

Table of Contents

Orders in Council
Foreword

Summary of the Report of the Commission of Inquiry on the Pharmaceutical Industry	xvii
Compulsory Licensing	xix
Product and Process Patents and Reverse Onus	xxiii
Drug Regulation	xxiv
The Use of Committees of Non-governmental Experts	xxvi
Safety: Original Package Dispensing and Information Inserts	xxvii
The Retail Market and Provincial Plans	xxvii
Research and Development	xxix
Conclusion	xxx
Introduction	xxxiii

PART I DESCRIPTION AND ANALYSIS

Chapter 1 The Legislative Framework	1
Patent Legislation	1
Brief History	1
General Provisions	2
Regulation of Drug Use and Sale	4
Hospital and Medical Care Insurance	5
Pharmicare	6
Private Insurance Schemes	7
Provincial Reimbursement Schemes	7
Appendix 1 International Regulations	11
 Chapter 2 The Pharmaceutical Industry in Canada: A Historical Overview	 39
The Number and Size of Establishments	39
Manufacturers of Pharmaceuticals and Medicines: Specialization and Coverage	41
The Coverage Ratio	42
The Specialization Ratio	43

Employment, Wages and Salaries, and the Value of Factory Shipments	43
Real Gross Domestic Product	46
Net Fixed Assets and Total Assets	49
Imports and Exports	49
Foreign Ownership	54
Research and Development Expenditures	61
Principal Statistics of the Pharmaceutical Industry in Canada and the United States	64
Appendix Tables A2.1 to A2.8	67
Chapter 3 The Pharmaceutical Industry in Canada: A Market Profile	79
The Relative Size and Growth of Expenditures on Pharmaceuticals and Medicines	79
Sales by Manufacturers Compared to Purchases by Drugstores, Pharmacies, and Hospitals	80
Relative Size and Growth of Expenditures on Pharmaceuticals and Medicines	85
Coverage of the Population by Third-party Pharmicare Insurance.....	91
Patterns of Use of Pharmaceutical Products	94
Utilization Patterns by Age and Sex	94
The Age Distribution of the Population	97
Principal Economic Agents on the Demand Side	101
Drug Utilization by Illness Episode	104
The Competitive Nature of the Final Market	104
Appendix Tables A3.1 to A3.11	107
Chapter 4 The Market Structure	125
Concentration of Output	125
Overall Market Concentration	125
Concentration Compared to Other Industries	127
Concentration in Sub-markets Defined by Therapeutic Classes	128
Concentration in Sub-markets Defined by Illness Diagnosis	135
Concentration in the Pharmaceutical Industry in Canada Summarized	138
International Comparisons of Concentration	142
The Stability of Market Shares	142
A Visual Consideration of the Stability of Market Shares	142
Instability Indices of Market Shares	146
Market Share Stability for Therapeutic Classes	150
Source of Instability: Reliance by Firms on the Sales of a Few Products	150
Other Elements of Market Structure	154
Economies of Scale	154

Concentration of Buyers	156
The Nature of Generic Firms.....	157
The Competitive Structure of the Pharmaceutical Industry in Canada Reviewed.....	158
Appendix Tables A4.1 to A4.16.....	160
Appendix Charts A4.1 to A4.3	215
Chapter 5 Market Behaviour	219
Sales and Promotion Activities	219
Manpower Allocated to Sales and Promotion Activities	219
Expenditures on Advertising.....	225
International Comparisons of Sales, Promotion, and Advertising Activities	226
Research and Development and New Products	229
Expenditures on Research and Development Relative to Sales	229
Sources of New Pharmaceutical Products	233
Therapeutic Value of New Pharmaceuticals and Medicines	237
Negative Outcomes	244
Vertical and Horizontal Integration	245
Geographic Horizontal Integration	245
Horizontal Product Integration	248
Vertical Integration	249
Summary of Chapter	251
Chapter 6 Market Performance: Profits	253
Introduction	253
Industry Profits	254
Alternative Measures of Profits in the Pharmaceutical Industry in Canada, 1968-82.....	254
Pharmaceutical Profits Relative to Other Canadian Industries	257
Pharmaceutical Profits in Canada Compared to Pharmaceutical Profits in the United States.....	261
Profits at the Level of the Individual Firm	267
Profitability and Firm Size.....	267
Profitability and Specialization in the Production of Pharmaceuticals and Medicines.....	268
The Impact of Compulsory Licensing on Firm Profitability.....	268
Variation in Firms' Profits	269
Profitability of Parent Versus Canadian Subsidiary Firms.....	270
International Comparisons of Pharmaceutical Profitability	271
Appendix Tables A6.1 to A6.19.....	278
Appendix Charts A6.1 to A6.4	297
Chapter 7 Market Performance: Prices.....	301
Introduction	301

