ANTI-INFECTIVE DRUGS MARKETS
(SAMPLE COPY, NOT FOR RESALE)

Trends, Industry Participants, Product Overviews and Market Drivers
TABLE OF CONTENTS

1. Overview 9
   1.1 Statement of Report 9
   1.2 Scope of the Report 9
   1.3 Methodology 10
   1.4 Executive Summary 11

2. Clinical Syndromes and Therapy 20
   2.1 Head and Neck 22
      2.1.1 Sinusitis 22
      2.1.2 Pharyngotonsillitis 23
      2.1.3 Deep Neck Infections 23
      2.1.4 Otitis Media and Externa 23
      2.1.5 Acute Suppurative Thyroiditis 23
   2.2 Eye 24
      2.2.1 Conjunctivitis 24
      2.2.2 Keratitis 24
      2.2.3 Iritis 24
      2.2.4 Retinitis 25
      2.2.5 Endophthalmitis 25
   2.3 Skin and Lymph Nodes 25
      2.3.1 Complicated Skin and Skin Structure Infections (cSSSIs) 25
      2.3.2 Lymphadenitis 25
   2.4 Respiratory Tract 26
      2.4.1 Bronchitis 26
      2.4.2 Laryngitis 26
      2.4.3 Pneumonia 26
      2.4.4 Influenza 28
      2.4.5 Avian Bird Flu 29
      2.4.6 Swine Flu 29
      2.4.7 Respiratory Syncytial Virus 33
      2.4.8 Tuberculosis 33
   2.5 Heart and Blood Vessels 37
      2.5.1 Endocarditis 37
      2.5.2 Acute Pericarditis 37
      2.5.3 Myocarditis 37
      2.5.4 Vascular Infections 38
   2.6 Gastrointestinal Tract, Liver and Abdomen 38
      2.6.1 Acute Viral Hepatitis 38
      2.6.2 Chronic Hepatitis 39
      2.6.3 Biliary Tract Infections 40
      2.6.4 Pancreatitis 40
      2.6.5 Esophageal Infections 41
      2.6.6 Gastroenteritis 41
      2.6.7 Peritonitis 42
      2.7 Genitourinary Tract 43
         2.7.1 Urethritis 43
         2.7.2 Prostatitis 43
      2.7.3 Urinary Tract Infections 44
      2.7.4 Pelvic Inflammatory Disease 44
      2.7.5 Candiduria 44
      2.7.6 Human Papilloma Virus 44
   2.8 Nervous System 45
      2.8.1 Bacterial Meningitis 45
      2.8.2 Viral Encephalitis 46
2.8.3 Reye’s Syndrome  46
2.8.4 Myelitis and Peripheral Neuropathy  46
2.9 Musculoskeletal System  46
2.9.1 Osteomyelitis  46
2.9.2 Polyarthritis  47
2.9.3 Bursitis  47
2.9.4 Psoas Abscess  47
2.10 HIV Infection  47
2.11 Blood-Borne Infections  53
2.11.1 Malaria  53
2.11.2 West Nile Virus  56

3. Anti-Infective Drugs Market  58
3.1 FDA Approvals of New Anti-Infective Therapy  60
3.2 Anti-Infective Drugs in Current Pharmaceutical Developmental Programs  68
3.3 Factors Determining Anti-Infective Drug Development  70
3.4 Pharmaceutical R&D Expenditures  71

4. Description of Anti-Infective Therapeutic Agents  73
4.1 Anti-Bacterials  73
4.1.1 Anti-Bacterial Therapeutic Agents in Current Formulation  76
4.1.1.1 β-Lactam Antibiotics  77
4.1.1.2 Fluoroquinones  78
4.1.1.3 Glycopeptides  79
4.1.1.4 Macrolides  80
4.1.1.5 Oxazolidinones  81
4.1.1.6 Other Classes of Anti-Bacterial Agents  82
4.1.2 Older Classes of Antibiotics  82
4.2 Anti-Virals  83
4.2.1 Overview  83
4.2.2 Anti-Viral Therapy  83
4.2.3 Anti-Viral Market Leaders  84
4.2.4 Principles of Anti-Viral Therapy  84
4.3 Anti-Fungals  90
4.3.1 Overview  90
4.3.2 Major Classes of Anti-Fungal Therapy  90
4.3.3 Anti-Fungal Agent Resistance  91
4.3.4 Anti-Fungal Agent Market Leaders  92
4.4 Vaccines  92
4.4.1 Overview  92
4.4.2 Principles of Vaccine Therapy  95
4.4.3 Vaccine Market Leaders  95

5. Market for Anti-Infective Drugs and Vaccines  99
5.1 Molecular Diagnostics in Determining Demand  99

6. Decision-Making Activity in the Anti-Infective Drugs Market  103
6.1 Net Present Value in Making Decisions to Develop and Market Antibiotics  104

7. Economics of Anti-Microbial Drug Resistance: the Persistent Need for Anti-Bacterials  106
7.1 Resistance and Antibiotic Usage  109

