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# INFECTIOUS DISEASES DRUGS MARKETS *(SAMPLE COPY, NOT FOR RESALE)*

**Trends, Industry Participants, Product Overviews and Market Drivers**

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## 1. Overview

### 1.1 Statement of Report

According to the World Health Organization (WHO), six infectious diseases—pneumonia, tuberculosis, diarrheal diseases, malaria, measles and HIV/AIDS—account for half of all premature deaths worldwide, killing mostly children and young adults. In addition, threatening pandemics such as swine flu (H1N1 influenza A virus) are exerting significant pressure on already strained healthcare budgets of governments around the world. This report provides a detailed description of the current infectious diseases drugs market and highlights the existing and developing anti-infective agents used to ameliorate diseases' afflictions on mankind. Anti-infective agents 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/biotechnology companies involved in manufacturing anti-infective agents, 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 agents target the human immunodeficiency virus (HIV, the virus that causes AIDS), 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 infectious diseases 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 agents targeted at infectious diseases that continue to devastate developing countries, including: cholera, dengue fever, malaria, meningitis, rotavirus, tuberculosis, typhoid, yellow fever and onchocerciasis ("river blindness").

### 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 also provided. Also discussed are market drivers, 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 on how certain drug resistant bacterial strains are influencing the future of this market. The advance of drug efficacy and specificity will further shape the anti-infective therapeutics environment, and thus, analysis of emerging market share, treatment regimens and payment platforms will 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 emphasis on technological advances.

The specific objectives of this report are to:

- Examine the 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-infectives market.
- Provide in-depth descriptions and analysis of first line therapies and future therapies.

- Provide a detailed understanding of the principles of anti-biotic, anti-viral, anti-fungal and vaccine therapy.
- Discuss the role of bacterial resistance and disease pandemics in shaping the future of the anti-infective 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 predict the growth of the anti-infectives market.

The advantages for the reader are:

- Up-to-date information on current and future therapies in the infectious diseases drugs market.
- Detailed descriptions of the most prominent infectious diseases worldwide, and their current therapeutic status.
- 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 antimicrobial drug resistance.
- Identification of business trends of 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 is a Ph.D. in biochemistry with 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 annual reports for publicly-held firms. Additionally, sources of information include non-governmental organizations (NGOs) such as the World Health Organization (WHO) 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 Food and Drug Administration (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 for the results obtained by the use of such information. Key information from the 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 in 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 important items, as follows:
  - 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 [REDACTED] to [REDACTED] deaths globally. According to the WHO, no more than six deadly infectious diseases—pneumonia, tuberculosis, diarrheal diseases, malaria, measles and more recently HIV/AIDS—account for half of all premature deaths worldwide, killing mostly children and young adults. 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 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. A case in point is the recent outbreak of swine flu, which spread unabated in Mexico in the spring of [REDACTED], where the outcome was more devastating than in the U.S. through the summer of [REDACTED].

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 *Schistosomia*, while the bacterium *Helicobacter pylori* can cause peptic ulcers. These diseases exist in industrialized countries as well, who 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 antimicrobial drugs has severely limited the ability of the current arsenal of drugs to treat infectious diseases, underscoring the importance of introducing new

