Surge in Biosimilars to Drive SIGNIFICANT CHANGE IN HEALTH SYSTEM COSTS

Trending now: Sustainable competitive markets and support for innovation, clinical education, and incentives are needed to deliver full value.

GREATER ACCEPTANCE of biosimilar medicines in a growing number of therapy areas and an active pipeline of 56 new products in clinical development are expected to deliver total savings of as much as $110 billion to health systems across Europe and the U.S. through 2020, according to new research released by the IMS Institute for Healthcare Informatics.


Murray Aitken

Biosimilars, which compete with original biologic medicines, can provide physicians and patients with greater access to advanced treatments and offer budgetary relief to payers in the face of intensifying healthcare cost pressures. Health systems best positioned to capitalize on the benefits of biosimilars support functioning competitive markets — where manufacturers are motivated to participate over the long term, and where physicians are at the heart of the decision-making process.

By 2020, biosimilars will start competing with original biologics that have current sales of $50 billion annually. The extent that these biosimilars provide savings opportunities will depend on policy and implementation approaches that to date have varied across the European Union. As these medicines also become available in the United States, stakeholder education and incentives will play a vital role in ensuring biosimilars deliver their full potential.

"The prospect of more affordable biologic options that are safe and effective opens up opportunities for health systems to expand access to more patients, and frees up resources for investment in new areas," says Murray Aitken, IMS Health senior VP and executive director of the IMS Institute for Healthcare Informatics. "This also can yield significant cost savings — but not all markets are ready to fully benefit from the imminent surge of biosimilar molecules."

Only 40% of Surveyed Global Groups Collect CER Through Dedicated Trials

Among surveyed companies, 40% of global teams and 20% of country-level teams collect comparative effectiveness research (CER) through dedicated trials, according to primary intelligence provider Cutting Edge Information. Comparative effectiveness research is a significant cost-driver for many health economics operations. These data also carry a heavy risk that a product might come out less favorably after a study, which can make convincing internal stakeholders of their importance very difficult. As a result, many companies actively look for ways to generate useful comparative effectiveness data without having to budget for dedicated CER trials.

Database studies are another popular method for obtaining comparative effectiveness data. Although 80% of surveyed global teams and 100% of country-level teams leverage database studies for CER, best practices from the study warn that they are not standardized and that the lack of uniformity can undermine the validity or viability of a potential database study.

"Due to the marketplace becoming increasingly crowded, companies are pursuing CER to meet payer demands," says Jacob Presson, senior research analyst at Cutting Edge Information. "Payers want to make informed decisions when choosing medicine, thus magnifying the importance of CER and broader research on health economics and outcomes."

Pharmaceutical Patent Litigation Filings Have Risen since 2014

Abbreviated new drug applications (ANDAs) patent litigation has risen sharply, according to Lex Machina, a LexisNexis company and creator of Legal Analytics. The second Hatch-Waxman/ANDA Report, which surveys the landscape of patent litigation related to ANDAs submitted to the FDA under the Hatch-Waxman Act, focuses on trends and insights from 2,249 ANDA cases filed in U.S. district courts between January 1, 2009 and December 31, 2015.

Between 2009 and 2013, the average number of ANDA cases filed each year was 269, but over the last two years the average number of filings rose to 451 — a 68% increase.

Other findings:

- Sandoz has participated in the most ANDA cases since 2009 (426), followed by Actavis (including Allergan and Watson Laboratories; 359 cases), and Teva Pharmaceutical Industries (188 cases)
- Among the top parties, AstraZeneca (139 cases), Novartis (133 cases), and Pfizer (130 cases) have the largest number of cases as claimant
- OxyContin remains the most litigated trade name
- The vast majority (97%) of applications are for prescription drugs; over-the-counter and discontinued drugs are a tiny minority
- Only 25% of temporary restraining order motions are granted in ANDA cases, while the success rate for preliminary injunctions is 50%
- ANDA cases are less likely to end in a settlement (57.9%) than other patent litigation (77.1%), and more likely to be won by the claimant (14.6% in ANDA cases vs. 4.4% in other litigation)
- Only five ANDA cases filed since 2000 have resulted in actual damages.

Regulatory Affairs Outsourcing Expected to Grow

The global regulatory affairs outsourcing market was valued at $1.9 billion in 2014 and is expected to reach $5.7 billion by 2023, a compound annual growth rate of 11.5% during the forecast period from 2015 to 2023, according to Transparency Market Research. Regulatory writing and publishing services account for one of the major services outsourced frequently by the pharmaceutical companies. Regulatory consulting and legal representation service segment is estimated to record second highest growth rate of more than 12% during the forecast period.

Therapeutic trax

Cardiovascular Diseases

The heart failure market is set to rise from around $3.2 billion in 2015 to $11.8 billion by 2025, representing a CAGR of 13.7%. The major drivers of this growth, which will occur across the seven major markets of the U.S., France, Germany, Italy, Spain, the UK, and Japan, will be the launch of Novartis' first-in-class drug, Entresto, and several acute heart failure add-on therapies, as well as an increase in the global prevalence of chronic heart failure.

