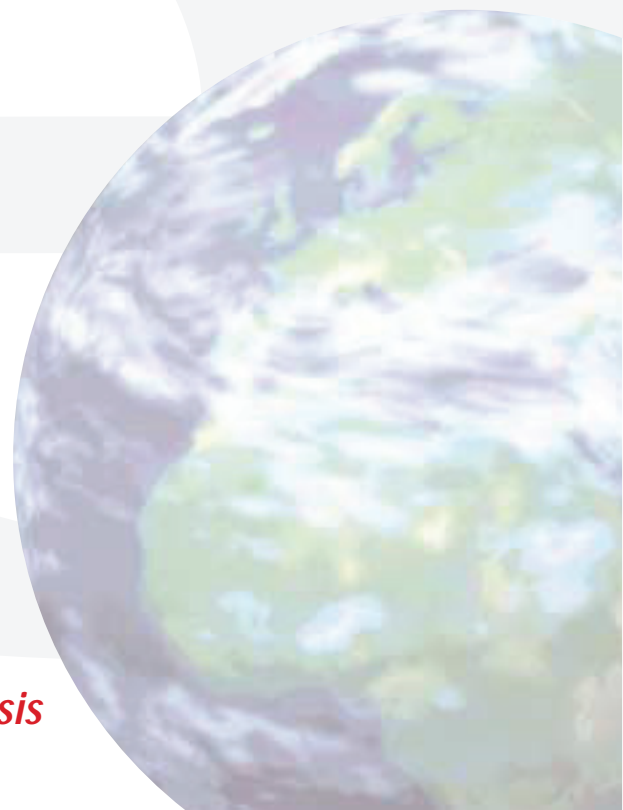


The World Generic Market Report 2012

Volume II: National Markets



World Leaders in Health Industry Analysis



The World Generic Market Report 2012, Volume II: National Markets

ISBN: 978 1 85822 441 1

© Copyright 2012 Espicom Business Intelligence Publications Limited

All rights reserved. No part of this publication may be reproduced or used in any form or by any means graphic, electronic or mechanical, including photocopying, recording, taping or storage in information retrieval systems without the express permission of the publisher.

Every care has been taken to ensure that the information contained in this report is correct. The publisher accepts no liability for decisions made on the basis of information contained

British Library Cataloguing in Publication Data.

A catalogue record for this report is available from the British Library.

TABLE OF CONTENTS

Overview	1
Population	1
GDP per capita	2
Health Expenditure	2
Total Pharmaceutical Expenditure	4
Generic Pharmaceutical Expenditure	5
Generic Market Projections	8
Australia	13
Introduction	13
Pharmaceutical Market	14
PBS prescription data	15
Generic Market	21
Summary Outlook.....	22
Regulation	23
<i>International harmonisation</i>	23
Intellectual Property	24
<i>US Free Trade Agreement, Generic Amendments</i>	24
<i>Parliament passes patent springboarding Bill</i>	25
Pricing & reimbursement	25
<i>Therapeutic Group Premiums</i>	26
<i>US Free Trade Agreement</i>	26
<i>Government announces new pricing measures for newly listed drugs</i>	27
<i>Government announces further PBS reforms, 2006</i>	27
Manufacturing	29
<i>Alphapharm</i>	29
<i>Apotex (formerly GenRx)</i>	29
<i>Arrow Pharmaceuticals Pty</i>	29
<i>Ascent Pharmahealth (formerly Genepharm)</i>	30
<i>Aspen Australia</i>	30
<i>Generic Health/Bellwether Pharma</i>	31
<i>Mayne Pharma (Hospira)</i>	31
<i>Ranbaxy Australia</i>	32
<i>Sandoz</i>	32
<i>Sigma Pharmaceuticals (Australia)</i>	32
<i>Winthrop Pharmaceuticals</i>	33
Brazil	35
Introduction	35
Pharmaceutical Market	36
Generic Market	37
Size.....	37

<i>Patent expiries</i>	38
Outlook & Projections.....	39
Intellectual Property.....	40
Pricing & reimbursement.....	41
<i>Drug Price Authority</i>	41
<i>Drug Price Readjustments</i>	42
<i>Drug Price Control</i>	42
<i>The Tax Substitution System</i>	44
REIMBURSEMENT	44
PFPB.....	45
Manufacturing.....	46
<i>Pró-Genéricos</i>	46
<i>Aché</i>	47
<i>Cimed</i>	47
<i>Cristália</i>	48
<i>EMS Sigma Pharma</i>	48
<i>Eurofarma</i>	49
<i>Hipolabor</i>	52
<i>Hypermarcas</i>	53
LAFEPE	54
<i>Libbs Farmaceutica</i>	55
<i>Teuto</i>	55
<i>União Química</i>	56
Canada	57
Introduction.....	57
Pharmaceutical Market.....	58
Generic Market.....	60
Size	60
Outlook & Projections.....	61
<i>Generics have saved Canadian healthcare system C\$26 billion in past five years says CGPA</i>	62
<i>Ammunition for the CGPA's stance regarding EU trade negotiations</i>	63
Intellectual Property.....	64
<i>Evergreening</i>	65
<i>Canada's Access to Medicine Regime</i>	66
Pricing & reimbursement.....	66
Manufacturing.....	69
<i>Apotex</i>	69
<i>Cobalt Pharma</i>	70
<i>Mylan Pharmaceuticals ULC (formerly Genpharm)</i>	70
<i>Pharmascience</i>	71
<i>Ranbaxy</i>	71
<i>Sandoz</i>	71
<i>Taro Pharm</i>	71
<i>Teva Canada</i>	72
France	73