8. Global Market Analysis of Anti-Infective Drugs  111
8.1 Market Size  111
8.2 Market Share  111
8.3 Market Drivers  113
9. Global Market for Anti-Bacterial Therapies 114
9.1 Amoxicillin 116
9.2 Nafcillin 117
9.3 Ticarcillin 117
9.4 Imipenem 117
9.5 Ceftriaxone 117
9.6 Cefotetan 118
9.7 Dalbavancin 118
9.8 Doripenem 119

10. Global Market for Anti-Fungal Therapies 120
10.1 Amphotericin B 121
10.2 Azoles 121
10.3 Echinocandins 122
10.4 Flucytosine 122

11. Global Market for Anti-Viral Therapies 123
11.1 Antiretroviral Market 123
11.1.1 The Viral Drug Resistance Crisis 123
11.1.2 Emtricitabine 126
11.1.3 CCR5 Receptor Antagonists 127
11.1.4 Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs) 127
11.2 HCV Infections 128
11.2.1 Pegintron Alpha 128
11.2.2 Ribavirin 129
11.2.3 Boceprevir 129
11.3 Acyclovir 129
11.4 Adefovir 129
11.5 Cidofovir 130
11.6 Entecavir 130
11.7 Fomiviren 130
11.8 Foscarnet 130
11.9 Ganciclovir 130

12. Market, Demographic and Economic Trends 131
12.1 Emerging Trends in Infectious Diseases Worldwide 131
12.2 Global Burden of Infectious Diseases 132
12.3 The AIDS Model 133
12.4 Dead-End Transmission of Zoonotic and Vector-Borne Diseases 133
12.5 Environmentally-Persistent Organisms 134
12.6 Old Microbes and New Diseases 134
12.7 Microbial Agents and Chronic Diseases 134
12.8 Remerging and Resurging Infections 135
12.9 Geographical Spread of Infectious Diseases 135
12.10 Drug-Resistant Microbes 136
12.11 Opportunistic Re-Emerging Infections 136
12.12 Re-Emerging Zoonotic and Vector-Borne Diseases 136
12.13 Influenza 136
12.14 Deliberately-Emerging Infections 137
12.15 Meeting the Challenge of Emerging Diseases 137

13. Political and Legal Trends 138
13.1 AATF and Legislation 138
13.2 Bioterrorism and Biowarfare 140
14. Technological Trends 141
14.1 Anti-Microbial Discovery in the Post-Genomic Era 141
14.1.1 Anti-Bacterial Polypharmacology 141
14.1.2 Topology of Targets 142
14.1.3 Designer Polypharmacology and Designing HIV Therapies 142

15. Socio-Cultural Trends 143

16. Competitive Landscape 144
16.1 Introduction 144
16.2 Strengths and Weaknesses in Anti-Microbial Drug Discovery—Commercial 145
16.3 Strengths and Weaknesses in Anti-Microbial Drug Discovery—Academic 146
16.4 Regulatory Hurdles 146
16.5 Business Hurdles 147
16.6 Strategic Alliances, Licensing Activity, and Mergers and Acquisitions 148

17. Sales Performance: a Detailed Analysis of Leading Anti-Infective Players 151
17.1 GlaxoSmithKline 151
17.1.1 Overview 151
17.1.2 Sales Focus by Drug Class 151
17.1.3 Marketed Product Portfolio 152
17.1.4 R&D Pipeline Analysis 154
17.1.5 Strategic and Growth Analysis 154
17.2 Merck 155
17.2.1 Overview 155
17.2.2 Sales Focus by Drug Class 156
17.2.3 Marketed Product Portfolio 156
17.2.4 R&D Pipeline Analysis 158
17.2.5 Strategic and Growth Analysis 159
17.3 Pfizer 159
17.3.1 Overview 159
17.3.2 Sales Focus by Drug Class 160
17.3.3 Marketed Product Portfolio 160
17.3.4 R&D Pipeline Analysis 162
17.3.5 Strategic and Growth Analysis 163
17.4 Novartis AG 163
17.4.1 Overview 163
17.4.2 Sales Focus by Drug Class 163
17.4.3 Marketed Product Portfolio 164
17.4.4 R&D Pipeline Analysis 165
17.4.5 Strategic and Growth Analysis 165
17.5 Gilead Sciences 166
17.5.1 Overview 166
17.5.2 Sales Focus by Drug Class 166
17.5.3 Marketed Product Portfolio 167
17.5.4 R&D Pipeline Analysis 167
17.5.5 Strategic and Growth Analysis 168
17.6 Abbott 168
17.6.1 Overview 168
17.6.2 Sales Focus by Drug Class 168
17.6.3 Marketed Product Portfolio 169
17.6.4 R&D Pipeline Analysis 169
17.6.5 Strategic and Growth Analysis 170
17.7 Wyeth (Acquired by Pfizer) 170
17.7.1 Overview 170
17.7.2 Sales Focus by Drug Class 170
17.7.3 Marketed Product Portfolio 171
17.7.4 R&D Pipeline Analysis 171
17.7.5 Strategic and Growth Analysis 172
17.8 Sanofi-Aventis 172
17.8.1 Overview 172
17.8.2 Sales Focus by Drug Class 172
17.8.3 Marketed Product Portfolio 173
17.8.4 R&D Pipeline Analysis 174
17.8.5 Strategic and Growth Analysis 174
17.9 Bristol-Myers Squibb 175
17.9.1 Overview 175
17.9.2 Sales Focus by Drug Class 175
17.9.3 Marketed Product Portfolio 175
17.9.4 R&D Pipeline Analysis 175
17.9.5 Strategic and Growth Analysis 176
17.10 Johnson & Johnson (J&J) 176
17.10.1 Overview 176
17.10.2 Sales Focus by Drug Class 177
17.10.3 Marketed Product Portfolio 177
17.10.4 R&D Pipeline Analysis 177
17.10.5 Strategic and Growth Analysis 178
17.11 Roche Pharma AG 178
17.11.1 Overview 178
17.11.2 Sales Focus by Drug Class 179
17.11.3 Marketed Product Portfolio 179
17.11.4 R&D Pipeline Analysis 179
17.11.5 Strategic and Growth Analysis 179

