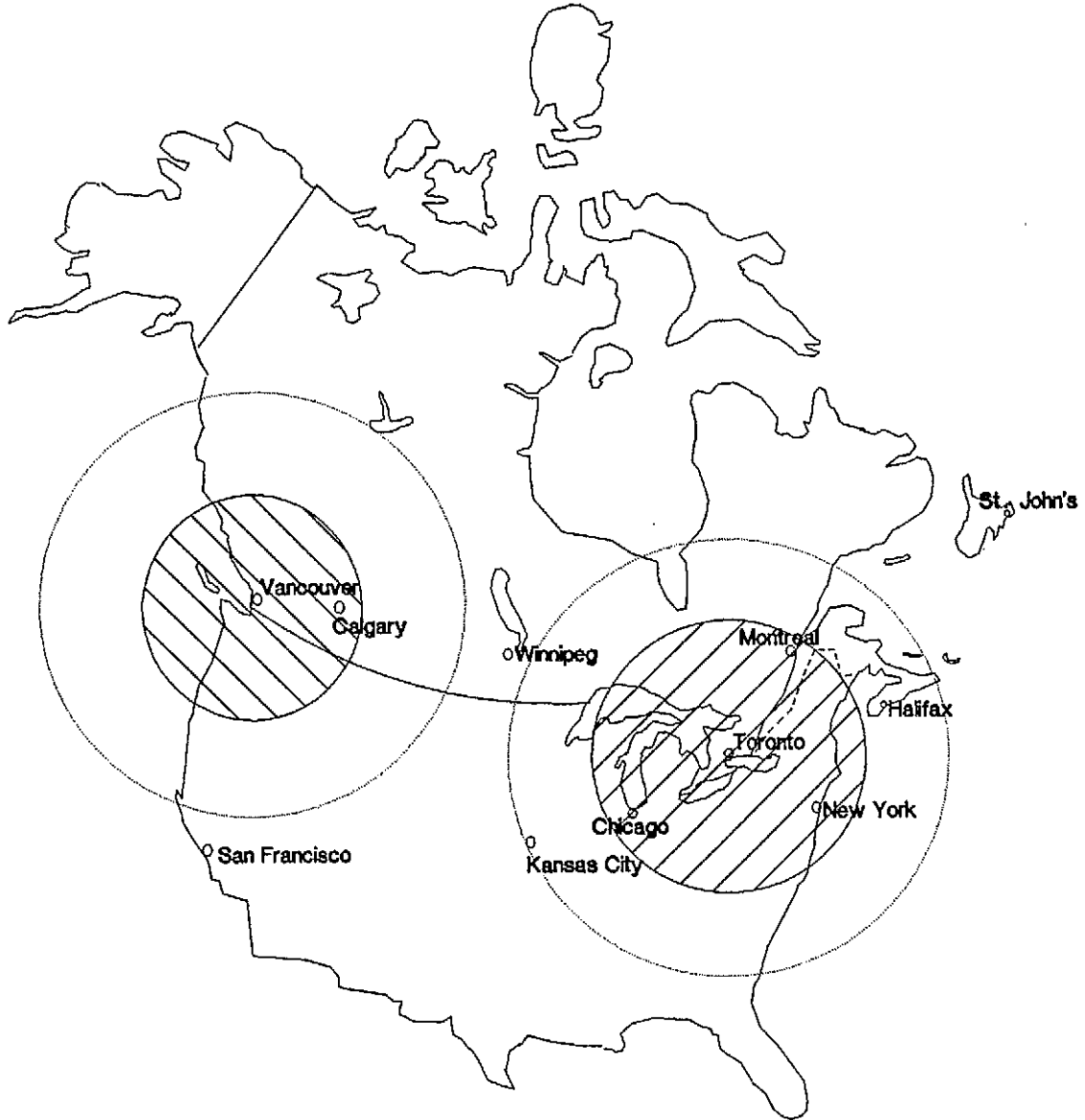
Notes:

1. The allowable deduction for both current and capital R&D expenditures is reduced by the amount of the tax credit claimed (otherwise the deduction for R&D expenditures would exceed the actual amount spent). Specialized R&D buildings, such as wind tunnels, are eligible for the immediate writeoff and investment tax credit; other buildings used for R&D do not receive preferential tax treatment.
2. In the U.S., the tax credit applies only to **incremental** R&D expenditures of a current nature. The tax credit is 20% of the excess of R&D in the year over the average R&D in the previous three years. R&D expenditures of a capital nature are not eligible for the tax credit, and for tax purposes must be written off over the useful life of the asset.

Source: Investment Canada, 1988.

CHART 11

ACCESS TO NORTH AMERICAN MARKETS
FROM CANADIAN CENTRES



Source: The Canadian Edge, Investment Canada, 1987.

CHART 12

EXAMPLES OF JOINT VENTURE INTERESTS AMONG CANADIAN BIOMEDICAL FIRMS

Rehabilitation Products

Ventech (Toronto), Mediquip (Toronto), Extendicare (Toronto), Obus Forme (Toronto)

Human and Veterinary Diagnostics

Quadra Logic Technologies (Vancouver), Joldan Diagnostics (Toronto), Pro Lab Inc. (Toronto), Rougier Diagnostics (Montreal), Allelix Diagnostics (Toronto), Sterivet Labs Ltd. (Toronto), Biostar Inc. (Saskatoon), Inter Haemotol (Burlington), Diagnostic Chemicals Ltd. (Charlottetown), QA Labs (Toronto), Bocknek (Toronto), APO Diagnostics (Toronto).

Catheters and Related *in vivo* Instruments

Vas-Cath (Toronto)

Monitoring Instruments

Cyberfluor (Toronto)

Vaccines and Immunostimulants

Connaught Laboratories Ltd. (Toronto), IAF Biochem International Ltd. (Montreal), Vetrepharm Inc. (London), Biostar Inc. (Saskatoon)

Sensors

Paradigm (Toronto)

Medical Devices

Ingram & Bell (Toronto), Strite Industries (Cambridge)

Imaging

Atomic Energy of Canada Limited (Ottawa), Equipment Moniteur (Montreal)

Drugs and Therapeutics

Allelix Biochemicals (Toronto), Quadra Logic Technologies (Vancouver), Nordic Laboratories Inc. (Montreal), Richmond Pharmaceuticals Inc. (Toronto), Novopharm Ltd. (Toronto), Connaught Laboratories Ltd. (Toronto), MDS Health Group Ltd. (Toronto), Apotek (Toronto).

CHART 13

HIGHLY QUALIFIED WORKFORCE IN SELECTED FIELDS
IN CANADA

University Graduates, 1984

Discipline	Bachelor and Professional Degree	Master and Doctoral Degree
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 and Other Engineering	1,529	454
Biochemistry	420	64

Community College Graduates, 1984

Diagnostic and Treatment Technologies	2,763
Medical Equipment and Prosthetics	197
Other Health-related Technologies	538
Chemical Technologies	677

Source: Statistics Canada

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