



# Health R&D Expenditures by Therapeutic Class, 2003

Reporting organization name and address



Si vous préférez ce questionnaire en français, veuillez cocher

Please correct any mistake in name or address.



## Information for Respondents

### Survey objective

This survey collects data which are essential to plan and evaluate research and development programs. Data will be used by the Applied Research and Analysis Directorate (ARAD) of Health Canada to monitor and support the development of science and technology policy.

### Authority

This survey is conducted under the authority of the *Statistics Act*, Revised Statutes of Canada, 1985, Chapter S19.

### Legal requirement

Organizations are required to provide this information.

### Confidentiality

Statistics Canada is prohibited from publishing any statistics which would divulge information relating to any identifiable organization without the previous written consent of that organization. The data reported on this questionnaire will be treated in strict confidence, used for statistical purposes and published in aggregated form only.

### Federal/Provincial Agreements

In order to avoid duplication of enquiry, to reduce the cost of data collection and to provide consistent statistics, agreements have been made with:

- the Institut de la statistique du Québec (ISQ), under Section 11 of the *Statistics Act*, Statutes of Canada, where data on firms

located or having research and development (R&D) activities in Québec will be transmitted to the ISQ. The *Statistics Act* of Québec includes the same provisions for confidentiality and penalties for disclosure of information as the Canada *Statistics Act*.

- the ARAD, under Section 12 of the *Statistics Act*, Statutes of Canada, for the joint collection and sharing of information. However, the ARAD will not be given access to your questionnaire if you send a letter to the Science, Innovation and Electronic Information Division, with your completed questionnaire, stating that you do not want it made available to the ARAD.

### Reporting period and coverage

This questionnaire should be completed for the 2003 fiscal year for research and development activities **performed by your organization** in Canada (exclude foreign operations). Please report all amounts in **Canadian currency**.

**Note:** Total R&D reported on page 5 should equal the 2003 total expenditures reported on line 605 of your T661 form "Claim for Scientific Research and Experimental Development (SRED) carried out in Canada."

The first level classes of the Anatomical Therapeutic Chemical (ATC) system are used in this questionnaire. Some basic information about this system is provided in Appendix A

Fiscal year ending in 2003



FROM

2	0		
year	month	day	

month	day		

TO

2	0	0	3
year	month	day	

month	day		

### Please return the completed questionnaire within 30 days of receipt.

If you are unable to do so, please inform us of the expected completion date. If you receive more than one copy of this survey questionnaire for the same business, please complete one and attach and return the duplicate(s). If you require assistance in the completion of this questionnaire or have any questions regarding the survey please address all enquiries to:

Science and Innovation Surveys Section  
 Science, Innovation and Electronic Information Division  
 Statistics Canada  
 Ottawa, Ontario K1A 0T6

Telephone: (613) 951-9662 (call collect)  
 FAX : (613) 951-9920  
 E-mail: sieidinfo@statcan.ca

1. Is your organization: *Please check appropriate category.*

- a brand name pharmaceutical company     a contract research organization (CRO)  
 a generic pharmaceutical company     a biotechnology or biopharmaceutical company  
 Other (please specify) \_\_\_\_\_

2. Did your organization perform any R&D related to the discovery and/or development of therapeutic products for human use in 2003?

- Yes ► *Please go to Question 3*  
 No ► *Please complete **certification** on page 6 and return this questionnaire in the prepaid envelope. Thank you for your cooperation.*

3. For each therapeutic class listed below, please indicate, by stage of development, the number of R&D projects performed by your organization in 2003 and their related expenditures, for new\* product development and for existing\* product improvements. Please report R&D performed in Canada only.

In cases where no R&D was performed, please check "No" and move to the next class.