General Price Level Changes	302
Prices in Manufacturing	302
Price Level Changes in the Retail Market.....	305
Product Replacement and Potential Product Upgrade.....	307
Estimated Impact of Compulsory Licensing on Expenditures of Multiple-source Drugs	311
Estimated Impact of Compulsory Licensing on Expenditures on a Sample of Drugs Sold to Drugstores and Pharmacies—1968, 1976, 1982, and 1983: Study A	312
Estimated Impact of Compulsory Licensing on Expenditures on a Sample of Drugs Sold Both to Hospitals and to Drugstores and Pharmacies in 1983: Study B	314
Other International Price Comparisons	317
Generic Prices Versus Prices of Patented Products	318
Price Comparisons with Europe and Japan	319
Appendix Chart A7.1	323
Appendix Tables A7.1 and A7.2.....	324

PART II POLICY AND RECOMMENDATIONS

Text of Recommendations.....	329
Chapter 8 Patents and Royalties	333
Introduction	333
General Principles: The Purpose of Patents.....	335
Effects of Variation of Patent Protection.....	337
The Characteristics of the Pharmaceutical Industry Resulting from Patent Protection.....	340
Competitive Strategies in the Pharmaceutical Industry.....	341
Costs in the Pharmaceutical Industry	344
Profits in the Pharmaceutical Industry	345
Small Country Policies and World-wide Markets.....	347
Compulsory Licensing and the Growth of Generic Production in Canada	348
Reward to the Patentee.....	354
The Period of Exclusivity.....	354
The Research and Development Component.....	356
The Promotion Costs Component.....	358
Calculating the Research and Development Elements of the Pharmaceutical Royalty Fund and Disbursements.....	359
Royalties for Compulsory Licences to Manufacture: The Research and Development Component.....	361
Variable Royalty Rates and Incentives to Strategic Behaviour.....	362
The Total Royalty Payments.....	363

The Proposed Royalty Arrangements and Canada's International Agreements	365
Product and Process Patents	366
Reverse Onus	368
Conclusion.....	369
Chapter 9 Authorization for Marketing: Safety and Efficacy	371
Introduction	371
Stages in the Clearance Process.....	372
The Objectives and Effects of Drug Regulation.....	374
The Canadian Regulatory Process.....	375
A Comparison of Canadian and Foreign Clearance Processes	384
The Acceleration of the Clearance Process in Canada	387
The Use of Committees of Non-governmental Experts.....	390
Notices of Compliance for Compulsorily Licensed Drugs	391
Safety: Original Package Dispensing and Information Inserts.....	392
Chapter 10 The Retail Pharmacy Market	395
Substitution and Selection of Drugs.....	398
The Cost of Acquisition and of Reimbursement	405
The Realization of Potential Savings	407
The Effect of Price Regulation	408
The Sensitivity of Consumers to Prices.....	410
Chapter 11 The Regional Distribution of the Pharmaceutical Industry in Canada	413
Chapter 12 Pharmaceutical Research in Canada	421
Chapter 13 International Trade, Transfer Prices and Tariffs	429
Intra-corporate Transfer Prices	431
The Canadian Tariff	440
Chapter 14 Conclusion	443
Appendices	
A. List of Submissions	445
B. Witnesses Before the Commission of Inquiry on the Pharmaceutical Industry	467
Select Bibliography	471