18. Company Profiles 181
18.1 Abraxis BioScience, Inc. 181
18.2 Acambis (Now Sanofi Pasteur) 181
18.3 Achillion Pharmaceuticals, Inc. 181
18.4 Adlyfe, Inc. 182
18.5 Advanced Life Sciences Holdings, Inc. 183
18.6 Affinium Pharmaceuticals 183
18.7 Akonni Biosystems 183
18.8 Alnylam Pharmaceuticals 183
18.9 APP Pharmaceuticals 184
18.10 Aquapharm Biodiscovery 184
18.11 Arbor Vita Corporation 184
18.12 Arpida Ltd. (Now Evolva) 185
18.13 AveXa Ltd. 185
18.14 Basilea Pharmaceutica AG 185
18.15 Baxter International, Inc. 185
18.16 Biophage Pharma, Inc. 186
18.17 CEL-SCI Corporation 186
18.18 Cerexa, Inc. (a Subsidiary of Forest Laboratories) 187
18.19 CombiMatrix Corporation 187
18.20 Cubist Pharmaceuticals, Inc. 187
18.21 Daiichi Sankyo Co., Ltd. 188
18.22 Hospira, Inc. 188
18.23 Incyte Corporation 189
18.24 Idenix Pharmaceuticals, Inc. 189
18.25 Medivir AB 190
18.26 Meiji Holdings Co., Ltd. 190
18.27 MerLion Pharma 191
18.28 Mutabilis 191
18.29 NanoBio® Corporation 191
18.30 Nanosphere, Inc. 192
18.31 NanoViricides, Inc. 192
18.32 Novabay Pharmaceuticals, Inc. 192
18.33 Obetech, LLC 193
18.34 Optimer Pharmaceuticals, Inc. 193
18.35 Panacos Pharmaceuticals, Inc. 194
18.36 Paratek Pharmaceuticals, Inc. 194
18.37 Pharmasset, Inc. 194
18.38 Pico Pharmaceuticals, Inc. 195
18.39 PolyMedix, Inc. 195
18.40 PowderMed Ltd. (Subsidiary of Pfizer) 195
18.41 Presidio Pharmaceuticals, Inc. 196
18.42 Progenics Pharmaceuticals, Inc. 196
18.43 Protez Pharmaceuticals (a Novartis Subsidiary) 196
18.44 Ribomed Biotechnologies, Inc. 197
18.45 Rib-X Pharmaceuticals, Inc. 197
18.46 Targanta Therapeutics Corporation, Inc. (Acquired by The Medicine Company) 197
18.47 Theravance, Inc. 198
18.48 Trius Therapeutics 198
18.49 Vertex Pharmaceuticals, Inc. 198
18.50 X-GEN Pharmaceuticals, Inc. 199

Appendix 1: FDA Compliance Policies Regarding Approved New Drug and Antibiotic Drug Products 200
Appendix 2: Anti-HCV Drugs in Development 202
Appendix 3: Market for Anti-Infectives in Animal Health 205
Appendix 4: Diagnostics for Infectious Agents 211