Introduction	73
Pharmaceutical Market	74
Generic Market	75
Size.....	75
Outlook & Projections	78
Intellectual Property	80
<i>Supplementary Protection Certificates</i>	<i>80</i>
Pricing & Reimbursement.....	80
Pricing.....	80
<i>Pricing of Reimbursable Medicines in the Retail Pharmacy Market</i>	<i>80</i>
Price Revisions	81
Pricing Activity.....	82
Pharmacy Margins	83
Reference Pricing (TFR).....	83
Pricing of Hospital Medicines.....	83
Reimbursement	84
Manufacturing	85
Local Manufacturers & Suppliers.....	86
Arrow Génériques	86
Biogaran.....	86
EG-Labo (Stada).....	86
Mylan (formerly Merck Génériques)	86
Ranbaxy.....	87
ratiopharm.....	88
Sandoz.....	88
Teva.....	89
Winthrop.....	89
Wockhardt.....	89
Zydus France.....	90
Germany	91
Introduction	91
Pharmaceutical Market	92
Retail Pharmaceutical Expenditure	92
GKV Drug Expenditure	93
Generic Market	94
Size.....	94
Outlook & Projections	97
Intellectual Property	98
Pricing & Reimbursement.....	98
Pricing.....	98
Reimbursement	98
AOK Negotiates Pharmaceutical Supplier Contracts for 2012-14.....	99
Generic Substitution Policies.....	99

Compulsory Manufacturer Rebates	100
AVWG, 2006	100
Manufacturing.....	100
Accedo Arzneimittel GmbH.....	100
Actavis Deutschland	100
betapharm	101
CT-Arzneimittel	101
Heumann Pharma Generics/Torrent Pharmaceuticals.....	101
Hexal.....	101
Hospira Deutschland GmbH.....	102
Mylan Dura (formerly Merck Dura)	102
Neuraxpharm	102
Ribosepharm.....	102
Sandoz.....	103
Stada Arzneimittel.....	103
Teva	103
Winthrop Arzneimittel.....	103
Italy	105
Introduction.....	105
Pharmaceutical Market.....	106
Retail Pharmacy Sales	107
Generic Market.....	108
Size	108
Outlook & Projections.....	110
Intellectual Property.....	111
National Supplementary Protection Certificate.....	111
Pricing & reimbursement	112
Pricing	112
Reimbursement.....	113
Austerity Budget Measures.....	113
Manufacturing.....	114
ASSOGENERICI.....	115
Local Manufacturers	116
Angenerico.....	116
DOC Generici.....	116
Mylan.....	116
Sandoz.....	116
Stada Arzneimittel.....	116
Teva Pharma Italia.....	116
Japan.....	117
Introduction.....	117
Pharmaceutical Market.....	118
Generic Market.....	119

Size.....	119
Outlook & Projections	120
Regulations.....	121
<i>Generic regulation, 2005</i>	122
Intellectual Property.....	122
<i>Data Exclusivity</i>	123
<i>Exclusion of Use</i>	123
<i>Patent term extensions</i>	123
Pricing & Reimbursement.....	123
<i>Generic drug pricing</i>	123
Manufacturing.....	124
<i>MHLW Stable Supply Requirements, 2006</i>	124
<i>Actavis ASKA</i>	125
<i>Daiichi Sankyo Espha</i>	125
<i>Lupin</i>	126
<i>Mylan Seiyaku</i>	126
<i>Nichi-iko</i>	126
<i>Pfizer</i>	126
<i>Sanofi</i>	127
<i>Sawai</i>	127
<i>Taiyo</i>	127
<i>Teva</i>	127
<i>Towa</i>	127
Russia	129
Introduction	129
Pharmaceutical Market	130
<i>Pharmacy Market</i>	130
<i>Hospital Market</i>	131
<i>APS Market</i>	131
Generic Market	132
Size.....	132
Outlook & Projections	132
Intellectual Property.....	134
Pricing & Reimbursement.....	135
<i>Pricing</i>	135
<i>Registration of Maximum Prices</i>	136
<i>Price Freezes</i>	136
<i>List of Vitally Important Drugs for 2011</i>	136
<i>Reimbursement</i>	137
<i>DLO Budget</i>	137
<i>Procurement of Pharmaceuticals for the DLO</i>	138
<i>Future of the DLO</i>	138
<i>Subsidising of Prescription Medicines</i>	138