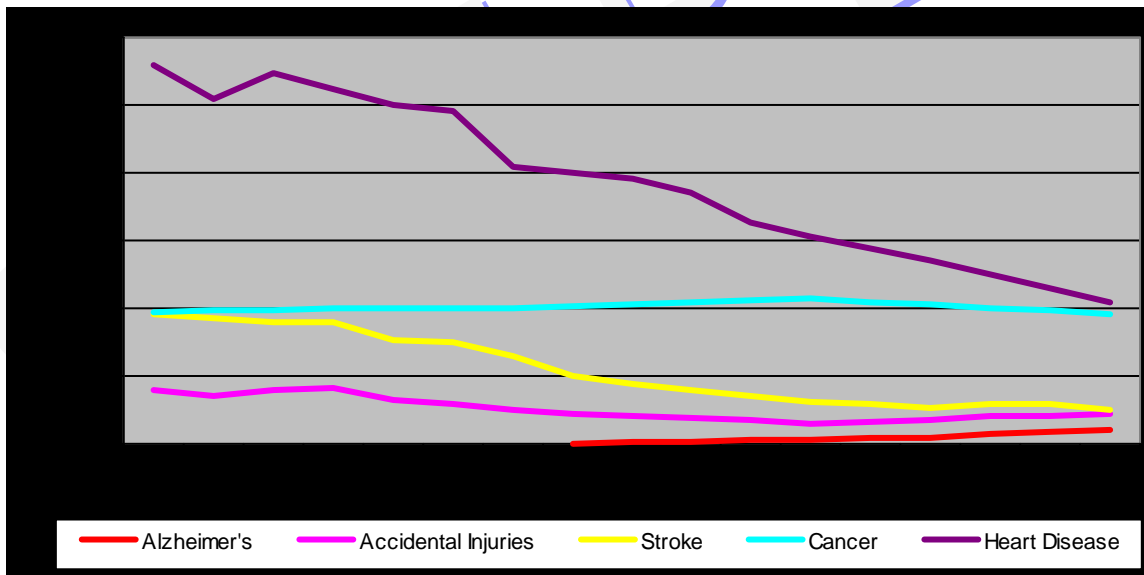
drugs, possibly with novel mechanisms of action, to the market. As the targets for these drugs, the bacteria, viruses and fungi, continue to evolve, so must the base of drugs that are designed to tackle them.

**Table 1.1: Top Ten Causes of Death Worldwide**

Cause	Deaths in Millions	% of Deaths
Coronary heart disease	█	█
Stroke and other cerebrovascular diseases	█	█
Lower respiratory infections	█	█
Chronic obstructive pulmonary disease	█	█
Diarrheal diseases	█	█
HIV/AIDS	█	█
Tuberculosis	█	█
Trachea, bronchus, lung cancers	█	█
Road traffic accidents	█	█
Prematurity and low birth weight	█	█

Source: The World Health Organization

**Figure 1.1: Leading Causes of Death in the U.S., 1958-2005**



Note: Age-adjusted annual death rates per 100,000.

Source: National Center for Health Statistics, National Cancer Institute and *The New York Times*

According to CDC and the WHO, globally, an annual figure of █ 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 █ and █.

- **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. WHO estimates [REDACTED] cases occur annually. Symptoms include diarrhea, vomiting and leg cramps; cholera can 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 [REDACTED] 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. WHO estimates [REDACTED] cases annually. There are four 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 [REDACTED] countries in Africa, the Americas, the Eastern Mediterranean, South-east Asia and the Western Pacific. Symptoms include fever, severe headaches, muscle and joint pains, and rash.
- **Hepatitis A:** This disorder is caused by the hepatitis A virus (HAV) and the mode of transmission is generally by ingestion of contaminated water or food. WHO estimates [REDACTED] cases annually. Symptoms include fever, jaundice and fatigue. HAV does not lead to chronic infection.
- **Hepatitis B:** Infection with the hepatitis B virus (HBV) causes this disease and there are approximately two billion 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, sharing contaminated needles to inject drugs, or from an infected mother to her newborn.
- **Hepatitis C:** Infection with the hepatitis C virus (HCV) causes this disease and there are an estimated [REDACTED] 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:** Acquired immunodeficiency syndrome (AIDS) is caused by infection with the human immunodeficiency virus (HIV). In [REDACTED], there were an estimated [REDACTED] people globally living with HIV infection, of which approximately [REDACTED] infected people lived in the U.S. Progression to AIDS may induce initial symptoms such as flu-like condition, fever, fatigue and swollen glands. However, in immunocompromised patients AIDS is eventually fatal.
- **Influenza:** Worldwide, annual influenza epidemics result in about three to [REDACTED] cases of severe illness, and about [REDACTED] to [REDACTED] deaths. Symptoms include fever, headaches, fatigue, coughing, sore throat, nasal congestion and body aches.
- **Japanese Encephalitis:** Caused by the *Flaviviridae* virus and is spread by mosquitoes, predominantly in Asia. WHO estimates approximately [REDACTED] cases annually.
- **Leishmaniasis:** Leishmaniasis caused by the trypanosomal parasite *Leishmania* and is spread by sand flies, mainly in tropical countries. Symptoms include fever, weight loss, anemia and a swelling of the spleen and liver. Approximately [REDACTED] 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.