Source: GlobalData

CNS Disorders

The treatment market for bipolar disorder is set to decrease from $5.8 billion in 2014 to $4.2 billion by 2024, at a negative CAGR of 3.2%, as generic erosion continues to deter the development of novel therapies. This decline, which will occur across the eight major markets of the U.S., France, Germany, Italy, Spain, the UK, Japan, and Canada, is going to be particularly steep between 2015 and 2017.

Source: GlobalData

Infectious Diseases

The methicillin-resistant staphylococcus aureus (MRSA) treatment market will experience very limited growth over the next decade, rising from $1.4 billion in 2014 to $1.45 billion by 2024. The $50 million increase, which will occur across the seven major markets of the U.S., Japan, the UK, France, Italy, Spain, and Germany, represents a very modest CAGR of 0.4%. This minimal increase will be largely the product of a treatment space dominated by three primary agents, namely vancomycin, Zyvox (linezolid), and Cubicin (daptomycin).

Source: GlobalData

Pain

The U.S. market for opioids, which accounts for 70% of the global arena, will grow from $11 billion in 2014 to $17.7 billion by 2021, at a CAGR of 7%. This increase will primarily be due to a rising prevalence of chronic pain among the U.S. population, owing to an aging population and an increasing incidence of diabetes, obesity, cardiovascular disorders, arthritis, and cancer.

Source: GBI Research

Respiratory Diseases

The pulmonary arterial hypertension (PAH) therapeutics market will experience modest growth from $3.45 billion in 2014 to $4.75 billion by 2024, the increase in PAH treatment sales, which will occur across the seven major markets of the U.S., France, Germany, Italy, Spain, the UK, and Japan, will be driven by new drug launches, the increased use of double and triple combination therapies, and patient assistance programs by manufacturers.

Source: GlobalData

The global alpha-1 antitrypsin drugs market are expected grow at a CAGR of more than 35% during the period 2016-2020. About 3% of all people who have diagnosed with COPD may have undetected alpha-1 antitrypsin deficiency.

Source: Technavio

Vaccines

The global market for human vaccines experienced strong growth through 2015. Through 2022, growth will be fueled by continued new product introductions, indication expansions for some products and rising usage, particularly in South America, Europe, India, and China.

Source: Kalorama Information

Viral Infections

The global viral infections market will grow from $74 billion in 2014 to $117.6 billion by 2021, representing a compound annual growth rate of 6.8%.

An expanding treatment population, which has resulted from improved treatment options and global initiatives to improve access to treatment for many people living with chronic debilitating viral infections such as HIV, will be a key driver of this growth. Rising therapy costs resulting from the uptake of recently approved, highly priced antiviral agents, as well as promising late-stage candidates, which are expected to be priced highly, will also be a factor.

Sources: GBI Research

The global chronic hepatitis B therapeutics market will rise in value from $2.4 billion in 2014 to $3 billion by 2024. This expansion will occur over the eight major markets and will be due to the patent expiration of all existing branded drugs in the chronic hepatitis B therapeutics space during the forecast period as well as continued low HBV diagnosis and treatment rates. Generic drugs will take up a major slice of the patient share during the forecast period.

Source: GlobalData

Oncology Corner...

News and updates around cancer-related R&D, trends, services, and products.

Moonshot Update

Cancer MoonShot 2020 has formed a Radiation and Immuno-Oncology Working Group. This team, consisting of more than 15 medical oncologists, radiation oncologists, and scientists, has been formed to harness collective wisdom in developing treatments for cancer by identifying the most effective combinations of low dose radiation with cancer-directed immunotherapy.

"Creating a broad platform of independently creative scientists and physicians, who work together in a collaborative climate as a single team with a common vision of innovation, deep conviction and persistence, is essential to winning the war on cancer," explains Patrick Soon-Shiong, M.D., founder and CEO of NantWorks and leader of the Cancer MoonShot 2020 program. "We believe that radiation administered at a lower dose could play an important immuno-modulatory role without the toxicities associated with current standards of care."

In other news, Vice President Joe Biden has called for a more open research culture to encourage cancer research. Addressing the American Association for Cancer Research in April, Mr. Biden stressed the importance that research be immediately available once it is published. He said he hopes the initiative will spur significant progress toward curing cancer over the next five years, and that he hopes to bring together people and resources and break down silos to advance research.

Cancer Costs Increased at Same Rate as Other Healthcare Spending

Over the last decade the total costs of treating patients with cancer in the United States have risen no faster than overall costs for Medicare and commercially insured populations, according to a recent study by Milliman. Contrary to a commonly held misbelief that cancer care costs have rapidly outpaced other healthcare spending trends, the study actually found that total costs of treating patients with cancer have increased at essentially the same rate as all healthcare spending since 2004.

The three key findings of the COA study are:

- The increases in costs from 2004 to 2014 were essentially the same in actively treated cancer patients and the non-cancer population.
- Drug spending, which made up one-fifth of the total costs for treated cancer patients in 2014, has increased at the highest rate of all component costs, fueled by new biologic cancer drugs.
- Cancer care has moved significantly into the more expensive hospital setting since 2004 and is an important component of the increase in the cost of care.