INDEX OF FIGURES

Figure 1.1: Leading Causes of Death in the U.S., 1961-2007 12
Figure 1.2: Global Distribution of Anti-Infective Drug Sales by Geography 15
Figure 2.1: Incidence Rates of Invasive MRSA Infections by Age 20
Figure 2.2: U.S. Child Death Rate from Preventable Diseases, 2007 22
Figure 2.3: Infection Rate of Serotype 19A by Age Group in the U.S., 1998-2006 27
Figure 2.4: U.S. Hospitalizations for Types of Respiratory Diseases in Children Under 15 Years of Age 27
Figure 2.5: Economic Burden of Select Lung Diseases in the U.S., 2007 28
Figure 2.6: Infection Rate of Invasive Pneumococcal Disease in the U.S., 1998-2007 28
Figure 2.7: Status of H5N1 Avian Influenza, 2009 29
Figure 2.8: Number of Reported and Confirmed Cases of Influenza H1N1 Strain Worldwide, 2009 31
Figure 2.9: Distribution of H1N1 Flu in the U.S., May 22, 2010 32
Figure 2.10: Novel H1N1 Confirmed and Probable Case Rate in the U.S. by Age Group 32
Figure 2.11: Number of Tuberculosis Cases Among U.S.-Born and Foreign-Born Persons by Year Reported in the U.S., 1993-2009 34
Figure 2.12: Rate of Tuberculosis Cases Among U.S.-Born and Foreign-Born Persons by Year Reported in the U.S., 1993-2009 34
Figure 2.13: Rate of Tuberculosis Cases by State/Area in the U.S., 2009 35
Figure 2.14: U.S.-Born Tuberculosis Cases by Ethnicity, 2008 36
Figure 2.15: Rate of New Hepatitis A, B and C Infections in the U.S., 1982-2007 39
Figure 2.16: Countries Reporting Outbreaks of Cholera, 2007-2009 42
Figure 2.17: U.S. Rates of Sexually-Transmitted Diseases, 1940-2008 43
Figure 2.18: Rate of New Cases and Deaths of Cervical Cancer by Age Group Worldwide, 2008 45
Figure 2.19: Global Trend of HIV Infection, 1991-2008 48
Figure 2.20: Worldwide Percentage of Adults Living with HIV, 1990-2006 48
Figure 2.21: Worldwide Rate of New HIV Cases, 1990-2008 49
Figure 2.22: Percentage of Adult Population in African Countries with HIV, 2007 49
Figure 2.23: Ethnic Distribution of AIDS Patients in the U.S., 2007 51
Figure 2.24: Ten Best-Selling AIDS Drugs in the U.S., 2009 51
Figure 2.25: U.S. Rates for New HIV Cases, 2008 52
Figure 2.26: Global Malaria-Endemic Areas in the Eastern Hemisphere 54
Figure 2.27: Anti-Malarial Vaccine Pipeline, 2009 55
Figure 2.28: Global Anti-Malarial Drug Pipeline, 2008 56
Figure 2.29: West Nile Virus Activity in the U.S., 2009 57
Figure 3.1: Anti-Infective Drugs Market Projections, 2006-2013 58
Figure 3.2: Leading Companies in Anti-Infectives Market Share, 2008 59
Figure 3.3: Number of New Anti-Bacterial Agents Approved by the FDA in the U.S., 1983-2008 62
Figure 3.4: Total Spending on Healthcare in the U.S., 1960-2008 64
Figure 3.5: Percentage Breakdown of U.S. Healthcare Spending, 2008 65
Figure 3.6: International Per Capita Healthcare Spending by Country, 2008 66
Figure 3.7: Generic Drug Applications and Approvals in the U.S., 1995-2006 67
Figure 3.8: Savings Generated by Generic Use in the U.S. by Therapeutic Category, 1999-2008 71
Figure 3.10: Cost for New Drugs by Primary Indication, 2007 72
Figure 4.1: Market Share by Leading Anti-Bacterial Drug Class 74
Figure 4.2: Anti-Virals in the Marketplace 83
Figure 4.3: Anti-Virals Market by Indication, Excluding HIV and HCV 84
Figure 4.4: Anti-Viral Therapeutics Market by Drug Class 85
Figure 4.5: Global Distribution of the Lack of Childhood Vaccination 93
Figure 4.6: GAVI Alliance Members 95
Figure 4.7: Global Vaccines Market, 2008 96
Figure 4.8: GlaxoSmithKline’s Vaccine Pipeline, 2008 96
Figure 4.9: Vaccine Market by Geographical Area, 2008 97
Figure 5.1: Global Market for Molecular Diagnostics, 2002-2013 100
Figure 5.2: Number of Non-Elderly Americans without Health Insurance Coverage, 1994-2008 104
Figure 5.3: Percentage of Non-Elderly Americans without Health Insurance Coverage, 1994-2008 104
Figure 7.1: Global Multidrug Susceptibility in P. Aeruginosa 108
Figure 7.2: Global Frequency of Vancomycin-Resistant Enterococci, 2006 108
Figure 7.3: MRSA Trends According to Patient Location, 1998-2005 109
Figure 9.1: Market for Injectable Anti-Bacterials, 2008 and 2013 115
Figure 9.2: Market Share for Major Anti-Bacterial Classes, 2008 and 2013 116
Figure 9.3: Frequency of S. Aureus in Skin and Soft Tissue Infections 119
Figure 11.1: Current and Projected Market Size for Injectable Antiretrovirals by Drug Class, 2008 and 2013 123
Figure 11.2: Market Share for Injectable Antiretrovirals by Drug Class, 2008 124
Figure 11.3: HCV Market: Growth and Projections by Drug Class, 2008 and 2013 128
Figure A3.1: Growth in Global Sales of Antibiotic Products in Animal Health, 2005-2012 205
Figure A4.1: FIND Pipeline for TB Diagnostics 222