1. **Alimentary Tract and Metabolism.**

- No ► *Move to next class*  
 Yes →

	R&D expenditures in 2003				Number of R&D targets*		
	Discovery R&D	Pre-clinical Trials*	Phase I Trials	Phase II Trials	Phase III Trials*	Pending Approval	Approved*
a) Number of R&D projects for <b>new product development</b>	#	#	#	#	#	#	#
b) R&D expenditures in 2003 for <b>new product development</b>	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)
c) Number of R&D projects for <b>existing product improvements</b>	#	#	#	#	#	#	#
d) R&D expenditures in 2003 for <b>existing product improvements</b>	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)

2. **Blood and Blood Forming Organs.**

- No ► *Move to next class*  
 Yes →

	R&D expenditures in 2003				Number of R&D targets*		
	Discovery R&D	Pre-clinical Trials*	Phase I Trials	Phase II Trials	Phase III Trials*	Pending Approval	Approved*
a) Number of R&D projects for <b>new product development</b>	#	#	#	#	#	#	#
b) R&D expenditures in 2003 for <b>new product development</b>	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)
c) Number of R&D projects for <b>existing product improvements</b>	#	#	#	#	#	#	#
d) R&D expenditures in 2003 for <b>existing product improvements</b>	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)

3. **Cardiovascular System.**

- No ► *Move to next class*  
 Yes →

	R&D expenditures in 2003				Number of R&D targets*		
	Discovery R&D	Pre-clinical Trials*	Phase I Trials	Phase II Trials	Phase III Trials*	Pending Approval	Approved*
a) Number of R&D projects for <b>new product development</b>	#	#	#	#	#	#	#
b) R&D expenditures in 2003 for <b>new product development</b>	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)
c) Number of R&D projects for <b>existing product improvements</b>	#	#	#	#	#	#	#
d) R&D expenditures in 2003 for <b>existing product improvements</b>	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)

\* see definitions in Appendix A

4. **Dermatologicals.**

- No ► *Move to next class*  
 Yes →

	R&D expenditures in 2003				Number of R&D targets*		
	Discovery R&D	Pre-clinical Trials*	Phase I Trials	Phase II Trials	Phase III Trials*	Pending Approval	Approved*
a) Number of R&D projects for <b>new product development</b>	#	#	#	#	#	#	#
b) R&D expenditures in 2003 for <b>new product development</b>	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)
c) Number of R&D projects for <b>existing product improvements</b>	#	#	#	#	#	#	#
d) R&D expenditures in 2003 for <b>existing product improvements</b>	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)

5. **Genito-urinary Systems and Sex Hormones.**

- No ► *Move to next class*  
 Yes →

	R&D expenditures in 2003				Number of R&D targets*		
	Discovery R&D	Pre-clinical Trials*	Phase I Trials	Phase II Trials	Phase III Trials*	Pending Approval	Approved*
a) Number of R&D projects for <b>new product development</b>	#	#	#	#	#	#	#
b) R&D expenditures in 2003 for <b>new product development</b>	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)
c) Number of R&D projects for <b>existing product improvements</b>	#	#	#	#	#	#	#
d) R&D expenditures in 2003 for <b>existing product improvements</b>	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)

6. **Systemic Hormonal Preparation excluding Sex Hormones and Insulin.**

- No ► *Move to next class*  
 Yes →

	R&D expenditures in 2003				Number of R&D targets*		
	Discovery R&D	Pre-clinical Trials*	Phase I Trials	Phase II Trials	Phase III Trials*	Pending Approval	Approved*
a) Number of R&D projects for <b>new product development</b>	#	#	#	#	#	#	#
b) R&D expenditures in 2003 for <b>new product development</b>	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)
c) Number of R&D projects for <b>existing product improvements</b>	#	#	#	#	#	#	#
d) R&D expenditures in 2003 for <b>existing product improvements</b>	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)

7. **Anti-infectives for Systemic Use.**

- No ► *Move to next class*  
 Yes →

	R&D expenditures in 2003				Number of R&D targets*		
	Discovery R&D	Pre-clinical Trials*	Phase I Trials	Phase II Trials	Phase III Trials*	Pending Approval	Approved*
a) Number of R&D projects for <b>new product development</b>	#	#	#	#	#	#	#
b) R&D expenditures in 2003 for <b>new product development</b>	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)
c) Number of R&D projects for <b>existing product improvements</b>	#	#	#	#	#	#	#
d) R&D expenditures in 2003 for <b>existing product improvements</b>	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)

