

## Table of Contents

<b>Executive Summary</b> .....	9
<b>Introduction</b> .....	21
<b>Chapter 1. Key Characteristics of the Pharmaceutical Sector in OECD Economies</b> .....	23
Introduction .....	24
Pharmaceutical expenditures .....	24
Pharmaceutical consumption and relative price levels determine pharmaceutical expenditures .....	30
Financing .....	38
The pharmaceutical industry is important in the economies of several OECD countries .....	40
Conclusions .....	42
Notes .....	43
References .....	44
Annex 1.A1. Distribution Mark-ups and Value-added tax for Pharmaceuticals in OECD Countries .....	46
<b>Chapter 2. The Pharmaceutical Industry and its Activities</b> .....	51
Introduction .....	52
Concentration of the industry .....	52
Research and development .....	52
Pharmaceutical manufacturing .....	56
Pharmaceutical sales .....	58
Ex-manufacturer prices .....	62
Product life-cycle management .....	63
Profits of the pharmaceutical industry .....	70
Conclusions .....	70
Notes .....	71
References .....	73
Annex 2.A1. Price Comparisons at the Ex-manufacturer Level .....	78
<b>Chapter 3. Pharmaceutical Pricing and Reimbursement and the Broader Pharmaceutical Policy Environment</b> .....	85
Introduction .....	86
Coverage schemes .....	86
Pharmaceutical price regulation .....	97
Regulators, payers and purchasers use a mix of techniques for defining price levels .....	101

All components of the retail price of pharmaceuticals are subject to regulation . .	113
Many OECD countries regulate price increases and try to contain pharmaceutical expenditure growth . . . . .	113
The stability, consistency and predictability of regulation . . . . .	114
Other aspects of the pharmaceutical policy environment that affect the achievement of policy goals . . . . .	115
Conclusions. . . . .	118
Notes . . . . .	118
References. . . . .	120
Annex 3.A1. Pharmaceuticals and Intellectual Property Rights in the European Union . . . . .	125
Annex 3.A2. Marketing Authorisation in the European Economic Area . . . . .	128
<b>Chapter 4. The Impact of Pharmaceutical Pricing Policies on Performance in Meeting Health Policy Goals . . . . .</b>	<b>131</b>
Introduction . . . . .	132
Promoting public health . . . . .	132
The impact of pricing and reimbursement policies on pharmaceutical price levels . .	140
Pharmaceutical cost containment. . . . .	148
Pursuing good value for money in spending on pharmaceuticals . . . . .	152
Conclusions. . . . .	155
Notes . . . . .	156
References. . . . .	157
Annex 4.A1. The Relationship between Retail Pharmaceutical Price Levels and Economy-wide Price Levels in OECD Countries . . . . .	161
<b>Chapter 5. The Impact of National Pricing and Reimbursement Practices on Prices and Availability of Medicines in Other Countries . . . . .</b>	<b>167</b>
Introduction . . . . .	168
National pricing policies are likely to impact the availability and prices of drugs in foreign countries . . . . .	168
Manufacturers use various strategies in order to maximise net revenues in the global market and counter spill-over effects of national policies . . . . .	171
There is some evidence of market entry price convergence among OECD countries. .	174
Conclusions. . . . .	179
Notes . . . . .	179
References. . . . .	180
<b>Chapter 6. The Impact of Pharmaceutical Pricing Policies on Pharmaceutical Innovation . . . . .</b>	<b>183</b>
Introduction . . . . .	184
Pharmaceutical R&D investment. . . . .	184
Ways in which pricing and reimbursement practices contribute to trends in innovation . . . . .	192
Conclusions. . . . .	198
Notes . . . . .	199
References. . . . .	200