INDEX OF TABLES

Table 1.1: Top Ten Causes of Death Worldwide 12
Table 1.2: Leading Pharmaceutical Companies in the Anti-Infective Market, 2009 16
Table 2.1: Annual Rates of Global Infectious Diseases 21
Table 2.2: Drugs in Development for Chronic Hepatitis B, 2010 40
Table 2.3: Global HIV Statistics, 2008 50
Table 3.1: Top-Selling Anti-Infective Drugs, 2008 59
Table 3.2: Sales for Leading Companies’ Infectious Diseases Segments, 2008 60
Table 3.3: Current Drug Development Times and Rates by Therapeutic Indication 61
Table 3.4: Emerging Therapeutic Approaches 61
Table 3.5: New Drug Approvals in All Categories from the FDA, 2000-2009 62
Table 3.6: Top Ten Global Pharmaceutical Markets, 2008 63
Table 3.7: Percentage of GDP Healthcare Spending in BRIC Countries, 2008 63
Table 3.8: Percentage of GDP Healthcare Spending by Country, 2008
Table 3.9: Top 20 Generic Drugs by Prescriptions, 2008
Table 3.10: Anti-Bacterial Agents Undergoing Clinical Development
Table 3.11 Leading Tuberculosis R&D Candidates
Table 3.12: Pipeline for Repositioned Drugs
Table 4.1: Potential Anti-Bacterial Protein Drug Targets
Table 4.2: In Vitro Susceptibility of Staphylococci to New Agents in Development
Table 4.3: Anti-Staphylococcal Vaccines and Immunoglobulins in the Late-Stage Pipeline, 2009
Table 4.4: Bacterial Targets of Antibiotics and Resistance Mechanisms
Table 4.5: Guideline Summary for Antibiotic Selection for Skin and Soft Tissue Infections
Table 4.6: Selected Anti-Viral Drugs
Table 4.7: Antiretrovirals in Development, 2008
Table 4.8: New Types of HIV Drugs
Table 4.9: Recommended Daily Dosage of Seasonal Influenza Anti-Viral Medications for Treatment and Chemoprophylaxis in the U.S., 2008-2009
Table 4.10: Percentage of Population Drug Resistance for Common Influenza Virus Strains, 2009
Table 4.11: Selected HCV Drugs in Development, 2009
Table 4.12: Therapeutic Agents in Development for Treating Hepatitis B, 2008
Table 4.13: Anti-Fungal Compounds in Late-Stage Development
Table 4.14: New Vaccines Licensed, 2005-2010
Table 4.15: Global Top-Selling Vaccines, 2008
Table 4.16: Selected Anti-Infective Monoclonal Antibodies in Clinical Development, 2009
Table 4.17: Recommendations for Diagnostic Testing for Hepatitis C
Table 5.1: FDA-Approved Commercial Kits for the Detection of Infectious Agents
Table 5.2: Examples of Personalized Medicine in the Treatment of Infectious Disease
Table 6.1: Competitive Landscape for Anti-Viral Drugs in Development, 2009
Table 6.2: Competitive Landscape for Antibiotic Drugs in Development, 2009
Table 8.1: Anti-HIV Therapeutics Approved by the FDA
Table 9.1: Major Classes of Antibiotics
Table 10.1: Major Classes of Anti-Fungals
Table 11.1: CCR-5 Receptor Agonists in Development, 2009
Table 12.1: Major Pathogens Identified in the Last 30 Years
Table 12.2: Emerging and Re-Emerging Infectious Diseases and Their Geographical Location
Table 16.1: Pharmaceutical Companies Ranked by Total R&D Expenditures, 2008
Table 16.2: International Regulatory Measures Indicated by the International Forum of Anti-Bacterial Resistance
Table A2.1: Anti-HCV Pipeline, 2009
Table A3.1: European Sales of Animal Health Antibiotics, 2005-2012
Table A3.2: Use of Antibiotics as Growth Promotants
Table A4.1: Market Structure for Infectious Disease Diagnostics
Table A4.2: Rapid Strep Tests on the Market
Table A4.3: Rapid Tests for Chlamydia
Table A4.4: Rapid Tests for Gonorrhea
Table A4.5: Burden of Influenza
Table A4.6: Global Market Potential for TB Diagnostic Testing, 2000-2010
Table A4.7: Global Market for HBV Diagnostic Testing, 2000-2012
Table A4.8: U.S. Market for HBV Diagnostic Testing, 2000-2012
Table A4.9: Serological Diagnosis of Hepatitis B Virus Infections
Table A4.10: Lower Detection Limits of HBV DNA Assays
Table A4.11: Type of Test: Lateral Flow
Table A4.12: Type of Test: Flow-Through
Table A4.13: Type of Test: Agglutination
Table A4.14: Type of Test: Immunoblot
Table A4.15: Global Market for HCV Diagnostic Testing, 2000-2009
Table A4.16: Efficiency of Available HCV Screening Tests
Table A4.17: Recommendations for Diagnostic Testing for Hepatitis C
1. Overview

1.1 Statement of Report

Six infectious diseases—pneumonia, tuberculosis, diarrheal diseases, malaria, measles and human immunodeficiency virus (HIV)/acquired immunodeficiency syndrome (AIDS)—account for 33% of all premature deaths worldwide, killing mostly children and young adults, according to the World Health Organization (WHO). In addition, threatening pandemics such as H1N1 influenza A virus (swine flu) are exerting significant pressure on the already-strained healthcare budgets of governments around the world. This report analyzes the anti-infective drugs market and highlights the existing and developing anti-infectives used to ameliorate infectious diseases’ afflictions on mankind. Anti-infective drugs covered in this report include anti-viral therapeutics, antibiotics, anti-fungal agents and prophylactic treatments such as vaccines. Particular attention is paid to the clinical market segment and the pharmaceutical and biotechnology companies involved in manufacturing anti-infective drugs, with specific emphasis on each company’s sales focus, product portfolio and research and development (R&D) pipeline.