\* see definitions in Appendix A

**8. Antineoplastic and Immunomodulating Agents.**

- No ► *Move to next class*  
 Yes →

	R&D expenditures in 2003				Number of R&D targets*		
	Discovery R&D	Pre-clinical Trials*	Phase I Trials	Phase II Trials	Phase III Trials*	Pending Approval	Approved*
a) Number of R&D projects for <b>new product development</b>	#	#	#	#	#	#	#
b) R&D expenditures in 2003 for <b>new product development</b>	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)
c) Number of R&D projects for <b>existing product improvements</b>	#	#	#	#	#	#	#
d) R&D expenditures in 2003 for <b>existing product improvements</b>	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)

**9. Musculo-skeletal Systems.**

- No ► *Move to next class*  
 Yes →

	R&D expenditures in 2003				Number of R&D targets*		
	Discovery R&D	Pre-clinical Trials*	Phase I Trials	Phase II Trials	Phase III Trials*	Pending Approval	Approved*
a) Number of R&D projects for <b>new product development</b>	#	#	#	#	#	#	#
b) R&D expenditures in 2003 for <b>new product development</b>	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)
c) Number of R&D projects for <b>existing product improvements</b>	#	#	#	#	#	#	#
d) R&D expenditures in 2003 for <b>existing product improvements</b>	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)

**10. Nervous System.**

- No ► *Move to next class*  
 Yes →

	R&D expenditures in 2003				Number of R&D targets*		
	Discovery R&D	Pre-clinical Trials*	Phase I Trials	Phase II Trials	Phase III Trials*	Pending Approval	Approved*
a) Number of R&D projects for <b>new product development</b>	#	#	#	#	#	#	#
b) R&D expenditures in 2003 for <b>new product development</b>	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)
c) Number of R&D projects for <b>existing product improvements</b>	#	#	#	#	#	#	#
d) R&D expenditures in 2003 for <b>existing product improvements</b>	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)

**11. Antiparasitic Products, Insecticides and Repellents.**

- No ► *Move to next class*  
 Yes →

	R&D expenditures in 2003				Number of R&D targets*		
	Discovery R&D	Pre-clinical Trials*	Phase I Trials	Phase II Trials	Phase III Trials*	Pending Approval	Approved*
a) Number of R&D projects for <b>new product development</b>	#	#	#	#	#	#	#
b) R&D expenditures in 2003 for <b>new product development</b>	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)
c) Number of R&D projects for <b>existing product improvements</b>	#	#	#	#	#	#	#
d) R&D expenditures in 2003 for <b>existing product improvements</b>	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)

\* see definitions in Appendix A

**12. Respiratory System.**

- No ► *Move to next class*  
 Yes →

	R&D expenditures in 2003				Number of R&D targets*		
	Discovery R&D	Pre-clinical Trials*	Phase I Trials	Phase II Trials	Phase III Trials*	Pending Approval	Approved*
a) Number of R&D projects for <b>new product development</b>	#	#	#	#	#	#	#
b) R&D expenditures in 2003 for <b>new product development</b>	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)
c) Number of R&D projects for <b>existing product improvements</b>	#	#	#	#	#	#	#
d) R&D expenditures in 2003 for <b>existing product improvements</b>	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)

**13. Sensory Organs.**

- No ► *Move to next class*  
 Yes →

	R&D expenditures in 2003				Number of R&D targets*		
	Discovery R&D	Pre-clinical Trials*	Phase I Trials	Phase II Trials	Phase III Trials*	Pending Approval	Approved*
a) Number of R&D projects for <b>new product development</b>	#	#	#	#	#	#	#
b) R&D expenditures in 2003 for <b>new product development</b>	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)
c) Number of R&D projects for <b>existing product improvements</b>	#	#	#	#	#	#	#
d) R&D expenditures in 2003 for <b>existing product improvements</b>	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)