<b>Conclusions</b> .....	203
<b>Glossary</b> .....	207
<b>List of Abbreviations</b> .....	214
<b>Boxes</b>	
1.1. Pharmaceutical expenditure: definition, deviations and sources .....	25
1.2. Purchasing power parities and comparative price levels for pharmaceuticals ...	31
1.3. The role of retail price components in explaining relative pharmaceutical prices .....	34
2.1. Making a drug and getting it to market .....	57
2.2. Pharmaceutical pricing strategies in a competitive market .....	67
3.1. Formulary management in the US Veterans Health Administration .....	89
3.2. The use of reference pricing to define reimbursement amounts .....	92
3.3. Approaches used to influence physician prescribing behaviour .....	95
3.4. Pharmaceutical pricing in the US Medicaid programme .....	99
3.5. Approaches used in pharmaco-economic assessment .....	107
3.6. Risk-sharing arrangements for pharmaceuticals .....	109
3.7. The British Pharmaceutical Price Regulation Scheme .....	110
3.8. The French State – Industry agreements .....	112
3.9. Intellectual property rights (IPR) exhaustion regime .....	116
4.1. The price sensitivity of consumer demand for pharmaceuticals and potential consequences of increases in cost-sharing .....	138
4.2. Pharmaceutical cost containment and industry policy: conflicts between policy goals .....	141
5.1. Manufacturers strategies in a world of separable markets .....	172
6.1. Getting a drug to market .....	185
6.2. Private investment in pharmaceutical R&D benefits from public support ...	187
<b>Tables</b>	
1.1. Launch lags for 122 new molecules that were first marketed in 1986-1992 .....	37
1.2. Private sector and out-of-pocket (OOP) expenditure as a percentage of total expenditure, by healthcare function, 2005 .....	39
1.A1.1. Distribution mark-ups and VAT in OECD countries, 2007 or last available information .....	46
2.1. The level of innovation of new chemical entities (NCEs) launched between 1975 and 2002 .....	55
2.2. Global pharmaceutical sales at ex-manufacturer prices, by region, 2006 .....	58
2.A1.1. Bilateral comparisons of ex-manufacturer prices: review of recent studies ...	81
3.1. The use of external price benchmarking in OECD countries, as of 2007 .....	103
3.2. Categories used by pricing authorities to differentiate drugs according to therapeutic value .....	105
4.A1.1. Economy-wide price levels and retail price levels for pharmaceuticals, 2005 ..	162
<b>Figures</b>	
1.1. Total expenditures on pharmaceuticals, 2005 .....	25
1.2. Per capita spending on pharmaceuticals, 2005 .....	26
1.3. Pharmaceutical expenditure per capita and GDP per capita, 2005 .....	26

1.4.	Share of prescription and over-the-counter (OTC) drugs in total pharmaceutical expenditures, 2005 . . . . .	27
1.5.	Share of pharmaceutical expenditure in total health spending and in GDP, 2005 . . . . .	28
1.6.	Real annual growth in pharmaceutical spending and total health expenditure (net of pharmaceutical expenditure), 1997-2005 . . . . .	29
1.7.	Trend growth in pharmaceutical and total health expenditure for 15 OECD countries, and GDP, 1980-2005 . . . . .	30
1.8.	Relative retail pharmaceutical price levels in OECD countries, 2005 . . . . .	32
1.9.	Components of retail pharmaceutical prices, selected OECD countries, 2004 . . . . .	33
1.10.	Retail pharmaceutical price levels and GDP per capita, 2005 . . . . .	35
1.11.	Real per capita spending on pharmaceuticals, 2005 . . . . .	35
1.12.	Real per capita pharmaceutical expenditure and GDP per capita, 2005 . . . . .	38
1.13.	Share of public expenditure in pharmaceutical and total health expenditure, 2005 . . . . .	39
1.14.	Pharmaceutical industry trade balance in OECD countries, 2003 . . . . .	42
2.1.	Global trend in market launch of new chemical entities, 1982-2006 . . . . .	54
2.2.	Global pharmaceutical sales growth at ex-manufacturer prices, 1998-2006 . . . . .	59
2.3.	Contribution to total world sales growth at ex-manufacturer prices, by region, 2001 and 2006 . . . . .	59
2.4.	Top ten therapeutic classes by global sales at ex-manufacturer prices, 2006 . . . . .	61
2.5.	Market share of generics in terms of value and volume, 2004 . . . . .	62
2.6.	Hypothetical cash-flow profile of a pharmaceutical . . . . .	63
2.7.	Average time from first world application for marketing authorisation to application in market, 1999-2003 . . . . .	65
3.1.	Average time from application for market authorisation to approval, 1999-2003 . . . . .	116
4.1.	Average number of days from pricing and reimbursement application to decision, 1997-2001 . . . . .	133
4.2.	Average number of months between first world application for marketing authorisation and launch in country, 1999-2003 . . . . .	134
4.3.	Retail pharmaceutical price levels and economy-wide price levels, 2005 . . . . .	145
4.4.	Original pharmaceutical price levels and economy-wide price levels, 2005 . . . . .	146
4.5.	Generic pharmaceutical price levels and economy-wide price levels, 2005 . . . . .	147
4.6.	Share of GDP spent on pharmaceuticals and income per capita, 2005 . . . . .	148
4.7.	Share of GDP spent on health (net of pharmaceutical spending) and income per capita, 2005 . . . . .	149
4.A1.1.	Retail price – economy-wide price level differentials for original and generic pharmaceuticals, 2005 . . . . .	164
5.1.	Multilateral comparisons of UK pharmaceutical prices to comparator countries' prices, 1992-2004 . . . . .	175
5.2.	Bilateral comparisons with Canada of ex-manufacturer prices for patented pharmaceuticals, 1997 and 1999-2004 . . . . .	176
5.3.	Price convergence of market entry prices in the EU countries . . . . .	177
6.1.	R&D expenditures and sales in the pharmaceutical industry, 2006 . . . . .	190
6.2.	The R&D investment decision . . . . .	191
6.3.	Retail pharmaceutical price levels and real per capita pharmaceutical expenditure, 2005 . . . . .	194