To date, the most successful anti-infective drugs target HIV, the herpes virus (HSV-1 and HSV-2), bacterial infections and hepatitis C (HCV). A number of exciting novel anti-viral and antibiotic compounds are currently revolutionizing the anti-infective drugs market, including Truvada and Valtrex, which are anti-HIV and anti-herpes therapies, respectively. Significant resources are also being dedicated toward hepatitis A (HAV), hepatitis B (HBV) and staphylococcal infections, including methicillin-resistant Staphylococcus aureus (MRSA). This study will also examine the existing and developing anti-infective drugs targeted at infectious diseases that continue to devastate developing countries, including cholera, dengue fever, malaria, meningitis, rotavirus, tuberculosis, typhoid and yellow fever.

1.2 Scope of the Report

This report provides a review of the pharmaceutical agents, biologics and vaccines that are currently in use; it weighs their advantages and disadvantages and introduces the most up-to-date U.S. Food and Drug Administration-(FDA-) approved drugs that are their main competitors. In addition to an analysis of past and future FDA drug approvals, a review of the current legislative and regulatory documentation is provided. Also discussed are market drivers, market inhibitors and current and future trends for the anti-infective market.

Analysis of cutting-edge scientific research is provided, including novel drugs that are currently involved in clinical trial testing. Progress in technology and R&D will impact future therapeutics, and their influence on the anti-infectious diseases market is comprehensively analyzed in this report. Detailed descriptions covering the most prominent infectious diseases, their origins and current first-line treatments are given to provide the reader with a broad understanding of this market. The impact of the most significant infectious diseases on the marketplace is highlighted, with an emphasis placed on how certain drug-resistant bacterial strains are influencing the market’s future. Since the advancement of drug efficacy and specificity will further shape the anti-infective therapeutics environment, an analysis of emerging market share, treatment regimens and payment platforms will also be outlined.

This study contains a comprehensive overview of the current and forecasted sizes of the infectious diseases drugs market, with detailed descriptions of each submarket. Market segmentation is addressed, and the influence of healthcare workers, investors, scientists and patients on future trends is analyzed in detail. A number of negative parameters that are inhibiting the growth of the market are identified, as are the main market drivers; the global need for novel classes of pharmaceuticals is also discussed in depth. Current trends in R&D are reviewed, with an emphasis on technological advances.

The specific objectives of this report are to:

- Examine current and future anti-infective therapies and provide a critical analysis of their advantages and disadvantages to the market.
- Provide a comprehensive review of current infectious diseases which are most likely to impact the anti-infective drugs market.
- Provide in-depth descriptions and analysis of first-line therapies and future therapies.
- Provide a detailed understanding of the principles of antibiotic, anti-viral, anti-fungal and vaccine therapy.
Discuss the role of bacterial resistance and disease pandemics in shaping the future of the anti-infective drugs market.

Analyze the current anti-infective market in detail, identify current and prospective FDA-approved therapeutics, and document agents in current R&D and clinical trial programs.

Evaluate the global economic impact of current therapeutics.

Present market sales figures, identifying how much each submarket is worth and predicting the growth of the anti-infectives market.

The advantages for the reader are:

- Up-to-date information on current and future therapies in the anti-infective drugs market.
- Detailed descriptions of the most prominent infectious diseases worldwide and their current therapeutic statuses.
- Easy-to-interpret graphs and tables documenting current and predicted statistics on market segmentation, sales, healthcare spending, infection and mortality rates, and FDA approvals.
- In-depth analysis of prominent pharmaceutical players, including their drug portfolios, R&D product pipelines, sales and market share.
- Assessment of the economics and future of anti-microbial drug resistance.
- Identification of business trends in the anti-infective market.

1.3 Methodology

The author holds a Ph.D. in immunology and has significant academic and research experience in the fields of biochemistry, genetics and microbiology. As an expert in the infectious disease field, she has managed many research programs and has held senior scientist positions in academia. The author has significant experience in international scientific writing and has peer reviewed cutting-edge research. The editor of the report holds a Ph.D. in biochemistry and has many decades of experience in scientific writing and as a medical industry analyst.

Company-specific information is obtained mainly from industry trade publications, academic journals, news and research articles, press releases, and corporate websites, as well as from annual reports for publicly-held firms. Additionally, sources of information include non-governmental organizations (NGOs) and governmental entities like the U.S. Department of Health and Human Services (HHS) and U.S. federal agencies such as the National Institutes of Health (NIH), the FDA and the Centers for Disease Control and Prevention (CDC). Where possible and practicable, the most recent data available have been used.