**14. Various Others (please specify)**

- No  
 Yes →

	R&D expenditures in 2003				Number of R&D targets*		
	Discovery R&D	Pre-clinical Trials*	Phase I Trials	Phase II Trials	Phase III Trials*	Pending Approval	Approved*
a) Number of R&D projects for <b>new product development</b>	#	#	#	#	#	#	#
b) R&D expenditures in 2003 for <b>new product development</b>	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)
c) Number of R&D projects for <b>existing product improvements</b>	#	#	#	#	#	#	#
d) R&D expenditures in 2003 for <b>existing product improvements</b>	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)	(\$000)

**TOTAL**

Total Health R&D (sum of 1 – 14)	(\$000)	Total number of R&D targets	
Other R&D in 2003 . . . . .	(\$000)		
Total R&D in 2003 <sup>1</sup> . . . . .	(\$000)		
Planned Health R&D for 2004 . . .	(\$000)		
Forecast Health R&D for 2005 . .	(\$000)		

<sup>1</sup> Should equal the 2003 total expenditures reported on line 605 of your T661 form "Claim for Scientific Research and Experimental Development (SR&ED) Expenditures" carried on in Canada.

\* see definitions in Appendix A

**CERTIFICATION**

Please complete **certification** below and return this questionnaire in the prepaid envelope.  
Thank you for your cooperation.

Name of person who completed this report ( <i>please print</i> )		Business address			
Official position	Date	Postal code	Telephone No. (      )       -	Extension	
Email address		GST No. (BN No.) 	Fax No. (      )       -		

**COMMENTS**

FOR INFORMATION ONLY

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**APPENDIX A**

**Targets** – R&D targets refers to the number of end-products that are hoped to evolve from the current research being performed.

**New product development** – please consider new to mean totally or essentially new/unknown to the personnel of your organization.

**Existing product improvement** – please consider existing to mean that personnel of your organization would be improving a product or process about which they have at least basic information.

**Pre-clinical trials** – includes toxicology testing.

**Phase III trials** – please include phase IIIB bioequivalence testing and all other testing before submitting for approval.

**Approved** – please include phase IV trials and other testing in comparison with other competing products on the market.

## The ATC classification – structure and principles

The Anatomical Therapeutic Chemical (ATC) system is recognized by the World Health Organization (WHO) as an international standard for drug utilization studies. The purpose of the ATC system is to serve as a tool for drug utilization research in order to improve quality of drug use. ATC codes are maintained by the WHO Collaborating Centre for Drug Statistics Methodology in Oslo, Norway.

In the ATC classification system, the drugs are divided into different groups according to the organ or system on which they act and their chemical, pharmacological and therapeutic properties. Drugs are classified in groups at five different levels. The drugs are divided into fourteen main groups (1st level), with one pharmacological/therapeutic subgroup (2nd level). The 3rd and 4th levels are chemical/pharmacological/therapeutic subgroups and the 5th level is the chemical substance. The 2nd, 3rd and 4th levels are often used to identify pharmacological subgroups when that is considered more appropriate than therapeutic or chemical subgroups.

Medicinal products are classified according to the main therapeutic use of the main active ingredient, on the basic principle of only one ATC code for each pharmaceutical formulation (i.e. similar ingredients, strength and pharmaceutical form). A medicinal product can be given more than one ATC code if it is available in two or more strengths or formulations with clearly different therapeutic uses.

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## ATC pharmacological / therapeutic 1st level groups and 2nd level subgroups

### 1. Alimentary Tract And Metabolism

- A01 Stomatological Preparations
- A02 Drugs For Acid Related Disorders
- A03 Drugs For Functional Gastrointestinal Disorders
- A04 Antiemetics And Antinauseants
- A05 Bile And Liver Therapy
- A06 Laxatives
- A07 Antidiarrheals, Intestinal Antiinflammatory, Antiinfective Agents
- A08 Antiobesity Preparations, Excl. Diet Products
- A09 Digestives, Incl. Enzymes
- A10 Drugs Used In Diabetes
- A11 Vitamins
- A12 Mineral Supplements
- A13 Tonics
- A14 Anabolic Agents For Systemic Use
- A15 Appetite Stimulants
- A16 Other Alimentary Tract And Metabolism Products