The study found that per patient costs for the total population, actively treated cancer population, and non-cancer population increased at very similar rates over the 11 year study period. For the commercially insured, the cost increases were 62.9% for the total population, 62.5% for the actively treated cancer population, and 60.8% for the non-cancer population. PV

Oncology Trax

The global treatment market for non-hematological cancers, which includes breast, colorectal, lung and prostate cancers, among others, will almost double from $72.9 billion in 2014 to $140.8 billion in 2021, at a CAGR of 9.9%.

This robust growth will occur in spite of the patent expiries of a number of very commercially successful products, including Avastin, Erbitux, and Herceptin. Avastin will see its first patent expiry in the EU in 2018, with the two others having already experienced EU expiries in 2014.

Source: GBI Research

The market for hematological cancers, which covers leukemia, lymphoma, and myeloma, is expected to more than double from $30.7 billion in 2015 to $70.1 billion by 2022, representing a compound annual growth rate of 12.5%. This strong growth will occur in spite of a number of key patent expirations for drugs, including Rituxan, Gleevec, and Velcade, as new drugs hit the market and the prevalence of hematological cancers increases.

Source: GBI Research

The glioblastoma treatment market will increase five-fold from $659 million in 2014 to $3.3 billion by 2024.

This rise, which will occur across the seven major markets of the U.S., Spain, France, the UK, Italy, Germany, and Japan, will primarily be due to the launch of new therapies for glioblastoma patients with high unmet needs. Adults with glioblastoma have some of the highest levels of unmet need of any cancer patients.

Source: GlobalData

The total immuno-oncology market will be worth about $14 billion by 2019, rising to $34 billion by 2024, as the treatment of cancer patients undergoes drastic changes over the next decade. The approval and uptake of immuno-oncology products is set to burgeon due to increased recognition of their long and durable tumor responses, which are similar to targeted therapies. Furthermore, these treatments have shown efficacy in a wide variety of indications and are not associated with the adverse side effects produced by traditional chemotherapy.

Source: GlobalData

Total drugs sales in the head and neck squamous cell carcinoma (HNSCC) markets in the seven major markets, will increase from $386 million in 2014 to $1.53 billion in 2024. The recent surge in investment in HNSCC has resulted in a diverse and innovative pipeline.

Source: GlobalData

The B-cell non-Hodgkin's lymphoma (NHL) treatment market is set to rise slowly in value from $4.38 billion in 2014 to reach $5.45 billion by 2024. Such limited growth, which will occur across the seven major markets of the U.S., France, Germany, Italy, Spain, the UK, and Japan, will be hindered by the entry of biosimilars and generics during the forecast period, combined with a weak pipeline.

Source: GlobalData

The market for tests for cancer using biomarkers grew to $4.8 billion in 2015. The firm projects that the market will grow to $7.4 billion in 2020. The most common types of cancer worldwide include breast cancer, colorectal cancer, lung cancer, and prostate cancer. For these and other types of cancer, novel biomarkers, therapies, and diagnostic tests are being developed.

Source: Kalorama Information

DIA 2016

JUNE 26–30 | PHILADELPHIA, PA

DIA 2016 is a global annual meeting to advance health care product development around the world by connecting stakeholders to interdisciplinary insights and innovation. It is our largest event, packed with 175+ cross functional educational offerings over 22 tracks on today's hottest topics, bringing together a global network of 7,000+ life sciences professionals from industry, academia, regulatory and government agencies, and patient and philanthropic organizations, to foster innovation in the discovery, development, and life cycle management of health care products.

Keynote Speaker:

Larry Brilliant, MD, MPH
Acting Chairman of the Board, Skoll Global Threats Fund
Monday, June 27 | 2:30–4:00PM

Program Co-Chairs:

Hans-Georg Eichler, MD, MSc
Senior Medical Officer, European Medicines Agency

Gigi Hirsch, MD
Executive Director, MIT Center for Biomedical Innovation

Featured Sessions:

- Value-Based Health Care Decision Making: The Quest for Smarter Spending
- International Regulatory Convergence, Collaboration, and Cooperation
- Changing Cultures to Advance Patient Engagement
- Europe and the US: Making Outcomes-Based Health Care Possible
- Next Generation Collaborations: Transforming the Industry
- The Future of Big Data
- Protocol Development Is a Team Sport

Featured Speakers:

- **Dalvir Gill, PhD,** Chief Executive Officer, TransCelerate Biopharma Inc.
- **Andy Lee, MA,** Senior Vice President, Head of Global Clinical Trial Operations, Merck & Co., Inc.
- **Sally Okun, RN,** Vice President, Advocacy, Policy and Patient Safety, PatientsLikeMe

Register by May 20 to Make the Advance Attendee List

#DIA2016

A GATHERING OF GLOBAL PERSPECTIVES

Visit **DIAglobal.org/DIA2016** for more information and to register.

49	105	15	20	10	14	9	13
Forums	Sessions	Symposiums	Tutorials	Workshops	Innovation Theaters	DIAmond Sessions	Engage and Exchange Sessions