Some of the statistical information was taken from Biotechnology Associates’ databases and from TriMark’s private data stores. The information in this study was obtained from sources that we believe to be reliable, but we do not guarantee the accuracy, adequacy or completeness of any information or omission or the results obtained by the use of such information. Key information from business literature was used as a basis to conduct dialogue with and obtain expert opinion from market professionals regarding commercial potential and market sizes. Senior managers from major company players were interviewed for part of the information in this report.

Primary Sources

TriMark collects information from hundreds of database tables and many comprehensive multi-client research projects, as well as Sector Snapshots that it publishes annually. TriMark extracts relevant data and analytics from its research as part of this data collection.

Secondary Sources

TriMark uses research publications, journals, magazines, newspapers, newsletters, industry reports, investment research reports, trade and industry association reports, government-affiliated trade releases, and other published information as part of its secondary research materials. The information is then analyzed and translated by the Industry Research Group into a TriMark study. The Editorial Group reviews the complete package with product and
market forecasts, critical industry trends, threats and opportunities, competitive strategies, and market share determinations.

**TriMark Publications Report, Research and Data Acquisition Structure**

The general sequence of research and analysis activity prior to the publication of every report by TriMark Publications includes the following items:

- Completing an extensive secondary research effort on an important market sector, including gathering all relevant information from corporate reporting, publicly-available data and proprietary databases.

- Formulating a study outline with the assigned writer, including the following important items:
  - Market and product segment grouping, and evaluating their relative significance.
  - Key competitors’ evaluations, including their relative positions in the business and other relevant facts to prioritize diligence levels and assist in designing a primary research strategy.
  - End-user research to evaluate analytical significance in market estimation.
  - Supply chain research and analysis to identify any factors affecting the market.
  - New technology platforms and cutting-edge applications.

- Identifying the key technology and market trends that drive or affect these markets.

- Assessing the regional significance for each product and market segment for proper emphasis of further regional/national primary and secondary research.

- Completing a confirmatory primary research assessment of the report’s findings with the assistance of expert panel partners from the industry being analyzed.

**1.4 Executive Summary**

According to the Global Health Council, every year, infectious diseases account for an estimated 14 to 17 million deaths globally. According to the WHO, six deadly infectious diseases—pneumonia, tuberculosis, diarrheal diseases, malaria, measles and more recently HIV/AIDS—account for half of all premature deaths worldwide. The majority of these people live in developing countries, and despite the remarkable advances in anti-infective medicine, it is the lack of access to therapy and care that increases mortality rates. In these countries, lopsided development and the growth of densely-populated cities generates the perfect breeding ground for communicable diseases, which thrive under the conditions that widespread poverty creates, such as poor sanitation and unsafe water. Children from deprived inner-city areas may not have access to vaccines or medication, which are essential to prevent and control the spread of infectious disease. Under these circumstances, diseases that were once under control can rapidly gain a foothold and re-establish themselves.

But infectious diseases are not just a problem for developing countries. Infectious diseases have become more relevant with the understanding that many diseases which were earlier considered unrelated to infectious diseases—especially cancers—are now known to be the result of chronic infections. Cervical cancer, for example—one of the most common cancers among women in the developing world—is now known to be associated with human papillomavirus (HPV) infection. Similarly, chronic infections of hepatitis B and hepatitis C can both cause liver cancer, bladder cancer can result from chronic infection with *Schistosomiasis*, and the bacterium *Helicobacter pylori* can cause peptic ulcers. These diseases exist in industrialized countries as well, and these countries are facing the challenge of battling multi-drug-resistant strains which are erupting in increasing numbers across species. Diseases once thought to be under control, such as tuberculosis and diphtheria, have occurred in explosive epidemics in Europe and other industrialized countries. Increasing resistance of microbes to existing anti-microbial drugs has severely limited the ability of the current arsenal of drugs to treat infectious diseases, underscoring the importance of introducing new drugs, possibly with novel mechanisms of action, to the market. As the targets for these drugs—the bacteria, viruses and fungi—continue to evolve, so must the base of drugs that are designed to tackle them.
Table 1.1: Top Ten Causes of Death Worldwide

<table>
<thead>
<tr>
<th>Cause</th>
<th>Deaths (Millions)</th>
<th>% of Deaths</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coronary heart disease</td>
<td>7.20</td>
<td>12.2</td>
</tr>
<tr>
<td>Stroke and other cerebrovascular diseases</td>
<td>5.71</td>
<td>9.7</td>
</tr>
<tr>
<td>Lower respiratory infections</td>
<td>4.18</td>
<td>7.1</td>
</tr>
<tr>
<td>Chronic obstructive pulmonary disease</td>
<td>3.02</td>
<td>5.1</td>
</tr>
<tr>
<td>Diarrheal diseases</td>
<td>2.16</td>
<td>3.7</td>
</tr>
<tr>
<td>HIV/AIDS</td>
<td>2.04</td>
<td>3.5</td>
</tr>
<tr>
<td>Tuberculosis</td>
<td>1.46</td>
<td>2.5</td>
</tr>
<tr>
<td>Trachea, bronchus, lung cancers</td>
<td>1.32</td>
<td>2.3</td>
</tr>
<tr>
<td>Road traffic accidents</td>
<td>1.27</td>
<td>2.2</td>
</tr>
<tr>
<td>Prematurity and low birth weight</td>
<td>1.18</td>
<td>2.0</td>
</tr>
</tbody>
</table>