### 2. Blood And Blood Forming Organs

- B05 Blood Substitutes And Perfusion Solutions
- A10B Oral Blood Glucose Lowering Drugs
- B05A Blood And Related Products
- A10Bx Other Oral Blood Glucose Lowering Drugs
- B02Bd Blood Coagulation Factors
- B05Aa Blood Substitutes And Plasma Protein Fractions
- V07Ac Blood Transfusion, Auxiliary Products
- V07Ad Blood Tests, Auxiliary Products
- B05Aa03 Fluorocarbon Blood Substitutes

### 3. Cardiovascular System

- C01 Cardiac Therapy
- C02 Antihypertensives
- C03 Diuretics
- C04 Peripheral Vasodilators
- C05 Vasoprotectives
- C07 Beta Blocking Agents
- C08 Calcium Channel Blockers
- C09 Agents Acting On The Renin-Angiotensin System
- C10 Serum Lipid Reducing Agents

### 4. Dermatologicals

- D01 Antifungals For Dermatological Use
- D02 Emollients And Protectives
- D03 Preparations For Treatment Of Wounds And Ulcers
- D04 Antipruritics, Incl. Antihistamines, Anesthetics, Etc
- D05 Antipsoriasis
- D06 Antibiotics And Chemotherapeutics For Dermatological Use
- D07 Corticosteroids, Dermatological Preparations
- D08 Antiseptics And Disinfectants
- D09 Medicated Dressings
- D10 Anti-Acne Preparations
- D11 Other Dermatological Preparations

*Continued on page 8*

## 5. Genito Urinary System And Sex Hormones

- G01 Gynecological Antiinfectives And Antiseptics
- G02 Other Gynecologicals
- G03 Sex Hormones And Modulators Of The Genital System
- G04 Urologicals

## 6. Systemic Hormonal Preparations, Excl. Sex Hormones And Insulins

- H01 Pituitary And Hypothalamic Hormones And Analogues
- H02 Corticosteroids For Systemic Use
- H03 Thyroid Therapy
- H04 Pancreatic Hormones
- H05 Calcium Homeostasis

## 7. Antiinfectives For Systemic Use

- J01 Antibacterials For Systemic Use
- J02 Antimycotics For Systemic Use
- J04 Antimycobacterials
- J05 Antivirals For Systemic Use
- J06 Immune Sera And Immunoglobulins
- J07 Vaccines

## 8. Antineoplastic And Immunomodulating Agents

- L01 Antineoplastic Agents
- L02 Endocrine Therapy
- L03 Immunostimulants
- L04 Immunosuppressive Agents

## 9. Musculo-Skeletal System

- M01 Antiinflammatory And Antirheumatic Products
- M02 Topical Products For Joint And Muscular Pain
- M03 Muscle Relaxants
- M04 Antigout Preparations
- M05 Drugs For Treatment Of Bone Diseases
- M09 Other Drugs For Disorders Of The Musculo-Skeletal System

## 10. Nervous System

- N01 Anesthetics
- N02 Analgesics
- N03 Antiepileptics
- N04 Anti-Parkinson Drugs
- N05 Psycholeptics
- N06 Psychoanaleptics
- N07 Other Nervous System Drugs

## 11. Antiparasitic Products, Insecticides And Repellents

- P01 Antiprotozoals
- P02 Anthelmintics
- P03 Ectoparasiticides, Incl. Scabicides, Insecticides And Repellents

## 12. Respiratory System

- R01 Nasal Preparations
- R02 Throat Preparations
- R03 Drugs For Obstructive Airway Diseases
- R05 Cough And Cold Preparations
- R06 Antihistamines For Systemic Use
- R07 Other Respiratory System Products

## 13. Sensory Organs

- S01 Ophthalmologicals
- S02 Otologicals
- S03 Ophthalmological And Otological Preparations

## 14. Various Others

- V01 Allergens
- V03 All Other Therapeutic Products
- V04 Diagnostic Agents
- V06 General Nutrients
- V07 All Other Non-Therapeutic Products
- V08 Contrast Media
- V09 Diagnostic Radiopharmaceuticals
- V10 Therapeutic Radiopharmaceuticals
- V20 Surgical Dressings