Manufacturing.....	139
<i>Government Programme for the Development of the Pharmaceutical Industry.....</i>	140
Trade Associations.....	141
AIPM.....	141
Manufacturers.....	141
Akrikhin.....	141
JSC Farmacon.....	142
KRKA.....	142
Pharmstandard.....	143
Ranbaxy.....	143
STADA CIS.....	143
Teva.....	144
Valenta.....	144
Veropharm.....	144
Yugrafarm.....	144
Spain.....	145
Introduction.....	145
Pharmaceutical Market.....	146
<i>Pharmacy Sales.....</i>	148
Generic Market.....	150
Size.....	150
Outlook & Projections.....	151
<i>Spain rules to prevent biosimilar substitution.....</i>	152
<i>Regional INN Prescribing.....</i>	152
Intellectual Property.....	155
Pricing & Reimbursement.....	155
COST-CONTAINMENT MEASURES IMPLEMENTED IN 2011.....	156
<i>Prescription by Active Ingredient.....</i>	156
<i>Reference Prices.....</i>	157
<i>Price Reduction of 15.0% for Generic Medicaments.....</i>	157
Manufacturing.....	158
AESEG.....	158
Local Manufacturers.....	159
Adamed.....	160
Alter.....	160
Barr.....	161
Cantabria Pharma.....	161
Cinfa.....	161
Combino Pharm.....	161
DOMAC.....	162
Dr Reddy's.....	162
Kern Pharma.....	162
Mabo-Farma.....	162
Mylan (Formerly Merck/Prasfarma).....	163
Normon.....	163

<i>Pharmagenus</i>	163
<i>Ranbaxy</i>	163
<i>Ratiopharm (now Teva)</i>	163
<i>Sandoz</i>	164
<i>Stada</i>	164
<i>Teva</i>	164
<i>Zydus Cadila</i>	164
Switzerland	165
Introduction	165
Pharmaceutical Market	165
Generic Market	166
Size.....	166
Outlook & Projections	167
Intellectual Property	168
Pricing & reimbursement	168
<i>Generic pricing</i>	169
<i>Generic reimbursement</i>	169
Manufacturing	169
<i>Intergenerika</i>	170
<i>Acino Pharma (formerly Cimex)</i>	171
<i>Helvepharm</i>	172
<i>Mepha Pharma AG</i>	172
<i>Sandoz Pharmaceuticals</i>	172
<i>Spirig</i>	173
<i>Streuli Pharma</i>	173
United Kingdom	175
Introduction	175
Pharmaceutical Market	176
Market Structure	176
NHS Prescription Medicines Market	177
Generic Market	179
Size.....	179
Generic Prescribing	179
<i>Outlook & Projections</i>	182
Regulation	183
Intellectual Property	183
<i>Supplementary Protection Certificates</i>	183
Pricing & Reimbursement	183
<i>Pricing</i>	183
<i>PPRS Reforms, 2008</i>	184
<i>Further reforms on the way</i>	184
<i>Unbranded Generic Pricing</i>	185
<i>2005 generics reimbursement scheme</i>	185

Reimbursement.....	186
Manufacturing.....	186
Actavis	190
Arrow Generics	190
Bristol Laboratories.....	190
Dexcel Pharma	190
Dr Reddy's	190
Focus Pharmaceuticals.....	190
Generics (UK) – now Mylan.....	191
Genus Pharmaceuticals.....	191
Goldshield Pharmaceuticals	191
Kent Pharmaceuticals.....	191
Pliva Pharma (Teva).....	191
Ranbaxy.....	192
ratiopharm.....	192
Rosemont Pharmaceuticals.....	192
Sandoz.....	192
Teva Pharmaceuticals	192
Winthrop Pharmaceuticals.....	193
Wockhardt.....	193
USA.....	194
Introduction.....	194
Pharmaceutical Market.....	195
President Obama's Healthcare Reforms.....	197
Generic Market.....	197
Size	197
Outlook & Projections.....	198
Intellectual Property.....	199
Hatch-Waxman	200
Hatch Waxman reform, 2003.....	200
Bolar Amendment	201
Biosimilar regulation - BCPIA	201
Major Product Approvals	203
Generic Initiative for Value and Efficiency (GIVE).....	205
Approvals in 2011	206
Forthcoming Patent Expiries.....	231
Atorvastatin	231
Clopidogrel.....	231
Nexium.....	232
Pricing & Reimbursement.....	234
Public Drug Procurement.....	234
Medicaid.....	234
Average Wholesale Price (AWP).....	235
Medicare	235
H.R.1 (Medicare Prescription Drug, Improvement, and Modernization Act of 2003).....	236

State pricing/reimbursement moves	237
Manufacturing	237
Sources	239
Directory	240
Regulators	240
Industry Associations	241