Source: The World Health Organization

Figure 1.1: Leading Causes of Death in the U.S., 1961-2007

Note: Age-adjusted annual death rates per 100,000.
Source: National Center for Health Statistics and National Cancer Institute

According to the CDC and the WHO, globally, an annual figure of 5 million deaths can be attributed to tuberculosis, malaria and HIV/AIDS. Below is a synopsis of the most common infectious diseases in the world today, as compiled by the WHO.

- **African Trypanosomiasis (Sleeping Sickness):** This condition is prevalent in African countries and is caused by *Trypanosoma brucei*, a flagellate parasite. If untreated, *African Trypanosomiasis* can be fatal. Symptoms include fever, headaches, joint pains, sensory disturbances and poor motor skills. According to the WHO, the estimated number of cases is currently between 50,000 and 70,000.

- **Cholera:** An intestinal *Vibrio cholerae* infection is spread through contaminated drinking water and unsanitary conditions, and it is prominent in India, Russia and sub-Saharan Africa. The WHO estimates that 3 to 5 million cases occur annually. Symptoms include diarrhea, vomiting and leg cramps; cholera can also cause death by dehydration.
- **Cryptosporidiosis**: This infection is caused by the parasite *Cryptosporidium parvum* and is spread through contaminated water. Prevalence is worldwide, but it is becoming more common in the U.S., where an estimated cases of cryptosporidiosis occur each year. Symptoms include diarrhea, stomach cramps and fever.

- **Dengue Fever**: This viral fever is transmitted through the bite of *Aedes aegypti* mosquitoes and is common in Asia and Africa. The WHO estimates cases annually. There are distinct, but closely related, viruses that cause dengue. Recent years have seen dengue outbreaks all over Asia and Africa. The disease is now endemic in more than countries in Africa, the Americas, the Eastern Mediterranean, Southeast Asia and the Western Pacific. Symptoms include fever, severe headaches, muscle and joint pains, and rash.

- **Hepatitis A**: This disorder is caused by HAV and the mode of transmission is generally by ingestion of contaminated water or food. The WHO estimates cases annually. Symptoms include fever, jaundice and fatigue. HAV does not lead to chronic infection.

- **Hepatitis B**: Infection with HBV causes this disease, and there are approximately people infected globally. Symptoms include nausea, fatigue, jaundice, vomiting and stomach pain. Chronic hepatitis B infection can lead to cirrhosis of the liver or liver cancer. HBV may be acquired through contact with infectious blood, semen and other body fluids from having sex with an infected person; shared contaminated needles to inject drugs; or an infected mother and her newborn.

- **Hepatitis C**: Infection with HCV causes this disease and there are an estimated people infected globally. Usually a person with HCV is asymptomatic; however, HCV infection most often becomes a chronic condition that can lead to cirrhosis of the liver and liver cancer. It spreads via contact with the blood of an infected person, primarily through sharing contaminated needles to inject drugs.

- **HIV/AIDS**: AIDS is caused by HIV infection. There are an estimated people globally living with HIV infection, of which approximately infected people live in the U.S. Progression to AIDS may induce initial symptoms such as flu-like conditions, fever, fatigue and swollen glands. However, in immunocompromised patients, AIDS is eventually fatal.

- **Influenza**: Worldwide, annual influenza epidemics result in about to cases of severe illness and about to deaths. Symptoms include fever, headaches, fatigue, coughing, sore throat, nasal congestion and body aches.

- **Japanese Encephalitis**: Caused by the *Flaviviridae* virus and spread by mosquitoes, this disease occurs predominantly in Asia. The WHO estimates cases annually.

- **Leishmaniasis**: Caused by the trypanosomal parasite *Leishmania* and spread by sand flies, mainly in tropical countries. Symptoms include fever, weight loss, anemia and a swelling of the spleen and liver. Approximately cases of leishmaniasis exist globally.

- **Methicillin-Resistant Staphylococcus Aureus (MRSA)**: MRSA is a type of bacteria that is resistant to certain antibiotics such as methicillin and other more common antibiotics such as oxacillin, penicillin and amoxicillin. Staph infections, including MRSA, occur most frequently among persons in hospitals and healthcare facilities (such as nursing homes and dialysis centers) who have weakened immune systems. According to the CDC, the estimated number of people developing a serious (i.e., invasive) MRSA infection in was about : this is higher than estimates using other methods. In the U.S., approximately persons died during a hospital stay related to serious MRSA infections.

- **Malaria**: Malaria is transmitted by *Plasmodium*-infected mosquitoes and is prevalent in tropical and subtropical climates. It affects people annually. Symptoms include fever, severe headache, anemia, weakness and swelling of the spleen.